Europe Edition
October 22-24 2014

Design of Medical Devices conference

Programme & Abstracts
Programme & Locations
Wednesday - Oct 22

08:30 - 09:00  Registration
09:00 - 09:30  Opening
Keynote: Thomas Lango

10:00 - 11:00  Invited: Nicolas van Mieghem
Fast Forward Session
Special Session: BioInspired Technology

11:00 - 12:00  Demo Session: Endovascular Devices
Abstracts on pages 11-30
Lunch

12:00 - 13:00  Welcome
Keynote: Gino Kerkhoffs

13:00 - 14:00  Invited: Rui Loureiro
Fast Forward Session
Special Session: MR Safe Devices

14:00 - 15:00  Demo Session: Exoskeletons & Orthotic Devices
Abstracts on pages 31-62
Coffee Break

15:00 - 16:00  Special Session: Surgical Robots
Keynote: Maarten Steinbuch

16:00 - 17:00  TU AULA LOCATIONS:

Entrance hall
Foyer
Senaatszaal
Commissiekamer 3

17:00 - 18:00  Diner at “Belgisch Bier Café Belvédère”, Beestenmarkt 8, Delft
Thursday - Oct 23

08:30 - Registration
09:00 - Welcome
  Keynote: Andreas Melzer
10:00 - Invited: Noemi Bitterman
  Fast Forward Session
11:00 - Demo Session: User Centered Devices
  Abstracts on pages 63-86
12:00 - Lunch
13:00 - Welcome
  Keynote: Amir Szold
14:00 - Invited: Joachim Kettenbach
  Fast Forward Session
15:00 - Demo Session: Robotic Devices
  Abstracts on pages 87-108
16:00 - Coffee Break
  Special Session: Fetal Therapy
  Keynote: Dick Oepkes
17:00 - Drinks at “Botanical Garden”, Poortlandplein 6, Delft
Friday - Oct 24

08:30 - Registration
09:00 - Welcome
10:00 - Invited: Padraig Cantillon-Murphy
11:00 - Fast Forward Session
11:00 - Demo Session: Hand Held Devices
12:00 - Lunch
13:00 - Special Session: Devices for Interventional Cardiology
14:00 - Keynote: Hubertus Feussner
15:00 - Closing
15:00 - Lab Tours
15:00 - Departure

 TU AULA LOCATIONS:
- Entrance hall
- Foyer
- Senaatszaal
- Commissiekamer 3

Abstracts on pages 109-127
Map of Relevant Locations in Delft

- Belvédère
- Parking “Zuidpoort”
- NS
- Botanic Garden
- TUDelft Aula
- EWI Faculty
- 3mE Faculty
- ID Faculty

Secondary road or pedestrians only

Main road

Building

Water

200m
Abstracts per session
Wednesday 22 October, 10 am

Chair: Ton van der Steen, Erasmus MC Rotterdam

Helene Clogenson, Andrea Simonetto, John van den Dobbelsteen

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Tianshi Wang, Charles T Lancee, Robert Beurskens, John Meijer, Bart Knapen, Antonius F. W. van der Steen, Gijs van Soest

[17] A flexible catheter system for combined intravascular photoacoustic and ultrasound imaging
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Liilana Peinado-Cortes, Paul Bloemen, Daniel Martijn de Bruin, Dirk J Faber, Ton G van Leeuwen

[37] Integrated Pressure Sensor Powered and Read-out via a Single Optical Fiber
Martin Pekaf, Anneke van Dusschoten, Martin van der Mark

[38] Crossing CTO Lesions: A Review of the State of the Art Devices
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[40] Elastic Scattering Spectroscopy in combination with OCT in a rotating probe
Abel Swaan, Xu Zhang, Paul Bloemen, Martijn De Bruin, Dirk Faber, Henricus Sterenborg

[45] Miniaturization of an Optical Data Link for IVUS Imaging Guidewires
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Design Optimization of a Deflectable Guidewire

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Andrea Simonetto  
John van den Dobbelsteen

Department of Biomedical Engineering  
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1 Background

Interventional radiologists navigate through the blood vessels using long, thin, and flexible catheters and guidewires. In most instances, the maneuverability of the instruments decides whether a target can be successfully reach, and consequently affects greatly the success rate [1]. However, these tools typically have a fixed tip shape and a limited flexibility, which makes it difficult to maneuver in the desired direction [1-3].

In order to deal with the described navigation limitations, an endovascular instruments for peripheral navigation with improved maneuverability at the tip is desired. While the geometry of the tip of catheters and guidewires was traditionally defined by a set of trials and errors, this approach would not only be time consuming but also very costly with a deflectable tool. Therefore, another solution for the design needs to be found. In this paper, we formulate the design of the length of the tip of a deflectable guidewire as an optimization problem in order to determine the proper dimensions of the instrument.

The aim of this study is to apply an optimization-based design to determine the length of the deflectable tip that enables the instrument to cannulate several target bifurcations of the peripheral anatomy. The paper first specifies the main requirements of the developed guidewire and then describes the optimization approach that was used to define the dimensions of the deflectable tip. Following the length specifications defined by the optimization, a new prototype was assembled and evaluated.

2 Methods

The prototype consisted of the guidewire itself, composed of a shaft and a deflectable tip, and a detachable handle. The handle, previously presented in [4], is not discussed in this paper. The length of the 1DOF deflectable tip was optimized using the dimensions of the main bifurcations of the peripheral anatomy as input (diameters and angles). The aim is to have an instrument with the shortest deflective tip as possible that still allows navigation in the peripheral vasculature.

The tip of the guidewire was defined as composed of two parts: a steerable deflectable segment $ℓ$, that can bend and a straight tip, $s_t$ at its distal end (Fig. 1). The length of these two segments was defined in an optimal way to accommodate cannulation in the main arteries of the peripheral vasculature, which geometries (diameter and angles) were collected from the literature.

The tip dimensions of the design were obtained through an optimization procedure under the assumption that a direct relationship exists between the different parameters that are involved in the cannulation of a branch. When the shaft of the guidewire is placed along the vessel wall and the tip is deflected to have the same angle $α$ of the target bifurcation to cannulate, the distal end of tip must at least touch the diametrically opposed wall of the vessel (and therefore the entrance of the bifurcation). In other words, it is difficult to direct the tip of the instrument into a target vessel when its shape is smaller than the vessel diameter. This observation leads to the definition of a maximal diameter, indicated as $\text{max} \ D_a$, in which a steerable guidewire of a given steerable tip length $ℓ$ and the straight tip length $s_t$ can be used to cannulate a bifurcation with a given angle $α$ (Eq. (1)).

$$\text{max} \ D_a = \frac{1 - \cos α}{α}ℓ + s_t \sin α$$

The task of finding the shortest $ℓ$ and $s_t$ for which the guidewire could cannulate all the considered bifurcations (defined by the vessel diameter $D_a$, and the bifurcation angle $α$) was formulated as the following optimization problem (linear program)

$$\text{minimize} \quad ℓ + s_t$$

$$\text{subject to} \quad D_{a,i} \leq \frac{1 - \cos α_i}{α_i}ℓ + s_t \sin α_i,$$

for all bifurcations $i = 1, \ldots, N$

$$s_t \leq 3 \text{ mm}$$

The solution of the optimization is not only the shortest $ℓ$ and $s_t$ that can accommodate the constraints of cannulation,
but also a feasible region, (marked in red in Fig. 2), where one could decide to pick \( \ell \) and \( \alpha \) and still cannulate all the bifurcations. Different points in such region define different design strategies (Fig. 2). The chosen design is marked in Fig. 2 and corresponds to \( \ell = 33.5 \text{mm} \) and \( \alpha \approx 3\text{mm} \). Following the length specifications defined by the optimization, a new 1.4m long, 0.95mm diameter prototype (Fig.3) was assembled, and evaluated.

3 Results

The deflectable tip of the deflectable guidewire could be actuated for angles \( \alpha \in (10^\circ; 223^\circ) \), by actuating a pull wire via the handle. Measurements were performed to assess the behavior of the tip, which was compared to the modeled one used in Eq. (1) with \( \ell = 33.5 \text{mm} \) and \( \alpha \approx 3\text{mm} \) (Fig.4). The calculated and measured curves are close to each other with only a small variation (less than 1mm) for \( \alpha \approx 120^\circ \). Above \( 120^\circ \), the curves progressively differed from each other with a maximum deviation of 3.4mm for \( \alpha \approx 223^\circ \).

The observed deviation above \( \alpha > 120^\circ \) was assumed to be due to the softness of the deflectable segment that allowed the straight tip to bend when the tip is actuated, while the straight tip was assumed to be tangent to the arc of circle formed by the deflectable segment. However, this effect is of minor influence for our application as we are interested in angles below \( 120^\circ \) [4].

The aim of the developed deflectable guidewire was to have an instrument with suitable dimensions for the cannulation of various bifurcations of the peripheral anatomy. Therefore, the deflectable guidewire was tested in 350 bifurcations, which diameters and angles were defined based on the bifurcation geometry found in the literature (and implemented in the optimization). The dimensions of the tip of the deflectable guidewire were found suitable in 341 cases out of the 350 cases tested. Furthermore, it was shown the guidewire could cannulate all the bifurcations with an angle \( \alpha \leq 70^\circ \), independently of their diameters (119 bifurcations out of the 350 case tested). In only 9 cases, the deflectable tip was shown to be too short.

4 Interpretation

The geometry of the main bifurcations of the peripheral anatomy was used as input for defining the length of the different parts of the deflectable guidewire. By using these data and the optimization-based design a 1.4m long, 0.95mm guidewire with a deflectable tip of with \( \ell = 33.5 \text{mm} \) and \( \alpha \approx 3\text{mm} \) was designed and assembled. The design was tested to evaluate its cannulation properties in bifurcations of defined geometries. The deflectable part of the guidewire showed suitable dimensions for most of the branches but could only cannulate bifurcation with an angle \( \alpha \leq 70^\circ \). This latter limitation was ascribed to the mechanical properties of the instrument.

The presented deflectable guidewire was compared to the widely used 0.035" angled Glidewire from Terumo (Tokyo, Japan) and it was found that the conventional instrument had only suitable dimensions for 203 of the 350 case tested. The Glidewire showed suitable dimension for bifurcations of small diameter (\( \alpha \leq 10^\circ \)) but its tip shape was shown to be too short for branches of larger diameters. This result indicates that the dimensions of the tip of the deflectable guidewire were more suitable for the cannulation of various bifurcations of the peripheral anatomy, small and large branches alike. However, the Glidewire could cannulate branches with angles up to \( 110^\circ \). It is therefore crucial that the mechanical properties of the deflectable guidewire are improved to match these results in the future.

A new mathematical method that can help to define the required length of the different parts of the deflectable tip of the instrument, while taking the geometry of the targeted bifurcations in account, was presented. By using these geometries as input for the optimization problem, we were able to obtain the minimally required lengths of the different parts of the deflectable tip. Based on the results, a deflectable guidewire with optimized dimensions was assembled and tested. The dimensions of its tip were shown to be more polyvalent than a standard Glidewire for navigating in the peripheral anatomy. However, the mechanical properties of the instrument should be increased in order to be able to cannulate branches with angles \( \alpha > 70^\circ \).

References

Steerable forward-looking IVUS for coronary chronic total occlusion

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1 Background

Chronic total occlusions (CTO) in the coronary circulation are the most challenging lesions to treat percutaneously, with a limited success rate (55%-80%). The major difficulties during CTO interventions are the localization of the best entry point into the occlusion and crossing with a guidewire avoiding dissection (Fig. 1A). Although percutaneous coronary intervention of CTO is technically problematic, the benefits for the patient are relief of angina pectoris, improvement of left ventricular function and better long term survival [1].

Our aim is to develop a support catheter with a forward-looking (FL) ultrasound transducer and an accurate steering mechanism in order to find the optimal entry point, such as loose tissue regions and microchannels (Fig. 1B). When the entry point is found and reached, the ultrasound imaging and the steering mechanism should enable a safe cross of the lesion.

2 Methods

A catheter for CTO crossing requires a maximum outer diameter of 1 mm (3F). Although smaller diameter increases the chance of successfully crossing the lesion, it limits the space available for the steering components and the ultrasound elements. The catheter has to accommodate a 0.014” guidewire which is passed through the lesion in the intervention. In order to achieve that, the catheter has to be hollow.

The FL ultrasound transducer has to be able to identify the optimal entry point and to visualize the vascular anatomy in order to assist steering. A transducer with a frequency in the range 10-30 MHz should be able to satisfy these requirements.

Different array designs are investigated through simulations using the k-wave Acoustics Toolbox. Few elements have been arranged in multiple configurations (see Fig. 2) and synthetic aperture images of 10 scattering points spaced 200 μm in all the directions (Fig. 3) are obtained. The distance between the points was chosen to mimic the average dimension of the microchannels seen in CTO [4].

The central frequency for all the simulations is set to 30 MHz. For all the designs the kerf is 20 μm. In the first design (A) 8 squared elements are arranged around the central hole and each element size is 150 μm x 150 μm.

In the second design (B) 6 elements are arranged linearly, element width is 150 μm and the height varies according to the circular shape of the catheter tip.

3 Results

In Fig. 4 and in Fig. 5 the images obtained with the different designs are shown. The dynamic range in all the images is 20 dB. In Fig. 4 the maximum intensity projection in the xz plane is shown for the design A together with a 3D volume.
reconstruction. Only 3 of the 10 points are imaged due to the limited aperture and the directivity of the elements.

The image obtained with the linear array design (B) is shown in Fig. 5. Here the imaged points are 4 because of the bigger aperture. However, grating lobe artifacts are seen for both the designs, affecting the quality of the images.

4 Interpretation

The steerable FL-IVUS probe is challenging to realize because of space limitations. This leads to a limited number of ultrasound elements that can be accommodated on the tip of the catheter.

The size of the element simulated in the present study is greater than λ leading to grating lobes and reduced dynamic range. On the other side, dimensions smaller than λ reduce the sensitivity of the few element array. A trade-off between these two requirements has to be found.

Steering mechanisms may help in obtaining better quality images. Combining the images obtained from different angles and orientations may help improving the image quality leading to better resolution of the structures located in front of the catheter tip. The final goal is to develop a volumetric data set that can enable guidance during the crossing procedure of CTO.

References


Figure 4. Maximum intensity projection in the xz plane and 3D volume reconstruction for the design A.

Figure 5. Image obtained with the design B.
Development of a high-speed synchronous micro motor and its application in intravascular imaging

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Summary
In this study, we demonstrate the design, fabrication and characterization of a synchronous micro motor. The size of the motor is 2.0 mm length and 1.0 mm outer diameter. With 1.0 A effective driving current, the motor can generate a torque of 0.25 to 0.27 Nm and rotate a 0.3 mm mirror at a maximum speed of 3640 revolutions per second. The uniformity and accuracy of the motor was characterized at 50 Hz, 200 Hz and 3200 Hz driving frequencies. The performance improved by increasing the driving frequency, which was represented as better speed uniformity and lower angular error. We describe the application of the micro motor as a distal actuator for intravascular imaging. We constructed optical and ultrasonic imaging catheters and show the intravascular images of coronary arteries obtained with these catheters.

1 Background
The synchronous micro motor is a preferable type of actuator where precisely constant speed is a critical requirement. One of these applications is minimally invasive imaging catheters. Catheters with a distal scanning mechanism show more uniform rotation and control in mechanically challenging geometries, compared to devices, which use a proximal motor and a flexible drive shaft [1-3]. The scanning of the image beam in such catheters is realized by rotating a small mirror by a micro actuator at the catheter tip. This application requires a micro actuator that can generate constant high speed at low driving power.

In this paper we describe a synchronous micro motor, rotating at constant high speed. By using a flexible print coil design, and a permanent magnet rotor, the motor can generate several thousands RPS speed with a relatively low current requirement. The size is 1.0 mm outer diameter (OD) and 2.0 mm length.

2 Methods
The micro motor in our study is a two-phase, four-pole synchronous motor with a two-pole permanent magnet rotor. The stator consists of single-strand coils, realized in copper on flexible printed circuit. The magnet on the rotor (Sm2Co17) has a center bore containing a stainless steel shaft. Two ruby bearings were used to hold the rotor shaft inside a non-magnetic cylindrical housing (stainless steel). The front ruby bearing has four holes on its perimeter to allow the leads connecting to the coils to enter. The components of the micro motor and the photo of the motor are shown in Fig.1 [5].

3 Results
We measured the maximum speed of the motor under different effective values of current. Fig. 2 shows that the stable maximum speed increased with driving current.
We measured the speed uniformity and angular error upon 20 revolutions at 50 Hz, 200 Hz and 3200 Hz at the lowest required driving current. The speed uniformity and angular error at different driving frequencies are shown in Table 1.

Table 1. Speed uniformity and angular error of the motor

<table>
<thead>
<tr>
<th>Driving frequency</th>
<th>Maximum Relative speed error (%)</th>
<th>Maximum angular error (degree)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 Hz</td>
<td>17.9</td>
<td>24.2</td>
</tr>
<tr>
<td>200 Hz</td>
<td>12.6</td>
<td>13.1</td>
</tr>
<tr>
<td>3200 Hz</td>
<td>1.7</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Having characterized the micro motor, we built a catheter for intravascular imaging using Optical Coherence Tomography (OCT) [6]. In the catheter, far-infrared laser beam (1310 nm central wavelength) was focused by a gradient refractive index (GRIN) lens and deflected sideward by a mirror mounted on the rotor. The dimension of the catheter is 1.3 m length and 1.1 mm OD at the tip. The schematic diagram and the photograph of the catheter, a photograph of the catheter tip, and the motor are shown in Fig. 3 (a-c). The high-speed rotation of the motor allows us to acquire up to 3200 frames per second (FPS). With a pullback speed of 100 mm/s, an imaging speed of 400 FPS provides a frame pitch of 250μm, which is close to the current commercial IV-OCT systems. On the other hand, 3200 FPS rotating speed reduces the frame pitch to 31μm. The eightfold difference in frame pitch has a clear impact on the longitudinal image quality as showed in Fig. 3.

In summary, we demonstrate a synchronous micro motor consisting of a permanent rotor and a flexible coil. Within a size of 1.0 mm OD and 2.0 mm length, the micro motor can rotate a micro prism at 3620 RPS with a driving current of 1.0 A. We found that the rotation at high speed was uniform to within 2%, and increased for lower speed and with increasing the drive current above the minimum required for stable rotation. By using our micro motor as the distal actuator in intravascular catheters, IV-OCT images and IVUS images were acquired in vitro and in vivo separately. The acquired images show that the motor rotation during pullback is not affected by passage through tight sections with hard (calcified) tissue. We believe that the micro motor has many other potential applications due to its rotating performance and low current requirement.

### 4 Conclusions

In summary, we demonstrate a synchronous micro motor consisting of a permanent rotor and a flexible coil. Within a size of 1.0 mm OD and 2.0 mm length, the micro motor can rotate a micro prism at 3620 RPS with a driving current of 1.0 A. We found that the rotation at high speed was uniform to within 2%, and increased for lower speed and with increasing the drive current above the minimum required for stable rotation. By using our micro motor as the distal actuator in intravascular catheters, IV-OCT images and IVUS images were acquired in vitro and in vivo separately. The acquired images show that the motor rotation during pullback is not affected by passage through tight sections with hard (calcified) tissue. We believe that the micro motor has many other potential applications due to its rotating performance and low current requirement.

### References

A flexible catheter system for combined intravascular photoacoustic and ultrasound imaging

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1 Background

The rupture of the vulnerable atherosclerotic plaques is a major contributor to acute cardiovascular events and sudden cardiac deaths in western countries[1]. Intravascular photoacoustic (IVPA) imaging, a catheter based optical-acoustic hybrid modality, is a promising new tool to detect atherosclerotic plaques based on the optical contrast of different tissue types [2, 3]. It can be used as a diagnostic tool to image the inside of the coronary arteries, allowing for atherosclerotic plaques to be visualized and localized, so that treatments can be more precisely targeted.

In this study we developed a type of flexible integrated IVPA/IVUS catheter system for intravascular imaging, which can achieve frame rate as high as 50 frames per second (fps) with sufficient the SNR of lipid signal (more than 20 dB).

2 Methods

The flexible catheter system for combined IVPA/IVUS imaging mainly consists of several parts: the fiber optic rotary joint, the motorized pullback device, and the catheter tip. The overall structure is shown in fig. 1 (a).

The output fiber of the laser is connected to a fiber optic rotary joint (Princetel Inc., Pennington, New Jersey). It can rotate at the maximal speed of 5000 rpm and the insertion loss is 0.22 dB. For intravascular imaging with our system, at least 100 A-lines are required to fulfill one cross-sectional image. Combined with the 5 kHz repetition rate laser, imaging frame rate as high as 50 fps can be achieved.

A custom designed motorized pullback device is connected to the rotary joint and the pullback can be performed at the speed between 1 to 10 mm/s.

Figure 1(b) shows the details of the catheter tip. The catheter tip shares the similar design of our previous work [4]. The laser light is delivered towards the vessel wall by an angle-polished fiber (Pioneer Optics, 100 μm core diameter, low OH). The fiber tip is polished at a 34° angle and covered with a glued-on quartz cap to preserve an air-glass interface reflecting the beam by total reflection at a 68° angle. A square ultrasound transducer with a size of 0.4 x 0.4 mm, made of lead magnesium niobate-lead titanate (PMN-PT) is used. The center frequency of the transducer was 45 MHz with a ~6 dB fractional bandwidth of 45%. A gold layer was sputter-deposited on the front of the transducer to serve as an electrode and optical isolation. An outer matching layer of parylene with 14 μm thickness was applied by vapor deposition (Philips Innovation Services, Eindhoven, the Netherlands). The optical fiber tip and transducer were mounted in a custom machined PEEK tip assembly with an outer diameter of 0.7 mm. The whole catheter tip is covered with a PE tube for protection. The transducer surface was positioned at a small angle of 6° with respect to the catheter axis to avoid the direction reflection from the outer tube.

![Figure 1](image)

Figure 1. Picture of the catheter. (a) Overall setup of the flexible catheter system. (b) Picture of the 0.7mm outer diameter catheter tip
3 Results

To evaluate the imaging capability of the catheter, a vessel mimicking phantom made of PVA was designed. The phantom had a 3 mm diameter lumen and four 1.5 mm diameter round by 5 mm deep cylindrical cavities at 0.5 mm from the lumen. They are filled with pure samples of cholesterol, cholesterol oleate, cholesterol linoleate and the human peri-adventitial fat tissue, respectively. The first three type cholesterol are the most dominant lipid compounds in human coronary plaque lesions [5] and used to be representative of human plaque lesions. The photo of the phantom is shown in fig. 3(a).

The IVPA imaging was performed at 1718 nm with a prototype of the flexible catheter. The output laser energy from the catheter tip is up to 50 $\mu$J/pulse and repetition rate of the laser pulse is 5 KHz. In the wavelength of 1718 nm, lipids are highly absorbers due to the first overtone of C-H bonds. The co-registered cross-sectional IVPA and IVUS images are acquired by rotating the catheter at the step of 1°.

The raw data were digitally band pass filtered between 10 and 70 MHz, and subsequently Tukey windowed and envelope filtered. No averaging was performed to the data. The IVPA and IVUS images are shown in fig. 3(b-d). In both PA and US images, all four cavities filled with different lipid samples are clearly visible. The PA SNR of lipid signal is more than 20 dB.

4 Interpretation

The result of the vessel mimicking phantom measurement demonstrates the capability of the catheter system for imaging plaque lipids in the phantom. Moreover, the catheter system with the 5 kHz repetition rate laser system can achieve the frame rate of 50 fps, which can enable the real time in-vivo IVPA imaging in the future.

References

Optical performance of a MEMS-based endoscopic OCT probe: Experimental validation

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1 Background

Bladder cancer is the ninth most common cancer in the world [1]. Bladder cancer can be detected during cystoscopy, a medical procedure that checks any abnormality in the bladder. Improvements in bladder cancer detection can be achieved with optical cytoscopes (probes) that acquire high image resolution of the affected bladder tissue [2]. Probes based on optical coherence tomography (OCT) may improve the diagnosis of cancer because they permit obtaining high resolution images [2].

As part of the iMIT program, we are currently designing a miniaturized endoscopic OCT probe (Fig. 1) to detect bladder cancer in vivo (“OBAMA”). On the current stage, an optical simulation of the probe functioning has been performed on Zemax software. We have validated this Zemax simulation through some optical experiments using the Santec system. Comparable results from the experiments with the results obtained in Zemax were obtained. In the current article, we present a brief description of the experiments. Subsequently, some results are shown and a short conclusion is given.

2 Methods

The optical simulation of the probe has been performed in Zemax. The probe is designed to work with a light wavelength of 1050nm. To validate some important parameters as the numerical aperture (NA) and the spot sizes of our simulated optical probe, we have performed three experiments using a Santec OCT system, a commercially available OCT system that is commonly used to perform experimental measurements at AMC. The Santec OCT system uses swept sources to create 2-D high resolution images in real time. The first experiment is to measure the collimated beam diameter of the lens-less Santec system, this is, without any lens focusing the light on the tissue. The second experiment is to measure the spot size of two different lenses (explained below) and the third one is to measure the attenuation coefficient vs. concentration using Intralipid, a fat emulsion that is commonly used in optical experiments to study the scattering of biological tissues [3].

2.1 Measurement of beam diameter in the Santec system

In this experiment, we measure the collimated beam diameter of the Santec OCT system. The beam diameter was measured using the knife edge method [3]. This method uses the edge of the knife to block gradually the light of the collimated beam. A detector is placed behind the knife to measure the light power. The movement of the knife edge is controlled by a precision tool on the optical table. In this way, the beam diameter will be measured by the detector.

2.2 Measurement of image resolution of new lenses

In this experiment, we use two lenses that mimic the functioning of our OCT probe. The use of two lenses is due to the difference between the wavelength of the Santec system (1300 nm) and the design wavelength of our OCT probe (1050 nm). Therefore, we need to use two lenses instead of one to simulate both the Airy disc and the NA of our OCT probe. The Airy disk is referred to the spot size of the beam at focus and the NA is the angular spread of a light beam at focal point.

The result of the previous experiment, the collimated beam diameter of the Santec system was used as an input for a Zemax simulation. This simulation gives information about two new lenses needed to mimic our 1050nm probe. In this manner, we obtained that to mimic optically our probe, we need a 150mm lens and a 200mm lens.

2.2.1 Experiment of the spot size with knife edge method

We used the knife edge method to measure the spot size of the Santec system using the two lenses that mimic our probe.

2.2.2 Experiment of the attenuation vs. concentration in Intralipid

We prepared fifteen different concentrations of Intralipid (0.00006%, 0.0625%, 0.125%, 0.25%, 0.5%, 1%, 2%, 2.5%, 5%, 7.5%, 10%, 12.5%, 15%, 17.5% and 20%).

The Intralipid containers were located at focal distance of the Santec probe. A 2D scan was made for each sample with different lens every time. Using Matlab program, the data of each 2D scan is fitted using an exponential decay model to obtain the attenuation coefficient for each concentration [4].
3 Results

3.1 Measurement of beam diameter in the Santec System

Several measurements of the collimated beam of the Santec has been perform. All the data has been average through a Matlab program. The result of the average beam diameter of Santec is 2.54 +/- 0.002mm.

3.2 Measurement of image resolution of new lenses

3.2.1 Experiment of the spot size with knife edge method

The first experiment was performed using the 150mm lens. The measured spot size is 121 μm and the Zemax simulation of the spot size is 143 μm. The second experiment was using the 200mm lens. In this case, the simulated spot size was 189 μm and the measured spot size is 158 μm.

3.2.2 Experiment of the attenuation vs. concentration in intralipids

Each Intralipid concentration was scanned in two-dimensions using one lens at a time. Figure 2 shows the attenuation coefficient vs. percent of intralipid concentration for 150mm, 200mm and 60mm lenses. The 60mm lens is the reference lens that is used to compare all the measurements. The 60mm lens is the default lens of the Santec system.

4 Discussion

The OCT experiments were performed to mimic the functioning of our OCT probe. There were accomplished three experiments. The measurement of the beam diameter of the Santec system was used to simulated two lenses that mimic the airy disk and the NA of the MEMS-probe. In the second experiment, we obtained that the values of the spot sizes at focal point were close to the simulated ones. As a consequence, the image resolutions that are obtained from the measured spot sizes are acceptable. However, the values of the spot sizes were smaller than we expected. Usually, the physical measurement of spot sizes are higher than the simulated ones. We assume that there were some inaccuracies on the measurement system.

The third experiment was to measure the scattering coefficient vs. the intralipid concentration using each lens (Fig. 2). The continuous line represents the scattering concentration using the default lens of Santec (the 60 mm lens). This continuous line is the reference measurement that has been also simulated in Zemax. In figure 2, note that in all measurements the changes in the scattering coefficient for very low intralipid concentrations has a linear behavior. However, the high intralipid concentrations does not have this behavior, this is attributed to multiple and dependent scattering [5].

Besides, in figure 2, the scattering coefficient measured using both 150mm lens (dash line) and 200 mm lens (dotted line) are comparable to our reference measurement (continuous line). However, the scattering coefficient for the 60mm lens presents slightly higher values than for both the 150mm and 200mm lenses. This differences can be as a result of some dispersion issues due to the calibration of the Santec system using new lenses that are not the reference one.

After the experiments, we concluded that the measured attenuation using the two lenses are close to the reference attenuation that was also simulated. Besides, we obtained also comparable both simulated and measured resolution. This is related to the fact that both, the measured and the simulated spot sizes values are approximate to each other. After analyzing the previous conclusions, we have validated the optical simulation performed in Zemax with the physical measurements done in laboratory and we decided to continue to the next phase of our OCT probe design. This phase consist in the mechanical support design of our probe.

Acknowledgments

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References


Abstract [19]

Session - Endovascular devices
Integrated Pressure Sensor
Powered and Read-out via a Single Optical Fiber

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1 Background

Developing safe and compatible catheter devices for magnetic resonance imaging (MRI) is the chief obstacle to overcome before minimally invasive interventions under MRI guidance can be widely applied at hospitals \cite{1}. An intrinsic property of optics-based devices is its MRI compatibility and safety \cite{2}. A lot of research effort is therefore put in developing all-optical catheters and probes to be used in combination with real-time MRI in minimally invasive interventions for catheter guidance and intravascular imaging \cite{3, 4}. Development of such devices encounters two major challenges. Firstly, the available space for integration of optics is usually limited to a few millimeters or even less. Secondly, any catheter being a disposable device has to be affordable. Therefore readily available inexpensive components and easy integration are essential.

In this paper we present an integrated pressure sensor powered and read-out via a single optical fiber. The novelty of powering and reading-out the sensor lies in using a GaN light emitting diode (LED) also in a reverse mode as a photovoltaic converter \cite{5}. When light of sufficient energy is introduced on a LED surface, the photons get absorbed by the GaN and a photocurrent is generated. If no electric circuitry is connected to the LED terminals, the voltage builds up to the point when the LED has no other way of getting rid of its energy than by luminescing at its own wavelength. The intensity of this photo-induced electroluminescence light depends on the electric load on the LED’s terminals \cite{6}. Recently, a patent was published on the idea of using this photo-induced electroluminescence light dependency on load at LED contacts as a simple return data channel \cite{5}.

2 Methods

Figure 1 shows the schematics of the optical power and data read-out set-up. A Blu-Ray laser was used to illuminate the GaN blue LED at the wavelength of 405 nm. Preliminary results before the tip assembly shows that the input laser current of 36.3 mA generated a voltage of 2.35 V and an electrical current of 0.37 mA to power the low-voltage dedicated circuitry and sensor connected at the LED’s terminals. The laser power from the fiber at the LED was 3.8 mW as measured by a photodiode (Hamatsu S2386-8K).

Figure 2: Concept drawing of the pressure sensing catheter tip.

3 Results

Figure 3 shows the assembled pressure-sensing flexfoil ready to be fit on the previously described mechanical support and subsequently integrated into a catheter tip.
The assembled flexfoil was tested at atmospheric pressure. By design the expected pressure-dependent signal from the pressure sensor should be a square wave of frequency around 1 MHz. However, due to the internal capacitance of the LED, the observed signal detected by the photodiode was a bandwidth-limited continuous sine wave with a frequency of 940 kHz. This observation is consistent with the previous experiments done with the same chip on a standard printed circuit board and it doesn’t affect the ability to read-out the pressure data.

In order to test the device at elevated pressure, for example inside a pressure chamber, the flexfoil needs to be fully integrated into the designed catheter tip. This work is currently in progress. Fig. 4 shows the most recent results - the flexfoil was bended and glued to the mechanical support. The black bulky part on the side of the pressure-sensing chip is a mechanical and electrical protection of the thin and very fragile aluminum bondwires (there are seven in total) running from the top side of the chip to the bonding pads on the flexfoil.

The top side of the chip also accommodates multiple pressure-sensing membranes, out of which only two are used. The other membranes represent a test structures. The whole chip, being currently the size limiting factor in minimizing the catheter dimensions, could therefore be reduced to approximately one quarter of its current size.

**Figure 3: Double-sided flexfoil with the LED, pressure sensing chip, and dedicated electronics: (A) bottom view, (B) top view.**

**Figure 4: Pressure-sensing flexfoil assembled on a mechanical support.**

### 4 Conclusion

A pressure sensor powered and read-out via a single optical fiber was integrated into a fully functional all-optical catheter with a diameter of 2.6 mm. The built demonstrator shows the first step towards feasibility of integrating the optical link into a minimally invasive device which is potentially suitable for MRI interventions.

### Acknowledgements

The authors would like to acknowledge Peter Dirksen and Jeannet van Rens for providing the MEMS pressure sensor. Thanks also belong to Wim Weekamp and Henk Compen for their help on tip design and manufacturing and to Ferry van der Linde for the catheter shaft development.

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### References


Crossing CTO Lesions: A Review of the State of the Art Devices.

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1 Background

Most people are aware that an acute occlusion of one of the coronary arteries will lead to a Myocardial Infarction (MI), more commonly known as a heart attack. But what if a coronary vessel gradually occludes? This is the case with people suffering from a Chronic Total Occlusion (CTO). Since a CTO forms gradually, the body is able to form bypass blood vessels, called collaterals, to supply oxygen and nutrients to the heart distally to the CTO. Therefore, the symptoms are less severe than with a MI, but still include pain in the chest and shortness of breath.

To relieve the patients of their symptoms, a surgical procedure similar to what is used in MI needs to be performed. Unfortunately, however, most patients go untreated, since the nature of the CTO and the devices used, make the procedure very cumbersome, time-consuming, and risky. Even if a surgical procedure is undertaken, the success rate is relatively low, between 50 to 80% [1]. In comparison, surgical treatment of a MI has a success rate that is often higher than 95%.

The main contributor for CTO treatment failure can be found during the crossing phase [2]. In the crossing phase, the guidewire needs to puncture the fibrous proximal or distal cap of the CTO, and subsequently cross the CTO. Since, the guidewire is relatively small (<0.4 mm) and flexible, it often buckles before it is able to penetrate the cap of the CTO. Additionally, since the guidewire is not steerable, blood vessel wall dissection can occur, especially in tortuous or bend CTOs. Failure to cross, will automatically lead to overall failure of the procedure.

In this study an overview will be given of the patented tools were included in this study. Recommendations will be made for an improved crossing device based on the requirements needed for successful and safe CTO crossing.

2 Methods

A literature search was executed in the database of Scopus and Espacenet. The literature search was limited to the English or Dutch language from the time period from the 1950 to the present. Note that, only endovascular crossing tools were included in this study.

The search terms in the SCOPUS web engine were subdivided into four categories: (1) occlusion, (2) treatment, (3) medical area, and (4) instrumental. In the occlusion category, the search terms: occlu*, obstruct*, plaqu*, thromb*, *clot*, obstacle*, and barrier* were used. The treatment category included the following terms: *canal*, remov*, resect*, dissec*, and cut*. In the area category, the following terms were used: device*, instrument*, prototype*, guidewire*, catheter*, and apparatus*. The categories were connected with the “AND” operator, the search terms either with “AND” or “OR”.

The Espacenet database was searched using the following keywords in the title and in the title & abstract, respectively: Occlu* OR obstruct* OR plaqu* OR thromb* OR clot*, and (Vasc* OR vessel*) AND (canal* OR remov* OR resect*).

After analyzing the data, the crossing tools, were subdivided into four main categories: (1) Following the Path of Least Resistance, (2) Following the Centerline, (3) Following the User Defined Path, and (4) Following a Straight Path.

In the first approach (1), the devices follow the path of least resistance through the CTO, if possible, circumnavigating calcified lesions. This category is further subdivided into True Lumen Crossing and Subintimal Crossing. In the former approach, the crossing tool navigates through the CTO. In the latter, the CTO is crossed subintimally, in between the intima and adventitia.

In the second approach (2), the devices are able to keep the distance to the blood vessel constant. In the third approach (3), the surgeon or operator is able to actively navigate the crossing device through the lesion. The last approach (4) comprises all crossing devices that independently from the direction of the blood vessel or path of least resistance cross the CTO in a straight path.

3 Results

Following the Path of Least Resistance

In most cases the CTO is crossed using a guidewire. This guidewire simply follows the path of least resistance through the CTO or subintima. The main difference between true lumen and subintimal crossing is that in subintimal crossing, a different reentry device is needed to return to the true lumen.

To improve crossing different designs and coatings are suggested. These designs include, tapered core wires, nitinol wires, enlarged tip portions, and hypotubes to increase the columnar strength and thus prevent buckling. Furthermore, once the guidewire has punctured the fibrous cap, a hydrophilic or thrombolytic coating can be used to decrease the sliding friction. Finally, combined guidewire/treatment combinations are proposed that in collapsed state function as a crossing tool and in expanded state as a treatment tool (similar to a retrievable stent mechanism).

Next to guidewires, imaging techniques, such as Optical Coherence Tomography (OCT) and IntraVascular UltraSound (IVUS) are proposed. These devices are able to distinguish between different tissue types and can therefore be used for CTO crossing via the path of least resistance. Other proposed methods for tissue distinction, include the use of electrical impedance or lasers. It must be noted, however, that these
devices alone, cannot follow the path of least resistance accurately without a steerable crossing tool.

Additionally, a pressure chamber was suggested that increases the pressure between CTO and the device until a crack is formed. Crack propagation along the CTO will follow the path of least resistance until the distal cap is breached.

Finally, spark erosion was suggested. This technique uses a spark to fragment tissue in close proximity to the electrodes. Since this technique is less effective on calcified regions, it will also follow the path of least resistance.

**Following the Centerline**

In some cases it is absolutely imperative to follow the centerline of the CTO, to prevent, for example, blood vessel wall damage. The same imaging techniques as described above could be used to aid in centerline crossing. However, it can also be achieved with crossing tool incorporating balloons or self-expandable mechanisms. These devices adapt to the shape of the blood vessel wall and use this information to determine the center point of the blood vessel. By translating the centering device forward during crossing, the centerline of the blood vessel can be followed.

**Following a User Defined Path**

In the most ideal case the surgeon is able to actively steer the crossing tool through the CTO. Multiple techniques have been proposed that allow this. However, none are currently available for CTO treatment.

One of the proposed devices incorporates a segmented balloon. This balloon enables the crossing tool to be steered on plane. Furthermore, a directly steerable device is proposed that uses electrowave polymer actuator to create complex curvatures.

An indirect steering approach is suggested that uses an asymmetric tip configuration. By rotating the device proximally, the distal tip can be steered based on the difference in friction between the tip and CTO.

Finally, an external approach is suggest that uses a magnetic and electric fields to steer a crossing tool inside the body. Inside the tip of the device, a magnet, coil, or ferromagnetic material is present that responds to the magnetic or electric field.

**Following a Straight Path**

In most cases, unfortunately, the crossing tool does not allow for steering. The workspace of these devices is independent from the geometry or features of the CTO. Therefore, these devices are operated at a higher risk of blood vessel wall trauma.

A currently FDA approved rigid crossing tool is Frontrunner XP (Cordis Corporation, Miami, FL). Frontrunner XP uses a hinged cutter mechanism to cross and subsequently treat the CTO. Other FDA approved devices include the atherectomy drills Amplatz Thrombectomy Device (Microvena, White Bear Lake, MN), Wildcat catheter (Avinger, Redwood City, CA), and the ultrasonic Crosser catheter (FlowCardia, Sunnyvale, CA).

Other proposed devices that have been in use but are currently abandoned include fluid jets, lasers, and ultrasonic vibrational dissectors. Among other reasons, these devices illustrated an increased risk of blood vessel wall trauma causing them to be abandoned.

**4 Interpretation**

Even though many different devices have been proposed for the treatment of CTOs, only a handful is actually used in clinical practice. To get a truly functional crossing device it is necessary to look into novel ways to combine an imaging technique such as OCT or IVUS with a steerable and stiff crossing tool that is able to penetrate even the calcified regions without buckling.

**5 References**


Fig. 1: Overview and subdivision of crossing tools for CTO treatment. CTO = Chronic Total Occlusion, OCT = Optical Computed Tomography, IVUS = IntraVascular Ultrasound, GW = Guidewire.
Elastic Scattering Spectroscopy in combination with OCT in a rotating probe

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1 Background

Diagnosis of solid tumors in the prostate is currently done by biopsies, the gold standard. Often, after review, pathology shows that the biopsies are inconclusive. Then another series of biopsies is necessary for sufficient information. To reduce the amount of biopsies we are developing a new probe that provides real time images of cell layers as well as physiological information. This can help to reduce the number of inconclusive biopsies. This probe supports both Optical Coherence Tomography (OCT) and Elastic Scattering Spectroscopy (ESS). OCT will visualize the cell layers. ESS provides physiological information. The goal is to develop a probe analyzing the prostate and, if present, the cancer by multiple insertions. In this abstract the general approach and the design of a combined probe is given. The goal is to design a probe with following features: OCT plus ESS at the same location, a sideway looking tip that rotates 360 degrees, 20 cycles per second and a pullback over 5,5 cm. During the design phase we took care of the following critical issues: combining the two different optical pathways with very distinct optical specifications, the side firing rotating approach and the internal reflections occurring at the interfaces of the different components. A usual design of an ESS-probe is forward looking multimode fiber with a range of 360-1000nm. The conventional OCT probe (C7-XR, St. Jude) has a 1310nm light source, sideway looking, rotating tip, 5 cm pull back, which provides cylindrical data of the cell structures. To include ESS in a sideway looking, rotating OCT probe extra challenges will come across. This will include extra mechanisms and lenses which results in extra losses and undesired internal reflections.

2 Methods

To enable the probe to rotate without damaging the tissue a static outer hull is used. The inner probe can then rotate without damaging the tissue. Between the two hulls index matching fluid will be placed for flushing and reduction of internal reflections.

To transport light to the tip of probe two different optical pathways are necessary with specific requirements. First, for OCT a single mode fiber is required. Second, ESS will need a multimode fiber. A double clad fiber (DCF) offers these pathways with the advantage of rotational symmetry. The fiber will have a core and two claddings (SM-9/105/125-20A, Nufern). The single-mode core is used for the OCT-signal at 1310nm and the first cladding will be used for the ESS light ranging from 360 to 1000nm.

To connect the rotating probe to the static light sources and signal processing devices we need a Fiber Optic Rotary Joint (FORJ). The FORJ consists of a static and a rotating Gradient Index (GRIN) lens with an anti-reflection coating that is fused to the double clad fiber. The GRIN lenses ensure that the light will be transmitted from the static fiber to the rotary fiber and vice versa.

To split the double clad fiber into a fiber to the static OCT light source and detector and to the ESS source and spectrograph a Double Clad Fiber Coupler (DCFC) [1] is commercially available. This device separates the coaxial light paths for ESS and OCT from the static double clad fiber into two separate fiber optics.

The tip of the probe will direct the light from the fiber sideways to the tissue. The combination of a GRIN lens together with a prism fused on the tip of the fiber ensures the redirection and focusing the light sideways.

The ESS setup: The light source used is a Halogen-Deuterium lamp (AvaLight-DHc, Avantes). This broad band light source generates sufficient optical output power (Deuterium: 0.2mW, Halogen: 7mW in a 600µm fiber) for a rapid acquisition of ESS spectra. The spectrograph is sensitive for a range of 360-1100nm, has a spectral resolution of approximately 1 nm has a sample speed of 1.1ms/scan and a minimal integration time of 1.05ms (Avaspec ULS2048, Avantes).

![Figure 1. The schematic approach of the setup. The fibers from the OCT and ESS will be coupled into a double clad fiber (DCF) by the double clad fiber coupler (DCFC). In the Fiber Optic Rotary Joint the static DCF and the rotary DCF are coupled using two GRIN lenses. At the end of the rotary DCF the tip of the probe is located.](image-url)
The OCT setup: A commercially available OCT system (OCT system, Santec) will be used with the following specs: wavelength 1310nm, speed 100kHz, resolution 5um.

3 Results

The design of a rotating probe with OCT and ESS is shown in figure 2. The light transport through the hulls, flushing fluid, double clad fiber, fiber optic rotary joint and the GRIN lens fused on the prism were simulated using Zemax.

The properties and locations of the components were optimized on the basis of these simulations. Internal reflections were limited by different techniques; anti-reflection coating on the GRIN lenses in the FORJ, index matching fluid between the inner hull and the outer hull, fusion of the GRIN lens and the prism with the fiber in the tip of the probe.

4 Interpretation

The promising results of the simulation suggests the feasibility of a rotating probe with ESS and OCT.

In the next period we hope to realize the first prototype and test the performance. Preliminary results will be demonstrated at the conference.

References


Acknowledgements

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Miniaturization of an Optical Data Link for IVUS Imaging Guidewires

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1 Background

We propose a novel concept for a high-speed optical data link in 360 μm diameter cardiovascular interventional imaging guidewires. The concept is based on the recently introduced Flex-to-Rigid (F2R) technology platform. This technology allows for new intravascular imaging devices which fit the required small form-factor. We extended the existing F2R technology with a new optical link assembly method to enable high speed data communication from the distal tip of the catheter to the proximal side. In this method, the fiber is aligned by inserting it into a through-wafer hole directly underneath the flip-chipped Vertical-Cavity-Surface Emitting Laser (VCSEL). Therefore, the total diameter of the optical data link is primarily limited by the size of the VCSEL. A wafer-scale demonstrator setup was fabricated with a commercially available 350x250 μm VCSEL and an 80 μm diameter multimode optical fiber. Test results of our demonstrator showed a good coupling of the VCSEL into the fiber.

Taking 7.25 million lives per year Coronary Artery Disease (CAD) is the leading cause of deaths worldwide [1]. With this number increasing every year there is a high demand for improvement in imaging methodology for CAD. Intravascular ultrasound (IVUS) catheters are used in the evaluation of the plaque deposition on the arterial wall due to the disease. Furthermore, they give insight into the effectiveness of the treatment during and after minimally invasive surgery. In order to reach into the smaller vessels there is an ongoing trend in the miniaturization of the IVUS catheters. A logical next step is to integrate IVUS directly into the guidewire that is inserted at the beginning of the procedure (Figure 1). Here, the miniaturization is approaching a limit as the required electrical data connection of 500 Mbit/s is difficult to fit into the small diameter of the guidewire.

To overcome this problem we propose a concept using an optical data link (Figure 2). The smallest optical data link designed for minimally invasive surgery fits in a catheter of 7 Fr. (Ø 2.33 mm) [2]. The optical data link can be downsized further to guidewire sizes by making use of the F2R technology [3]. F2R is a planar process technology that allows the resulting device to be folded up to fit the desired form-factor (Figure 3). To prove the feasibility of the assembly method on the F2R platform a wafer-scale demonstrator was fabricated.
2 Methods

To construct the demonstrator, a VCSEL and an oscillator Application-Specific Integrated Circuit (ASIC) were mounted on a substrate processed with F2R (Figure 4). A commercially available 350x250 μm VCSEL was used as light source. The ASIC was available from an earlier experiment and served as a 10 Mbit/s driver. The ASIC was post-processed with F2R, hence the 360 μm diameter disc-shaped chip could be made. In the microfabrication of the simplified F2R substrate, first a Polyimide (PI) layer of 5 μm was spin coated on top of a 400 μm thick silicon wafer. On top of this layer 1.5 μm aluminum (Al) was deposited and patterned to form the bondpads and interconnects. From the backside a through-wafer hole was etched with the PI as etch-stop layer. The wafer was diced and glued to a Printed Circuit Board (PCB). The ASIC and VCSEL were mounted on the bondpads by thermo-compressive bonding with gold studbumps. An 80 μm thick multimode fiber was inserted in the hole and fixed with EPO-TEK 353 heat curing epoxy. The other end of the fiber was aligned to a reverse biased Osram SFH203P photodiode. The oscillating output of the ASIC was connected to the VCSEL input through the Al layer of the F2R substrate. Gold wire bonds from the substrate to the PCB provided the ASIC of power. Both the ASIC and the photodiode signal were measured with an Agilent 54642D Oscilloscope.

3 Results

The wafer-scale demonstrator was successfully created (Figure 5). In order to test the optical data connection an oscillator Application-Specific Integrated Circuit (ASIC) available from an earlier experiment was used. The ASIC provided a 10 MHz oscillating signal to the VCSEL. A photodiode measured the optical signal at the other end of the 2 m optical fiber. Test results showed that this measured frequency matches with the input signal of the VCSEL (Figure 6). As expected, a signal delay of 50 ns is observed due to parasitic capacitances.

4 Interpretation

This result confirms a successful optical coupling between the fiber and the VCSEL. This shows that the minimum footprint required for an optical link on F2R is limited by the size of a VCSEL. For a next iteration, the ASIC will be replaced by a custom designed 2.5 Gbit/s VCSEL driver. Solder-self alignment is planned to replace the thermocompressive bonding, reducing the needed placement accuracy. The ultimate step will be to use the full F2R processing for the fabrication of the foldable IVUS transducer, including the optical link. This work is supported by the Technology Foundation STW as a part of the Instruments for Minimally Invasive Techniques (iIMIT) program.

References


Abstract [45]

Figure 4. Design sketch of the demonstrator setup. An F2R processed wafer without flexible sections was used to test the integration of components.

Figure 5. Picture of the wafer-scale demonstrator. The VCSEL and ASIC were flipchipped on studbumps. Power to the ASIC was delivered through wire bonds.

Figure 6. Measurement of a signal communicated through the optical data link. The frequencies match and an expected phase shift is observed.
Wednesday 22 October, 2 pm
Chair: Bart Verkerke, University of Groningen

2. Knee Orthosis for Cartilage Repair
GJ Verkerke, R Kuijer, EEG Hekman, SK Bulstr

11. A Pressure-Redistributing Insole using Soft Sensors and Actuators
Jin-Huat Low, Khin-Phone May, Chen-Hua Yeow

13. Customizable Pneumatic Bending Actuator for Finger Rehabilitation
Hong Kai Yap, Jeong Hoon Lim, Fatima Nasrallah, James Cho Hong Goh, Chen Hua Yeo

16. Hand tracking for an exoskeleton for home-based wrist and hand rehabilitation
Angelo Basteris, Beatriz Leon, Farshid Amirabdollahian

18. Adherence and arm function improvements with home-based distal arm training using robotics and gaming after stroke

21. A Soft-Actuator-Based Ankle Rehabilitation Device to Prevent Deep Vein Thrombosis
Fanzhe Low, Jeong Hoon Lim, Chen Hua Yeow

22. Developing a system for robot-assisted stroke rehabilitation through user centered design methods
Ellinor Johansson, Franziska Schaetzlein, Peter Klein, Stefanie Mueller, Nasrin Nasr, Sharon Nijenhuis, Patrizio Sale

28. MyHand: Assistive Hand Orthosis to Overcome Stroke Impairments
Johannes van Wijngaarden, Laura Smulders, Gert Jan Lijbers, Gerdienke Prange, Peter Veitink, Arno Stienen

30. Wheelchair for hemiplegic patients
Kelly Hesselink, Edsko Hekman, Bart Verkerke

43. Development of a motion controlled arm support from a user perspective
Loek van der Heide, Gert Jan Gelderblom, Luc de Witte

44. Evaluation of a Wearable Trunk Support for Working in Sustained Stooped Posture
Chris Baten, Remon van der Aa, Annechien Verkuyl

46. Functional Strength Measurement for the Upper Limb in Children with Cerebral Palsy
Eugene Rameckers, Jos Aarts

49. Three Stages of Development of the Robust SCRIPT Active Orthosis
Serdar Ates, Israel Mora Moreno, Martijn Wessels, Piet Lammertse, Arno Stienen

50. Evaluation of Motion Controlled Arm Support
Arjen Bergsma, Hans Essers, Alessio Murgia, Edith Cup, Dick van der Pijl, Paul Verstegen, Imelda de Groot, Kenneth Meijer

51. Flextension A-Gear: Progress of Developing a Natural Arm Support for Duchenne Patients
Joan Lobo Prat, Alje G. Dunning, Mariska M.H.P. Janssen, Arjen Bergsma, Peter N. Kooren
Knee Orthosis for Cartilage Repair

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1 Background

Damage of joint tissues usually starts with damage to articular cartilage. The ultimate result, degenerative joint disease or osteoarthritis, is frequently occurring: approximately 80% of people over 60 years of age have osteoarthritis features in X-rays of their knee and hip joints. The ultimate treatment is inevitably a total joint prosthesis.

Since several years a new, successful treatment exists: joint distraction (1). Key elements are unloading the joint and preservation of motion. Unloading prevents further cartilage damage and creates favourable restoration conditions. Motion of the joint enables transportation of nutrition to the damaged area and removal of waste products. It has been proven that restoration of the cartilage can be obtained in 2-3 months (2).

Currently only one surgical method of joint distraction is known with an application in the knee, see figure 1. Pins are inserted into the bone proximally and distally to the joint. The pins are connected by a hinged frame that distracts and unloads the joint. The hinge allows the patient to walk with a fully functional knee joint without mechanically loading the cartilage. One drawback of this method is the invasive character of it. Pins are penetrating the skin, thus infection is likely to occur. Not many people take this risk. Also, wearing the external frame poses a social burden (e.g. patient cannot wear normal clothes) as well as a psychological burden on the patient.

Orthoses exist which can to some extent unload a joint, but which do not allow functional use of the joint. An example is the Thomas Splint, which is a leg brace intended to unload the hip joint. Ideally it would fully remove the weight on one leg. Literature reports, however, that it removes at the most 50% of the body weight from the hip. It does not remove any of the muscle forces on the hip joint. It also does not provide distraction of either the hip or the knee joint, nor does it allow motion of the knee joint.

Our newly designed and fabricated orthosis combines the best of both worlds. It can unload the knee joint, like the distraction frame, at the same time allowing full ROM of the joint. And, as being an orthosis it does not require transcutaneous connections to the bone. The movement should be sufficient for efficient distribution of nutrients and removal of waste products such that the joint tissue can regenerate. The unloading should be enough to start regeneration of cartilage. A first clinical trial has been performed. Results are presented in this paper.

2 Methods

The orthosis (fig. 1) is derived from an upper leg prosthesis. The bottom of the socket is removed to allow the leg to be present. The lower leg is forced to have a slight angle with the upper leg. In this way the loading of the knee is decreased. In a fully extended position the femoral condyles and the tibia plateau are in close contact to realize sufficient stability for the leg to land on the ground and to bear load. In a more flexed position the contact is less severe and thus the loading on the cartilage is limited. The orthosis will support the body via an adapted upper leg socket. Forces between socket and body are transferred via a tuberosity support. The weight is transferred directly to the floor by the orthosis, bypassing the knee and the ankle. That is, the patient stands on the orthosis, not on his foot. The orthosis contains a lower leg part connected to the upper leg part by a hinge. The lower leg part is also connected to the lower limb. The hinge is aligned with the anatomical knee joint. To make up for the leg length difference, the shoe on the contralateral side is provide with a thicker sole and heel.

Traction can be applied on the lower limb by the orthosis, causing unloading of the joint under muscle activity. Several types of hinges are applicable, such as the automatically locking Basko SPL-joint. Using an automatically locking joint will reduce muscle activity around the knee as the patient does not need to stabilize the joint. For the first clinical trial, a traditional hinge mechanism without locking mechanism was applied.

The first patient was a female with severe cartilage damage according to the X-rays. She walked for two weeks with the knee orthosis and used crutches all the time. The orthosis was always applied when walking. To improve the flow in the joint each day exercises on a home trainer bicycle was done at the lowest possible resistance.

After two months the orthosis was removed. X-rays were taken to register the amount of knee cartilage recovery. Gradual loading was prescribed over a period of 6 weeks.
3 Results

Recruiting a patient for this trial was rather difficult. In spite of the prospect of possible cartilage regeneration without the need for percutaneous pins, several prospective users were reluctant to agree to wearing an orthosis. The orthosis was comfortable enough to use it for a period of 2 months in every walking or standing situation. Although it should be possible to use it without crutches, this patient felt too unsecure to do so. Her motivation was high enough to use the orthosis all the time.

Detailed results about cartilage repair are not available yet, but will be presented during the congress.

4 Interpretation

Spontaneous cartilage repair was found to be impossible until some 15 years ago. Animal experiments showed that joint distraction with preservation of motion could start a healing process of damaged joint cartilage. After 2 months repair was visible. And when after 2 months knee loading was brought back to normal, the repair process continued. Cartilage apparently needs a period of rest to allow the repair process to start.

However, this treatment is very uncomfortable and risky for patients. Due to the percutaneous pins there is a high risk of infection, with the risk of the infection spreading to the bone. The pins that are present could cause damage to the skin or clothing of the other leg.

As a more patient-friendly alternative a knee orthosis was developed. The orthosis proved to be comfortable enough for this single patient to be used for a period of 2 months. Results are not present yet, but will be discussed during the congress.

References

A Pressure-Redistributing Insole using Soft Sensors and Actuators

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Summary

Abnormal high repetitive stresses acting on the foot tissues can cause immediate breakdown of foot tissues, which will lead to ulcers and even foot amputations. Therefore, this study aimed to design a pneumatic insole system with soft pressure sensors and soft pneumatic actuators which can reduce localized high pressure at regions that are typically at high risk of developing foot ulcers, such as first metatarsal head and heel region. Four healthy young participants were tasked to walk normally on a 9m walkway with a standardized shoe (Power model, Bata, Inc.), whereby the shoe is fitted with two different insoles: regular insole and pressure-redistributing insole. The findings showed that the peak plantar pressure was significantly reduced in first metatarsal head region (-45%, p=0.01) and heel region (-63%, p=0.02). The results demonstrated the feasibility of developing an active therapeutic insole system that comprises of localized pressure sensors which monitor the plantar pressure in real-time and soft pneumatic actuators to redistribute the pressure.

1 Background

The foot is the weight bearing interface between the ground and the body during daily locomotion activities. It experiences high stress and strain during walking particularly in heel region during heel strike [1] and in forefoot region during toe off [2]. High repetitive pressure and shear acting on the plantar aspect of the feet for prolonged period will cause the breakdown of plantar foot tissue [3]. The plantar soft tissues such as heel fat pad and metatarsal head pad are specialized structures, in which their viscoelasticity allows them to undergo deformation in order to facilitate shock attenuation during walking. Therefore, the damaged soft tissue may not be able to transmit weight during walking and can eventually result in ulceration.

Moreover, diabetic patients are prone to have ulcers due to the risk factors such as neuropathy, lack of sensation, muscle atrophy or foot deformity. For instance, glycosylation of collagen and stiffer plantar foot tissue caused the reduction in adaptability of the tissue to respond to repetitive stress, resulting in higher incidence of ulceration [4]. Moreover, foot deformity such as hammertoes or Charcot foot may cause elevated plantar pressure which has been reported to be a contributing factor of diabetic foot ulcers on first metatarsal head and hallux region [5].

It is therefore important to design new effective approaches which can assist in reducing the abnormal plantar pressure. The objective of this study was to design a pneumatic insole system, which comprises of soft insole pressure sensors and soft insole pneumatic actuators that are capable of redistributing plantar pressure at localized high-risk regions.

2 Methods

Piezoresistive material Velostat (3M, USA) was used in fabrication of the sensor. Insole pressure sensors, of 1cm² sensing area, were made by placing the Velostat on top of two parallel strips of conductive sheet. In between the resistive and conductive layer, an interface of evenly distributed thin Poly(vinyl chloride) (PVC) strips was placed. The interface prevents the Velostat from being in contact with conductive layer when force is not applied (Figure. 1).

Figure 1. The configuration of the insole pressure sensor.

Pneumatic Actuator

The soft pneumatic actuator was made of elastomeric material (Ecoflex 00-30, Smooth-On Inc., US). It was fabricated using a combination of 3D printing and soft lithography techniques. 3D computer-aided-designed (CAD) molds with pneumatic channel (Figure. 2) were created and then the elastomeric material can be poured into the mold. Another sealing layer will then be bonded to the structure to seal the pneumatic channel. The insole actuator functions when air is introduced into the actuator by a pump to induce inflation and redistributes plantar pressure. The pressure exerted by the air causes the pneumatic channels to inflate in regions that are most compliant, particularly in areas where the walls are the thinnest. The peripheral pneumatic ring channel is inflated when pressurized (Figure. 3).

Figure 2. 3D printed mold and the pneumatic actuator with peripheral pneumatic channel.

Figure 3. A demonstration of the pneumatic channel inflation at heel region.
3 Results

Four healthy subjects (age: 20-25) were tasked to walk normally on the 9m walkway with a standard shoe (Power model, Bata, Singapore) integrated with a regular insole and with a pressure-redistributing insole. For the latter, the pneumatic actuators were located at the second metatarsal head (MTH2) region and heel region and the sensors were put on the first metatarsal (MTH1), MTH2 and heel region. These regions are where high plantar pressures were usually present [6]. The peak plantar pressure was significantly lower in MTH1 region in pressure-redistributing insole (-43%, p=0.02) and heel region (-57%, p=0.02), as compared to regular insole (Figure 4). No significant difference in plantar peak pressure was detected at the second metatarsal head region (p=0.35).

Figure 4. The mean peak plantar pressure in first, second metatarsal head and heel region. * Significant p<0.05

4 Interpretation

The aim of this study was to design a pressure-redistributing insole based on soft pressure sensors and soft pneumatic actuators. To the authors’ knowledge, this is the first study to design a soft pneumatic insole actuator which can be inflated to redistribute localized plantar pressure. Of particular interest is the peripheral pneumatic channel that can be inflated to cushion the metatarsal head or the heel regions. The findings showed that the pressure-redistributing insole reduced mean peak plantar pressure significantly by 43% in first metatarsal head region and 57% in heel region when compared to regular insole. While there is no known plantar pressure threshold above which ulceration will occur, the direct proportional relationship between the plantar pressure and risk of developing ulcers has been reported [7, 8]. The possible explanation on the reduction in mean peak plantar pressure is that the inflation of the pneumatic channel covered the metatarsal head and heel region which provide more cushioning on the areas. Moreover, the pneumatic actuator was made using a soft elastomer material, hence allowing the inflated part of the pneumatic actuator to conform well to the weight bearing region and hence increase the contact surface so as to redistribute the localized peak plantar pressure more effectively. However, there is no significant difference in mean peak plantar pressure in MTH2 region for both insoles. It showed that a single pneumatic actuator may not be suitable to reduce the peak plantar pressure in both MTH1 and MTH2 region. When the pneumatic channel on MTH2 region inflates, it provides cushioning on the peripheral locations, such as MTH1 region, but does not provide cushioning on MTH2 which means that the inflation may not be enough to support the whole weight bearing regions on metatarsal heads. It may be possibly resolved by including a pneumatic actuator array which cover more metatarsal regions.

However, there are a number of limitations that need to be considered in this study. First, the sample size used in this study is small and considering that the variation in gait pattern in human beings is large, a larger sample size is needed in order to have conclusive findings on the effect of pneumatic actuator on the redistribution of plantar pressure. Second, diabetic patients or elderly were not included in this study. Therefore, it remained unknown if the beneficial effects of the pressure-redistributing insole on healthy young participants would be found on diabetic patients as most patients tend to develop foot deformities which will directly change their gait pattern. Lastly, the control of the soft pneumatic actuator in this study is not autonomous. It is manually controlled and may not provide the true effect of the soft pneumatic actuator on pressure redistribution during real time dynamic walking when high foot pressure is detected.

Soft pneumatic actuator array which cover the entire metatarsal head regions (MTH1, MTH2, MTH3-5) should be considered in future. Moreover, future work should focus on the real-time control of the soft pneumatic actuator based on the feedback from the soft insole pressure sensor. A prospective study with diabetic patients will also be conducted in order to investigate the therapeutic effect of pressure-redistributing insole in clinical applications. Lastly, a comparison of the effectiveness in reduction of peak plantar pressure between the pressure-redistributing insole and commercial therapeutic insole, such as diabetic offloading insole, should be done to validate the efficacy of our design.

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References

Customizable Pneumatic Bending Actuator for Finger Rehabilitation

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1 Background
Impairment of hand function is one of the most common problems after neurological disorders such as stroke or post-traumatic arthritis. Various robotic devices have been proposed for rehabilitation in order to provide physical therapy and recovery of the hand [1]. Exoskeleton is one of the robotic approaches for hand and finger rehabilitation, which is placed around the hand to actuate and guide the finger joints without impeding their natural movement and provides functional hand training. However, designing robotic device for hand rehabilitation remains a challenging task due to the complexity of the hand.

Currently, the actuation mechanism of hand exoskeleton devices includes cable-driven, linkage-based and pneumatically-driven mechanism. However, these mechanisms have their own limitations. Cable-driven actuation can only transmit the force uni-directionally and bi-directional movements are not permitted. Linkage-based mechanism is able to transmit the force bi-directionally; however, this kind of mechanism is normally bulky and not comfortable. Pneumatically-driven mechanism involves the use of pneumatic artificial muscles, which can be made compact and integrated into the main body. However, in this kind of mechanism, precise attachment of the actuators to the human joint centers is required [2].

Considering the limitations of current existing devices, we employed the soft robotics approach to develop a wearable soft pneumatic actuator gloves. Soft pneumatic actuators are drawing a lot of research interest recently due to their low inherent stiffness and high compliance [3]. This approach typically embeds soft pneumatic networks in elastomers to achieve different desired motion by air pressurization [3]. Additionally, rehabilitation devices that utilized soft pneumatic actuators for hand or finger therapies are also being developed recently [4, 5].

In this paper, we proposed a wearable rehabilitation glove that utilized soft pneumatic bending actuators. Our group has developed a soft pneumatic actuator that is highly customizable in terms of its bending motion profile, which may be potentially beneficial for patient-specific rehabilitation application.

2 Actuator Design
In this wearable soft pneumatic actuator glove design, the actuators were attached on top of the finger segments of a fabric glove, which guide and assist the fingers to achieve the bending motion upon pressurization (Fig. 1a). The soft actuator was made from silicon elastomer (Dragon Skin® 20, Smooth-On Inc, US) with a restraining layer adhered to the bottom. Upon pressurization, the upper surface of the actuator expands due to the inflation of the embedded pneumatic channels, while the elongation of bottom surface remains unchanged due to the restraining layer. As a result, bending movement and torque were produced during actuation (Fig. 1b).

The control feature channels at the top of the actuator served as the motion control mechanism, which was able to mechanically control the bending profile of the actuator. By embedding Kevlar thread at a specific segment of the actuator, the bending motion of the segment will be inhibited due to the restriction of Kevlar thread. Different bending profiles can be achieved through embedding the Kevlar thread at different segments (Fig. 2). This mechanism allows for the customizability of the actuator for different hand geometry and therapy exercises (table top, PIP blocking, straight fist, DIP blocking, hook fist and fist) [6].

Fig. 1 (a) Proposed design of the wearable glove. (b) Bending actuator and its bending motion.

Fig. 2 Bending profiles of the soft actuator with additional control from Kevlar thread. (a) Front end bending restricted. (b) Front and back end bending restricted. (c) Middle bending restricted.
3 Actuator Characterization

3.1 Output Force. The output force of the bending actuator upon pressurization was measured using a customized platform (Fig. 3a). The platform consisted mainly of a linear free-moving plate, fixed plate and a load cell. Load cell was attached at the end of the platform and connected to computer in order to measure the horizontal force output from the bending actuator. One end of the bending actuator was fixed on the linear moving plate and the other end was mounted on the fixed plate. Upon pressurization, the bending actuator bent and pulled the free-moving plate towards itself. As a result, the free moving plate pulled the load cell and the load cell measured the resultant horizontal force. The maximum force output for the actuator was 10.35N at 225kPa (Fig. 3b).

3.2 Bend Radius. The bending actuator achieved the minimum bend radius of 30mm at 210kPa. The actuator responded faster at first and slowly reached its steady state. When the bend radius reached the steady state, further increase in input pressure did not result in substantial changes in the bend radius (Fig. 3c).

4 Interpretation

Based on our preliminary tests of the prototype, the device could produce substantial force to flex the index finger. The bending actuator was able to actuate the DIP and PIP joint of the index finger during hook fist exercise (Fig. 4).

In conclusion, this pilot work demonstrated the feasibility of developing wearable devices for biomedical applications using soft pneumatic actuators. Future studies will seek to incorporate other therapy exercises with bending profile control of the actuator. Microcontroller system, portable air source as well as joint angle and force feedback would also be included into subsequent design iterations.

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References

Hand tracking for an exoskeleton for home-based wrist and hand rehabilitation

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1 Background

The SCRIPT project focuses on robot-assisted hand and wrist exercise for stroke survivors. However, gross movements of the arm are expected to contribute to higher functional recovery, and we hence incorporated the recognition of such movements within our system.

The first prototype of our passive-actuated orthosis [1] fitted an inertial measurement unit (IMU), mounted on the forearm. Formative feedback gathered from 24 participants showed technical difficulties in having such movements recognized consistently. Such difficulties arose as a consequence of many factors such as limited amplitude and speed of motion, electromagnetic interference of other metallic parts in the surroundings and displacement of the IMU with respect to the hand.

We hence developed an alternative solution which provides information about the 3D position of the hand in space by optically tracking a color marker.

The requirement of performing in a non-controlled environment such as the patients’ homes raises potential issues for an optical tracking system, which we have taken into account in our design. Ambience lights (either artificial or natural) and objects in the surrounding workspace might interfere with such a system. Affordability is another driving requirement of our project. In this paper we describe a webcam based system for home-based rehabilitation and show preliminary results from the calibration of such system.

2 Methods

In order to achieve the desired affordability of the final system, we used an off-the-shelf webcam (Sony Playstation Eye, approx. cost of 20 euros) on top of a touchscreen display. The image is acquired and post-processed with a free open source software for computer vision (OpenCV, www.opencv.org), and the output of such post processing is fed to a software for therapeutic human robot interaction which controls some videogames.

The concept is that of measuring the 3D position of a marker placed on the back of the hand. Figure 1 shows a green marker mounted on top of the passive orthosis, with the webcam on top of the touchscreen. In order to prevent the color confusion, the markers (25 mm diameter) are easily replaceable by the therapist or the patient, who are instructed to do so in case there are other areas of the desired color.

Figure 1. System for hand tracking based on webcam and passive marker

The tracking is based on the hue, saturation, values (HSV) representation of the picture. During a preliminary calibration phase (which happens prior to each session) subjects are required to hold their hand so that the marker appears in a specific point of the screen. At this time, the system identifies the corresponding HSV values as a reference. This makes our system less sensitive to changes in environmental light as those which could happen due to the presence of the sun.

The image is acquired at 100 Hz, with a resolution of 640x480. Areas with HSV values around the reference are identified on each picture.

The centre of such areas depends on the position of the marker on the camera plane. We chose a spherical marker, so that the surface of its projection on the camera plate mostly depends on the distance from the focal point. Also, the spherical shape makes the area independent from the hand orientation. Thus, the antero-posterior and lateral movements are identified by the mean coordinates of the area on the picture, while vertical movements are estimated based on the size of the marker area.

Another concern was the possible presence of windows or other sources of light in the background. Hence, we decided to orientate the camera downwards. Doing so, we reduce possible interferences due to objects in the background. Also, we center the field of view of the camera on the volume in which the hand moves. To achieve this, we designed and produced a custom bracket which turns the camera 45 degrees downwards. We printed this tool with a 3D printer available at the University of Hertfordshire (shown in Figure 2).
We assessed the size of the workspace and the optical deformation introduced by the tracking system by moving a green marker in 16 (4 rows, 4 columns) on a grid of size 5 cm.

3 Results

Figure 3 shows the setup used for assessment. From the picture, it is noteworthy that the workspace overcomes 0.5 m for both anteroposterior and lateral directions. From the same picture one can note the deformation due to the camera perspective, positioning and tilting. The vertical plane is indeed not normal to the camera axis. Figure 4 shows the acquisition while we moved the marker on the grid. The abrupt changes in the lateral and vertical coordinate represent respectively transitions among columns and rows. It is noticeable how in the center of the workspace (interval between approximately 20 and 90 s, figure 4 middle panel) the deformation due to the camera is not affecting the lateral component. Similarly, this is not an issue when considering the values of the same row for different columns (e.g. the top values in figure 4 bottom panel).

4 Interpretation

We designed a system which allows tracking of the hand with affordable solutions to problems which could be encountered in a domestic set up.

Our preliminary experience and results show that the system provides a workspace large enough for the practice of rehabilitation exercises and that despite the distortion due to the camera optics the position of a color based marker can be acquired. Such distortion could be corrected with direct linear transform, by using the calibration data shown in this work.

Future work include formative evaluation of our system with subjects with stroke.

References

Adherence and arm function improvements with home-based distal arm training using robotics and gaming after stroke

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1 Background

Functional recovery from stroke requires extensive rehabilitation with a high training dose, active initiation and execution of movements, and application of functional exercises [1, 2]. In clinical practice however, intensity of post-stroke treatment is often restricted due to limited availability of healthcare professionals and/or high costs of neurorehabilitation.

Technological innovations provided an opportunity to design interventions that enable intensive training, such as rehabilitation robotics. Contemporary robot-aided therapy focuses mainly on the proximal arm, without generalization of gains to the wrist and hand [3, 4], while the wrist and hand play a major role in a person’s functional independence [5]. If a system that supports active, distal arm practice can be applied in a patient’s home within a telerehabilitation concept [6], high intensity training is facilitated due to independent practice by a patient, while supervised remotely by a healthcare professional. In such a home-based application, the adherence of a patient to the training programme is an important but often unknown factor that likely affects the actual dosage of treatment delivered [7].

In the current study (Supervised Care and Rehabilitation Involving Personal Tele-robotics, SCRIPT), a custom-designed orthosis that passively supports wrist and hand function is combined with a gaming environment, connected to a remote module for off-line supervision by a healthcare professional. This system (SCRIPT1) is used independently at home by chronic stroke patients for distal arm training. The present paper aims to examine the adherence of chronic stroke patients to home-based SCRIPT1 training and associated changes in arm function.

2 Methods

The present study applied a longitudinal (pre-post) study design, with an intervention of six weeks of home-based arm/hand training with the SCRIPT1 system, in 24 chronic stroke patients with impaired arm/hand function. Participants were included across 3 clinical sites: Roessingh Research and Development (the Netherlands), IRCCS San Raffaele Pisana (Italy) and University of Sheffield (United Kingdom). The study was approved by the local medical ethics committees and all participants provided written informed consent before entering into the study.

Participants performed six weeks of self-administered distal arm training at home. It was recommended to exercise 180 minutes per week, but participants were free to train as they preferred. They wore a custom-designed hand/wrist orthosis (Fig. 1) that passively supported wrist extension and hand opening across all fingers of the affected arm. With the instrumented orthosis they controlled custom-designed games displayed on a touchscreen, while they were supervised remotely, off-line, by a trained healthcare professional (details about design of the orthosis, user interface and games can be found in [8] and in related contributions to the current conference). Additionally, all participants used the SaeboMAS (Saebo Inc, Charlotte NC, USA) arm support for the proximal arm, set to provide 100% of arm weight compensation.

Evaluation involved adherence in terms of training duration (in minutes, recorded in-game) and arm motor function assessment using the Fugl-Meyer scale (FM [9, 10]) one week before (T01) and after (T08) the 6-week training. Changes in arm function were compared pre- and post-training using the Wilcoxon signed-rank test (significance level \( \alpha < 0.05 \)).

3 Results

Of the 24 patients, 3 dropped out during the study, due to shoulder complaints acting up, dislike of the system and technical issues. Mean age of the remaining 21 participants was 58 years, mean time post-stroke was 17 months.

Average training duration was 105 (±66) minutes per week. This comes down to about 15 minutes of self-administered training each day for 6 weeks. Individually, training duration varied substantially, ranging from 13 up to 284 minutes (4 hours and 44 minutes) per week.

Arm function had improved after training (Fig. 2). Mean FM scores increased significantly by 4.0 (±4.8) points (p=0.002): from mean 33.1 ± 15.8 (median 37.0) to 37.1 ± 16.3 (median 41.0) points. On individual level, 8 out of 21 (38%) participants achieved minimal clinically important differences (MCID: +6.6 points [11]).

Figure 1. SCRIPT1 passive hand/wrist orthosis

40 Abstract [18]
Some participants even reached a maximal training duration of 1¾ hours per week was observed. This amount of use was associated with an improvement in arm motor function of on average 4 points and with clinically relevant changes in 38% of participants.

These improvements in arm function are along similar lines as those found in robot-aided studies in chronic stroke [11], as well as actively [12] and passively [13, 14] actuated arm support for the proximal arm. In contrast to the current intervention, these studies involved face-to-face supervision and a fixed schedule of practice (ranging from ½ hours per week [12, 14] to 3 hours per week [13]) in a clinical setting. It is noteworthy that self-administered training at home resulted in a similar average training duration of 1¼ h/wk.

There are only a few studies that have examined home-based arm/hand training after stroke so far. A review by Coupar et al. 2012 included only four studies on telerehabilitation focusing on training of the upper limb after stroke in the home situation [15]. Although no negative results of home-based training were reported with regard to usual care or a similar treatment in the hospital setting, there was insufficient evidence to conclude whether home-based training is equally or more effective to improve arm function. In these studies, participants received direct real-time (remote) supervision from a therapist and the actual amount of self-administered training at home wasn’t examined.

In contrast, the SCRIPT1 system allowed stroke patients to choose their own training time and duration and have a more active role in their rehabilitation, involving their family members and carers as well. This hinders a comparison of adherence and associated improvements in arm function with similar studies. Anecdotal evidence from physiotherapists involved in the present study have mentioned that an adherence of about 15 minutes per day of actual in-game practice is rather high for chronic stroke patients to exercise at home on personal incentive.

The preliminary findings in the present study indicate that when provided with the opportunity, stroke patients have the personal incentive to perform substantial amounts of practice at home as a mean training duration of 1¼ hours per week was observed. Some participants even reached a recommended 10h of additional practice across the 6-week training that has been proposed as the minimal amount of additional training for achieving functional gains [7]. This suggests that technology-supported arm/hand training is a promising tool to enable self-administered practice at home for (certain) chronic stroke patients. Further research is needed to optimize the current design for more functional exercises to increase its clinical potential and to obtain more insight in mediating factors (such as initial stroke severity, age, motivation) of adherence and clinical improvements.

4 Interpretation

The majority of participants (87%) were able to use the SCRIPT1 system as a tool for self-administered training, with an average adherence of 105 minutes per week. This amount of use was associated with an improvement in arm motor function of on average 4 points and with clinically relevant changes in 38% of participants.

These improvements in arm function are along similar lines as those found in robot-aided studies in chronic stroke [3], as well as actively [12] and passively [13, 14] actuated arm support for the proximal arm. In contrast to the current intervention, these studies involved face-to-face supervision and a fixed schedule of practice (ranging from ½ hours per week [12, 14] to 3 hours per week [13]) in a clinical setting. It is noteworthy that self-administered training at home resulted in a similar average training duration of 1¼ h/wk.

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References


Figure 2. Mean Fugl-Meyer scores (±SD) pre- and post-training
Pneumatic Actuators Design for Ankle Rehabilitation to Prevent Deep Vein Thrombosis

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1 Background

Deep vein thrombosis (DVT) is a severe complication of various medical conditions, especially stroke whereby DVT develops mostly within 2 weeks after onset [1]. Factors that are associated with the development of venous thrombosis included hypercoagulability, vascular wall injury, and venous stasis [2], where stroke patients are at high risk of venous stasis due to inability to move their limbs. Without preventative measures, 53% of bedbound patients experience DVT and 16% experience pulmonary embolism (PE). The development of PE due to DVT is the leading cause of mortality in the first 2-4 weeks post-stroke [3].

Current thrombosis prophylaxis can be separated into two groups, pharmacological prophylaxis and also mechanical prophylaxis. Currently, for the prevention of DVT, the standard intervention used is pharmacological prophylaxis, in the form of anticoagulants such as low-molecular weight heparin (LMWH) and unfractionated heparin (UFH). Although anticoagulants are effective in preventing DVT in ischemic strokes, there are associated serious side effects such as re-bleeding in intracranial lesion, which may preclude the use of anticoagulants in hemorrhagic stroke patients. Therefore in this case, anticoagulants drugs are hardly used as the risk of bleeding outweighs the benefits that patients can get from preventing DVT [4].

On the other hand, there are also several forms of mechanical prophylaxis such as compression stockings and also intermittent pneumatic compression devices. Such devices can also act as a contra-indication for antithrombotic prophylaxis [5]. However, for these forms of mechanical prophylaxis, the efficacy of such treatment is limited in their ability to prevent prophylaxis (poor evidence), and therefore most patients will have to turn to antithrombotic therapy eventually despite the risk of bleeding [6]. Furthermore, current mechanical prophylaxis such as the graduated compression stockings (GCS) has limitations such as problem of compliance issues arising from both the patients and the nurses due to the need to wear the stockings daily [7]. Furthermore, should the GSC be of wrong fitting, there will be complications arising such as the problem of distal venous trapping where a cuff system compresses both the calf and thigh simultaneously, hence preventing the blood ejected from the calf from returning to the heart by the compressed thigh [8].

Therefore, an alternate solution of an ankle wearable device following a pneumatic actuation approach was developed to replace current mechanical prophylaxis methods to prevent DVT. This device would be able to mimic the inherent mechanism of the feet to promote blood flow back to the heart with ankle dorsiflexion-plantarflexion exercises.

2 Actuator Design

Figure 1 shows the design of the 3D-printed mold to fabricate an extensible actuator with zigzag channels using silicon elastomer (Ecoflex® 30, Smooth-On Inc). The resultant actuator worked such that when there was pneumatic pressurization, the actuator would extent and bend slightly.

![Figure 1. Top and side view of the zigzag mold for an extensible actuator.](image)

![Figure 2. (a) Placement of two soft bending actuators onto the ventral and dorsal parts of a sock donned on a mannequin foot model. (b) Pneumatic actuation for dorsiflexion motion with ventral (base of foot) actuator strained and dorsal (top of foot) actuator inflated. (c) Pneumatic actuation for plantarflexion motion with ventral (base of foot) actuator inflated and dorsal (top of foot) actuator strained.](image)
actuators with air while the valves were able to control the release of air from the actuators. Such alternate pneumatic actuation of the actuators would provide the ankle dorsiflexion-plantarflexion motion by alternating the strained-relaxed state of the actuator (Figure 2b, 2c).

3 Actuator Characterization

To determine the effectiveness of such a design incorporating double actuators, the device was placed within a wooden model with a torsional spring attached to mimic the inherent stiffness of the ankle. The torsional spring was attached in a neutral position of 30° plantarflexion where further dorsiflexion induced negative feedback from the spring, mimicking the stiffness profile of the ankle of a stroke patient [9]. The initial test of the current configuration of actuators showed that the device can flex from 25° plantarflexion to 5° dorsiflexion, with the spring having a stiffness of 0.0658Nm/deg.

4 Interpretation

Based on the preliminary tests on the prototype, it was shown that such a setup was indeed able to induce ankle dorsiflexion-plantarflexion to promote passive ankle exercises. However, the design can still be further improved to improve the overall range of motion of the device. One possible modification could be to rearrange the actuators to be located around the shin and calf region (Figure 3) where change in length of actuators will result in movement of guiding cloth thereby leading to ankle dorsiflexion-plantarflexion.

Figure 3. Attachment of soft extensible actuators for assisted ankle dorsiflexion-plantarflexion. (a) Ventral (top) actuator inflated and dorsal (bottom) actuator deflated for plantarflexion. (b) Dorsal (bottom) actuator inflated and ventral (top) actuator deflated for dorsiflexion.

In conclusion, this paper demonstrated the ability of soft actuator to replace current mechanical prophylaxis to prevent DVT by inducing passive ankle exercises mimicking the inherent ankle mechanism to promote blood flow. Further work will include clinical trials to determine the effectiveness of this form of device on stroke patients.

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References

Developing a system for robot-assisted stroke rehabilitation through user centered design methods

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1 Background

The SCRIPT (Supervised Care and Rehabilitation Involving Personal Tele-robotics) project aims to create a rehabilitation device to be used by stroke patients in their homes for training wrist and hand movements. The goal of the project is to make training more motivating and therefore more effective/efficient. For this purpose, gesture controlled games are used for training, including an orthosis to support and measure the movements.

The SCRIPT system consists of a user interface (UI) on a touch screen, a set of games for training and an orthosis which supports the patient’s movements. The patient’s system is remotely connected to a therapist application for supervision. Defined user groups of the SCRIPT system are chronic stroke patients with affected hand or arm movements, as well as treating therapists.

The SCRIPT project follows a User Centered Design (UCD) process as described in ISO 9241-210. According to the process the needs of the user are in focus throughout the project, as well as the whole context in which the product will be used. To gather reliable information, users are involved in the development process. The UCD process consists of iterations of four phases: (1) analyzing the context of use, (2) defining the requirements, (3) concept and creation and (4) evaluation.

Within the SCRIPT project several studies have been conducted to define requirements and to evaluate the system. In the first phase a first prototype of the system (SCRIPT1) was created and evaluated. The feedback was used to improve the second prototype (SCRIPT2) which will be evaluated in a second round.

This paper will mainly focus on the evaluation feedback regarding the UI and the gesture controlled games and will discuss the main conclusions drawn from the results.

2 Methods

The user involvement in the SCRIPT project consists of two parts: formative evaluation phases aimed to gather feedback for improvement of the system during development and summative evaluation phases aimed to assess the feasibility of the system, to analyse validity and usefulness of the system.

For the formative evaluations, participatory methods as cognitive walkthrough and cooperative evaluation [1] was used and the evaluations were carried out across three clinical sites. Members of the steering group committee including patients, careers and stroke professionals provided feedback and, in addition, six home-visits were conducted where tasks were carried out in the system by patients and their cares. Additionally, two usability tests have been carried out during the project, focused on the UI for patients and therapists, to find and correct usability issues. The first usability test (for SCRIPT1) was carried out in three countries with three patients and three therapists. The second usability test (SCRIPT2) was carried out in one country with three patients and three therapists.

For the summative evaluations, currently one out of two planned evaluations has been carried out (SCRIPT1). Twenty-one subjects were included in a clinical study, where they used the system for independent training at home for six weeks, with remote supervision by a healthcare professional. Feasibility was evaluated in terms of actual use (training duration in minutes), usability was measured by the System Usability Scale (SUS) [2] and user acceptance of the total SCRIPT1 system was assessed by a semi-structured interview.

Session - Exoskeletons & orthotic devices
3 Results

Through formative and summative evaluations, insights regarding the user experience of the system (SCRIPT1) was gathered and fed into the development of the next version of the system (SCRIPT2). A set of learnings regarding the system were drawn from the formative evaluation results, the following being the main conclusions:

Games

- The scoring element is crucial for motivation. Most patients liked to improve their previous earned scores, which motivated them to practice more and more. The variation in difficulty, like the automatic speed correction of the obstacles, also acts motivating.
- Understanding and remembering what gestures to perform is difficult for patients in some situations. Visual gesture hints within the games are important, as well as clear instructions presented to the user before starting the game.
- Clear feedback in the games is a must, e.g. visual or acoustical hints to indicate when an object is selectable, or was successfully handled. This is also a matter of motivation.
- The orientation of grasps must relate to the orientation of the corresponding objects, e.g. if a banana is shown horizontally the grasp has to be performed horizontally.
- The ability of the game to correctly react on the patients’ movements influences the user experience. Any technical issues resulting in poor control of the movements of the games demotivates the patients.

Patient UI

- The appearance of the gestures images, explaining the gesture to be used in a particular game, must be elaborated to clearly show what gesture and what movement is meant to be carried out. Extra care must be given to clearly and unambiguously visualize the direction of the gesture, e.g. forward/backward or left/right.
- The calibration process is experienced as too long and clear visual instructions are needed to have the patient performing the correct gesture at a certain point in time.

Therapist UI

- The overview page showing a table of current patients plays an important role and the navigation from the table to the rest of the application must be quick and easily understandable. Visual keys were used to improve the navigation from table cells to each section of the tool.

The summative evaluation results showed an average amount of use of 105 (± 66) minutes per week, which is about 15 minutes of self-administered practice at home per day. The individual training duration per subject varied however considerably, ranging from 13 up to 284 minutes per week. The group average SUS score was 69%, indicating that usability of the SCRIPT1 system is promising with a good chance of acceptance in the field. Three subjects scored ‘usability difficulties in the field’ (SUS <50%), whereas ten subjects scored the SCRIPT1 system as promising or high acceptability (SUS >70%) [3].

4 Interpretation

A system targeted for stroke patients to practice hand exercising at home with the aid of gesture controlled games has been developed and evaluated within the SCRIPT project. Training duration and SUS scores where promising and further work will aim to improve these aspects further. Based on the results on the evaluations, improvements have been carried out for the new version of the system (SCRIPT2) regarding the UI and the games. The system will again be tested by patients at home in a second summative evaluation.

References

MyHand: Assistive Hand Orthosis to Overcome Stroke Impairments

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1 Background

Many stroke patients suffer from impaired motor control, synergies and overactive flexor muscles in the arm and hand [1]. The peak aperture of the hand is often greatly reduced, preventing the patient from effectively grasping and manipulating objects and hindering them during Activities of Daily Life (ADL). The MyHand project aims to improve the functional hand use of stroke patients during ADL at home. For this goal, we are developing an active hand orthosis that can be worn throughout the day and will assist hand movements through active compensation of the neural impairments. This "therapy at home" should help to prevent contractures and learned disuse. The orthosis will provide active extension in order to compensate for the overactive flexion. It will feature a series elastic actuation in order to provide a compliant system which allows the users to move the orthosis themselves, but still compensates for the unwanted flexion components. This provides a very natural and comfortable way of controlling the orthosis. A major goal in designing the orthosis is to keep it lightweight in order to improve comfort for the user.

2 Methods

In order to establish the requirements and specifications for the orthosis a literature research has been performed and five stroke patients have been interviewed. The interviews were open interviews, meaning that a few predetermined questions were asked and the patients were encouraged to elaborate and were also allowed to start other subjects. The questions mainly focused on the patients’ stroke manifestation, their rehabilitation program, their lack of hand function, the ADL-tasks which they are unable to perform, the benefits and drawbacks of the devices they use and how they imagine an orthosis for assisting in ADL-tasks at home. The following questions were asked:

1. When did you have your CVA? Where was this located? How severe was the CVA?
2. What are your problems due to the CVA? What are your limitations in ADL? For what tasks do you need help?
3. Describe the rehabilitation process. How long have you been rehabilitating?
4. Which devices did you encounter during your rehabilitation? What was your opinion on them? What are advantages and disadvantages of these devices?
5. If you would receive an ADL-task supporting orthosis, what are the most important tasks you would use it for?
6. What do you think is most important in an orthosis for daily use?
7. If you could choose between a rehabilitation training device for at home use or an orthosis for functional use during ADL-tasks, what would you prefer?
8. What would you be willing to pay for an orthosis for functional use during ADL-tasks?

Furthermore interviews with a rehabilitation physician and occupational therapist were held with the focus on the benefits and drawbacks of devices they prescribe for their patients. The interviews were not transcribed nor recorded; only the important points were put on record. From these, the explicitly named requirements and hidden requirements were deducted.

After establishing these requirements, several concepts were developed. Three of these concepts were selected and a drawing and explanation was made for each of them and sent to patients accompanied by a questionnaire. In order to evaluate concepts based on the requirements a fusion deposition modeling 3D printer was used to rapidly prototype parts. With the use of a 3D scanner, 3D scans of the arms and hands were obtained. With these scans custom made parts were printed which perfectly followed the contours of the hand. These parts were then tested on the team members of the MyHand project.

In order to select materials for the orthosis-hand interface different materials, such as leathers, foams, rubbers were worn on the arm and hand. These materials should evenly distribute pressure. Special attention was paid to the touch of these materials to the skin and the forming of sweat under the material.

3 Results

The MyHand orthosis, which is an assistive aid for long-term use, differs greatly from other rehabilitation devices which are used at the clinic or at home for shorter periods of time each day [2]. Key design aspects as determined through user interviews are easy donning and doffing, high comfort, low weight, compact size and easy cleaning of the orthosis. The user should be able to don or doff the orthosis without help of others and within 3min. The patient should be able to wear the device for up to 12h without experiencing discomfort. The weight should be around 300g. The orthosis may add a maximum of 1cm of material on top of the hand of the patient in order to keep it compact. The orthosis should be easy to clean to prevent unwanted odours. For example a
removable washable sleeve could be incorporated. Every MyHand orthosis will be custom made to fit each patient perfectly. The custom made fit prevents pressure points and therefore it ensures better comfort.

The interviews and literature showed that after stroke, the affected hand tends to become the supporting hand and the non-affected hand the dominant hand during bimanual activities. Therefore the MyHand orthosis will help achieve cylindrical and lateral grasps, which are the most frequently used supporting hand movements. Figure 1 illustrates which grasps the MyHand orthosis will focus on. To achieve this, an advanced detection system is needed that will be able to make a distinction between desired movements and undesired muscle activation caused by abnormal muscle control (spasticity, synergies, etc.). The orthosis then needs to compensate for the undesired muscle activation, while allowing the user to perform voluntary movements. Furthermore, the orthosis needs to be wearable all day long. This puts high demands on the mobility, wearability, usability, aesthetics and safety of the device.

4 Interpretation

In the current concept, only extension of the fingers is actively controlled as to compensate for the overactive flexion. The user still needs to actively extend his fingers, as the orthosis only creates an offset moment which counteracts the pathological flexion of the fingers. The flexion of the fingers is also provided by the users themselves. The orthosis encourages the user to actively use both extensors and flexors which is beneficial for the rehabilitation process. The extension force is provided by one actuator with flexible connections to each finger. By using only one actuator, weight is saved. The flexible connection between the fingers and actuator ensures a compliant mechanism rather than a stiff position controlled mechanism for the fingers. The actuation does not need to be active constantly as a passive offset is created with the elastic components. This offset will provide in some cases enough hand aperture for the patient to grab objects. The series elastic actuation also allows the fingers to move with respect to each other, which enables the hand to follow the contours of objects. Thumb abduction will be actuated too in order to compensate for the overactive adduction. The wrist is passively supported using an elastic palmar cuff. The wrist will be put in a cock-up position in order to ensure easy grabbing of objects. The wrist is not powered in order to save weight and reduce complexity of the orthosis. The flexibility in the wrist is needed to be able to adapt to the change of activation in the flexors of the wrist and hand during the day. The flexibility allows the wrist to flex accordingly to the current activation, therefore contributing to the comfort of the user and intuitive and functional use of the orthosis. Furthermore the user is now able to make small changes in wrist angle during the performance of ADL-tasks. Muscle activity is measured of the extensor and flexor muscles in the forearm and the deltoids of the shoulder. The battery needs to provide enough energy to power the orthosis for up to twelve hours at a time. In figure 2 the vision of the MyHand project is shown.

References

Wheelchair for hemiplegic patients
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1 Management Summary

The majority of stroke survivors will have to rely on a wheelchair for transportation. However, these people usually suffer from hemiplegia or even hemiparesia, which makes it impossible for them to easily and fluently operate a conventional self-propelled wheelchair. Therefore we designed an ergonomic wheelchair which allows hemiplegic patients to propel and steer in an easy and energy efficient manner. The wheelchair is propelled by knee flexion/extension, by choice either unilaterally or bilaterally. Steering is done manually. The next steps will be creating a 3D model and a prototype of the wheelchair.

2 Background

In the Netherlands annually 47 000 persons are affected by a stroke, and over 240 000 persons are living with the effects of a stroke [1]. Of those patients who survive the acute phase of a stroke 20% to 30% is unable to walk, while many others have moderate to severe walking problems [2]. The cause of their inability to walk or walking problems are respectively hemiplegia and hemiparesis [3, 4].

Most hemiplegic patients are using a manually operated push-rim wheelchair. Their propulsion style, however, is greatly different from wheelchair users with a healthy upper extremity. In general, they propel the wheelchair with their unaffected arm and leg. With their arm they push the wheelchair via the push-rim. The unaffected leg is used to guide the wheelchair by stepping and pushing. Therefore in the most cases the footrest at the unaffected site is removed. This propulsion method is very inefficient and dangerous on slopes[4, 5].

This inefficient propulsion method leads to a high risk of overuse injuries in shoulder, wrist and hand, as even among wheelchair users with a healthy upper extremity (those who can use both arms for propelling) 70% experience pain or overuse injuries [6]. Especially because hemiplegic patients need to do all daily live activities with just one arm, the strain and stress on this shoulder, wrist and hand are quite high. This propulsion method is also exhausting for the patients, which in effect confines patients to their own home or the department of a nursing house where they are living. For longer distance transportation the patients are dependent on (voluntary) nurses [4, 7, 8].

A few wheelchairs exist which have been specifically designed for hemiplegic patients, but these are not often used, because they are too complex in use or require more power for propelling than the patient can deliver.

For most stroke victims, hemiplegia is not the only effect of the disease. Usually they also suffer from cognitive problems. This results in, among other things, concentration and orientation problems. These problems directly affect the ability to use or even learn to use a wheelchair [3, 4]. This is paramount to the fact that in general healthy older people already have problems with fine movements, balance control, reduction of force and orientation problems [4]. Another problem which may occur is hemianopsia, which is a decreased vision (or even blindness) in one side of the visual field.

These findings lead to the conclusion that there is a need for a manually driven wheelchair for hemiplegic stroke victims which specifically takes their mental and physical abilities into account. Therefore, we aim to design such a wheelchair, which should be energy efficient, easy to propel and steer, and ergonomic in design.

3 Design

As explained above, the design is based on the abilities and disabilities of the hemiplegic patients. Therefore first this target group is described with their limitations and abilities.

Target group

The target group for this device are hemiplegic or hemiparetic patients (stage 1 until 4 of the Brunnstrom Approach [9]) by cause of a stroke. The patient needs to be able to independently perform simple ADL-tasks (Activities of Daily Living), such as eating, with their unaffected side. Due to the cognitive problems which most stroke victims experience, the device needs to be simple to use. The user must also be able and willing to understand user instructions. Any added (manual) propulsion system needs to be safe, not only for the user, but also for the surrounding. To avoid having to deal with too many restrictions in the design of the wheelchair, patients with hemianopsia and neglect are excluded from the target group. The age of the target group is over 18 year, because of the dimensions of the device and the power which is required for propulsion. The user group may be expanded at a later stage, depending on the applicability of the new design. Probably patients with hemiplegia due to other causes than stroke are also able to use the device.

After a stroke a patient may remain fully hemiplegic, but in most cases some functionality will return. Trunk function is first to recover, then leg function and finally arm function. 75% Of the patients who are treated in a rehabilitation centre (these are the patients with a good prospect) are able to walk after the treatment is completed, but mostly only short distances or with support from other people [7, 8].

For the design trunk instability is one of the main limitations. Most patients also have spasticity on the affected side. This spasticity increases when they deliver power with the unaffected side[7, 8].

User requirements

In order to design a wheelchair which fits the limitation and abilities of the users, (user) Requirements are defined. Two of the most important user requirements and technical specification are listed below.

- The device must be efficient. Mechanical efficiency of minimal 4%(efficiency of a push-rim wheelchair by a user with a healthy upper extremity)[10].
- The device must be useable inside and outside. It should be possible to pivot the wheelchair and the minimal speed with a average propulsion should be
5 km/h (the average walking speed of an able-bodied person)[11].

Design

The design allows the user to propel the wheelchair by knee flexion and extension (Figure 1). Motivation for this design choice is that, according to our calculations, wheelchair users can deliver 8 times more power with leg lever propulsion than when using push-rim propulsion. The stationary footrest of the healthy leg is replaced by a footrest mounted on a movable leg support, which can be moved forward and rearward by resp. extension and flexion of the knee. The leg support is connected by a crankshaft to the differential, which is located in the rear wheel axle. With this mechanism, the user can propel the wheelchair either forward or backwards, using only the unaffected leg.

As an option, the wheelchair can be provided with a similar driving leg support with footrest for the affected leg. This way the wheelchair can be propelled using both legs. This can be used as training function and for patients who have some leg function, but not enough to walk for longer distances. This second support can be made to move in phase or 180 degrees out of phase with the first leg support.

Steering is possible via the steering handle (Figure 1). The handle is attached to the castor at the unaffected side. When the user turns the steering handle the castor is turned with the same angle. The differential in the rear wheel axle allows riding curves while maintaining propulsion power. A direct pull brake is attached to the rear wheel on the unaffected side. The brake is activated by a handle at the steering hand lever.

4 Results an interpretation

Currently the mechanical design of the wheelchair is being completed. One of the requirements was that it must be possible to obtain a velocity of at least 5 km/h. This allows the wheelchair user to propel the wheelchair with the same speed as the average walking speed of an able-bodied person [11]. Our calculations show that, in order to achieve this, the user only needs 35% of the maximal power which elderly people can deliver.

We expect that our design will not only be more energy efficient than push-rim wheelchairs, but that it will make it much easier for the user to drive straight or in fluent curves. In the next month’s a prototype will be constructed to test the design.

References

Development of a motion controlled arm support from a user perspective

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1 Background

Not being able to eat independently, to brush your teeth and use the computer are common in people who suffer from neuromuscular disorders, stroke, or for example multiple sclerosis. Due to limitations in their arm function these persons might rely on the help of caregivers to fulfill these Activities of Daily Living (ADL). For some activities however, help from others is not desired. For example, people might find it important to eat independently at their own pace. In order to perform such ADL tasks independently assistive technology can be used. Dynamic arm supports are an example of assistive technology specifically designed to provide ADL support to people with limited upper extremity function. The first devices augmenting arm functionality in the weak upper extremity were introduced after the polio epidemic in the 1940s. Improved polio treatment resulted in large numbers of polio survivors whose arms were too weak to bring their hands to their mouth to feed themselves [1]. Technological advances since the 1940s resulted in a steady development of new dynamic arm supports. It is expected that the application sensor technology in dynamic arm supports will be advantageous to its users, because it allows for the development of intuitive, actively-actuated dynamic arm supports. Practically this implies that it is possible to detect movement intentions. In theory, also persons whose arm function is severely decreased who now rely on robotic manipulators, could benefit from these dynamic arm supports. Therefore, the aim of the McARM project is to develop a motion controlled dynamic arm support in a multidisciplinary (technical, medical, research) team. Contextual and personal factors affect use of these devices in daily life. For the design of dynamic arm supports, this stresses the importance of designing dynamic arm supports within the context of daily life of the potential end-users. This study therefore reports on the development of a dynamic arm support from a user (in a daily life) perspective.

2 Methods and Results

The development of a motion controlled dynamic arm support comprises several phases from investigating the current state of the art of these devices until the evaluation. The following phases are described in more detail:

- Provide an overview of dynamic arm supports developed
- Provide an overview of the effects and effectiveness of dynamic arm supports
- Capturing user requirements: Interviews and observations with users of currently available devices
- Capturing user requirements: Kinematic analysis of daily activities in the domestic setting
- Pilot study of a method to assess the impact of a new dynamic arm support in daily life

Create an overview of dynamic arm supports developed

A systematic review was performed to identify the dynamic arm supports that have been developed in the past decades and to better understand the current status of this family of devices. A total of 104 dynamic arm supports were identified in the scientific literature and the internet, with developments originating from 1936 to 2011. Devices could be categorized in four groups. There were devices based on the functional electrical stimulation principle (N=7). There are non-actuated dynamic arm supports (N=39), examples of commercially available devices are the Standard Mobile Arm Support (JAECO) and the Ergorest designed to support computer use specifically. A total of 24 Passively-actuated devices were found, examples are the WREX (JAECO) that uses elastics to store energy, and the Sing (Focal Meditech) that uses contra weights. Actively-actuated devices (N=34), such as the DAS (Exact Dynamics), require external energy for operation. This categorization showed the limited diversity in functioning principles of devices. For the non-actuated and passively-actuated devices, similar devices were found among the commercially available devices and those not available on the market. Actively-actuated devices that are commercially available work either as an arm-lift, or they allow the user to adjust the amount of gravity that the device compensates for. All need to be operated actively by the end-user, for example with a switch. Prototypes of active devices that assess the user’s intentional movement, by for example force sensors and EMG, had also been designed, but were not available to end-users yet [2].

Provide an overview of the effects and effectiveness of dynamic arm supports

For most of the devices developed it is unknown what effects they produce in daily life of their users. This finding was a result of a second systematic literature search. Contradicting findings were found when dynamic arm supports were evaluated under controlled conditions and in field studies. Studies performed under controlled (laboratory) conditions in general reported positive outcomes for example at the level of body functions or the ability to perform ADL with the devices. Field studies evaluating long term use in daily life often reported a relatively high level of non-use [3].

Capturing user requirements: Interviews and observations with users of currently available devices

Users of currently available dynamic arm supports and robotic manipulators were visited at home to learn how current devices meet the needs and preferences of users. Seven dynamic arm support users and three robotic manipulator users (one subject used both devices) were involved in a face-to-face semi-structured interview and observation on standardized task execution by an Occupational Therapist (OT). The interview consisted of the ADL part of the long version of the Life-Habits questionnaire (v3.0). Subjects were asked how they normally perform.
common ADL tasks (51) such as eating, drinking, and dressing, how much effort it takes, whether they need help from others, and whether they use their dynamic arm support. Additionally, subjects were asked how important it was for them to perform that activity independently. The Brooke scale was administered to assess arm function. The execution of six common ADL activities was assessed by the OT. Of the seven dynamic arm support users, three wheelchair bound subjects used their device daily. The remaining four made limited to no use of their device. These participants had too much arm function to benefit from an arm support, were able to perform tasks by means of compensatory movements, or had had no opportunity to use of the device due to being restricted to bed. The devices that were used daily were mainly used to support eating, drinking, combing hair, brushing teeth, and blowing the nose. These were also the tasks people found important to perform independently. Problems encountered during the execution of these important tasks were: difficulties in lifting objects, for example a glass filled with water. Additional support was needed during eating (especially the last part of the movement). The construction of the device sometimes made it difficult to keep a phone on the ear or to perform other tasks around the head. Far reaching (downwards/up) was in some cases limited by the devices and/or a weak upper body. Other issues mentioned were: unable to put the arm in the device independently, technical issues such as torn strings (sling-type), irritation of the armscale in summer, appearance and in general needing much space.

Capturing user requirements: Kinematic analysis of daily activities in the domestic setting

Dynamic arm supports are prescribed to support in the performance of activities of daily living and ideally result in an upper extremity function similar to healthy subjects. The aim of this study was to assess how use of the dynamic arm support affects the upper extremity function during ADL in terms of achieved range of motion. A total of five dynamic arm support users and five subjects without upper extremity limitations participated in this study. The Brooke scale was administered to assess arm function. Upper extremity movement was measured during nine ADL tasks in the home setting with the MMAAS, a portable upper extremity motion capturing instrument [4]. Comparing the ability to perform this set of tasks with and without device showed that one subject was able to perform more tasks with the dynamic arm support than without device. It was the other way around for the other four subjects. All subjects could eat and drink with their device. Joint range of motion was calculated and compared (with dynamic arm support, without, and subjects without limitations) for the three tasks that were the most difficult to perform with the dynamic arm support. These were the tasks: touching the seat between the upper legs, combing hair and the reaching task.

Pilot study of a method to assess the impact of a new dynamic arm support in daily life

Within the McARM project a dynamic arm support will be developed. To determine how this device is used and whether it is effective, the device needs to be evaluated in daily life. To anticipate on this development, a test protocol was created and tested with persons who received the recently developed Darwin (Focal Meditech). If the protocol proves to be eligible, the protocol will be applied on a bigger scale to evaluate the dynamic arm support developed within the McARM project. Home visits were conducted prior to the delivery of the Darwin and after two weeks of using the Darwin. A change in manual ability (ABILHAND), upper extremity pain and stiffness, and the perceived effectiveness (IPPA) was assessed based on these visits. Additionally, an observation on standardized tasks execution and evaluation of user experiences was performed at the second visit. A use period of two weeks proved to be too short to assess the impact of a dynamic arm support in daily life. Although it was possible to detect a change in manual ability and problematic activities seemed to be solved to some extent, not all functionalities of the device had been explored yet, and subjects were not completely used to the device.

3 Interpretation

Based on the continuous development of dynamic arm supports it can be concluded that there is a persistent need for these devices and there remains potential for improvement of the functionality. The interviews and observation in the home situation resulted in the needs and preferences of potential end-users regarding the device being developed within the McARM project. This information was adopted by the designers involved in the project and currently the device is being built. To determine if this device meets the requirements of the user, the devices will be evaluated in daily life.

References


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1 Background

Low back pain (LBP) is a major health problem in Western Society [Freburger, 2009]. The prevalence of long-standing LBP is around 20% on population level. On individual level, around 70% of the population will experience an episode of LBP at some time in their lives [van Oostrom, 2011]. The substantial costs are estimated at 0.6% of the Dutch gross national product in 2007. Common occupational risk factors associated with LBP include heavy physical work, a static work posture, repetitive bending, twisting, lifting and whole-body vibration (systematic review of B.K. Kwon et al, 2011). Minimizing occupational factors causing LBP through primary prevention and coping strategies is therefore called for [Lambeek 2011]. For this both new assistive devices are required as well as methods to accurately evaluate low back load exposure during actual work to identify and monitor risk factors and evaluate suggested solutions.

Recently a unique method has been further developed by Baten et al. [2002, 2007, 2009] for direct estimation of low back load exposure to low back structures during actual work in terms of the net moment around the intervertebral body at level L5/S1. This paper applies this method to evaluate a concept version for a novel wearable trunk support [Laevo, Intespring]. This is a comfortably wearable trunk support device that claims to assist the low back structures in generating the extension net moments required to cope with the load exposure of working in repetitive static stooped posture. This paper discusses the experimental evaluation of this claim in simulated real life working conditions.

Methods

Three series of experimental sessions were done (each around 30 trials); one series under laboratory conditions to test hardware and software, one session in a hospital setting with five nurses as subjects and one session in an industrial environment with four metal workers as subjects. For each subject a series of recordings was done comprising calibration movements, a series of simulated tasks with the Laevo prototype not active, plus a series of the same simulated tasks with the prototype actively supporting the trunk of the subject. For each subject 3D kinematics of all body segments was recorded using 3D Inertial Magnetic Motion tracking Units (Xsens MTw) and surface EMG recordings (2 x TMSI, Moby) from the main back extensor and flexor muscles. In the first session and also in two of the subjects of the second session also 6-DOF ground reaction forces were recorded with instrumented shoes (own development). All data was recorded synchronously together with 2 wireless video streams and analyzed with the FusionTools ambulatory monitoring software suite (RRD). Net moment generated by the back structures are estimated by an artificial neural network (ANN) from surface EMG and kinematics data, that was trained with target net moment estimates from kinematics and force shoes alone (supervised, known load handling).

For these sessions the net moment estimates for training and testing of the ANN method were calculated using a linked segment model from the ground up (LSM-BU) validated against those calculated top-down (LSM-TD), applying:

\[
\mathbf{M}_{\text{ANN}} = -\mathbf{M}_{\text{GRF}} - (r_{\text{ext}} - r_{\text{flex}}) \times \mathbf{F}_{\text{GRF}} + \sum_{i} \left( m_{i} \times r_{\text{an}} \times \mathbf{F}_{\text{an}} \right) + \sum_{i} \mathbf{d}_{i} \times \mathbf{\dot{a}}_{i}.
\]

ANN estimates were trained with, and validated against, both LSM methods. Comparisons were made visually and numerically (peak net moments differences estimates and coefficient of determination (R²)).

The differences in net moment generated by the trunk structures with and without active support of the Leavo prototype were assessed in a variety of tasks by comparing the net extension moments curves estimated with the ANN method for all corresponding trials.
3 Results

Net sagittal extension moments estimated from kinematics assessments from the upper body (LSM-TD) versus those estimated from kinematics assessments of the lower body (LSM-BU) appear to be similar within ca. 10% of the maximum in both all stooped tasks in the sagittal plane and also in all stooped tasks somewhat to the side (Figure 3, green lines). Also all ANN estimates were within 10% of corresponding LSM-TD and LSM-BU estimates.

4. Interpretation

The data suggests that extension net moments normally generated by the low back structures are taken over by this version/configuration of the Laevo prototype trunk support for about 90% from a certain stoop angle. Still some freedom of movement can be enjoyed in this Laevo prototype, because it is constructed in such a way that when the subject first flexes the knees the Laevo prototype trunk support is deactivated. Current development of the Laevo is directed towards scaling shape and construction in such a way that the support percentage is a more gradual, individually adaptable function of the trunk flexion angle. This study implies that the ANN method for net trunk extension moment estimation can be a valuable tool in evaluating the actually support percentage function achieved in test and final versions.

Acknowledgement

We thank partners VUMC dep. Intensive Care and Hankamp, Enschede plus the Ministry of Economic Affairs for financial support.

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Functional Strength Measurement for the Upper Limb in Children with Cerebral Palsy

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1 Background

Several instruments are available to measure muscle strength in children with unilateral cerebral palsy. However, these measurements do not represent functional daily life activity tasks. Therefore, in effective co-operation with IPSEN and the Departments of Rehabilitation Medicine and Instrument Development, Engineering & Evaluation at Maastricht University a new instrument and protocol are developed to measure functional strength of the upper limb in children with cerebral palsy in the context of important daily life activities.

2 Methods

The measurement of functional strength for the upper limb in children with cerebral palsy requires both an instrument and a protocol. The development of the total measurement system comprises six steps:

1) Translating the knowledge and experience of the clinician into essential technical and usability instrument requirements.
2) Building a prototype version of the instrument.
3) Building the final version of the instrument.
4) Developing the measurement protocol.
5) Performing a feasibility study on the instrument.
6) Performing a reliability and validity study on the total measurement system (pilot study).

Essential requirements are the on-line registration and measurement of the peak and duration strength of the upper limb in units from 0.01 to 40 kg with an accuracy of ±0.25% full scale during the following daily life activity tasks: unimanual lifting task, bimanual lifting task, cup task, measuring cup task and crate task.

The mechanical construction of the instrument is designed such that only (positive and negative) forces in the sensitive direction of the one-directional load cell are felt and therefore correctly measured by the load cell, while the patient can move the object freely as part of a daily life activity task. Different objects can be attached to the instrument to simulate the daily life activity tasks. The objects are easily interchangeable to switch between tasks.

Based on the findings of the feasibility study the measurement setup (instrument and objects) is finalized. With the final instrument the measurement protocol is realized. This protocol describes the standardization of the testing, including standing position of the child, height of the instrument related to the child, protocol for verbal feedback, standardization of lifting speed, trajectory and duration.

The reliability and validation study comprises a study in 19 children with unilateral or bilateral CP in which intrarater reliability and construct validity has been tested. Grip strength –using the e-link of Biometrics- has been used as a golden standard.

3 Results

For the measurement unit of the instrument different load cells have been taken into account. Ranging from one-directional load cells to load cells that can measure both force and torque in three perpendicular directions. Comparing the data sheets of these load cells showed a decrease in accuracy with the number of possible measurement directions. Only the accuracy of one-directional load cells was above the required accuracy.

The mechanical construction of the instrument is designed such that only (positive and negative) forces in the sensitive direction of the one-directional load cell are felt and therefore correctly measured by the load cell, while the patient can move the object freely as part of a daily life activity task. To test the technical requirement of this construction different known weights within the required range are attached to the instrument under different angles.
The usability tests are performed on a group of 20 children with cerebral palsy to test if the test can be performed and if the lifting of the objects can be performed in a standardized way. Important findings of these tests are that the material of the objects has to be light and strong, the connection of the objects with the instrument is too rigid, the instrument needs to have an elastic disk to dampen the peak force.

Data for results of the reliability and validity study of the total measurement system are gathered in July and August 2014.

4 Interpretation

The decrease in accuracy of multi-directional load cells is due to cross talk between the different directions. Therefore, a one-directional load cell is used and the instrument is constructed such that during lifting the objects can be moved in multiple directions but only the vertical lifting component is measured.

The feasibility study showed that measurement of the peak and duration strength of the upper limb in this way can provide relevant rehabilitation information on children with cerebral palsy. The study also showed that the daily activity tasks: lifting a crate, a mug and a pitcher are easy to perform, with slide improvements on the object-instrument connection flexibility. Finally, the study showed that the protocol needs to be trained in order to get a good standardization of the tasks.

The standardized, objective measurement of functional strength for relevant daily live activities provides a new value that closely relates to the rehabilitation process of children with cerebral palsy. Both from a clinical, training and research point of view.

In the future more complex daily live activity tasks will be added to the measurement system, these tasks related to eating and getting dressed.

References
Three Stages of Development of the Robust SCRIPT Active Orthosis

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1 Background

Impairments in the hand are often the most debilitating for stroke survivors. 60% of all patients struggle with simple, everyday activities such as buttoning shirts, tying shoelaces, opening bottles, and eating with knife and fork. The movement impairments require intensive physical therapy to overcome.

In recent years, rehabilitation devices have reduced the workload for the therapists and have made physical therapy more efficient. As therapy intensity has a strong correlation with functional recovery, the most recent trend is to move the therapy from the clinic to the home, where patients can practice longer and at more convenient moments in their day.

In the SCRIPT project (EU-FP7), we have developed a passive wrist and finger orthosis (SCRIPT Passive Orthosis, SPO, [1]) that has been tested in the homes of 24 patients in three European countries. Based on the technical and clinical lessons learned [2], we have upgraded the orthosis to the SCRIPT Active Orthosis (SAO). To maximize our changes for success, we have upgraded it in three robust stages, which will be described in this abstract.

2 Methods

The SPO is a wrist, hand and finger orthosis that compensates for impairments caused by spasticity and abnormal synergies. These impairments are characterized by excessive involuntary flexion torques that severely inhibit hand function. The SPO physically interfaces with the forearm, hand and fingers of the users. It offsets the undesired flexion after stroke by applying external extension torque to the wrist and extension forces to the fingers via passive leaf springs and elastic tension cords. The amount of support can be adjusted. The SPO is equipped with sensors to measure the joint rotations and applied forces, and interact with the computer system. It also provides information on the users forearm posture and movements. The SPO cannot actively generated or control movements, thus the user needs to use voluntary muscle activation to perform movements and is therefore always actively involved.

Evaluations determined that the integrated bending sensors can differentiate between different grasps and can detect small changes of motion, but are only able to resolve between large absolute angle deviations. These limitations are caused by the flex sensors in the leaf springs suffering from natural decay in step response. For optimal tracking of patient progress, we determined that the SAO needed better sensing capabilities in the fingers.

It was also determined that the range of motion in the wrist, especially in the extension direction, was limited for some of the patients. This is due to the large variability of segment dimensions between subjects that could not be completely accounted for in the design. One issue was that the self-aligning mechanism caused both the hand plate and the forearm splint to slide towards the wrist. For this reason, and to simplify the design, we decided to use a conventional joint axis in the SAO.

3 Results

For SAO Robust 1 (SAO-R1, see Fig. 2), we temporary removed the self-aligning wrist mechanism and replaced it with a fixed wrist at a slight extension angle. This construction allows the electric motor that powers the fingers to be placed on the forearm, without further complications on the wrist. In the SAO-R1, the elastic cords have been replaced with nylon and steel cables connected to a whippletree mechanism. On both sides of the whippletree, the interaction with the fingers and motor is further mediated by compliant springs that decouple individual movement of the fingers. From this prototype we learned it was possible to set adjustable forces for all fingers via the motor, while still allowing individual control of each finger for the user.
The SAO-R2 (see Fig. 3) was built to test new finger mechanisms. Here, each finger is interfaced through a double-parallel mechanism that decouples the rotations from the translations [3], with the tension arms of the parallelograms replaced with drums and Dyneema cables. In effect, the torque provided by the motors is transmitted as a torque, not a force, to the digit caps, but without controlling the exact finger position. This allows the mechanisms to use the parallelogram as a self-aligning mechanism. The relative deflection of the parallelograms is measured through potentiometers to determine the finger position relative to the hand plate. Compliant springs distribute the motor torque over the fingers to allow individual deviation of the digits. It is important to note that the forces exerted by the motor in the SAO-R2 are up to five times higher as in the SAO-R1, as the moment arm of the drums in the parallelogram mechanisms is five times smaller than the effective moment arm on the fingers in the SAO-R1. From this prototype, we learned that friction forces in the parallelogram cables were essential to minimize, and that any non-smoothed surfaces has a strong detrimental influence on the durability of the cables.

Figure 3: SCRIPT Active Orthosis, Robust 2 (SAO-R2). The leaf springs have been replaced with double-parallel fingers that transmit the motor torque to torques at the digit caps. Each finger mechanism is equipped with two potentiometers each to measure finger position relative to the hand plate. Compliant springs distribute the motor torque over the fingers.

The SAO-R3 (see Fig. 4) adds a conventional wrist joint. Here, the fixed wrist has been replaced with a single-axis, conventional wrist joint. This allowed the wrist and the five fingers to be individually moved, although with only a single actuator providing interaction force for all six rotations. This single actuator necessitated a torque reduction mechanism on the hand plate. Compliant springs distribute the motor torque over the fingers.

Figure 4: SCRIPT Active Orthosis, Robust 3 (SAO-R3). Here, the fixed wrist has been replaced with a single-axis, conventional wrist joint. The moment arm at the fingers and the wrist, the tension in the motor cable needed to be reduced at the wrist, which was achieved with a torque reduction module on the hand plate. This module is the large set of drums with an (not visible) torsion spring in between.

4 Interpretation

The development of the SAO was split up in three phases, to test individual changes and additions to the SPO. Though development of a simplified version with an electric motor and a fixed wrist, a version with new finger mechanisms and a version that again added a wrist joint, we developed a mechanically robust version of the SAO that will be used at home by patients in three countries.

References

Evaluation of Motion Controlled Arm Support

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1 Background

Many attempts have been made to help people with upper extremity limitations in daily life by means of dynamic arm supports. Current devices vary from passive supports, with low level of complexity and easy to control to active arm supports with many functionalities, large dimensions and complex control (1). An example of a new development is the motion-controlled arm support (McArm, Focal Meditech) that aims to enhance the functional benefits of active support while maintaining the user friendliness of the simple passive support systems. In addition, it aims to stimulate the use of residual muscle strength in the user (2).

The effect of support on human arm movements needs to be investigated to understand how support can be optimized. The influence of assistive devices that compensate weakened muscles on the restoration of arm functions after stroke, has been investigated by Prange et al. (3). They have studied the effect of gravitational pull of arm support systems with braces. They found that the activity levels of shoulder and upper arm muscles during reaching movements using a forearm support system are significantly decreased. However there is still little evidence on how joint moments are changed by a support system and whether zero gravity support is the best biomechanical solution that designers should aim for. Moreover, it is still unclear how joint moments are affected in people suffering from, for example, neuromuscular diseases and how people perform with an arm support in a daily life situation. Information on the effects of dynamic arm supports on arm movements and the use of arm supports in daily life is needed to provide insight in the limitations of current designs. That knowledge can be used in the development of new motion controlled arm support.

The aim of this study was to investigate the impact of arm support systems on the arm function and use in daily life. This was realized by studying the effect of an available support system on the arm function at various levels of the International Classification of Functioning, Disability and Health (ICF). This knowledge is integrated in the design of the new McArm.

2 Methods

A test battery has been developed that combines questionnaires and ordinal clinical scales, with quantitative measures such as 3D motion analysis and EMG to provide a more complete picture of the compensatory movement patterns used by patients with proximal muscle weakness of the upper extremities in patients with neuromuscular disorders. Moreover, biomechanical models and inverse dynamic software were used to calculate the shoulder and elbow joint moments in three different conditions (a control set-up, a gravity compensation set-up and a simulated zero gravity environment). These measures were used to investigate movement capacities of people with various neuromuscular disorders. To evaluate the performance in daily life, a measurement protocol has been developed to measure how people use the arms and the arm support during daily activities. Ethical approval was obtained for the study (Ethical Committee Arnhem-Nijmegen, NL39024.091.11).

Questionnaires A web-based questionnaire containing questions on all ICF domains, was created to evaluate overall arm function and problems that people encounter in daily life. This questionnaire was distributed among various groups of people with neuromuscular diseases, namely Duchenne muscular dystrophy (DMD), fascioscapulohumeral dystrophy (FSHD), limb-girdle muscular dystrophy (LGMD) and spinal muscular atrophy (SMA).

3D Kinematics and EMG Motion analysis and electromyography (EMG) data from various tasks (e.g. shoulder abduction/extension, reaching and hand to mouth movement) were recorded during unsupported movement and during supported movement with a passive Sling arm support (SLING, Focal Meditech). In both cases the subject was asked to move the dominant hand from an initial position resting on a table in the sagittal plane to a target placed at a distance of a stretched arm, at shoulder height and one shoulder width on the ipsilateral side. The movements were recorded with a 3D camera Motion Capture system (Vicon). Reflective markers were attached on the subject’s body following the guidelines of the Vicon Upper Limb model. These data were subsequently used in simulations with a multi-body model of the arm to calculate joint moments. EMG data were obtained from biceps brachii, deltoid, triceps brachii, trapezius, pectoralis and latissimus dorsi muscles and were normalized as percentage of the EMG during maximum voluntary contraction. Subjects with FSHD were compared to a group of healthy controls.

Muscle-skeletal simulations An inverse dynamic analysis was carried out in AnyBody Modeling System (AnyBody Technology) to calculate the net joint moments at the shoulder and elbow. The musculoskeletal GaitFullBody model was scaled according to body length and mass among others, and was driven by the reflective markers’ coordinates. Two movements were analyzed: unsupported and supported ipsilateral reaching. The unsupported movement consisted of two parts: a normal gravity situation and a simulated zero gravity situation, in which the same motion data for the unsupported movement were used but gravity was set to zero in AnyBody’s model parameters. The supported movement was measured using a counterweight forearm support (SLING, Focal Meditech). To summarize the net joint moments were calculated in three conditions: I control, II gravity compensation with SLING and III zero gravity environment. These conditions were chosen to assess the influence of gravity compensation (I vs. II), the influence of a zero gravity environment (I vs. III) and the difference between simulated vs. mechanism-induced gravity compensation (II vs. III)(4).

Ambulatory Performance To evaluate the effect of arm supporting devices in a daily life setting, a protocol for monitoring the arm activity outside a laboratory setting was...
developed. A tri-axial accelerometer (MOX, Maastricht Instruments) was placed on the upper arm just above the elbow. The acceleration signals were post-processed to obtain elevation and intensity of upper arm movements. These data give an indication on how and how often the arm support is used in daily life (5).

3 Results

Preliminary results for the various studies are shown.

**Questionnaires** In total of 315 boys/men with DMD, 88 with FSHD, 61 with LGMD and 73 with SMA participated. Preliminary data show that pain, stiffness and functional limitations increased with age in DMD. Data of FSHD, LGMD and SMA are being analyzed.

**3D Kinematics and EMG** The maximum shoulder elevation angles and the minimal and maximal elbow flexion angles were analyzed in a group of 11 people with FSHD and in a group of 8 healthy controls. The data depicted in figure 1 represent the shoulder elevation angles of the healthy control group and the data of the FSHD subjects (6). Significant differences between the shoulder angles of the FSHD and the healthy control group were found for the shoulder elevation angle during the abduction and flexion tasks and during the two reaching tasks. Of the 11 subjects, only two were able to elevate the arm above 90 degrees. The EMG data showed higher muscle activity in the FSHD group compared to the control group.

**Muscle-skeletal simulations** The ipsilateral reaching task was completed by all subjects in all conditions. The FSHD subjects required more time to complete the task in the Control and the SLING condition than the healthy group (respectively 2.6 vs. 3.7s and 2.8 vs. 4.7s). Both groups required more time to complete the task in the SLING condition than in the control situation. In the control situation, the maximum value of the glenohumeral joint moment during shoulder abduction-adduction was greater by more than one order of magnitude than the moment in the SLING and the Zero gravity conditions in both groups (Figure 2). Between the two groups the signs of the average moments in the SLING condition were different, showing for the FSHD group a trend to maintain the arm more elevated and the elbow more flexed. The healthy group presented a lower mean glenohumeral joint moment in the SLING condition than the FSHD group, showing a trend to maintain the arm less elevated and the elbow more extended when using the SLING (4).

4 Interpretation

The current study presents some preliminary results of initial evaluation measures. Several existing measurement scales and instruments were combined into an analysis protocol. Application of these evaluation measures to the next McArm prototype is foreseen in the last stage of the project. The goals of these evaluations are multiple: to see if design goals of the new arm support and its specifications are met, to gain first outcomes on usage and usability of new prototypes and to compare functionality with high-end existing devices of this class. The proposed protocol of analysis can be also applied to the evaluation of other support systems.

References

Flextension A-Gear: Progress of Developing a Natural Arm Support for Duchenne Patients

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1 Background

Duchenne Muscular Dystrophy (DMD) is one of the most common types of muscular dystrophy, affecting 1 in 6000 living male births [1]. DMD is caused by the absence or defect of the dystrophin protein. Defective mutations in the dystrophin gene result in progressive degeneration of skeletal, respiratory and cardiac muscles leading to loss of independent ambulation in the early teens, followed by the development of scoliosis and loss of arm function. The life expectancy of boys with DMD used to be no more than 20 years [2]. Long-term survival has improved substantially in the last five decades due to improvements in care, drugs and the introduction of home care technology such as artificial respirators. As a result, there is currently a considerable group of adult individuals with DMD living with severe physical impairments and a strong dependency on care [2].

A special characteristic of DMD is that boys lose the ability to move their arms due to the weakening of proximal muscles, while distal muscles, such as hand and finger muscles, remain less affected [3]. Therefore, individuals with DMD can benefit from devices that support arm movement taking advantage of the user’s residual hand function. Commercially available arm assistive devices support arm function by compensating its weight using mainly passive gravity compensation strategies [4]. However, these devices present two important limitations: (I) they become insufficient at the last stages of the disease and (II) are often highly stigmatizing due to their large dimensions [4], [5].

The aim of the Flextension A-Gear project is to develop a body-bound assistive device that can be worn underneath clothing and supports the arm function for the execution of essential activities of daily living meeting the growing needs of individuals with DMD (Figure 1). The development towards the ultimate arm support is divided in two separate functional prototypes: the Passive A-Gear and the Active A-Gear, which are directly related to two levels of assistance. The Passive A-Gear is intended for younger individuals with DMD that are still able to perform activities of daily living when the weight of the arms is compensated. When the support provided by the Passive A-Gear becomes insufficient, the Active A-Gear will provide the extra assistance needed in adult individuals with DMD by actively actuating the arm support depending on the user’s movement intention.

Additionally, in order to identify the specific needs and capabilities of individuals with DMD at the different stages of the disease, we are carrying out a clinical study to investigate the functional and physiological consequences caused by the progressive muscle degeneration.

This paper provides an overview of the project’s intermediary outcomes after two years, and also highlights the challenges and difficulties faced so far.

2 End-User Analysis

In literature little is known about arm function in boys and men with DMD. To gain more insight in arm function of individuals with DMD an international survey was done, investigating functional abilities of the arms, pain and stiffness complaints in the arm and hands, and restrictions in social participation due to arm weakness [6]. Over 200 respondents from 14 different countries participated in this study. Main conclusions were that pain and stiffness in the arm and activity limitations increased with disease stage. Functional arm limitations already occurred in the early ambulatory stage, which was earlier than reported in literature. Compared to the healthy population, social participation was restricted in individuals with DMD and about 70% of the respondents experienced functional arm limitations when performing social activities. Despite the
existence of arm function impairments, only 9% of the respondents used arm assistive devices.

Next to the survey a case-control study including measurements of surface electromyography (sEMG), three-dimensional kinematics of single joint movements and activities of daily living, muscle force and muscle ultrasound, is currently being performed. The aim is to measure 25 individuals with DMD and 25 controls between 6 and 25 years old to gain more insight in how these outcome measures change along the different disease stages of DMD. This information will be used to develop the A-Gear prototypes.

Additionally, the validation of the A-Gear prototypes is carried out by comparing the arm function of healthy individuals and individuals with DMD with and without the arm support provided by the prototypes. Data from video recordings, three-dimensional kinematics and sEMG measurements is used for this comparative analysis.

3. The Passive A-Gear

The Passive A-Gear should support the users arms in the entire functional workspace of a healthy arm. This means that the device should support five degrees of freedom (DOF): three at the shoulder (adduction/abduction, flexion/extension and internal/external rotation) and two at the elbow (flexion/extension and pronation/supination). Taking into account that individuals with DMD can use their distal muscles for a longer time and that the Passive A-Gear is meant for patients in the earlier stage of the disease, it was decided to not support elbow pronation/supination in the Passive A-Gear.

We built two prototypes and tested them on four patients. The first prototype was an extended version of the WREX arm support (JAECO Orthopedic, USA) [7], with unconstrained trunk flexion/extension. In that way the user is able to lean forward and backwards.

From the first passive prototype we learned that unconstrained trunk movement is perceived as very important by the users: it increases the functional workspace of the arm and it allows for some compensatory movements needed to perform several activities of daily living. However, the structure of the WREX (with parallelograms along the arm) presented some kinematic limitation and was too large to fit underneath clothing. The users also mentioned that the support of both arms was necessary for the stability of the trunk and to be able to execute important activities of daily living.

Taking into account all the lessons learned from the first prototype, a second passive prototype was designed based on the principle described in [8]. With two zero-length springs (one from shoulder to forearm, and one from forearm to upper arm), the arm of the user can be balanced throughout the entire workspace without using parallelograms. This new kinematic architecture gave the possibility to bring the structure closer to the body.

4. The Active A-Gear

Actuation
An important advantage of using a passive gravity compensation mechanism in the Passive A-Gear is that the required power and size of the actuators is low. Many types of actuators are being considered and tested. Brushless DC motors have our preference based on the criteria: compact, silent, efficient, safe and technically feasible. In addition to the low power actuation system, we are implementing rotary series elastic actuation in each joint to enhance the user’s interaction experience and safety.

Motion Intention Detection
In order to operate the Active A-Gear the user needs to communicate his motion intention to the device through a control interface. The selection of the control interface in response to specific user needs and capabilities -which in the case of DMD, change significantly over time- is a crucial determinant of the usability of the assistive device.

After evaluating the state-of-the-art of movement intention detection strategies and the quality of several physiological signals in individuals with DMD, we decided to develop a sEMG- and a force-based control interface.

Control
The control of the Active A-Gear is based on generating joint torque reference signals from the low-amplitude sEMG and force signals that still remain measurable in adult individuals with DMD. The desired joint torque signals will then be applied to the human joints through the rotary series elastic actuators.

The ultimate goal of the A-Gear Flextension project is to develop functional prototypes which demonstrate that the arm function of individuals with DMD can be effectively supported with a body-bound assistive device. These developments will be further elaborated in future projects initiated as well by the Flextension foundation.

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[52] Design of a Stair Climbing Device for Active Wheelchair Users
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Comparison of Epicardial and Endocardial Monophasic Action Potentials Recorded Simultaneously from Reanimated Porcine Hearts

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Background
Monophasic Action Potentials (MAPs) are electrical signals that represent the focal depolarizations and repolarizations of cardiac myocytes [1]. These signals are synchronized to cardiac function, and show localized signals describing activation timings, densities, patterns, and/or velocities [2-4].

The detection of MAPs via applied catheters may aid in determining both characteristic waveforms as well as the relative viabilities of the underlying cardiac tissues. For example, such detection would be beneficial in cases of atrial fibrillation, where ablative therapies are employed to terminate the cells triggering the arrhythmias: in many cases it is desired to create transmural (or full thickness) lesions. By recording MAPs at the trigger site pre- and post-ablation, the success of the treatment can be assessed immediately, and modified if necessary. The purpose of the present study was to simultaneously collect and compare signature endocardial and epicardial MAPs from isolated porcine hearts.

Methods
Isolated hearts from Yorkshire swine were used in this study. All swine were anaesthetized and ventilated with a positive pressure respirator. The animals were euthanized by using a direct injection of Cardioplegia (a high potassium solution) into the aorta and then excised. Each specimen was cannulated and re-animated using previously described Visible Heart® methodologies [5]. Cardiac viability was monitored as the placement of the internal catheter was directly visualized with videoscopes. Additionally, the relative placements of mapping catheters endocardially and epicardially were assessed using fluoroscopy (Ziehm Vision R).

Results
To validate the use of MAPs for cardiac procedures, they were recorded from both endocardial and epicardial locations simultaneously. The timing of these signals were also monitored in relation to a recorded electrocardiogram (ECG) to further validate that the signals correlated with the depolarizations of either the atrium or ventricle, depending on the catheter locations. Hence, using the ECG and the relative profiles of the recorded signals, one can readily define them as MAPs.
MAPs were recorded from multiple locations in both the atria and ventricle. The waveform profiles of MAPs recorded epicardially were similar to those recorded endocardially (Figure 2). It is important to note, that the amplitudes of MAPs can vary depending on the amount of force applied to the tissue by the catheter: hence this was not used as a point of comparison. The timing of the MAPs were notably similar between the epicardial and endocardial signals.

Interpretation

MAPs recorded endocardially are very similar to those recorded epicardially. While changes in start time, amplitude, and repolarization rate were observed, it is unclear at this time if this is due to the placement of the catheters in relation to one another, or because of the transmural propagation of excitation.

In cases of arrhythmias, an ablation procedure may be performed either epicardially or endocardially: most often attempting to make induced lesions transmural. The detection of Monophasic Action Potentials using a MAPs catheter can be used to determine the relative, acute, viability of cardiac tissue in a specific anatomical area, which can lead to a higher rates of success for the treatment of such patients.

References

Ergonomic Body Support for Laparoscopic Surgery

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1 Background

Surgeons must often perform surgery in uncomfortable positions and for hours at a time [1], leading to work-related musculoskeletal disorders [2]. As a result of this, over 30% of practitioners indicate that discomfort influences their choice of operative method [3] and almost unanimously (97%–100%) surgeons “see ergonomic improvement in the OR as necessary” [4, 5]. Female surgeons are reported to be twice as susceptible to musculoskeletal disorders as their male colleagues [6]. Still, ergonomics are hardly practiced in the operating room (OR) [7]. With the workload of surgeons increasing [8], a more ergonomic operating environment is vital for sustainable healthcare, increasing both efficiency and safety. Eventually, this could, potentially, lead to a decline in adverse medical incidents, where fatigue is a contributing factor [9].

Two decades after widespread introduction of laparoscopy, the ergonomic challenges for surgeons of this technique are beginning to show. Compared to open surgery, laparoscopy is characterised by more discomfort in the upper back and extremities and more static standing postures [10]. Literature reports an increase of muscular fatigue, discomfort [11–13], and leg swelling. Lastly, operating tables were originally designed for open surgery and have not been altered to account for the different demands and length of laparoscopic tools. Studies have shown [14–16] a discrepancy between the ideal ergonomic operating surface height and the extents of operating tables’ adjustments. Additionally, surgeons forget about their posture because of high mental stress loads and as Rosenblatt et al. suggest [17], postural reset is an important method to counteract harmful postures and return to initial (more neutral) postures. Even though a significant body of literature now highlights the need to reduce surgeons’ discomfort, implemented solutions that actually support improved postures are limited.

Problem

Discomfort is a complicated, qualitative phenomenon and, therefore, in this study a multi-factored approach is taken to its origins, which are defined as a combination of three external parameters: Load, higher loads lead to more discomfort; Posture, harmful postures such as larger extensions result in more discomfort; and Exposure Time compounds the effects of both load and posture (Fig. 1).

Prior art solutions can be split into three groups: Firstly, are articulated mounts that increase the mobility of monitors so that they can be positioned with easy lines of sight; secondly, there are redesigns of conventional chairs, for use in the operating room; and thirdly, complicated, relatively overdefined “ergonomic platforms”. Of the latter two groups, the first does not provide sufficient upper body load reduction, determined to be a critical aspect from literature and direct surgical observations, while addressing this has resulted in large platforms that effectively restrict the surgeon to unusual, though ergonomic, postures, and take up precious OR space. Both strategies lack a means of reducing exposure time, the only parameter that has been proven in literature to decrease discomfort as mentioned by Jack Dennerlein (Personal interview, May 14 2014). An additional, recommended strategy, though not touched upon in this work, is a surgeon physical conditioning regime targeting those muscle groups affected during surgery.

Objective

The goal of this project is to create a physical, flexible body support that reduces discomfort, while respecting the surgeon’s autonomy and preferred operating postures.

2 Methods

Design Strategy

Surgeons are trained to follow standardized workflows for every procedure, so as to maximise efficiency, and changing techniques would be unpopular. The strategy is to provide intuitive, user selectable support that promotes postural variation, thus reducing exposure time. This is accomplished with a flexible support structure that guides and follows, rather...
than forcing the surgeon, and allows “micro” postural changes, while maintaining the same “macro” position. The design (Fig. 2) consists of two separate modules: an upper body abdominal support that connects to the side rail of the operating table and incorporates an arm rest and a standing platform.

Abdomen Support and Arm Rest

The abdomen support provides a soft, flexible plane that supports the body via the hips and around the abdomen, providing central rather than peripheral stability. The arm rest has three functions: reducing spinal loads, increasing surgical precision, and promoting postural reset. By supporting the forearms, the rest relieves the back muscles and by shortening the structural loop (Fig. 3), the arm rest is expected to allow for more precision during surgery, confirmed by Galleano et al. and Patil et al. [18, 19].

Standing Platform

The second module has two functions: promoting postural variation via micromotions and eliminating the discrepancy between optimal operating surface height and operating table height adjustments. In contrast to anti-fatigue mats, the platform consists of a stiff surface with compression springs, inducing postural sway while eliminating the compression set that makes anti-fatigue mats of limited use. Secondly, the device will replace the standing platforms, already commonly used in the OR.

Prototyping and Validation Testing

First, a set of modular wooden mockups, comprising the platform, with height adjustments, a posterior rest, a knee rest, an abdominal support, a chest support and a padded armrest were developed and fabricated. These were presented to select clinicians at Mt. Auburn Hospital, Cambridge, MA. Feedback indicated a preference for a flexible abdominal support and the platform. The design was further refined and again presented, leading to selection of a low abdominal support surmounted by a padded armrest and an optional platform. It was decided to mount the support directly to the operating table’s rail so as to minimize clutter.

Subsequently, a full scale, functioning prototype of the design was built for a validation test scheduled for 20 June. The goal will be to validate the hypothesis that the design results in less discomfort, changes in postural variation, more load variation, and more precision during laparoscopic surgery. The test subjects will perform an adaption of Fitts’s test [20] three times with intervals. The test will be executed three times: once with both the upper body support and the standing platform, once only with the upper body support, and once without any support.

Before, during, and after the set of tasks, a visual analog scale (VAS) will be used in combination with the local postural discomfort method [21], distinguishing six muscle clusters. Using a force plate, the center of pressure can be calculated, making it possible to analyse posture variation and assess load variation.

To take the effects of muscular fatigue into account, a second simple test will be executed. For this test, two non-surgeons will be recruited to play video games for 45 minutes, an activity comparable to laparoscopy [22]. The same three test setups will be used and both subjects asked to fill out visual analog scales in combination with the local postural discomfort method at different times.

3 Results

Results are expected by the end of June, in time for incorporating into the full paper. Based on preliminary tests, we expect the support to both lower and vary load, resulting in less discomfort. Also a change in posture variation is expected.

4 Interpretation

The new body support design aims to introduce a shift in ergonomic furniture from a focus exclusively on load reduction to a focus on exposure time. This follows the famous quote ‘the best posture is the next one’ that has so far only been materialized in Peter Opsvik’s exotic chair designs [citaat boek]. The support’s flexibility allows postural variation without forcing the user to take a completely different posture. In an everyday working environment, it is important that designs allow the user to remain autonomous, and, especially pertinent in the operating room, the surgeon should be in control and dominant over the environment he or she is using.

References


Abstract [8]


User-centered instrumented tissue expander

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1 Background

This research was in collaboration with the Design Education Lab, the Living Matter Lab as well as the Department of Medicine at Stanford University. The focus is on tissue expansion and the use case for infants with giant congenital melanocytic nevi. The intention is to include the user (e.g. clinician, patient) with his knowledge and experience into the engineering process. The resulting instrumented tissue expander provides the user quantitative feedback during the procedure.

A giant congenital melanocytic nevus is a birthmark, which covers a large part of the body. A nevus, with a certain diameter increases the risk of cancer and therefore will be removed. To replace the removed birthmark extra skin is needed. Therefore a tissue expander (TE) device is implanted into a subcutaneous pocket underneath the epidermis and dermis. One or more expanders are located around the birthmark under the skin. Over a couple of weeks, saline solution is injected into the implant. Filling the expander gradually stretches the skin, which triggers skin growth. This initial injection is followed by a protocol at home. From an engineering point of view, the therapy is non-ideal for three reasons. First, parents do not feel comfortable injecting fluid into an expander without any quantitative feedback. Second, due to an obligatory safety margin, the achieved stretch is not optimal, meaning that skin growth is minimal. Third, the injection intervals are not triggered by the skin condition. As a consequence, the treatment is unnecessary long and inconvenient for both the patient and the parents. [1]

2 Methods

In biomechanics, the modeling of tissue behavior is a central research topic. In this context an interesting correlation of the tissue growth is discovered. Moreover finite element (FE) simulations give valuable insights into the biomechanics of skin growth [2]. With reference to the user-centered design (UCD) process, FE simulations support the involvement of physicians into the medical device design process.

Tissue expansion is an experienced-based procedure. It is hard to learn for an inexperienced doctor. Literature only gives some indications of how to perform the procedure. The inflation protocol is triggered by subjective measures like the skin color or physical findings by the treating surgeon [3]. The only control variable during the following inflation is the volume of saline solution injected into the expander. The loss of volume because of a leakage is not measurable.

Based on the correlation of the skin area and the expander pressure, presented by Zöllner et al. [4] a trigger for the following inflation time point is investigated. The increase in expander volume is associated with an increase in expander pressure and an increase in skin area stretch [4]. It is believed that the skin growth is a strain-driven process. Skin grows as a result of a certain inflation volume. Equally, growing skin is accompanied by skin relaxation and a decrease in pressure [1]. The correlation between the expander pressure and the skin growth is illustrated in Figure 1.

When the expander pressure converges towards a certain threshold it is associated with a stagnating skin growth and a stress relaxation [5]. The treatment time could be decreased when skin growth over time is maximized. Skin growth, skin stress, and strain are not measurable in vivo without a surgical procedure. For that reason, the decrease of the skin growth is triggered by the concurrent expander pressure decrease. Once the first derivative of the pressure curve converges to zero, both, the pressure curve and the fractional area gain remain constant.

For a successful treatment the capillary pressure of ~0.004 MPa should not be exceeded for the longer term. Using the FE simulation, the contact pressure applying onto the skin is measured. The correlation of expander pressure and the skin surface pressure enables the physician to measure the contact pressure applying on the skin in vivo. This is a great possibility to determine a maximal filling volume, based on a patient-specific sense of pain and skin strain. As a result of the quantitative feedback the filling of the expander is triggered by the skin condition. The risk of necrosis or pressure-induced ischemia is minimized.

3 First results

Despite the progress of the reconstructive treatment, there are some limitations. Both, the inflation protocol and the filling volume vary for every patient. A first attempt of a sensor-featured tissue expander is presented in this chapter. This user-centered instrumented tissue expander provides the patient as well as the treating surgeon a sensory feedback to enhance a successful procedure.

The idea of an instrumented tissue expander is to plot pressure time diagrams to trigger the next appropriate inflation time point [1]. The injection is indicated by the saturation effect in the skin growth. Since skin growth is correlated to the expander pressure, the saturation effect is reflected in the first derivative of the pressure curve.
Using a pressure sensor inside the TE the current expander pressure and the pressure over time is displayed. Based on the first derivative the optimal inflation time point is triggered. This way of tissue expansion is simulated with a finite element model to facilitate the communication with the surgeon.

For the feasibility prototype, the pressure data is read-out via a SensorTag by Texas Instruments and displayed on an IPad. The maximal measured expander pressure is 1090.8 mbar. Figure 2 illustrates an interpolated pressure over volume diagram for both the simulation and the experiment. The material properties of the FE simulation is a rubber-like material according to Treloar [6]. For a certain volume, the pressure of the simulation converges whereby the pressure of the experiment increases significant.

According to [7] the pressure over volume diagram is within the range, given in literature.

Figure 2. The initial volume is defined for ambient pressure. The final expansion is set for a filling volume of 725 ml. The color scale of the FE model denotes the vertical displacement of the expander in relation to the bottom. Pressure over volume diagram: FE simulation (blue) compared to experimental results (red). The shell material of the simulated expander is modeled with a natural rubber in accordance to Treloar [6] and defined as Arruda-Boyce.

4 Interpretation

An instrumented tissue expander can have a great impact to the tissue expansion treatment. The injection timing is optimized by a patient’s sense of pain as well as the skin condition. Skin growth over time can be increased significantly.

An inflation triggered by the expander pressure has several benefits. Both, the surgeon and the patient get quantitative feedback during the treatment. The doctor is enabled to notice complications like leakage early in time. A patient-individual adjusted procedure allows a patient-specific skin growth. Since the sensor is located inside the expander, a FDA approval is facilitated.

In addition a FE simulation enables a calculation of the skin area gain based on pre-simulated results. The treating surgeon could use a computer program to simulate the treatment procedure and adjust the expansion individually.

To notice the appropriate time point for the next filling, a wireless remote control is imaginable. The instrumented tissue expander could also be used via a smartphone application. The patient is informed by a push-up notice anywhere and anytime. Since AirXpander [8] presented a wireless controlled AirXpander a collaboration seems expedient.

Based on the findings of Grocott et al. [9] many medical devices are generated in isolation of the ultimate users. User involvement is of extreme importance and not considered in most Medical Device Design Processes. The main benefit of user involvement are an increased access to user experiences, requirements and ideas [10]. As a consequence, the functionality, usability and quality of medical devices are enhanced.

For an user-centered medical device a user-centered design process is obligatory. A great degree of interdisciplinarity implies that the concerned disciplines are technically apart. This results in a more difficult cross-domain communication and cooperation [11]. FE simulations support the interdisciplinary collaboration to facilitate a user-centered medical device.

An instrumented tissue expander can improve quality of life of its user and assist the user to live more independent.

References

Development of a Mechatronic User Input Device for Surgical Instruments

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1 Background

One of the advantages of the DaVinci surgical system is the fact that the instrument manipulation is easier than in standard laparoscopy. The system offers a combination of an intuitive user interface and instruments with additional Degrees-Of-Freedom (DOFs) compared to standard laparoscopic instruments. It would therefore only be logical to develop instrument systems with similar properties. Examples of commercial developments include JAI MY by EndoControl [1], and DRIVE by Tuebingen Scientific [2]. Public research activities are also being undertaken to develop novel handheld instruments systems such as [3] and [4]. In their own analysis, they authors of [3] and [4] admit that they have not yet achieved the optimal design.

The objective of this development project is to design and later evaluate a novel handheld input device to a surgical instrument with 3 DOFs at the tip. As it should be handheld, the interface should weigh less than 300g and comfortably fit in the palm of a hand. It is assumed that the drives for the DOFs at the tip can be separated from the input device. For example, in the case where the instrument is powered by hydraulics. Hence, the input device would need to include sensors to record the user’s actions.

2 Methods

The development of the device consisted of two main tasks. The first task was the mechanical design and the second part the selection of the sensors to be integrated in the design. The mechanical design process consisted of informal discussions with surgeons from the Clinic of the University of Heidelberg in Mannheim as well as a survey of the literature. The sensor selection process consisted of a survey and evaluation of measurement principles given a number of requirements that were partly predetermined by the mechanical design. The design will dictate what physical property needs to be measured, and the approximate range. Given is that the bandwidth and accuracy need to be within human bandwidth and accuracy range. Also the intention to develop the interface as a medical product has to be taken into account. This means that the sensors have to be cheap enough to be a single-use product, or withstand a sterilization process by either being inherently robust or appropriately encased.

3 Results

It was shown [5] that users find direct mapping of the interface orientation and position to the instrument the most intuitive to use. Experienced laparoscopic surgeons however, performed equally well when the mapping was not direct. A direct mapping would be difficult to achieve with a handheld device, so this study gave the confidence that it is not an essential requirement. Not only is the control mode of importance, but also the ergonomics. Guidelines for ergonomic design of surgical instruments were developed by [6]. Some of these guidelines are easier to take into account than others: “The grasping forceps must be operated by one hand of the surgeon” [6] is simple, whereas “Forces may not be exerted on the ball of the thumb or the palm of the hand” [6] is more difficult. Even with these guidelines, it is important to evaluate the effect of a design on the ergonomics. The work by [7] presented a comparative study between a scissor-type grasper and a newly designed handle for a grasper. One of the study objectives was the physical workload required for the different designs. This load was notably reduced by the new design without a loss of accuracy. This study showed that there are many factors to include when validating a novel handle design. Besides ergonomics, the functionality of a new design would need to be evaluated. It was shown in [8] how a virtual reality simulator could be used to assess both criteria for different instrument systems. It was shown that additional degrees of freedom at the instrument tip improved the overall functionality, but required more learning time from the user with the new input system. It was also shown that decoupling the input device from the instrument shaft improved the ergonomics of the overall system. The result of the decoupling was increased system complexity and controls. This could be overcome by further development of the control modes. Further evaluation methods and results for intuitive designs of user interfaces were presented by [9]. Here the various motions of thumb, forefinger and wrist were analyzed to determine the best combinations of joint motion and resulting instrument motion. Using these data and an iterative design study, three user interfaces were developed to control 3 DOFs. These were in turn evaluated in vitro and rated according to subjective user feedback and task performance. The best design had the thumb control the deflection with a vertical wheel, the forefinger control the rotation with a horizontal wheel, and the rest of the fingers control the grasping with a horizontal lever. The informal discussions at the clinic added the desire to have a flexible sphere to control the grasping motion to the list of requirements.

Figure 1 Mockup of the mechanical design

Given the literature research and the clinical wish list a design with a type of joystick with a flexible sphere on the end was
developed as shown in Figure 1. It was thought to lie in the palm of the user’s hand and is controlled with only the thumb and the index finger. Via the joystick 3 DOFs can be measured: linear displacement, rotational displacement, squeezing of an elastic material. These DOFs were further defined as follows for the sensor selection:

- Linear displacement 10mm
- Rotational displacement 180 degrees
- Compression of at least 50% of an elastic sphere with a diameter of 10-20mm

To measure the linear and rotational displacement, the following measuring principles have been investigated:

1. Inductance using a Linear Variable Differential Transformer (LVDT)
2. Capacitance
3. Potentiometer
4. Hall Encoder

Given the requirements, the assessment results were as follows:

1. Commercially available LVDT translation measurement devices require too many components that take up too much space in this handheld device. Customized solutions are feasible for this application, but other sensor types were preferred. The moveable part of a typical LVDT sensor has a spring return, which was not desired for this application.
2. Capacitance sensors are not designed for measuring displacement in this range. Their precision is generally in the micro order of magnitude, which is not necessary for a joystick. Commercially available sensors that can measure the required 10mm displacement need a significant amount of signal processing electronics.
3. Like LVDT sensors, linear potentiometers need a housing, which means that they take up too much space. There are also not contactless, which may be a problem for this application. Additionally, the string potentiometers have a spring return, which means that the joystick will not remain in place when released. Finally, the latter potentiometer type has a very high cost, which is not desirable.
4. Hall encoders are the best technology for displacement measurement in terms of precision, flexibility and cost. They are not as precise as LVDT sensors, but precise enough for this type of application. There are several ways to integrate the magnets into the mechanical design, allowing for some design flexibility. The cost of a typical chip is within the single-use product range. They can be used to measure both linear and rotational displacement depending on how they are integrated in the design.

To measure the squeezing of the elastic material, several different methods can be applied:

1. Compression of the material
2. Tension of the material
3. Pressure changes of an increasingly compressed volume of air

These methods lead to the following measurement principles:

1. Force dependent resistance foils
2. Classic resistance changing strain gauges
3. Piezo resistive pressure sensors

The most promising method and measurement principle combination was measuring pressure changes using piezo resistive pressure sensors or force dependent resistance foils. Measuring material compression using force dependent resistance foils was also feasible, but possibly less robust.

### 4 Interpretation

The design followed the ergonomic guidelines, but remains to be thoroughly evaluated in terms of ergonomics and functionality. The literature presented various methods of measurement, hence for comparison purposes, these will be followed. Once the experimental environment has been established, variations on the design can be studied.

To measure the DOFs on the user interface, a number of measurement principles were investigated. The investigation took into account a number of requirements from the mechanical design as well as the intended use of the system. Both linear and rotational displacement are preferably measured using Hall encoders. Further investigation of the squeezing measurement are necessary especially in combination with the control algorithm and the user trials.

### References

Chairlift Compatible Sit-Snowboard For Paraplegics

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1 Background

Wheelchairs aid paraplegics to participate in activities of daily living and with specially designed wheelchairs even participation in several sports is possible[1,2]. However, until recently, there were no aids to help paraplegics to snowboard. Snowboarding requires meticulous control over the placement of one’s center of mass. The placement of one’s center of mass with respect to the snowboard determines the pressure applied by the board on the snow, which controls acceleration, steering and deceleration of the snowboard.

‘MINI’ (ProDaptive B.V., The Hague, The Netherlands) is a prototype sit-snowboard for people with disabled lower limbs. MINI (Fig. 1) consists of a snowboard on which a seat is mounted on a sitting tube, resting on flexible supports (limiters). Knee pads and feet straps fixed to the board constrain the user’s legs. Handlebars attached to the snowboard allow the user to transfer forces to the board that are normally applied by the legs to twist the snowboard and control the position of the user’s torso center of mass. Pilot tests with three disabled users (two with Spina Bifida, one with Spastic Quadriplegia due to cerebral palsy) showed that these users readily learned sit-snowboarding using MINI. However, MINI is not yet suitable for general use because it cannot be taken along with the user in a chairlift. Therefore, the aim of this work was to design and test an improved sit-snowboard that:

1) Can be taken along in existing chairlifts.
2) Retains the snowboarding performance of MINI.

2 Methods

Design criteria

The target users are people that have both legs but have little to no control over them, yet have full control over core, pelvic and arm muscles (e.g., people with spinal cord conditions). Written and oral surveys were conducted among 20 target users, a sit-skier, an abled snowboarder and an snowboard instructor. The outcome suggested that users want to be in control and should readily learn to use the sit-snowboard. Asking for help at times is acceptable as long as often-recurring maneuvers can be performed independently.

The snowboarding performance should at least be comparable to that of MINI. Force analyses of MINI use and literature data showed that: 1) the handlebars should be fixed to the snowboard during snowboarding to allow transferring twist and tilt forces, and to allow moving the user’s center of mass, 2) the limiters should be retained to allow tilting the snowboard and moving the center of mass past the snowboard’s long edges [3,4], without sudden impacts, 3) the bottom of the seat should no more than 665 mm above the bottom of the board to let the user experience a balanced, stable position. The weight of the improved sit-snowboard should not exceed 20kg to allow the user to effectively use body mass to control the sit-snowboard movements.

Riding a chairlift should ideally be possible without exiting the sit-snowboard. A chairlift ride generally has three phases: A) Loading, B) Riding, C) Unloading. During Loading, the sit-snowboarder should move towards the chairlift’s loading area in a self-propelled manner with the sit-snowboard. At the loading area, the user waits until a chairlift chair, having 2–8 seats, arrives and should sit down on one of the seats. During Riding, the user remains in the seat with the sit-snowboard and should be safely balanced to prevent falling out of the chairlift. During Unloading, the user should detach the sit-snowboard from or lift it off the chairlift seat. The user, on the sit-snowboard, will exit the chairlift at the speed of the chairlift and should be able to decelerate while going down a slope (<15°, based on measurements at indoor skiing tracks) and come to a stop without tumbling over. Dynamic models of a sit-snowboarder suggested that a safe exit requires the snowboard to be within 8° aligned longitudinally with the line of motion of the chairlift.

Design

Finite Element and kinematic models were used to ensure the strength of critical parts and to ensure the user’s stability when riding a chairlift with the sit-snowboard. The improved sit-snowboard design (Fig. 2), called ‘SnowGo’, features a seat that is mounted on a vertical tube, placed amidst the snowboard on a re-designed limiter. This new seat design was used to create a 457mm deep, free space between 200 and 550 mm above the snowboard’s bottom face. The free space should allow for all known chairlifts seats to fit under SnowGo’s seat so the user can stay in SnowGo’s seat during the chairlift ride. To allow safe chairlift loading and unloading, the sitting construction was made to rotate on top of the vertical tube. This allows the user to change from a snowboarding position (Fig. 2, left) to a chairlift riding position (Fig. 2, right).

Figure 1. Old sit-snowboard prototype MINI.
position (Fig. 2, right). A spring loaded locking mechanism that can be unlocked with one hand prevents any involuntary position changes. The knee pads and feet straps are fixed to the sitting construction and rotate along with it. The handlebars are detachable from the snowboard through a single squeeze locking mechanism. By taking the handlebars off the snowboard, the chairlift seat can slide under SnowGo’s seat. During the Loading and Unloading Phases the handlebars can be used as support and balancing sticks and to propel oneself towards or away from the chairlift. SnowGo weighs 25kg.

Preliminary Evaluation
Snowboarding performance was tested in Snowworld, Zoetermeer, the Netherlands, by 2 abled subjects (Subject 1: 25y/o male, 1.86m tall, 80kg weight, 25 accumulative days of snowboarding experience; Subject 2: 20y/o female, 1.72m tall, 58kg weight, 30 accumulative days of snowboarding experience) using MINI and SnowGo twice and in different orders. The subjects: A) slid downhill, making as many zig-zag motions as possible to demonstrate toe-side–heel-side balancing control, B) initiated turns in all directions to reach pre-placed targets as closely as possible to demonstrate snowboard motion control. Paired, two-tailed t-tests were used to compare the results for MINI and SnowGo. The threshold for statistical significance was set at $p=0.05$.

Chairlift compatibility was tested by a subject with Spina Bifida (28y/o male, 1.76m tall, 95kg weight, 10 accumulative days of sit-snowboarding experience) using the chairlift with SnowGo and repeating all 3 chairlift phases 5 times. Twice with an instructor and thrice independently.

3 Results

The prototype showed that sit-snowboards can be made to be compatible with chairlifts. During the snowboarding performance tests, subjects made 3.9 and 4.5 zig-zags on average using MINI and SnowGo, respectively ($p=0.25$). Both users seemed to have similar targeting control with MINI and SnowGo, ending 187 and 139m from the target cone, respectively ($p=0.39$). All five chairlift compatibility tests were successful, although in one of the tests the user lost balance and fell. SnowGo fitted through the chairlift gates and the user could get into and out of the chairlift with SnowGo without any assistance from others and without the chairlift having to be slowed down. When in the chairlift, the user and SnowGo together occupied only a single seat (Fig. 3) and the safety bar of the chairlift could be closed.

4 Interpretation

SnowGo is the first sit-snowboard that allows users to snowboard and ride chairlifts fully independently. Due to manufacturing and cost limitations, SnowGo is 5kg heavier than aimed for. Yet, full snowboarding functionality was retained and although the differences did not reach significance, users seemed to perform slightly better with SnowGo than with MINI. The independence of the user and the facts that one can ride the chairlift with SnowGo on a single seat and the safety bar of the chairlift could be closed, illustrate that SnowGo enables full social interaction during chairlift use, which adds to a positive sporting experience.

References
Assessing Patient and Information Flow in Surgical Day Care using RFID technology

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1 Background
Due to the rising number of elderly and the increase of chronic diseases, the number of patients requiring hospital care is rising. Hospitals are urged to improve efficiency to manage the growing healthcare costs (especially in surgery where the costs are the highest) and focus on patient centred care, such as service and patient satisfaction [1].

Information technology can help support to overcome these challenges. Recently, the potential of Radio Frequency IDentification (RFID) technology is being explored to facilitate healthcare processes, improve its efficiency and improve patient safety [2]. RFID technology can be used e.g., to track medical asset or equipment, to identify patients and staff and to track workflow and patient flow [3, 4]. The data generated by the RFID systems can be used to improve the efficiency of surgical processes, improve patient flow and can also be used to inform patients and staff about the progress in the surgical trajectory [4].

A first step to improve the efficiency of the surgical trajectory and to improve patient satisfaction is to gain insight in the current patient and information flow. The aim of this study is twofold:

• measure wait times for patients/escorts undergoing eye surgery during surgical day care,
• characterize the current information flow between staff and patients/escorts and between staff from different departments.

2 Methods
This study was conducted in the main surgical center (including four operating rooms) of the Rotterdam Eye Hospital. The Rotterdam Eye Hospital is a major referral center, performing approximately 14,000 surgical procedures annually. The study was divided into two parts: RFID tracking and interviews.

RFID tracking. Active RFID technology was used to automatically track the patients’ location during their entire hospital stay. Adult patients admitted for surgical day-care were tracked during 52 successive weekdays. The active RFID tag (pulse rate 0.8, frequency 433.92 MHz, power 1mW, weight 24 gram) was attached to the patient’s identification wristband and was tracked by readers (GW3D, RePoint, the Netherlands), which were placed at eight locations along the surgical trajectory, shown in Figure 1. The readers and controllers were connected to the existing wired network and rough data was pushed and stored at the stand-alone server (Dell OptiPlex 790).

Figure 1. Layout of the surgical trajectory, location of the RFID readers and active RFID tag attached to patient’s wrist band

Patients were grouped based on the type of anesthesia (general anesthesia (GA) versus local or topical anesthesia (LTA)). Standard descriptive statistical methods were used to calculate length of hospital stay and wait times per phase (i.e. pre-operative day ward, holding, OR, recovery, and post-operative day ward). For the recovery and the postoperative day ward “wait-recovery time” was calculated as wait time and recovery time (recovering from surgery and anesthesia) could not be separated.

Interviews. Escorts (family or friends accompanying patients during their stay at the hospital) and nurses from the day ward (ward nurses) were interviewed during the RFID tracking part of this study. Open questions were asked concerning: the current information flow between staff and patients/escorts and the current information flow between ward nurses and holding/recovery nurses using the current information systems and their wishes for the future. The interviews took a maximum of 15 minutes and notes were taken.

The current information system used at the day ward is a magnetic whiteboard including colored patient’s cards (male/female/child) stating name and type of anesthesia. They are placed in columns representing the different locations/phases. When a patient moves to the next phase the ward nurse moves the card accordingly.

3 Results
RFID tracking. In total 622 patients (405 GA, 217 LTA) were included in the analysis. 207 patients were excluded, reasons were: tag not detected by the OR reader (n=154), type of anesthesia unknown (n=23), patient did not wear/removed tag (n=20), tag could not be linked to patient data (n=6) and recorded OR time was less than a minute indicating a technical flaw (n=4).

In total, GA patients spent on average 7h01 in hospital and LTA patients spent on average 4h17 in hospital. Figure 2 shows the wait times and wait-recovery times per phase. For GA patients the total percentage of wait and wait-recovery time during the entire hospital stay ranged from 0-87.0% with
an average of 68.2%. For LTA patients this ranged between 20.8-85.7% with an average of 64%.

<table>
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</table>

No wait: 11 10 17 10
8 0 3 10

Figure 2. Wait and Wait-Recovery times [hh:mm] per phase (GA: general anesthesia; LTA: local or topical anesthesia)

**Interviews.** In total 30 escorts were interviewed. Thirteen escorts noticed the whiteboard, but only one escort used it. Eighteen escorts received information on the duration of the surgery and the arrival time at the day ward after surgery and eight escorts received information on what time to go home. In the future, most escorts would like to be informed about the progress in the surgical center (n=19) and the arrival time at the day ward after surgery (n=22). Twenty-one escorts would prefer a public screen in the waiting room to a personal device to portray the progress information. They did not have any privacy concerns related to this public screen nor did they mind that their names would be visible for other patients and escorts.

In total nine ward nurses (out of the 15 ward nurses) were interviewed. Current problems with the patient flow were: a patient is requested by the holding intake before (n=4), the ward nurse wants to bring a patient, but the patient is already taken (n=5), the holding calls to bring a patient who is already on its way (n=7) and the recovery calls to pick up a patient, but the ward nurses are already on their way (n=6). Furthermore, nine nurses indicated that the whiteboard is not updated regularly. In the future the ward nurses would like to be informed (via an information system) about: registration of the patient at the hospital (n=7), intake meeting conducted (n=9), patient ready to be brought to the holding (n=8), patient ready to be picked up from the recovery (n=8) and patient ready for checkout meeting and discharge (n=8).

**4 Interpretation**

This study showed that RFID technology can be used to measure wait times for patients undergoing eye surgery during surgical day care. It is a practical tool to track and perform time recordings automatically and real-time.

On average 66.7% of the entire hospital stay is wait and wait-recovery time for patients undergoing eye surgery and most patients had to wait in each phase of the trajectory. The longer wait than anticipated was partly caused by patients arriving early, surgery starting late, sporadic communication between the ward nurses and the patients/escorts and intermittent information exchange between the day ward and the surgical center.

Real-time information about the patient flow can support communication between departments concerning transfer of patients and can support the nurses to better anticipate and/or to automatically reschedule surgery to limit long wait times. Providing real-time realistic information about wait times and providing reasons for delays could also improve patient satisfaction with wait time [4, 5]. A display, automatically presenting the phase in the surgical trajectory to the escorts and the estimated wait times, could also reduce the number of questions concerning the patient’s progress, stimulate active involvement and actions of the patients/escorts (e.g. get dressed and get into bed without a nurse assisting them) and reduce anxiety [3, 5]. Automatic presentation of the patient’s phase first requires a technological system. RFID technology is already used in the healthcare domain [2-4] and this study showed that RFID is able to record and show real-time data on the patient’s location and time spent in the different phases. However, implementation and use of such a technological system also requires the organization, its working routines and protocols to change as well [3].

Based on the results of this study a “Patient Tracking System” was designed together with the ward nurses and patients/escorts (see Figure 3).

**References**

Development of an Adaptable Technology Demonstrator for Advancing Compliant Surgical Graspers

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This work is part of a larger research effort to accelerate medical device innovation within the EU through academic & industrial collaboration. This paper presents the development of a technology demonstrating platform that will be employed for user-centered design testing. Technology demonstrators introduce critical features of functionality and comfort to end-users. User criticism is then interpreted to redefine performance requirements necessary for successful commercialization. Here, a technology demonstrator is developed to advance the design of fully compliant statically-balanced surgical graspers with superior force-feedback capabilities. The final demonstrator is a user-friendly, highly-adjustable stiffness compensator with critical component interchangeability.

1 Background

User-centered design methodologies have proven success through effective communication and testing within end-user environments [1]. This work is part of a larger multidisciplinary effort to advance proof-of-concept technology towards fully compliant statically-balanced surgical graspers. The design offers improved force-feedback capabilities through the benefits of compliant mechanism design. The potential of the device has been proven within the medical market through proof-of-concept prototypes & related commercial medical products [2-4].

The device, shown in Fig. 1, consists of a compliant tool tip & a counteracting negative stiffness mechanism, or static balancer (SB). The tool tip is actuated by a central push/pull rod to open & close the device. The compliant monolithic (single-piece) design offers direct input/output transmission by replacing traditional rigid-linkages with elastic members that transmit motion & force. When combining SB technology, the positive stiffness (k+) associated with articulating the compliant tooltip is compensated by a counteracting negative stiffness (k-). The result is a zero-force operating range of motion.

The underlying research is on compliant mechanism design to manipulate force-feedback response systems for graspers & alike. Here, product development methods facilitate the design of a technology demonstrating platform intended for extensive verification/validation testing of technological solutions.

Figure 1. Basic design of a statically-balanced surgical grasper with close up of compliant tool tip & operating force profiles.

This work details the design of a linear SB mechanism developed to perform end-user testing. The following offer a glimpse of the design methodology through this particular case study. Excluded work includes tool tip design (Patent Pending), verification of conceptual solutions & preclinical end-user testing.

2 Methods

The design methodology employed in this project is illustrated in Figure 2. Design research filters the technical problem to form a basis of requirements. Technology demonstrators are then developed & evaluated within verification & validation testing to identify necessary modifications for successful commercialization. The process is repeated to satisfy all critical-users.

Figure 2. Simplified user-centered design methodology that combines extensive design research with direct user-feedback to optimize product functionality & user acceptance.

Employing traditional design methods, existing SB technology is surveyed, concepts are generated & then selected based upon a pre-defined design criteria. The final design is fabricated using traditional machining techniques.

3 Results

Existing research & technology formulates the performance requirements of the device [2-4]. The selected
mechanism functions according to the principles of static balancing using linear springs (Fig. 2) [Just]. Two design concepts, which are illustrated in Fig. 2, differ by the primary rotational joint connecting user-input (actuation handle) and device-output (push/pull rod).

The primary requirements of the functional demonstrator are functionality, comfort, & adaptability. This allows effective demonstration of critical functions without distract of discomfort. Adaptable demonstrators permit design parameters to be manipulated during testing for introducing multiple/alternative modes of functionality. The selection criteria for the demonstrator is displayed in Table 1, with rankings favoring the revolute joint concept. Although both solutions provide adequate product performance, the revolute concept has superior adaptable capabilities. Using an donor laparoscopic device, the final design features quick interchanging capabilities of tool tip components, in addition to the balancing springs. Although friction is introduced into the system through mechanical joints (Fig. 3b), the performance sensitivities linked to fabricating & assembling roller sheet supports outweighs the static frictional losses.

The final design is illustrated in Fig. 3. The result is a user-friendly, stiffness-adjustable demonstrator with critical component interchangeability. Two stiffness adjustment parameters (ϕ & δ) permit a continuous fine-tuning feature within predefined range of motions.

The design methodology has led to a user-friendly demonstrator that permits quick interchanging of critical stiffness components. The stiffness adjustment features enable deeper research investigations into human-device feedback sensitivities & user-preferences. The adaptability of the device provides an effective testing-platform to complete extensive end-user testing of conceptualized tool tip designs. Although the main focus of this report has been user-centered design, the platform also integrates with verification testing procedures. The final demonstrator will contribute to the advancement of compliant statically-balanced surgical graspers for improve force-feedback.

4 Interpretation

The design methodology has led to a user-friendly demonstrator that permits quick interchanging of critical stiffness components. The stiffness adjustment features enable deeper research investigations into human-device feedback sensitivities & user-preferences. The adaptability of the device provides an effective testing-platform to complete extensive end-user testing of conceptualized tool tip designs. Although the main focus of this report has been user-centered design, the platform also integrates with verification testing procedures. The final demonstrator will contribute to the advancement of compliant statically-balanced surgical graspers for improve force-feedback.

References

Design of a Stair Climbing Device for Active Wheelchair Users

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1 The problem

Approximately 60 million people worldwide rely on wheelchairs for mobility, which is roughly 1% of the world's population[1]. One of the major problems facing wheelchair users is the ability to overcome changes in elevation, for example ascending or descending sidewalk curbs, thresholds, and stairs. This paper focuses on climbing stairs.

Currently, many electronic systems are available to climb stairs when using a wheelchair. Furthermore, a significant amount of research has been done to provide better solutions to climb stairs with an electronic wheelchair[2]. The general drawback of these systems is that most of them cannot be applied to existing wheelchairs, since most of these systems require completely new wheelchairs with an integrated climbing system. Furthermore, the application of a battery and electric motor introduces the risk of running out of power, which would significantly reduce the independence of the user. Finally, since the battery and motor are fixed, they need to be transported all day even though they are seldom needed. This results in unnecessary added weight.

In contrast to the amount of research and development done on electronic systems, there has been minimal development done on manual powered systems. This is remarkable, since active wheelchair users have a healthy upper body. An exception is the work done on a special climbing wheel that is operated manually, however, this wheel requires a completely redesigned wheelchair, and is thus not applicable to existing wheelchairs[3].

2 The solution

The goal of this project is to design a mechanism that can be mounted to existing wheelchairs of active users, which allows the user to manually climb stairs.

User requirements

The market analysis showed that there is indeed a demand for such a mechanism. Based on the findings of a survey completed by 85 wheelchair users, it was found that the key user requirements in the development of this mechanism are the safety of the user and the ease with which the mechanism can be used. Using these key requirements, design specifications such as stability and a low mass are derived.

The design

This development project was divided into two distinct objectives. First, the optimal propulsion method for this mechanism was investigated. Second, the mechanism for climbing the stairs was developed.

The propulsion mechanism

The propulsion for the stair climbing mechanism can be accomplished in many different ways. The optimal method was selected using the following selection criteria.

- Use as many muscles as possible to spread the load.
- Use the strongest muscles as much as possible to increase the output force.
- Use a comfortable movement for the propulsion.

Also considered were mechanisms that had a low mass and a compact system since these characteristics would improve usability.

In general there are four different types of propulsion possible:

1. Using a hand-rim system
2. Using a lever
3. Using a hand bike propulsion system
4. Using a crank on the rear wheel

Using the results of research done to these propulsion types by Van der Woude [4, 5] and the work of Daams [6], who measured the maximum forces that could be delivered in various positions, it was determined that a lever operated between the legs of the user is the optimal solution that best matched the design requirements. Such a mechanism would require the fewest number of adaptations to the wheelchair while the output force is kept high. It also uses the largest muscles in the arms and upper body, making this an effective way to power the climbing mechanism.

The climbing mechanism

In order to select a suitable climbing mechanism, performance specifications were first defined. The first specification established was that climbing the stairs will be done backwards, and going down the stairs will be done forwards. This is due to stability issues when ascending stairs in the forward direction and descending stairs in the reverse direction.

The second performance specification established for the wheelchair stair climbing mechanism was that an assistant would be required when climbing stairs. Although this may appear to be a major limitation since it does not allow the users to climb stairs independently, it is actually a significant benefit. First, an assistant will give the user a much safer feeling when travelling on the stairs. Furthermore, the assistant can assure the stability of the device. Finally, due to the lack of electronic control systems, the assistant can act as a 'controller' to guide the transition of different stages of the stair climbing process. As a result, the climbing device can be kept much smaller and lighter.

With the selected propulsion system and with the performance specifications established, the mechanism as shown in Figure 1 is proposed.

With this mechanism, the user can power the rotation of a triangular wheel by moving the lever back and forth. A toothed belt connects the lever with the triangular wheel. If this wheel is rotated to a position where one of the wheels is at a 6 o'clock position, the wheelchair is elevated and the assistant can pull the wheelchair backwards. By doing this, the wheel at a 10 o'clock position can make contact with the next step. If the wheel is rotated further, the step is climbed.
Figure 1. Schematic drawing of wheelchair climber

It should be noted that the wheelchair is tilted backwards, such that the center of gravity is moved to a position between the contact point with the stairs and the assistant. This way a stable system is created such that the stairs can be climbed safely.

In order to maintain this position, the assistant needs to deliver a peak force of less than 100 N. Most of the time this force is significantly lower. This is because the distance from the contact point of the climbing wheel with the stairs to the centre of gravity changes due to the rotation of the climbing wheel. This can be seen in Figure 2.

Figure 2. The force on the assistant

3 Innovativeness

The proposed system as shown in Figure 1 has many innovative aspects. First, it is powered completely by the user and no batteries or electric motors are required. The system will therefore weigh significantly less than currently available stair climbing devices, and because it does not require a power source, this should make the system more reliable and user friendly.

Furthermore, the system can be mounted to every active wheelchair without changing the design of this wheelchair. Only some clamps are needed to connect it to the rear axis and the beam underneath the seat of the wheelchair. As a result, this design does not require the user to purchase a new wheelchair that is specially built to climb stairs.

Finally, the climbing system can easily be undone from the wheelchair. The lever that the user propels can be uncoupled from the climbing system. By doing this, the other part can be driven away by the assistant, leaving only the clamps on the frame of the wheelchair. This is shown in Figure 2.

Figure 2. Doffing the climber

4 Next steps

The first step that will be undertaken is to prove the proposed concept will actually work. To do this, a simplified full-scale version will be built and evaluated. If the design does not work as expected, it will be adapted and improved until it meets the performance and design specifications. If it does work, the next step can be taken.

Upon successful completion of the prototype testing, detailed CAD drawings of the mechanism will be made including all elements, such as the folding mechanism, the don/doffing mechanism etc. With this model it can be shown how all elements fit together and that the key requirements are met. This shows that a mechanism has been developed that fulfils a need, while being safe and easy to use.

Future work will include detailed testing and evaluation, design refinement, and detailed documentation. At that point, more knowledge is collected considering functioning, feasibility, safety and production costs. Using such knowledge, a detailed market analysis will be done to ensure the mechanism indeed fits the requirements of the user.

References

Pre-operative Fitting of Osteosynthetic Plate for Clavicle Fracture using Rapid Prototyping

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1 The clinical problem

40% of all clinically presented shoulder girdle injuries are clavicles fractures. Around 80% of those fractures are located in the mid third of the clavicle, the so-called group I of the Allman classification [1]. In the majority of the cases, group I fractures are treated conservatively by supporting the shoulder with a shoulder immobiliser. In cases where the fracture shows >100% displacement, and a shortening of 1.5-2.0 cm, it is also justified to perform an open reposition and internal fixation [2].

In the Isala clinics, there were 44 open reduction internal fixation (ORIF) cases of group I clavicle fractures in 2012 and 2013. At least one out of four osteosynthetic plates did not fit the curvature of the clavicle according to the surgery reports, therefore it had to be altered by bending the plate perioperatively. Other cases described a rotation of the placement of the plate, where the lateral part of the plate was placed medial, and vice versa.

This alteration process takes time and the quality of alteration between surgeries may differ. Moreover, the unpredictable incision time due to the alteration process makes it rather difficult to create efficient operating schedules.

2 The solution

Preoperative planning is the solution to improve current efficiency and workflow in ORIF procedures. The perioperative alteration process can be avoided by performing the osteosynthetic plate selection and adjustment preoperatively instead. This is done by constructing a physical three-dimensional model of the fractured clavicle or by constructing a mirrored version of the contralateral clavicle. In this way, the osteosynthetic plate can be adjusted to fit onto the (modeled) clavicle.

First, a CT scan of both clavicles has to be made in order to create such models. From this scan, the clavicles can be segmented with the mathematical program Matlab and converted into a three-dimensional surface mesh model (see figure 1). The mesh model of the contralateral clavicle is mirrored, and subsequently the models are exported as stereolithography files (.stl). Thereafter, the segmented models are processed in the program Meshlab to clean the mesh and separate the fragments, resulting in a representative model of the fractured clavicle and one of the mirrored contralateral clavicle. The next step is to create physical models by means of a rapid prototyping technique. In this case the models are created by fused filament fabrication, using a 3D-printer (see figure 2).

The printed models can be used for planning of the surgery. The location of the plate on the clavicle can now be predetermined. Subsequently, different available plates can be tested in a way that the plate has a solid contact to the bone and that three screws on the medial and lateral fragment are able to penetrate both cortical layers of the clavicle. If a plate meets these requirements, a sterile version can be acquired during surgery. In case none of the available plates fit properly, one, of appropriate length, needs to be bent to fit onto the curvature of the clavicle. Because the plate becomes unsterile from bending, it has to be sterilized before using it in surgery.

For fitting plates two models are available, the fractured clavicle and the mirrored contralateral clavicle. For relatively fresh fractures, the fractured model is recommended, since not all clavicles are symmetric [3], and because (due to missing or loose fragments) the angle of the connecting parts can change, resulting in a different geometry. Fragments are commonly not used in the fixation, because they have been cut off from blood supply and are most likely to become devitalized, which interferes in the healing process of the bone. That is why fitting the plate is without the fragments. Older fractures are often paired with callus formation. Because callus is recognized as bone in the segmentation, the fractured model will be less representative to reality. Therefore it is recommended to use the mirrored contralateral model for planning in such cases.

A pilot study was carried out with this procedure, when a patient presented herself with pseudarthrosis after a clavicle fracture. Using the described method both models were printed. Since this concerned an older fracture with callus formation, the contralateral model was used to determine the best fitting plate. With tools present in the OR the plate was altered to fit the model, figure 3, and sterilized. During
surgery no time was spend in altering the osteosynthetic plate and an improvement in workflow was observed. The accumulated time it took in the first case to prepare for surgery was around 4 hours.

3 Innovativeness

The pilot study showed that improvements in the fundamentals of the conventional operation can be made. Usually a plate is selected based on the reposition of the fracture perioperatively. But because of a better orientation of the situation preoperatively, the plate will be based on that knowledge and the repositioning of the fracture can be based on the preshaped plate. Another advantage of pre-selecting a plate is that only the necessary surface of the bone has to be cleaned, which limits the damage to surrounding tissue.

Also instead of using k-wires, the surgeon can use the plate to reposition and reconstruct the bone. This is possible when first one side of the fractured bone is attached to the plate and then subsequently the other part of the bone fixated the plate, as planned preoperatively.

In addition during the preparations, the type, length and angle of the screws can be predefined, which can also save time and avoid errors.

4 Conclusions

Through a pilot study it has been shown that the method has good prospects. The next step is to demonstrate the clinical relevance. With a clinical study, the gain in surgery time and the effect on the workflow of the surgeon can be investigated.

The expectations are that the average incision time will decrease. And maybe more important, the variability in incision time is expected to drop, resulting in tighter OR schedules. On top of that is it anticipated that the workflow will improve for the surgeon. In this investigation we have merely applied the method on the clavicle, but could easily be translated to other and different types of fractures, if clinically relevant.

References


A novel fusion imaging guiding system for bronchoscopy

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Background

Lung cancer is the most deadly cancer being responsible for 28% of all cancer deaths and causing 1.3 million deaths worldwide every year [1]. Currently, to diagnose lung cancer, pulmonologists plan the transbronchial biopsy procedure by examining a number of Computed Tomography (CT) scan slices before the procedure. Then they manipulate a video bronchoscope into segmental and sub-segmental bronchi as far as the diameter of the bronchoscope permits. Finally, they insert a biopsy forceps through the working channel of the bronchoscope, and, often (if the lesion is beyond the visual reach of the scope), blindly perform the biopsy. The diagnostic success rate is dependent on the size and location of the lesion. Consequently, a large percentage of the procedures fail to reach peripheral targets. When these failures occur, pulmonologists must repeat the procedure or follow up with more invasive methods that have increased complication rates, such as CT-guided percutaneous needle biopsy with increased level of radiation for surgeon and patient or surgical biopsy with high stress for patient.

At present there are other technologies for guiding like endobronchial ultrasound (EBUS) but they are still difficult to use for peripheral lesions and computed tomography fluoroscopy involving radiation for surgeon and patient [2]. The feasibility of electromagnetic navigation bronchoscopy (ENB) with a steerable instrument has been previously presented [3].

In the present study we developed a new fusion imaging system (FIS) for spatial guidance of a bronchoscopic forceps to reach peripheral targets within bronchial tree, outside the range than the video bronchoscope can reach. We tested the FIS for ease of use and improvement of navigation time on a bench top phantom, which simulates the bronchial tree.

Methods

The FIS includes an electromagnetic tracking system (ETS) AURORA (Northern Digital Inc., Ontario, Canada) for spatial positioning connected to a computer that runs a proprietary navigation software application, a disposable navigation forceps for biopsy, and an active marker placed on the patient’s skin. For a bronchoscopy procedure using FIS, the patient is moved from CT/MRI procedure to the interventional room where a specific set-up is necessary (Figure 1). The personal computer is connected to the video bronchoscope and the ETS system. The magnetic field generator is mounted on the bronchoscopy bed close to the patient, and the active marker (with positioning EM sensor) is placed on the patient’s xiphoid bone. The navigation forceps is introduced in the bronchoscope’s working channel and connected to the ETS. The navigation forceps is similar to a biopsy forceps for bronchoscopy and includes a 6DOF electromagnetic sensor at its tip to determine its spatial position and orientation in the AURORA magnetic field.

The FIS assisted bronchoscopy procedure starts by launching the software and loading the patient’s CT data. The navigation software uses multiple technologies for anatomy three-dimensional reconstruction, image-to-patient registration, manual calibration and navigation. The user loads the sagittal, coronal and transverse CT planes. The system automatically develops airways segmentation, semi-automated lung nodule segmentation, multiple targets selection (eight maximum), virtual bronchoscopy visualization and geodesic minimal path extraction and displayed it in the first screen window.

While navigating through the CT planes, the user finds the place of the active marker on patient’s skin to be used for the initial registration. Next the user indicates on the
virtual bronchoscopy or CT windows the entry point of the procedure and the anatomical target and then selects a pathway between the two points by picking several points along airways to create a median line between them.

The FIS can compute the instantaneous position of its tip relative to the patient and CT space and continuously overlaying it on the 3D model. Following the path to the target lesion in the bronchial tree, the user visually compares the live and virtual images of the bronchoscope video and can correct the registration by translating and rotating the virtual bronchoscopy while keeping the bronchoscope still, until the two images are similar.

When the bronchoscope diameter is too big to advance in the sub-segmental bronchi, the user extends only the navigation forceps further to the peripheral target. The navigation is performed using the virtual bronchoscopy image and the instantaneous position of the forceps tip overlaid on the 3D model. The user is also able to investigate surrounding tissues using the virtual CT section. The biopsy using the forceps can be performed when the target is reached.

The navigation software modules are developed using ITK, VTK and IGSTK open source libraries, to co-register the information from two imaging modalities ([http://www.igstk.org/](http://www.igstk.org/)) [4, 5]. The virtual bronchoscopy was developed based on a GPU implementation of the Marching Cubes algorithm for extracting surfaces from volumes using OpenCL and OpenGL. This algorithm has 6 stages:

1. Data storage as a 3D texture on a NVidia Quadro 6000 model GPU.
2. Base level construction of the histogram pyramids.
3. Histogram pyramid construction on a set of ND Range kernel calls in OpenCL.
4. Memory allocation on the graphics card (VBO) for all vertices and nodes needed to store the surface.
5. Histogram pyramid traversal when the memory is filled with the output of the Marching Cubes algorithm by running a ND Range kernel of the same size as the total sum of triangles.
6. Render. The vertices and normal are stored in the VBO made in the previous step.

For the FIS feasibility testing, a complex shape phantom of lung airways was used. A 3D CAD model was designed using SolidWorks by segmentation and surface reconstruction using a patient’s CT scans. The phantom was created on a precision Object260 Connex 3D printer from a rigid material VeroGray RGD850. Seven tumor models from ceramic powder, with diameters between 10-25mm were placed 110-254 mm deep inside the bronchial branches.

As active marker for this tests was used an Aurora 6DOF Reference, 25 mm disc from NDJ (part number 61066) and the exact position and orientation of the tumors on the phantom were measured using the Aurora system by touching every target with a 6DOF Probe, Straight Tip, Standard (part number 61065S). A check between CAD model and phantom model was performed using measured data, using the marker as reference and the tumors were located on the CAD model with a precision under 1 mm. The phantom and CAD model are used to test the navigation utility and accuracy, by steering the forceps in the tumor closest proximity, for locations where bronchial diameter is to small for bronchoscope.

**Results**

The feasibility tests were performed by three engineers and two experienced pulmonologists with instructions from the developer (LGG). An Olympus Bronchoscope was used in a bronchoscopy procedure room, at the Emergency Hospital from Craiova, Romania. There were seven “tumor” targets that the users had to reach at different depths inside the airway tract phantom. The absolute error (distance from the bronchoscope tip to the target) and the procedure time were measured. The engineers reached the targets in 79.5±2.7 sec with the FIS (8.3±0.5 mm error) vs. 204.2±3.7 sec with the bronchoscope alone (28.7±5.5 mm error). In comparison, the pulmonologists reached the targets in 71.3±7.9 sec with FIS (8.4±1.8 mm error) and 74.3±7.1 sec with the bronchoscope alone (16.2±3.3 mm error).

**Interpretation**

The preliminary tests using a complex phantom proved the FIS is easy to use and improves navigation through the bronchial tree in both unexperienced and experienced operators. Further studies on phantom and large animals are planned to prove its efficacy for clinical and training use. In addition, in the NAVICAD project (EEA grant), we will further automate some of the steps for navigated bronchoscopy. This research was supported in part by ANCS-CNDI-UEFISCDI from “PNII - Joint Applied Research Projects” program, contract number 887/2012, and code PN-II-PT-PCCA-2011-3.2-0482; and the EEA Financial Mechanism 2009-2014, project contract no. 3SEE/30.06.2014.

**References**

Thursday 23 October, 2 pm  
Chair: Gernot Kronreif, Austrian Center for Medical Innovation and Technology

[3] Robotic Steering Concept for Interventions in Flexible Endoscopy  
Esther Rozeboom, Jeroen Ruiter, Ivo Broeders

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[6] Closed loop control of an active tip-steered needle with FBG sensors  
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[7] Development of a Robotic Trans-esophageal Ultrasound Probe Manipulator  
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[33] Mobi-Mag: A compact device for medical research using wireless control of magnetic microrobots  
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Robotic Steering Concept for Interventions in Flexible Endoscopy

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1 Background

Flexible endoscopes are increasingly used to perform advanced intraluminal and transluminal interventions. The long flexible shaft with steerable tip is well suited for its original purpose of visualizing the inside of the gastrointestinal tract. The endoscope provides a minimal invasive route through the gastrointestinal tract, with associated advantages over surgery. Unfortunately, the 60-year-old design of the control interface is not ready for a future of advanced interventions.

Controlling the flexible endoscope is a dexterous task. Steering the camera and its protruding instrument is difficult to learn [1]. The non-ergonomic design causes increased physical workload and injuries [2]. Furthermore, multiple persons are required to simultaneously control the endoscope and its instrument, with associated risks due to communication errors. All of these aspects are undesirable in an environment where the risks of bleeding and perforation are eminent [3], [4]. As a result, advanced interventions are reserved for few highly trained endoscopists and their teams.

Robotics have the potential to overcome the difficulties of non-intuitiveness and non-ergonomics [5]. A robotic control interface allows single-person control of multiple degrees of freedom in an intuitive and ergonomic setup. Furthermore, the separation between user interface and motor unit enables the integration of computer intelligence.

We present a robotic system designed to enable intuitive and ergonomic control of the conventional flexible endoscope and its instruments [6], [7]. The Teleflex system consists of three modules to control the endoscopic tip, shaft and multiple instruments (Figure 1). Key factor of this design is that it allows coupling to conventional endoscopes without modifications to the costly endoscopic equipment. The new setup aims to make advanced endoscopic interventions part of daily practice.

This paper presents the results of pre-clinical evaluation studies focusing on efficiency, effectiveness and satisfaction of the system.

2 Methods

The design and evaluation of novel clinical technologies is an iterative process. Firstly, we evaluated usability of the tip steering module, followed by the shaft manipulation module and finally user evaluations of the instrument module. The systems intuitiveness and ergonomics are best evaluated with inexperienced volunteers (novices), since they are not biased to either the conventional or robotic setup. Clinical endoscopists were asked to provide targeted user feedback. Studies were performed on computer simulators and mechanical models to provide objective evaluations and to enable cross-subject comparison. All studies included user questionnaires to collect functional and design feedback.

The first studies consisted of efficiency, effectiveness and user evaluations of endoscopic tip steering. 24 novices used the conventional endoscope, a remote joystick and a remote touchpad interface to complete cecal intubation in a colon model [7]. Secondly, 14 novices steered an endoscopic instrument to touch targets on a circular trajectory, using intuitive controllers versus conventional endoscope control [8]. Position and rate control algorithms were used to optimize the control interface of the robotic setup. In the third study, we evaluated the learning curve of both endoscopists and novices when using the system to perform colonoscopy (Figure 2).

After tip steering, we evaluated the usability and intuitiveness of the shaft manipulation module for interventional endoscopy. 12 novices used the conventional endoscope with assistant, the robotic setup with assistant and single-person robotic control for pick-and-place tasks using a biopsy grasper instrument [9]. Nine endoscopists performed single and bimanual pick-and-place tasks using the instrument module [6]. They provided user feedback after learning to work with the robotic setup with two steerable grasper instruments (Figure 3).
3 Results

Considering tip steering functionality: the robotic steering concept allows control of the conventional flexible endoscope without reducing current efficiency and effectiveness of endoscope manipulation. Novices were able to improve or match the conventional colon intubation times while experiencing a reduced workload for both joystick and touchpad interfaces. Novices were more efficient in instrument positioning when using a joystick or touchpad interface compared to conventional control. Experts were able to reach their personal level of colonic intubation after a short learning curve. There was no significant difference between the novices’ learning curve when using the conventional versus the robotic setup.

The robotic setup with shaft manipulator reduced the time needed to perform intervention tasks. Novices valued the level of intuitiveness, experienced reduced mental effort and reduced frustration levels. There was no decisive difference in time between single-person robotic control or robotic control with assistant to manipulate the endoscopic instrument.

Endoscopists valued tip stabilization, the use of multiple instruments and instrument triangulation when using the robotic setup. They suggested improvements considering the tip’s responsiveness and user feedback.

4 Interpretation

The aim of the robotic steering concept was to allow efficient, effective and user friendly control of a conventional flexible endoscope and its instruments. Pre-clinical evaluations of tip steering, shaft manipulation and instrument control modules show that the setup allows better or equal performance in the hands of experts and novices.

In conclusion, the first results are promising and we are confident to improve these results after addressing the few drawbacks we experienced with this first prototype.

The first point of revision is the users’ feedback of the endoscopic tip position. When steering the conventional flexible endoscope, users experience direct haptic feedback to estimate the tip’s position. The addition of a motor drive unit intercepts this haptic signal. Instead we inform users with a visual tip bending diagram. Since users found it difficult to interpret the visual representation, we will simplify the feedback and confirm usability and intuitiveness with bench-tests.

A second limitation of the system is in the instrument’s responsiveness. The use of flexible, cable driven instruments introduces the problem of variable cable tension [10]. This reduces control accuracy because users find it difficult to estimate the instrument’s response when using remote controllers. Solutions are the addition of haptic, mechanical or software solutions to stabilize or predict cable responsiveness.

The tip steering studies showed that excessive endoscopic shaft rotation is a necessary tool to steer and stabilize the endoscopic tip. We experienced that while rotation is still technically possible after positioning the endoscope in a docking station, it is more difficult. Active compensation or frictionless setups will reduce the force needed to rotate the endoscope and minimize the experienced workload.

Despite the few mentioned drawbacks, we were able to design a system that allows the control of a flexible endoscope and its instruments. Both endoscopists and novices already value the potential benefits of robotic control. The next step is to implement and evaluate the mentioned redesigns. We will proceed with the evaluation using in-vitro anatomical models, and later in vivo experiments performed by experienced endoscopists.

References

DRAFT: DEVELOPMENT OF A NOVEL SYSTEM FOR CT-GUIDED PERCUTANEOUS NEEDLE PLACEMENT IN THE ABDOMEN AND THORAX

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BACKGROUND
CT-guided minimally invasive biopsies and therapies such as radio-frequency and microwave ablation of tissue in the abdomen and thorax are typically performed through a needle which is percutaneously inserted to reach the target tissue. The traditional method for needle placement is to apply a sheet of radio-lucent gridlines for reference onto the patient skin and acquire a first set of parallel CT images in which a target for the needle tip and a skin entry point are selected by the physician. The entry point is retrieved on the patient skin using the intersection of the gridlines and a laser line projected from the CT gantry. A short reference needle is then superficially inserted according to the estimated insertion angles from the entry point to the internal target, followed by a new CT scan to verify the direction of the needle. It is not unusual for this step to require five or more iterations before the reference needle is correctly aimed. The longer biopsy or therapeutic needle is stepwise inserted co-linearly with the reference needle and with intermediate CT scans for verification. The insertion depth of the needle from the skin is measured using linear markings on the needle. Once the needle has been placed to satisfaction, the physician proceeds to performing the biopsy or therapy.

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FIGURE 1. Rendering of the novel system including needle, patient, CT gantry (cut-through) and table.

Tissue damage, patient X-ray exposure and consumed time increase with each placement iteration, and the required number of iterations is highly user-dependent and significantly increases for needle placement oblique to the transversal plane. Numerous needle placement systems with various strategies have been developed to facilitate and improve needle placement [1]. However, few systems have become commercially available products and no system appears to have found widespread clinical adoption. We present the concept of a novel system for CT guided percutaneous needle placement, which aims at usability, versatility and integration with the existing workflow. A rendering of the system is shown in Fig. 1 with relevant components indicated.

METHODS
The main user requirement of the system is that it must user-independently reduce the procedure time and patient X-ray exposure by avoiding erroneous and iterative needle placement. The design philosophy behind the concept is that the system should only aid the physician where necessary and any changes to the
existing workflow should be well-considered. This reduces system complexity and costs and improves chances of clinical adoption. The workflow steps of entry point retrieval and manual insertion of the needle are straightforward. For many procedures, the main opportunity for improvement lies in setting the right angles before insertion. The main function of the novel system is therefore to automatically align a needle guide with the selected internal target.

The system embodies an Orientation Module (OM) which includes a needle guide on a two degrees of freedom (DOFs) mechanism which can set the lateral angles of the needle guide by rotation about a remote centre of rotation (RCR). After following the existing workflow up to the point of entry point retrieval, the physician places the OM manually using handlebars such that the end of a removable probe indicating the RCR coincides with the retrieved entry point. At this point, the physician presses a button to automatically lock the OM with respect to the imager table using the Locking module (LM). The LM is a linkage between the imager table and the OM, containing a 1 DOFs linear joint and two ball joints with 2 and 3 DOFs respectively, which enable a large range of motion of the OM within the CT gantry and around the patient. Upon locking of the joints using a pneumatic-hydraulic system, the position and orientation of the OM are fixed with respect to the imager table.

A CT scan is now performed of the relevant anatomical section of the patient together with the OM, which incorporates four spherical radiopaque aluminium-oxide fiducial markers in its handlebars and main body. The fiducials are used for automatic registration, i.e. the determination of the position and orientation of the OM with respect to the image set coordinate system. The target for the needle tip can be specified in the same image set, and consequently, the angles of the needle path from the RCR to the target can be calculated. The needle guide is now automatically moved by the mechanism of the OM, rotating about the RCR and skin entry point until it is axially aligned with the target. Insertion of the needle through the needle guide is performed manually by the physician.

The development of the system is technically challenging due to the combination of requirements on system accuracy and compatibility with the CT imager. The latter yields a tight space budget as well as restrictions on which materials can be used in the scanned part of the system. For example, the design incorporates various ceramic components including ball bearings, glass-fibre reinforced torsion springs, carbon electrical wiring and custom plastic fibre optic encoders. Furthermore, the two DOFs of the RCR mechanism are actuated via a cable transmission to keep the standard electrical servomotors outside the CT scanned volume.

RESULTS
A preliminary realization of the system has been CT scanned to verify the CT compatibility of the design, as shown in Fig. 2(a). A

![CT scan](image)

(b) 3D reconstruction of the acquired image set. Pixel values in Hounsfield units (HU).

FIGURE 2. CT scanning of a preliminary realization of the system.

3D reconstruction of the acquired image set is shown in Fig. 2(b). Indicated are several components and their material. Pixel values are in Hounsfield units (HU) and increase with the radiopacity of the material. No significant image streaking was caused by introduction of the OM next to the abdominal phantom.

INTERPRETATION
The acquired CT images of the preliminary realisation of the system verifies the CT compatibility of the design. Further development of the system is currently in progress. Once a first proof of principle of the complete system is completed and technically tested with positive results, phantom and in-vivo studies will follow to assess its clinical performance.
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Closed loop control of an active tip-steered needle with FBG sensors

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1 Background

Taking a liver biopsy, ablating malignant structures by means of radio frequencies, and placing radioactive seeds in the prostate for cancer therapy, are typical examples of needle interventions during which the clinical outcome relies on an accurate tip placement. However, this placement task can be complicated by intermediate bony structures and soft tissues (bloodvessels, nerves, other organs). Besides spatial restrictions, misplacement can result from human errors, imaging limitations, and unforeseen needle-tissue interactions [1]. Correcting the needle path can be difficult and unintuitive [2] and, as a result, needles are often completely retracted and inserted anew.

Needle steering has been coined as a possible solution to compensate for discovered errors on-the-go. Several steering techniques have been proposed, such as base manipulation [3], bevel-tip steering [4], pre-curved-tip steering [5], variable bevel steering [6], pre-curved-stylets protruding from rigid cannulas [7], and active cannulas [8]. These steering solutions are either active or passive, meaning the operator can either directly influence the needle geometry, or this influence is an indirect result of needle-tissue interactions. Both the optimal control of passive needles and the optimal design of active needles are on-going research fields.

This article presents a novel, active, tip-steered needle and assesses its functionality on behalf of a pilot study in phantom material. During insertion, the needle will deform as a result of asymmetric needle-tissue interactions at the tip. This deformation is measured by means of strain sensors, fiber Bragg gratings (FBG’s), incorporated in the needle stylet. To the author’s knowledge this is the first study to combine active tip steering with FBG-based shape feedback.

2 Methods

The actively steered needle used in this study is presented in Fig. 1. The needle has a conical tip, with an apex angle of 20°, placed on top of a flexible shaft by means of a ball joint. Four actuation cables are connected to the tip and run along the needle cannula to the hub. Each actuation cable is connected to a rack in contact with a servo motor (Hitec HS-5125 MG). The gear transmission is chosen so that the tip can rotate with approximately 20° (tip angle ) to any direction (steering angle ). Besides these two rotational degrees of freedom, a linear translation is achieved by placing the needle-actuator assembly on top of a linear stage (Festo EGSL-BS-55-250-12.7P).

The needle consists of a stainless steel stylet with a radius r1 of 0.5 mm, a PEEK (IDEX® Health & Science) plastic cannula with a radius r2 of 0.9 mm, and a transparent PET (Vention Medical®) plastic heat shrink tubing, bringing the total needle radius to approximately 1 mm.

Inserting the needle in tissue will result in cannula bending along neutral line a-a’, defined by the steering direction (). Cannula bending is measured by means of twelve FBG sensors incorporated in the three glass fibers (3x4). The sensors were calibrated under constant curvature and the needle shape, including the tip position, was extrapolated from the fiber strain data in the same manner and with a similar precision as presented by Henken et al [9].

The linear stage had an internal PID controller and was set to deliver insertion strokes with a speed of 5 mm/s up to a depth of 100 mm. The servo motors were regulated by means of a digital PI controller based on the acquired x-y tip-coordinates. The controller output for the x-direction was:

\[ u_x(t) = K_p e_x(t) + K_i \int_0^t e_x(\tau)d\tau \]  

Here, \( K_p \) (=0.1) is the proportional gain, \( K_i \) (=0.05) the integral gain, and \( e_x \) the measured error. The FBGs were used to sense first tissue contact (using a displacement threshold of 0.5 mm from the calibrated tip position), after which the control gains were gradually build-up (in 50 loops). This ensured an initially straight needle insertion in tissue.

The experiments were performed in a 15 m% porcine gelatin phantom. In total, nine different targets with respect to the needle insertion point were defined, each at a 100 mm
Targets were defined below the origin, and at a radial distance of 30 mm from this point, with steering directions (0) at every 45°. For each target, 6 repetitions were performed and the tip coordinates were tracked and recorded.

The trajectory coordinate vectors were filtered with a 3rd order low-pass Butterworth filter, using a cut-off frequency of 0.5 Hz, and the end-point error per target (mean ± std) was calculated. The targeting accuracy was determined by the in-plane error between the tip and target \((x_t, y_t)\) location:

\[
\text{accuracy} = \sqrt{(x - x_t)^2 + (y - y_t)^2}
\]

The error per target (mean ± standard deviation) was calculated and the average of these values over all nine targets is presented. In a similar way, the steering precision was presented, which is determined based on the variance around the average position \((\bar{x}, \bar{y})\) reached:

\[
\text{precision} = \sqrt{(x - \bar{x})^2 + (y - \bar{y})^2}
\]

**3 Results**

A top-view of the needle tip trajectories for each of the targeting tasks is shown in Fig. 2. A definite steering behavior in gelatin was witnessed. The targeting accuracy was 6.2 ± 1.4 mm, and the steering precision was 2.6 ± 1.1 mm.

As the control actions were deliberately kept low during the initial puncture phase, the slight variance in tip heading caused by this initial puncture had a significant impact on the subsequent control response. For some trajectories, s-curves resulted in the x-y plane. Sometimes, early path bifurcations for trajectories with the same target were seen. This happened for instance at the center \([(x, y) = (0, 0)]\) and lower \([(x, y) = (0, -30)]\) targets. These ‘random’ effects had an impact on both the mean and the spread of the reported steering precision. In addition, the control parameters were set equal for all steering directions, which was sufficient for some targets, but insufficient for others. These more systematic influences affected the targeting accuracy.

**4 Interpretation**

This article presents a novel, active, tip-steered needle that operates by means of four steering cables connected to a conical tip. This allows steering with two orthogonal, rotational degrees of freedom. FBG based shape sensing was used to construct a closed loop PI control scheme for tip placement. Steering was validated in a pilot study and the placement errors were reported.

Systematic components of the targeting error were attributed to needle mechanics. They included 1) a slight pre-curvature of the PEEK cannula, which came from a spindle, and 2) unequal pre-tension in the actuation cables and friction in the ball joint. As a result, steering was not equally successful in all directions. Now that these systematic differences are known, they can be compensated for in the future. This can be done either by implementing mechanical solutions or by elaborating the control scheme.

The current PI controller could be replaced by a more intelligent scheme that includes mechanical needle and tissue parameters. An overview of kinematics or mechanics-based, predictive models used for path planning of steerable needles is provided by Gao et al [1].

**References**


Development of a Robotic Trans-esophageal Ultrasound Probe Manipulator

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1 Background

Trans-esophageal echocardiography (TEE) is an important means of assessing the heart structure and function. It has been widely utilized for cardiac disease indication since it was introduced over a decade ago. The short distance between the transducer and the heart allows for the use of higher frequency transducers, yielding better spatial resolution and superior performance compared to external trans-thoracic echocardiography. TEE is particularly useful as a monitoring adjunct during minimally invasive cardiac surgery where trans-thoracic echo is impractical [1, 2].

However, a skilled operator, usually a cardiologist, is required to hold and manipulate the probe. Interventional procedures are usually accompanied by X-ray fluoroscopy imaging and in a typical setup, the TEE operator is required to stand close to the path of the X-ray. This is not practical for the duration of the longer interventional procedures, since this would expose the operator to a significant radiation dose.

Robotic systems for manipulating a flexible endoscope similar to a TEE probe have been proposed by other researchers, for example [3]. In this paper, we present a system to remotely operate the TEE probe via a robotic probe holder and remote control mechanism. Once the probe is placed in the esophagus, this system allows the TEE operator to precisely adjust the probe’s position using a PC interface, enabling TEE use for longer periods without significant radiation exposure.

2 Methods

2.1 The TOE probe

A standard TEE probe comprises a flexible gastroscope tube with a miniature transducer mounted on its tip. The cardiologist can precisely control the position and orientation of the imaged region by manipulating five degrees of freedom (DOFs) of the probe, as follows (see Fig. 1): (a) The probe can be advanced or withdrawn in the esophagus, (b) the rotation about the shaft, (c) left-right steering of the tip and (d) anteflexion-retroflexion of the tip.

Figure 1. The degrees of freedom of the TEE probe. The four degrees of freedom controlled by the robot are (a) the depth in the esophagus, (b) the rotation about the shaft, (c) left-right steering of the tip and (d) anteflexion-retroflexion of the tip.

2.2 The robotic system

The robot holds the probe handle and manipulates four of the five DOFs that are available in manual handling of the probe. Manipulation of the electronic steering buttons is not yet implemented. The robot comprises three structures: the handle control structure providing two DOFs to rotate the knobs; a one-DOF probe rotation mechanism to rotate the whole probe together with the handle control structure; and a final one-DOF structure providing linear translation of the probe and all other structures. The handle control structure consists of two rotational wheels precisely formed to mate with and drive the two knobs on the TEE probe via belt mechanisms. Magnetic sensing devices are embedded into the wheels to track their orientation. The probe rotation structure consists of a gear train mechanism driven by a balanced two-motor design. The final translation structure uses a linear belt and rail system.

The control of the robot is based on a master-slave configuration. A PC works as the master device and an Arduino-Nano microcontroller [4], integrated into the handle control structure, is used as the slave processor. The PC runs a user interface software written in C#, which communicates with the Arduino via a custom protocol. The interface software provides the ability to individually control the four DOFs. The software can also be interfaced with a gamepad or joystick connected to the PC, using Microsoft DirectX 9.0.
SDK to map physical buttons to motor control commands. This allows the possibility of a separate control approach in which the TEE robot is controlled using a wireless gamepad or joystick.

2.3 Safety features

The design incorporates two important safety features: motor current sensing and an eject mechanism. Apart from the probe’s built-in mechanical limit stops on the two knobs, the design includes a motor current sensor. Via this device, the software monitors the current levels in the two motors that control the steering of the probe’s tip. An increase in torque of the motor will result in an increasing current, which provides feedback on the contact force with the esophagus. The eject mechanism of the robot enables the user to release the probe from the mechanism immediately by pressing a single button on the robot. This will actuate another motor ejecting the probe from the manipulator.

3 Results

Figure 2 shows the final design and constructed robot, along with the interface software. In this realization of the design, the probe tip can be steered with a resolution of 0.1 degrees. Via the software, the steering of the probe tip can be accurately adjusted by either a specified step or with continuous motion while a button is held down. This stepped or continuous option is similar to a feature of the manual probe controls in which the knobs can be switched between allowing discrete steps or a continuous range of motion.

In order to track the tip orientation, two small magnets, monitored by Hall sensors, were embedded into the flange, allowing the knobs’ home position to be detected. These were used to test the repeatability of the steering controls. The result of this test was that the knobs are always able to return to the same home position, indicating that there is no slippage of the steering mechanism’s stepper motors. Therefore, in an unconstrained environment, the orientation of the tip can be reliably tracked by motor step counting with the home position as a reference.

4 Interpretation

In this paper, we have described the design and implementation of a TEE remote robotic control system. The current implementation manipulates four of the five DOFs of the manual TEE controls. A mechanism for the remaining electronic steering DOF was not included in this preliminary prototype, as it adds significant complexity to the eject mechanism. Future design iterations will incorporate this feature.

We have performed preliminary bench testing of the system sufficient to verify the correct working of the mechanism and controls. We have also determined that the tip steering angle can be reliably tracked using motor step counting and the homing sensor. Further experiments in phantoms and cadavers are required to fully verify the mechanism, establish a forward kinematic model, and to detect and fine-tune the force safety limits. Our current priority is to obtain clinical feedback from cardiologists on the control mechanism, control software, safety features and general usability.

Ultimately, we expect the system to have uses beyond just remote control. For example, we intend to develop an automatic view planning approach in which the probe is automatically driven to an appropriate location in response to the user requesting a particular view of the heart.

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Telemanipulation for reconstructive microsurgery and VR eye surgery

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1 Background

Following the trend of increasing demand for less invasive and more accurately targeted surgical treatments, qualified surgical capacity is becoming scarce. This is especially noticeable for complex procedures requiring a high level of expertise as well as an ability to handle the most delicate tissue structures. Examples can be found in reconstructive microsurgery and vitreoretinal (VR) eye surgery. In VR surgery (Figure 1, left), miniscule vein structures on the retina are manipulated to prevent blindness. Similarly, recovery procedures after dissection of cancerous tissue require a specialized team of microsurgeons to reconnect small veins and arteries (Figure 1, right).

These microsurgical procedures are generally performed using a microscope's 20-40x enlarged view and a set of fine instruments capable of handling microneedles and suture wire. The precision that can be achieved manually is limited by human capabilities. Fine motor skills, dexterity and concentration yield manual precision to range between 150-200 μm at best. Even then, physiological tremor causes low reproducibility in manual positioning and tracking tasks.

Robotic telemanipulation can play a role here, by facilitating to combine the highly precise and reproducible movements of a mechatronic system with the judgment and the creativity of a surgeon. This abstract describes the design and evaluation of two novel telemanipulation devices that are able to increase surgical performance during complex reconstructive and eye surgery.

Intuitive Surgical’s DaVinci system is the best known FDA and CE approved commercially available surgical telemanipulator. It is designed for laparoscopic surgery where precision is not essential to surgical outcome. Although its precision is limited to about 1 mm, it is increasingly being tried out in microsurgical procedures [4].

A number of research institutes worldwide are developing highly precise telemanipulation systems for surgical applications such as in cardiac, eye, and neurosurgery that do aim to achieve this high precision. Some of them have already been tested in a (pre-)clinical setting: Mitsuishi et al. [1] have developed a microsurgical telesmanipulator capable of suturing 0.3-0.5 mm diameter artificial blood vessels, with a reported accuracy of 30 μm. JHU’s Steady H and system has shown to successfully cannulate veins down to 80 μm diameter in a chicken embryo model [2]. At the University of Calgary, the MRI compatible NeuroArm has been used during brain surgery on patients, with a reported precision of 50 μm [3].

2 Methods

Recent developments in vitreoretinal (VR) surgery allow for micrometer resolution diagnoses. The according precision required for effective treatment is not achievable by the human hand. To enable reproducible and safe surgery for these diagnoses, a 4DOF telemanipulator system for eye surgery has been developed (Figure 2). The telemanipulation setup of the robotic system allows for user-dependent scaling, tremor filtering and semi-automatic execution of motions, facilitating the demanded high-precision manipulation precision.

The system is integrated in the current VR operating setting, preserving surgeon-patient contact and using the surgical microscope that is already in place. Moreover, it allows easy switching between manual and assisted surgery, targeting to support high-precision surgical tasks only, as opposed to demanding the surgeon to perform the entire procedure using the system exclusively.
The microsurgical telemanipulator for reconstructive surgery is a 7DOF system consisting of a number of modular slave arms on a suspension ring, each of which is controlled by a master device mounted to the side rail of a surgical table (Figure 3). The suspension ring is aligned with a surgical microscope already present in the operating room.

The surgeon operating the prototype system for assisted VR surgery during an in-vivo preclinical experiment with his right hand.

The master and the slave manipulators are identical, and are composed of three identical and symmetrical drive train modules. Each module produces a 2DOF output, actuated by DC motors and measured by absolute optical encoders. The master and the slave manipulators are identical, and are composed of three identical and symmetrical drive train modules. Each module produces a 2DOF output, actuated by DC motors and measured by absolute optical encoders. Microsurgical instruments that are also used during manual surgery are held and actuated by the manipulators’ end effector links.

3 Results

Validation of the reproducibility of the surgical system for VR surgery shows that the system provides an intrinsic precision of 2 to 10 $\mu$m, depending on the degree of freedom. This precision is calibrated at the tip of the instrument when positioned at the retina, representing an improvement of 10 to 20 times compared to the human hand [5].

A phantom eye model with a simulated retinal surface was used to determine the positioning and the penetration precision. Freehand and assisted performance were compared. Robotic assistance was adjusted to filter tremor and automatically execute small, predefined motion profiles. A manual penetration precision of 203 $\mu$m was achieved compared to an automated penetration precision of 19 $\mu$m, which represents a 10 times more reproducible result.

For the telemanipulator system for reconstructive microsurgery, a test setup has been designed, comprising a 2DOF module mounted on a measurement frame. An autocollimator and laser vibrometer are used to externally measure the position of a measurement tool containing reflective surfaces.

While tracking a 1DOF sinusoidal reference signal, the maximum tracking error is logged. Using feed-forward to compensate for position dependent friction, the tracking error is reduced to 1.7 mrad, which equals an error of 70 $\mu$m at the tip of the end effector [6].

4 Interpretation

The 10 to 20 times improved positioning precision of the surgical system for VR surgery enables treatments at manually unachievable precision, which is required for the development of new VR treatments. This is supported by cannulation experiments, where veins down to 30 $\mu$m are penetrated and injected with fluid using a spiked tip glass micropipette. Besides the clinical benefit that is achieved by the high positioning precision, the hybrid surgery setting in which the surgeon chooses when to use the assistant during surgery and when to perform surgery by hand, as well as the integration at the operating table and the use of the available microscope, significantly lower the barrier for integration of this technology in the operating room.

The telemanipulator system for reconstructive microsurgery allows using conventional microsurgical approaches and techniques in an unchanged operating-room setting. Preliminary tests using a proof-of-concept system indicate a maximum tracking error of 70 $\mu$m at the slave end effector. Compared to conventional manual microsurgery, this translates to a 3 times improved precision.

Using feedback from VR and microsurgeons, the current proof-of-concept telemanipulator devices will be developed further, to create technological solutions highly dedicated to reconstructive microsurgery and VR eye surgery applications.

References

Mobi-Mag: A compact device for medical research using wireless control of magnetic microrobots

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1 Background

Continuous efforts towards the development of less invasive surgical procedures and targeted therapies have led to experimental studies on the possible use of microrobotic agents (Fig. 1a) in medicine [1]. Due to their small size, these microrobots could navigate to deep-seated regions within the human body and perform a wide range of accurate tasks, e.g., micro-surgery [2], micromanipulation [3] and targeted pharmacotherapy [4]. Nonetheless, at the present time only a limited number of research centers possess the control setups which are required for research and development (R&D) of such novel applications. Within this context, a compact device for wireless control of magnetic microrobots, hereafter referred as Mobi-Mag, is introduced (Fig. 1b). Its components were conceived in order to allow biologists and clinicians to carry out practical studies that could take advantage of using magnetic microrobots. On that account, Mobi-Mag provides:

- A "plug and play" and modular design,
- Means of integration with clinical imaging equipment, such as a variety optical microscopes and ultrasound transducers [5],
- A waterproof suitcase for easy transportation,
- Electrically insulated electronics for increased safety in biological laboratory environments.

In order to carry out experiments with Mobi-Mag, the microrobots and the samples to be manipulated are placed in a water-based solution. A petri-dish of 4 cm diameter and 1.5 cm height is provided as the default reservoir for the solution. Additional types of reservoirs could also be used by modifying the open-source dish holder design. Furthermore, to illustrate the capabilities of Mobi-Mag, an example application is presented. The application consists on transporting synthetic mockups of biological cells to a desired location. These cell mockups, hereafter called microbeads (Fig. 1c), were made to facilitate the development of cell manipulation schemes, by minimizing the handling and storage requirements typical of biological tissues. The microbeads are composed of polystyrene and have an oval shape with an average diameter of 300 $\mu$m. In order to push the microbeads, biodegradable micro-particles of 100 $\mu$m diameter (PLA-M-redF-plain, Micromod Partikeltechnologie GmbH, Germany) were employed as microrobotic agents. The experimental results showed that the microbeads could be transported to a target location at an average speed of 130 $\mu$m/s and with an average position tracking error of 50 $\mu$m.

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2 Methods

In order to successfully fulfill the objectives of the Mobi-Mag device, two main components required particular design considerations: 1) the electromagnetic array, 2) the electronics and the base control software for development of microrobotic applications. First, since the device was conceived to manipulate small tissue samples or cells, the Mobi-Mag device has a small footprint (allowing an easy integration with optical microscopes) and requires very low magnetic field intensities (< 15 mT) for microrobotic control. A COMSOL Multiphysics model (COMSOL Inc., Burlington, USA) of the electromagnetic array was developed in order to optimize the dimensions of the coils. The coils were designed to guarantee that a magnetic field intensity of 10 mT is generated in the middle point of the workspace, whenever the current in one of the coils is set to 1 A (Fig. 2). The use of hollow iron cores for the upper and bottom electromagnets is a key feature to easily integrate common microscopic objectives (equipped with IEEE 1394 and/or USB cameras and their light sources) as the default source of feedback for the control system. Furthermore, the four plastic coil holders can be repositioned (Fig. 3), in order to integrate additional imaging equipment (e.g., a lateral microscopic objective or ultrasound transducer) in new application developments.

This work was supported by funds from the Netherlands Organization for Scientific Research (NWO) Innovative Medical Devices Initiative (IMDI) - Project: USE (Ultrasound Enhancement).
As for the control of the electromagnetic currents, the only interface required by the host personal computer (PC) to operate Mobi-Mag is an universal-serial-bus (USB) port. Once the Mobi-Mag software is installed in the host PC, the user can choose to employ the provided Cartesian PID position control (Fig. 4) and the OpenCV-based visual tracking C++ libraries, or to develop his own controllers by directly setting the electromagnetic coil currents through the device’s software library. Both, Windows and Linux operating systems are currently supported.

3 Results

Open-loop and closed-loop transportation of microbeads was carried out using Mobi-Mag. Magnetic microparticles were used to push the microbeads towards predefined targets (Fig. 5). In the open-loop scenario, a joystick was integrated into the control system using the SDL Library (Microsoft Inc., Seattle, USA). The use of the joystick allowed the user to manually control the position of the magnetic particles that interact with the microbeads. In the closed-loop scenario, the Cartesian PID controller (provided with the setup) and a simple task planner were used to automatically reposition the particle at predefined locations, while simultaneously controlling the orientation of the microbeads. In this latter case, the targets could be specified by the user by clicking with the mouse on the screen, or a pre-programmed task consisting of transporting the beads towards 5 targets with predefined locations and orientations in the image could be performed. The latter closed-loop control experiments revealed that the microbeads could be transported towards at a desired pose at an average speed of 130 μm/s and with a position tracking error of 50 μm when using the Mobi-Mag device and the base software.

4 Interpretation

An easy-to-use compact device for magnetic control of micro- and nano-sized magnetic agents has been presented. This device is intended to facilitate the development and in-vitro testing of novel medical technologies that could take advantage of such magnetically controlled agents. An example application illustrating the manipulation of a cell mockup has also been provided. Drug delivery experiments will be carried out next using the different microrobots supported by the presented device, including swarms of magnetotactic bacteria, microjets and janus particles.

References

Development of a Fiber-top Controlled Adaptable Stiffness Needle

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1 Background

Each year, in the Netherlands alone, more than 50,000 percutaneous procedures are performed for treatment or for removal of tissue from possibly diseased organs. Erroneous needle targeting can have disastrous effects for the patient. For instance, malignant cells may be missed due to inaccurate positioning of the biopsy needle. Furthermore, in local treatment of cancer by means of radiofrequency ablation, cryoablation or radioactive seeds, erroneous needle targeting can result in both reduced effectiveness of the therapy and damage to healthy tissue. Consequently, knowledge of the local environment of the needle tip is of paramount importance in minimally invasive, needle based approaches.

Secondly, as the trend towards minimally invasive surgery increases, the demand for less invasive, real-time assessment of tissue properties will grow. To date, the options for such a needle-based optical biopsy are limited.

The aim of this project is to develop an instrument that addresses both the issues of targeting, and on-line diagnosis through the first ever combined use of two mechanical devices: a needle with adaptable stiffness and a probe that can identify tissues via real-time measurements of their mechanical properties.

2 Methods

To accurately maneuver flexible needles through soft tissue one must account for variations in tissue stiffness which affects needle-tissue interaction and thus needle deflection. Optimal tissue penetration is achieved with a needle with stiffness comparable to that of the tissue. A needle with adaptable needle stiffness will be designed to compensate for such tissue inhomogeneity. The needle will consist of a flexible shaft with a fully actuated tip based on a miniature cable-driven steerable mechanism previously developed \cite{1}. The stiffness of both the shaft and the needle steerable mechanism can be adapted by adjusting the tensioning of the cables incorporated in the needle. Miniaturized deflection sensors based on Fiber Bragg Grating (FGB) technology will be used for real-time sensing of needle configuration \cite{2}. Dedicated motors and linear stages will be used for inserting the needle into the tissue and controlling its stiffness.

An instrument to monitor needle advancement through different types of tissue, by means of stiffness measurements, will be integrated into the needle. This probe is mounted at the tip of the needle and exploits an optical fiber interferometric technique. When the needle encounters the interface between two layers of tissue a fiber-top nanoindenter inside the needle is extended and used to accurately measure the stiffness of the tissue that is about to be perforated. This indenter consists of a micromachined cantilever which is fabricated on top of an optical fiber \cite{3}. Upon contact with the tissue the cantilever bends to a degree determined by the stiffness of the sample. By coupling light from the opposite end of the optical fiber, the cantilever position is assessed.

The fiber-top indenter performs local tissue stiffness measurements at the tip of the needle, allowing analysis of the mechanical properties of the tissue layers in front of the needle. Besides its diagnostic value, this information is fed back to the needle and used for active manipulation of the needle’s stiffness irrespective of the material properties and diameter.

3 Results

In order to obtain real-time stiffness measurements at the tip of needle, actuation of the indenter probe, with nanometer precision, is of great importance. Because the probe is mounted at the distal end of the needle, we propose an
actuation system utilizing the same cables used in the steering mechanics. The cables are tensioned with a spring and actuated with a piezoelectric translator. Figure 3 presents the movement of the probe at the tip of the needle. It can be appreciated from the graph that smooth and precise movement with nanometer accuracy can be transferred to the distal end of the needle.

Furthermore, it is necessary to validate the fiber-top nanoindenter on soft tissue. In order to do so, indentation experiments have been performed on ex vivo mouse brain tissue. A typical result of this experiment is presented in figure 4. Load-indentation curves are shown for 20 successive indentations at the same location. The Young’s Modulus (YM), a measure for tissue stiffness, can be derived from the slope of the retraction part of the load-indentation curve using the Oliver and Pharr method for spherical indentation [4]. The part of the curve that is used for derivation of the YM is highlighted with stars. The YM found for this sample was 10.14 ± 2.39 kPa.

4 Interpretation

We have shown that we are able to actuate the sensor at the distal end of the needle using a remote indentation system. Figure 3 shows, however, that there is certain amount of hysteresis in this system; the movement of the sensor is not equal to the movement of the piezoelectric translator. Although this is not ideal, the movement of the probe can be calibrated and, furthermore, closely monitored using FBG or interferometry. The smooth and accurate movement of the probe is promising for the integration in the needle in the final design.

Secondly, we have proven to be able to measure the mechanical properties, in terms of YM, of soft (ex vivo) tissue by means of indentation with results comparable to those previously reported [5, 6]. It can be seen from figure 4 that there is a stiffening response from the tissue as a result of successive indentation on the same location. The mechanism behind this response is not yet fully understood. However, as the needle proceeds through the tissue new locations will be probed constantly. Therefore, in the application of needle targeting, this time-dependent response of the tissue will most likely not lead to additional difficulties.

References


Figure 3. Relative movement from starting position of the probe at the tip of the needle (red) and the piezoelectric translator at the proximal end of the needle (blue).

Figure 4. Load-indentation curves for 20 indentations on the same location of ex vivo mouse brain tissue.
Design and Control of a CT-Compatible Needle Steering System

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1 Introduction

Image-guided minimally invasive interventions such as biopsies, brachytherapies and ablations are well-established procedures. Typically, such procedures require insertion of a needle into the body. The goal is to reach the cancerous or suspicious lesion accurately. To achieve this goal, different imaging modalities such as ultrasound, computed tomography (CT), magnetic resonance imaging (MRI) and fluoroscopy are used as feedback.

Insertion and manipulation of the needle is done manually in current clinical practice. However, extensive research has been done which aims at developing methods to perform these procedures using robotic setups to benefit from their precision.

One of the important topics in this field is cancer related diagnoses and therapies of lung, because lung cancer is the most common cause of cancer related death worldwide (1.59 million death in 2012) [1]. Early detection is very important to reduce mortality rates [2]. After a suspicious lesion is observed in CT images, usually a needle biopsy is performed, and the sampled tissue is tested to confirm the diagnosis. One of the main challenges involved in these interventions is that the lesion moves due to respiration. Therefore, patient compliance and clinician’s skill are important factors for a successful procedure. Different robotic setups has been developed to improve interventional accuracy and to make it less dependent on the clinician’s skills [3].

It is possible to categorize the robotic setups into different groups based on their insertion principle and the structure they use. Some of these setups are only positioning devices [4]. After the best insertion pose is determined, the device places a needle holder in the proper position and orientation and then needle insertion is done manually. On the other hand, there are Needle Insertion Devices (NID), which not only position the needle, but also perform the insertion [5].

Also, the positioning device or NID could be patient-mounted, bed-mounted or could have its own base. While patient-mounted devices compensate for the body motion (due to respiration, fluid flow and etc.), bed-mounted and base-mounted devices need to track the chest motion and compensate for it in the control scheme. In this work, we are interested in developing a test bed to be used in lung and liver biopsies using CT images.

2 Design

As mentioned earlier, our objective is to design a portable NID which could be used with an ultrasound system in the laboratory during our research, and within a CT scanner for in-vivo tests. Subsequently, the robotic system needs to be CT-compatible and compact enough to fit into the CT bore. Considering different Siemens CT scanners, the bore is about 78cm in diameter. When a patient is inside the bore, there is about 30cm free to place the device.

After studying different robot architectures, we concluded that our robot for the specific task of lung and liver biopsy, and also similar tasks, should have at least four degrees of freedom (DoF). It must consist of two rotational DoF around the entry point, plus two degrees of freedom (one rotational and one translational) for needle steering. In addition the device should be small enough, portable and light weight, to be placed on the patient in the CT scanner.

This study is focused on the steering mechanism and the issues involved in the design. As depicted in Figure 1, the total device is 55mm in diameter and 270mm long. The needle is attached to the carriage using a chuck mechanism. This prototype is designed to be used with the needles of 150mm length and the maximum insertion depth is 120mm. There are threads inside the contact hole of carriage with the drive shaft. Therefore, the carriage is pushed forward and backward against the motion. There are two oil free bushings placed in the carriage (Figure 1, 9) to reduce friction against the motion. Therefore, two oil free bushings are placed in the carriage and the drive shaft are made out of Delrin which has self-lubrication properties to reduce the friction.

Two motors are used to control the two degrees of freedom. One is used to rotate the needle along its axis and the other one is used to insert the needle into the tissue. The motors are brushed-DC 1016N012G with a HEM-3 quadrature encoder and a 10/1 planetary gearhead of 1:4 ratio (Faulhaber Group, Schönaich, Germany). In order to transfer the motor torque to
needle holder, 1:3 ratio spur gears are used. Choice of motors parameters and transfer ratios were calculated considering the force/torque needed to steer the needle, the maximum insertion and rotation speed and finally space limitations. The motors are controlled using proportional-integral-derivative (PID) controller which was implemented using an ATMEGA328 microcontroller. The feedback for the PID controller is based on the motor encoders. The motors speeds are controlled through Pulse Width Modulation (PWM).

One of the issues in needle steering using flexible needles is that the needle buckles if there is no support around it during the insertion. To overcome this problem, we have designed a disc mechanism which supports the needle and is pushed forward and backward with carriage.

3 Control and Steering Experiments

In order to test the proposed system, we use beveled-tip flexible needles made of nitinol. The needles are made from the nitinol rods with a diameter of 0.5, 0.75, 1.00 and 1.50mm and with bevel angles of 30, 45 and 60 degrees. The asymmetry of the needle tip cause the needle to bend while being inserted into the tissue because of asymmetric forces applied to the needle tip [6]. Smaller bevel angles cause more maneuverability of the needle in the tissue. In our experiments we have realized that the best choice of system parameters to reduce the target motion is 1mm diameter needle with insertion speed of 1mm/s and bevel angle of 30 degrees. As a result, we are using these values in the experiments.

In the experiments, gelatin phantoms were made by mixing 14.9% gelatin powder (Dr. Oetker, Ede, The Netherlands) with 85.1% water. This mixture will result in a transparent gel mixture with an elasticity of 35 kPa which mimics the properties of soft biological tissue. The steering was performed using duty-cycling [7] and with duty-cycles of 0%, 50% and 100%. Figure 2 provides a representative result.

4 Ongoing Work

This study presents the design and control of a CT-compatible needle steering system. The device has two DoF, which one is used for needle insertion and retraction and the other is used for needle rotation. The insertion is achieved by rotating the drive shaft which cause the carriage to move forward and backward due to the threads inside the carriage. The rotation is achieved by transferring the motor torque to the needle holder using spur gears. The motors are controlled using PID controller and the reference motor speed is achieved using PWM.

References

Feasibility of Additive Manufacturing Method for Developing Stretchable Electronics for Bio-integrated Devices

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1 Background

While the human body is soft and curvilinear with complex, irregular anatomical geometry, established classes of high-performance electronics utilized in medical devices use conventional semiconductor wafer-based technologies that make them rigid and planar. Such a mismatch hinders development of bio-compatible devices conformable to human anatomy [1]. This calls for the use of novel electronic materials that provide the capacity for integration into complex integrated circuits. While conventional manufacturing techniques using carbon nanotubes, nanowires, and composite conductive polymer rubbers are effective at creating fully functional stretchable electronics, they are planar, complex, and require prolonged fabrication time, dedicated facilities and infrastructure [2, 3]. Use of cost-effective additive manufacturing processes however, can exploit the power of low-cost 3D printing, enabling a simple, accessible, user-friendly and cost-effective multi-material manufacturing method for creating stretchable skin-like electronic devices that integrate with various parts of the body to create effective bio-integrated devices [4, 5].

This work documents the development and testing of fully functional stretchable and flexible embedded circuits created using additive manufacturing method. A custom-developed syringe-based controlled extrusion process using a conductive silicone material, was used for printing integrated circuits on stretchable substrates. The material characteristics of the silicone under stretching were studied. A proof-of-concept stretchable bio-compatible ‘skin’ device with an embedded voltage divider circuit was printed and its behavior studied under various working conditions.

2 Methods

An experimental syringe extrusion system was designed to extrude conductive (SS-26S, Silicone Solutions, OH) and non-conductive silicones (2-part RTV Elastosil 685, 7-Sigma, MN) at a constant extrusion rate. The extruder head used a 12V rotary DC motor (Phidgets 3275E) with E4P US Digital Encoder. 2 spur gears (Servo City ½” bore 32 pitch Aluminum gears) were used for linear displacement of a platform on two 1/8th inch lead screws (32 pitch) with a 3:1 speed reduction providing high torque at low speeds for extrusion of highly viscous thixotropic pastes from a plastic syringe (Duda Luer-lok syringe 1ml/20ml) with Luer-lok needle (21 and 16 gauge). An Arduino microcontroller subroutine with H-bridge is used for motor control. In order to implement velocity feedback for steady state volume flow rate, PID control was implemented for the plunger velocity. The complete unit was mounted on to the end of a 6-axis robot, CORVUS [6]. A trajectory-based method issues “start” or “stop” command via serial input to the extruder before the desired start or stop point, as well as desired extrusion velocity.

Testing was carried out at 7-Sigma (DMA testing) as well as in Medical Robotics Lab at the University of Minnesota. Material characterization of SS-26S printed traces was done on the Q800 DMA tester (courtesy 7-Sigma, MN) applying a force ramp of 2N/min and measuring current through the sample (Fig. 1D). Different sizes of conductive traces were printed and the variation of resistance with application of a uniaxial strain was studied for each. Upon studying the conductive properties of SS-26S conductive traces printed on a Elastosil silicone substrate, complete integrated circuits were printed using passive and active electrical components (resistors, LEDs, diodes, etc) using Inkscape to create required printing tool path from the circuit schematic (using Eagle PCB).
Testing of printed complete integrated circuits was carried out on a custom linear translation stage using computer vision to track the elongation of the device.

3 Results

Fig. 4: Resistance and conductivity of the SS-26S test sample 'skin' device (voltage divider), (D) wrapped on human anatomy.

Fig. 3: (A) LED circuit working under bending. (B) Self-contained fully-functional circuit with embedded battery. (C) Biocompatible 'skin' device (voltage divider), (D) wrapped on human anatomy.

Fig. 4: Resistance and conductivity of the SS-26S test sample under uniaxial strain.

Fig. 5: Resistance variation with strain (top) under stretching, constant strain and relaxation; (bottom) voltage output and resistance plotted against time for ramp strain function.

A voltage divider circuit was printed using an ATtiny85 8-pin chip programmed via ArduinoISP. The circuit (Fig. 3C) was designed so as to cause change in output voltage upon elongation due to the variation of resistance of the conductive traces in the divider circuit. ADC was used to measure the reference and output volatages and serial communication via Bluetooth (Sparkfun HC-06) was used to collect voltage, resistance and elongation data.

Fig. 4 shows clear variation of conductivity with applied strain, with nearly consistent behavior for different test samples (Fig. 1C). This demonstrates the capability of the SS-26S silicone to act as an effective conductive pathway under elongation in a printed integrated circuit. The plot from the voltage divider stretch test (Fig. 5) shows the variation of behavior of the printed device under elongation and relaxation, indicating the retained functionality of the voltage divider circuit under applied strain.

4 Next steps

3D printing was found to be a suitable manufacturing process for creating fully functional stretchable integrated circuits. From testing various methods for interfacing between electrical components and the conductive silicone traces, it is determined that the reliability of circuit performance could be improved further by ensuring adequate constant electrical contact through isolation of optoelectronic components from applied strain, either through the use of multiple durometer structural silicones or via non-conductive surface meshes.

Future experiments are planned for build and testing of a complete "skin-like" device like a surgical instrumented glove which can be 3D-printed with embedded sensors and miscellaneous electrical components, custom-built on to a clinician's hand to fit the anatomical geometry, utilizing the capability of Corvus to track human anatomy and print on complex and irregular surfaces.

5 Acknowledgment

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Friday 24 October, 10 am  
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Introduction

In case of a meniscectomy, the entrée points are routinely placed at the anterior side of the joint level medially and laterally from the patella tendon [1-2]. It often happens that the location of the defect (e.g. crack) in the menisci is either in a region that is difficult to reach or situated along a large part of the menisci edge (Figure 1).

![Figure 1](image)

Figure 1 Top: Surgeons use a punch (Left) and Scope (right) to repair defects in the menisci. Below L: Commonly seen lesions of the menisci. Below R: Side view of standard punch and pre-bended punch shafts.

In those cases, it is challenging to position a cutter in the crack making it difficult to remove loose parts efficiently with a straight instrument. To solve this problem, curved instruments have been developed to facilitate repairing cracks in all parts of the menisci [3]. However, there are some disadvantages. Since the location and type of crack is not known on beforehand around 10 different punches are needed in an ideal situation that all are cleaned, disassembled and sterilised even when they are not used. To reduce costs, surgeons need to find a balance between each in reachability and number of pre-bended punches available on the OR table. As a consequence, a reduced reachability means that the surgeon has to apply high forces on the surrounding tissue around the knee joint to force the instrument cutter in position.

This can cause chronic wrist pain to the surgeons and unnecessary portal pain to the patient [4-5]. However, finding a hinge mechanism that is small, strong and maintains its position under angels between 0 and 55 degrees remains a challenge. Especially when the user demands that the interface is as intuitive and simple as possible while the space within the hinge system needed to guide the gripper actuation cable is still adequate. In this paper we present the design of non-compliant, new steering mechanism and steerable punch prototype that can be easily cleaned, sterilised and (dis) assembled.

Methods

In order to get the new steerable punch accepted in the sterilisation process requirements were defined based on interviews with sterilisation department employees of the 5 largest Dutch hospitals. To get insight in the features of a new steerable instrument that are most important for the CSD employees we asked the following question: “If you had to design a new steerable endoscopic instrument, how should you do that from your point of view as a cleaning specialist.” In providing us with an answer, the employee was not restricted in any way. The interviewer was not giving any comments or feedback till all points raised by the employee were finished. This method provides us with a list of ideal requirements for the new steerable punch. In order to find the minimal requirements for the new steerable punch as; component size and dimensions, hidden surfaces, cannula diameter and length and (dis) assembly effort and time, a list of standardised questions was defined.

Results

Shaft Actuated Tip Articulation design

Since it is desirable to keep the instrument stiff it was chosen to create a non-compliant hinge system. To maintain a fixed position under high tangential tip load and to prevent problems during (dis)assembly it was decided to develop a hinge system that is actuated without cables. By giving existing elements of standard endoscopic instrument that uses a hollow tube for strength an additional function we found a new method to translate a movement created at the handle site towards the hinge for rotation of the tip. Figure 4 shows that by using two instead of one tubes that can rotate in respect to each other rotation of the outer tube at the handle side can be translated to axial translation of two sliders at the other end while no inner space is lost. With this method the shaft remains strong, hollow and the response of the tip on actuator movement remains direct even when the distance between hinge and handle is long. By simply choosing the angle of the cuts (Figure 4 top...
& middle) the trajectory of the tip can be determined.

Figure 2 Top: rotating the outer tube results in sideways rotation of the tip since cut-outs in the outer tube force the sliders up and backwards. Middle: To prevent axial rotation of the tip the cut-out in the inner tube allows the sliders to move only in axial direction. Below: view on the inner sliders showing that there are no cables used for hinge activation. Only the force on the pins move the sliders.

Steerable punch prototype
A prototype was build that requires only 4 simple extra parts in the hinge for steering (Figure 3). In this prototype the sliders that actuate the 3 point hinge mechanism are driven forwards and backwards by the cut-outs of each tube.

Figure 3 Picture of the SATA_V1 prototype with tip actuation handle (A) and wheel (B) for sideways tip rotation.

Since the driving pins are enclosed by the walls of the cut-outs at all times the tolerance is minimal (0.02 mm) while the tip accuracy after positioning remains high (0.1 mm) giving a very strong feel to three surgeons that were able to test the instrument to cut some paper sheets and to play with it on a mock-up (Figure 3). The CSD employees explained during the interview that inspection and easy access to all instrument components are the two most important issues with current instrumentation. Figure 4 shows that the instrument is easy to disassembly into 3 loose parts that are all accessible for inspection and rinsing without any hidden surfaces between lumen.

Figure 4 Steerable punch dismantled into tip assembly, outer tube with wheel and handle. Opening of the hinge results in better access to all openings for cleaning and inspection.

Figure 4-L shows that for cleaning and inspection the hinge can now be opened and the outer cable that shields the push/pull rod can be moved backwards. Compared with the instruments inventory performed in the 5 CSD’s in the Netherlands, the component and hinge dimensions, number of loose parts (3 vs 8), smallest loose component size (15x12x12mm vs ø6x3 mm), hidden surface dimensions (800 vs 6293 mm²) lumen length (540vs110mm and diameter (ø4 vs ø 0.4mm) all remain less critical. Disassembly of the SATA_V1 takes on average 29s shorter that the longest measured time at the CSD (110s).

Conclusion & Discussion
A easy cleanable, simple and novel steering concept was found that can be used in a simple reusable punch for meniscectomy. The strength of the hinge components needs to be determined during endurance tests. However, if the hinge mechanism is found not strong enough, it is possible to increase the number of pins that translate the forces from tube to sliders.

References
The HelixFlex: a new multi-actuated instrument

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1 Background
Endoscopic MIS (Minimally Invasive Surgery) is nowadays a well-established procedure for operating almost every district of the human body, including intracranial areas [1]. Endoscopic Endonasal Skull Based Surgery (EEBS) is, for instance, the MIS technique used to operate tumors on or near the pituitary gland, an endocrine gland protruding off the bottom of the hypothalamus. In this procedure the gland is reached by using the nostrils as first port of access and then perforating in the bony wall of the sphenoid sinus cavity, where it is placed Figure 1a. Because of all these multiple impediments, traditional straight instruments for MIS cannot appropriately approach the target area. The only solution currently used to gain more space for better maneuvering the instruments is to make a bigger hole in the bone and or excessively stretch the nostrils borders [1]. This is however against the scope of MIS surgery which should instead minimize the invasiveness of the procedure.

Steerable instruments are inevitably required in such contexts. They are essentially MIS instruments with an articulated segment fitted on the tip, which can bend in at least, two DOFs with respect to the shaft. This is the case of single steerable instruments [3], which, however, are not suitable for procedures presenting multiple impediments and anatomical obstacles, like the EEBS (Figure 1a).

Multi-steerable instruments are, instead, fitted with tip that can be articulated in more than two DOFs, allowing the surgeon to follow more complex paths and approach the target with an optimal orientation of the end effector [2]. Various examples of multi-steerable instrument can be found in [4] they are most commonly cable actuated and their construction involves several single segments placed one after each other, like in Figure 1b. Each segment has its own cables which run in parallel with its axis and, if differentially tensioned, bend it with a constant bending curvature. This actuation will be defined as parallel actuation and its functioning principle will be reassumed in the scheme of Figure 2, left. By summing up more segment’s curvatures a complex shaping of the instrument’s tip, like the one in Figure 1b, can finally be reached.

The fabrication and assembly of such conceived devices, however, turned out to be quite challenging [4]. Cable actuated segments arranged in series inevitably requires that the cables of the more distal segments need to be guided across the previous segments, passing also through the sections where the cables of the proximal segments are fixated, as shown in Figure 2 (left) for the case of a two segments. For these reasons both the miniaturization potential and the perspective for a commercial production of such instruments are quite limited.

The aim of this study is, therefore, the design and development of a new genre of multi-steerable instrument. Instead of having multiple parallel actuated segments, this instrument has just one segment which is however multi-actuated. The multi-actuation is a new method of cables actuation which allows to enhance the steering capabilities of a single steerable instrument. Its working principle will be explained in the following paragraph together with the construction description of the patented instrument implementing it.

2 Methods
Since the source of multi-steerable instruments complexity comes from the use of multiple segments in series, which require their own point of cable fixation, segmentation of the structure of the tip must be avoided. Therefore, the functionality of a steerable instrument needs to be enhanced, without increasing the number of its segments. Using different routings for the actuating cables of one single segment was found to be a solution to obtain different behaviors of such a segment. Instead of routing the cables just in parallel with the longitudinal axis, one could for example route them helically. Helical cables are cables that, by performing a helix around the structure, describe an angle with the central axis. This allows them to generate a bending moment which varies along the structure, and therefore bends the steerable instrument into curvatures with a non-constant bending angle. For instance, by using half-helix cables, that curve from left to right (blue cables in Figure 2) the segment is bent into a double curvature, with a bending angle that changes sign at the middle, essentially creating an s-shape. If one now uses
helix cables in combination with parallel cables, the instrument can potentially match the shapes that were reachable with multiple, but just parallel actuated, segments, Figure 2 (left). This synergetic combination of differently routed cables constitutes the essence of the multi-actuation method, which allows to reach multi-steerable functionality into a single steerable instrument. On this basis a new patented MIS instrument was designed. The instrument is called HelixFlex and it has a three dimensional steerable tip of 5 mm in diameter, Figure 3. As for single steerable instruments, the HelixFlex’s tip has all the cables fixed at one single point (at its most distal extremity) and routed all along its height with a fixed distance from the central axis. While parallel cables go in a straight line, the helices perform half a clockwise (CW) or counter-clockwise (CCW) revolution. The cables are properly guided inside the tip to keep their respective position around the axis. Additionally an inner lumen of about 1 mm has been left free along the entire the instrument, which can be exploited for feeding means of actuation of eventual end effectors placed on the tip. As indicated in Figure 3 the HelixFlex has also an handle allowing for a direct mechanical control of the tip. By adapting the direct mirrored control method used for parallel actuated instruments [4], the motion of the handle is directly coupled to the tip in a mirrored fashion. While the diameter of the tip has to respect the size limits of conventional MIS instruments, the diameter of the handle is enlarged to amplify the motion of the user at the tip side. Furthermore the HelixFlex is equipped with a locking mechanism, at the base of the handle (Figure 3). This locking system can be used to lock the tip in any given shape, thereby freeing one hand of the user.

3 Results

Figure 3 shows a global view of the HelixFlex device, being manually controlled by the author. The instrument’s tip demonstrated to follow all the shapes according to the handle control. The motion of the handle top part is mirrored and amplified at the tip of the instrument and, in contrast with traditional single steerable instruments, the HelixFlex can be shaped into complex curvatures. The multi-actuation method allows for the active control of the angle as well as position of the tip, which effectively makes the steerable tip a 4 DOF articulating structure, as shown in Figure 4. Here the HelixFlex tip is clearly making a double curvature in space. Additionally the locking mechanism demonstrated to work in keeping stable the tip in any position.

5 Interpretation

Current multi steerable instruments for MIS present severe limitations in terms of their fabrication and miniaturization. The main cause is the high complexity that accompanies the tip construction as a series of segments each one with its own actuating cables. With the aim of solving the problems related to such segmentation, we explored the multi-actuation method through the design of a single steerable instrument with enhanced steering capabilities, the HelixFlex. Thanks to the combined use of cables with different routings directions (parallel and helical), the HelixFlex can be shaped into complex curvatures, whilst having all the cables fixed only at its distal extremity, thus without any intermediate fixation points. With its construction, the HelixFlex resembles the assembly simplicity of single steerable instruments, while being actually multisteerable.

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References

The HelixFlex 2D: Multi-Actuation Control

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1 Background

Through the combination of medical insight and technical innovations, the field of Minimally Invasive Surgery (MIS) has been developing procedures enabling surgeons to operate on very difficult to reach places. One example is Endoscopic Endonasal Skull Base surgery (EESB), focused on reaching lesions on or near the pituitary gland situated just beneath the brain. With this procedure the surgeon is able to reach the pituitary by entering through one or both nostrils, and drilling through the two boney walls of the empty sphenoid sinus [1]. Such path does however severally restrict the maneuverability of the standard rigid instrumentation. This because these instruments are no longer only restricted by a single fulcrum point, as in laparoscopic procedures, but encounters multiple physical restrictions making the approach to the surgical site more like a tunnel. In the worst case, such restrictions only allow a translation or rotation of the instrument in reference to its longitudinal axis, making it difficult to effectively control the angle and position of its end-effector. Steerable instrumentation can however provide a solution.

Steerable instruments include a steerable tip between their shaft and end-effector, which may consist of one or multiple steerable segments. Actuating a steerable segment resolves into it changing shape, thereby altering the angle and or position of the end-effector relative to the distal part of the shaft.

A steerable segment is usually constructed out of joints or flexible members to create a flexible structure, which is most commonly actuated by cables. The routing of these cables will decide the shape into which the steerable segment can be actuated. The most frequently used cable-route is the parallel-variant, wherein the cables are routed parallel to, and with a fixed distance from the longitudinal axis of the steerable segment. By pulling a cable one can actuate this segment into a constant radius bend (Figure 1a), thereby allowing active control of the angle of the end-effector. An alternative cable-route is the diagonal-variant, which forces the steerable segment into an S-shape (Figure 1b), thereby allowing active control of the position of the end-effector.

Ideally a surgeon should be able to actively control the angle as well as the position of the end-effector. For EESB, an instrument with just one steerable segment with either parallel or diagonal cable routing is therefore not enough, since then only the angle or position can be actively controlled.

A solution to this problem can be found in a construction wherein multiple segments are placed in series onto one another, for example two parallel actuated segments as illustrated in Figure 2. In this so-called multi-steerable instrument, both segments can be actuated by the handle by using, allowing the surgeon active control of the angle as well as the position of the end-effector. This control strategy will be called direct-mirrored control, while the cables in the tip and handle are directly connected, and the shape of the handle is mirrored by the tip.

Such configuration does however drastically increase the control complexity of the instrument, while the operator needs to actively control both cable fixation points that are present along the longitudinal axis of the handle [2]. Figure 2. This paper presents an alternative method of creating multi-steerable qualities (active control of angle and position), whilst reducing the overall control complexity of the instrument.

2 Methods

The proposed solution is to create a single segmented steerable tip with multiple cable routings, as illustrated in Figure 1c. In this configuration, which will be referred to as multi-actuation, the parallel cables are used to control the angle, while the diagonal cables are used to control the position of the end-effector. The benefit of this approach is that both actuation cables can be fixated at the distal part of the steerable tip, resulting in just one point that needs to be actively controlled.

A control mechanism for such a cable configuration is however no longer as straightforward as controlling instruments with solely parallel cables. The reason lies in the different length-behavior of diagonal cables compared to parallel cables during actuation. For parallel cables, the shortening of a cable is accompanied by an equal lengthening of its symmetrically placed counter part, illustrated by the L & S in Figure 1a. This linear relation is present at any shape of the tip and is the theoretical basis for the direct-mirrored
control method. In this method a parallel cable in the tip is directly coupled to the symmetrically placed cable in the handle, as illustrated in Figure 2. On the contrary, for diagonal cables the relation between shortening and lengthening of symmetrically placed cables is non-linear, as illustrated in Figure 1b, meaning that the direct coupling of mirrored cables is no longer applicable. In search for a mechanical control method for a multi-actuated tip, one must therefore find a way of coupling, not symmetrically, but identically placed diagonal cables in the tip and handle. This means that a length change of a diagonal cable in the handle should result in an equal length change of its identically placed cable in the tip.

A solution can be realized by coupling the identically placed diagonal cables in the handle and tip to a mass, which cannot rotate, but only translate up or down. This configuration, as illustrated in Figure 3, functions as follows; 1) Initially the tip and handle are kept straight by the symmetrical force configuration in both structures. 2) Next, an external control force on the handle deforms it to a certain shape, resulting in the shortening and lengthening of its cables. 3) A shortening of a cable in the handle will pull the attached mass upward, resulting in a reduction of the force on its coupled and thus identical cable in the tip. 4) By the same principle, the shortening of a cable in the handle will increase the force on the coupled cable in the tip. 5) The resulting imbalance of actuation forces in the tip will deform it up until balance is restored, at which point the tip mimics the shape of the handle. This control strategy will be referred to as the indirect control method.

For an overall control method for a multi-actuated tip, one can choose to combine both direct and indirect control methods, as illustrated Figure 4. The parallel cables are then directly coupled, resulting in a mirrored relationship between handle and tip. The diagonal cables are indirectly coupled with the use of pulleys. The constant downward force, initially created by the mass, used in the indirect control method should now be replaced by a constant moment around the axes of these pulleys. Such constant moment can be realized by wrapping long springs halfway around the pulleys while fixing their other ends to the shaft.

### 3 Results

In order to attain a proof of principle, the previous described mechanism was integrated into a working prototype called the HelixFlex 2D as pictured in Figure 5. The device allows the user to separately control the angle and position of the distal part of the tip by only controlling the proximal part of the handle onto which the cables are fixated. Furthermore the mirrored configuration between tip and handle results in a control method where the tip points in the same direction as the handle. The positional relation between the handle and tip is such that if the handle moves up, the tip moves down.

![Figure 5. The HelixFlex 2D, a prototype used to proof introduced control method. The additional intermediate ribs along the tip and handle (not drawn in Figure 4) guide the cables to ensure their constant distance from the flexible structure.](image)
DIY Laser Speckle Imaging

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1 Background

This short paper provides Do It Yourself (DIY) instructions for building a very low cost Laser Speckle Contrast Imaging set-up.

Laser Speckle Contrast Imaging (LSCI) is a dynamic full-field imaging technique that can be used to measure, among other things, tissue perfusion. The technique makes use of a laser speckle pattern, which is an interference pattern, consisting of low intensity and high intensity spots, that arises when coherent (laser) light is scattered off a surface and collected by the objective of a camera (or the human eye).

A fixed scattering surface produces a static speckle pattern, and this pattern is blurred if the scatterer moves. Red blood cells moving under the skin surface also act as scatterers, causing the speckle pattern to blur. Thus, blurring of a speckle pattern on the skin can be used as a measure of blood flow. The degree of blurring can be quantified by the speckle contrast, which is the coefficient of variation of intensity values in a specified region of the image (spatial, temporal, or both) [1]: \( K = \frac{\sigma}{\mu} \), where \( \sigma \) is the standard deviation of intensity values in the specified region and \( \mu \) is the mean of the intensity values in that same region.

The technique of LSCI is well established both in theory and in practice, and commercial devices are available for clinical use, but the cost of a basic set-up is typically in the order of tens of thousands of euros. For many research applications, such costs are prohibitive. Recently, Richards et al. [2] described a low cost system comprising a webcam and laser pointer in combination with additional lenses, optical filters, and mounting hardware. Inspired by this work, we decided to try to reduce the system even further, to see if it would be possible to do away with the additional optical components altogether.

2 Methods

Our LSCI recipe has two main hardware ingredients: one Logitech C310 webcam (€23, Logitech, Newark, CA, USA) and one LM01RDD-A laser module, <0.95mW, 650±10nm, powered by two AA batteries (€30, Conrad Electronic, The Netherlands). The setup works equally well using a variety of much cheaper unbranded 650nm laser pointers.

Some minor hardware customization is necessary: The speckle technique requires coherent light, hence the use of a laser. A divergent beam is needed to illuminate a sufficiently large region. Our diode laser produces a divergent beam that is collimated using a lens, so it is sufficient just to remove this lens from laser module.

Removal of the webcam front uncovers the circuit board with onboard objective. The magnification can then be adjusted by unscrewing the lens a few turns (some force is required initially to break the seal).

Both speckle size and light collection are influenced by the camera aperture. As specular reflection from the laser is too intense for the standard camera aperture, the aperture needs to be reduced. This is easily achieved by taping a piece of cardboard with a small pinhole in front of the lens. The result is depicted in Figure 1.

The pinhole or aperture size is important, because it influences speckle size. To maximize speckle contrast, the speckle size should be more than twice the pixel size [3]. Pixel size is not specified by the manufacturer, but based on the approximate size of the C310’s CMOS sensor (4mm x 3mm) and native resolution (1280 x 960 pixels), pixel size is estimated to be 3μm. A lower bound for the speckle size is provided by the expression \( p = 2.44\lambda(1 + M)N \), where \( \lambda \) is the laser wavelength, \( M \) is the lateral magnification, and \( N \) is the f-number of the camera (\( N = \frac{D}{f} \), where \( D \) is the entrance pupil diameter) [1]. Thus, for a given wavelength and pixel size, we can either increase magnification or reduce the aperture in order to obtain a sufficiently large speckle size. Maximum achievable magnification for the C310 is achieved by unscrewing the lens as far as possible, and was found to be approximately \( M=0.6 \), providing a 7mm x 5.3mm working area at an object distance of 11.5mm. Focal length for the C310 is \( f=4.4\text{mm} \) according to the manufacturer’s specifications. The maximum allowable entrance pupil (aperture) diameter is then found to be:

\[
D = \frac{2.44\lambda(1+M)f}{\rho} \approx \frac{2.44 \times 650 \times 10^{-9} (1+0.6)4.4 \times 10^{-3}}{2.3 \times 10^{-6}} \approx 2\text{mm}.
\]

This provides an ample margin for adjusting the aperture to reduce light intensity. To be on the safe side, considering the uncertainty in pixel size, a pinhole of approximately 0.3-0.4mm was chosen. This was found to produce good results.

To keep things really low budget, the webcam and laser module were mounted on a coffee cup, as depicted in Figure 2. An opening in the side allows a finger to be inserted for imaging. A height spacer underneath the finger helps ensure proper focus.
Figure 2: Experimental set-up on a budget.

Figure 3: Up-close intensity image of fingernail (7mm x 5.3mm) with partial speckle contrast overlay (blue is low contrast, high speed).

Needless to say, some image processing is required for LSCI to work. This is achieved using the Matlab Image Acquisition toolbox (The Mathworks, Natick, USA). The standard Logitech webcam software and drivers are used and the camera’s Rightlight technology is turned off. No other adjustments need to be made to the camera’s settings. The camera can be used either in grayscale mode or in a color mode using one of the three channels. Our custom software supports both spatial and temporal speckle contrast analysis in real time (approx. 30Hz). The contrast analysis is applied to a subselection of the image, as depicted in Figure 3. Spatial contrast is calculated using the highly efficient algorithm described by [3]. Temporal contrast is calculated using an efficient recursive update method similar to that in [4]. The software will be made freely available online through Matlab Central File Exchange.

To illustrate the capabilities of the system, a preliminary test was conducted, imaging a small part of a the author’s fingernail during repeated occlusion by gently squeezing the upper arm. In the present example, the webcam was used in RGB24 color mode, considering only the red channel. A time history of 40 frames was used to calculate the temporal speckle contrast.

3 Results

Figure 3 shows a screenshot of the intensity image of a 7mm x 5.3mm part of the fingernail, with speckle contrast overlay in a 1mm² region. Speckle contrast images of this region in both normal and occluded state are presented in Figure 4 (spatial, 7x7 pixels, 20 frame average). The corresponding time history of the overall mean speckle contrast in the selected region is presented in Figure 5, clearly showing the increase in contrast during three subsequent occlusion events.

Figure 4: High contrast frame (left) and low contrast frame (right).

Figure 5: Mean speckle contrast in 1mm² region, during repeated occlusion of upper arm. Frames from Figure 4 are highlighted.

4 Interpretation

A very low budget Do-It-Yourself Laser Speckle Contrast Imaging system was presented, and preliminary tests suggest that it is able to detect changes in perfusion of the finger.

References

Design of a Crevice-Free Bi-Metallic Intramedullary Reamer


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1 Background

An intramedullary reamer is a tool used by orthopedic surgeons to prepare the medullary cavity for insertion of an intramedullary nail. Such nails are commonly used to treat fractures of the long bones (such as the thighbone or “femur”). In order to follow the existing curvature of the femur, these instruments have to be flexible. A typical current intramedullary reamer (Fig.1a) therefore consists of a long, spring-like shaft (either coiled, Fig. 1A, wound, fig. 1B, or spiral-cut out of a tube) to provide flexibility, connected to a reamer head. Alternatively, the shaft may be a solid tube fabricated from superelastic material like Nickel-Titanium (NiTi) (Fig. 1C). The reamer head may be connected to the shaft by welding, press fitting or other means. Head may (Fig. 1D) or may not be interchangeable. Due to the flexibility of the spring-like reamer shafts, they can not carry much torque. For this reason, reaming to the desired diameter is carried out in many small steps (0.5 - 1.0 mm). Using a tubular shaft with increased stiffness, it is possible to ream the medullary cavity in larger steps, possibly even in one pass.

Figure 1: A. Coiled shaft (Biax flexible power); B. Wound shaft (OptiMedical); C. Press-fitted head on NiTi shaft (Sentinel, Zimmer); D. Modular head on NiTi shaft (SynReam, Synthes)

There are a number of problems associated with current intramedullary reamer designs. The main problem of spring-like shafts is the challenge to properly clean and disinfect the reamer, due to the crevices. Sometimes repeated processes are necessary to completely remove all reaming debris. Typical cleaning steps include soaking in a enzymatic solution, ultrasonic cleaning, brushing of the cannulation and outer shaft, followed by a run in the automated washer-disinfector using a range of chemicals and detergents. The process is time-consuming and chemically intensive. Sterilization procedures are performed to inactivate all microorganisms present on the instrument. If the reamer cannot be cleaned effectively, complete sterilization might not be possible. The risk of cross infection is then relatively high.

[1] On the other hand, fixed reamer systems with NiTi shafts are easier to clean and disinfect. Reversing the spring-like shaft with power is not recommended. The reamer shaft may uncoil. [2] This means that reverse cutting is not possible if the head gets stuck.

Reaming increases the intramedullary pressure and can cause fat intravasation. [3, 4] This may lead to cardiorespiratory dysfunction and occlusion of pulmonary vessels. [5] Modular flexible reaming systems often use one shaft with multiple reaming heads. The ratio between head and shaft diameter therefore varies. Because large shaft diameters are associated with higher intramedullary pressures, reaming with a relative small head has a negative effect on the pressure peak. [6, 7]

In case the head becomes detached from the shaft the reamer head can be withdrawn by retracting the guide wire. Efforts have to be made to avoid detachment by ensuring an excellent joint performance. This may be a risk associated with NiTi-reamer shafts, since this material can not be welded to steel [8] and thus must be fixed by other means such as gluing or press-fitting.

Ideally, a medullary reamer should have a solid, flexible shaft, rigidly and solidly attached to a stainless steel reamer head. Advantages of such a design are manifold. Due to the absence of crevices, cleanability and sterilizability will be improved and cleaning costs reduced. Also larger steps in reamer size are possible since the torsional stiffness and strength of a solid reamer shaft are higher than of a spring-like reamer. The associated reduction of the required number of reaming steps reduces both surgery time and risk of infections. Larger reamer heads also mean more clearance between shaft and bone. Since this way reaming debris can be more easily drained, the pressure peak caused by reaming will be reduced;

We have constructed such a reamer using a steel reamer head and a NiTi reamer shaft. The two parts have been connected using Rotary Friction Welding. Rotary friction welding (RFW) has shown to be effective in joining NiTi to stainless steels. [8, 9] The reason is that during RFW no molten phase occurs. In this paper we present a means to produce a reliable, high quality joint between NiTi and stainless steel using RFW. The results are applied in the design of a crevice-free bi-metallic intramedullary reamer.

2 Methods

Rotary Friction Welding

RFW is a solid-state welding process that uses mechanical friction to generate enough heat to fuse materials when a compressive force is applied. Major parameters that are controlled during the rotary friction welding process include spindle speed, axial force and time duration. [10] An advantage of RFW is that the heat-affected zone is relatively small. This minimizes modification to the NiTi so that its properties are maintained.

Despite the small heat-affected zone, during welding of steel to titanium or to NiTi brittle intermetallic phases (Fe2Ti) develop close to the weld and decrease the joint strength. [11] A way to prevent the formation of brittle intermetallic phases is to use a suitable interlayer material which keeps the base materials completely separated. By using this material the
overall welding temperatures can be reduced and joint strength increased. [11]

**Design considerations**

Continuous drive rotary friction welding of small diameter NiTi tube to stainless steel is not an option on the currently available equipment. Therefore, for our prototype we used solid cylindrical bars through which an axial hole is drilled after the friction welding procedure is completed. The smallest diameter of material that can be handled by the available friction welding machine, i.e. 8mm, was used. Using this method we first created two ends of the reamer, i.e. the reamer head and the power tool connector, each of stainless steel with a stub of NiTi friction-welded to it. These two ends were laser-welded to a NiTi tube with suitable diameter. This leads to two additional welds.

Figure 2 displays the final product. The weld regions are highlighted with the friction welds indicated in blue and the laser welds in red. The diameter of the stainless steel cutting head is 15 mm. It is attached to a 6 mm NiTi shaft (3mm ID) which is sufficiently strong to withstand torques up to 17.8 Nm before the material reaches its superelastic plateau of 450 MPa. The overall length of the surgical tool is 350 mm. The reamer is fully cannulated with a 3 mm hole. The shear stress increases for higher torques. To reduce these stresses, the outer diameter of the weld region is increased to 8 mm for the friction welds.

Controlled trials have provided the best parameter values for the friction welding of the NiTi bar to Stainless Steel.

![Figure 2: The design of the intramedullary reamer.](image)

Advantages of the new design are as mentioned above. An additional advantage of a NiTi-shaft is vibration damping. In current reaming designs, the low stiffness of the shaft may lead to vibrations during reaming, which can damage the tool and can lead to multi-cornered or non-cylindrical holes. This may result in improper fixation of the nail. [12] In the new design damping occurs due to hysteresis in the flexible NiTi shaft.

Although NiTi tubing is relatively expensive compared to stainless steel, the overall costs of a complete reamer set will be low, because fewer reamers are needed to establish a full reaming procedure.

**Experimental setup**

A total of four prototypes was manufactured to investigate the ability to perform a reaming procedure with the new design. The testing material should closely reflect mechanical properties of compact bone. Two materials have been selected for this purpose, glass-fiber filled epoxy cylinders (Sawbones inc., OD 20 mm, 5.25 mm wall thickness, 250 mm length) and oak wood cylinders, OD 20 mm, pre-drilled to ID 12 mm. [12] Prior to reaming, the specimens were bent into a 1.2 m radius, which is similar to the radius of curvature of the human femur. [13]

Testing was carried out on a conventional lathe. The reamer was clamped in an instrumented clamp in a lathe chuck. The specimen to be reamed was clamped on the sled of the lathe and advanced towards the rotating tool. After each reaming pass, the tool was cleaned in a washer-disinfector (Miele Professional) and sterilized in an autoclave (Davenport), as would be the case in clinical practice. [14, 15] In total, 10 reaming passes were carried out, 3 on the Sawbones specimen and 7 on the oak wood specimen.

Each of the four prototypes passed the reaming and sterilization tests without failure of the friction welds. Upon visual inspection under a microscope, no damage to the welds or deterioration of the surface of the base materials was noted.

**3 Discussion**

In this design study a new rotary friction weld method for friction welding stainless steel to a nickel-titanium alloy was developed.

With this new knowledge intramedullary reamer prototypes were created. Weld performance was assessed by carrying out repeated reaming and sterilization procedures. Failure of the friction welds did not occur and no deterioration of base materials was noted.

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Design and evaluation of a patient-specific knee joint distraction device for treatment of knee osteoarthritis

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1 Background

Osteoarthritis (OA) is characterized by cartilage loss leading to a decreased joint space width (JSW) accompanied by mild synovial tissue inflammation and subchondral bone changes, such as sclerosis, subchondral cysts and osteophyte formation.1 In an advanced state of disease progress patients experience pain and loss of function. Common surgical treatment in this end-stage of disease is an arthrodesis or joint replacement. However, treatment options for knee osteoarthritis (OA) are limited in numbers, and limited in clinical outcome. Especially for young patients suffering from severe knee OA, the need for more effective options is increasing with the expected growing prevalence. Knee joint distraction (KJD) therapy has shown to be an effective treatment method for relatively young patients who are considered for conventional total knee prosthesis (TKP), by postponing a first TKP.2,3,4

During the 6-8 weeks lasting KJD procedure, the bony ends of the joint are set at a distance up to 5 millimeters with help of an external fixator which is attached to the patient by means of bone pins.3,4 Although different groups have shown KJD with positive clinical outcome in case studies and pilot studies, acceptance of the therapy is staying behind on those results.3,5,6 This is considered to be related to the invasiveness of the procedure. Secondly, most described studies have used a rigid distraction setup which fully restricts joint flexion. Articulation during knee distraction is expected to increase comfort for the patient and possibly reduces the need for revalidation. This is supported by the results of Salzmann et al that demonstrated improved clinical outcome in articulating ankle distraction therapy.7

The need for a dedicated device that combines joint distraction, articulation and ergonomics is the basis for development of such a device. General design considerations and preliminary outcome of feasibility testing is described in this abstract.

2 Methods

Requirements for an externally applied joint distractor were determined in a multidisciplinary setting, involving patients, clinicians, and engineers. Two requirements were decisive in the design approach, which are subsequently discussed.

First, the complexity of alignment of an externally attached distractor relative to the patients anatomy from most conservative devices. Positioning of the device needed to rely on optimal bone pin locations, as these optimal locations are limited from a clinical point of view. Secondly, mimicking joint specific motion without harming the joint side was aimed for, from which joint distraction in axial tibial direction was applied. A method for patient-specific motion reproduction was developed, incorporating both requirements. Evaluation of the method was performed with commercially available bone pins and pin clamps (Stryker, Triax Monotube), assembled to the articulating distractor parts.

The patient-specific approach comprises attachment of a first part to the femoral joint side, and attachment of a second part to the tibial joint side. Measuring of relative motion was performed bilaterally by scratching motion paths with sharp pens (femoral side) in a deformable counterpart (tibial side). A cam following mechanism of which the interconnecting elements dictate joint motion reproduces motion.

Feasibility of the motion reproduction method, including joint distraction, was tested on human cadaver knees (n=3) without signs of past surgery. Incorporating all soft tissues that contribute to active joint motion, including muscles attaching to the pelvis, preserved physiological representative passive joint motion.

After assembling the interconnecting elements to the femoral and tibial distractor parts at the medial and lateral...
joint side, joint motion was manually evaluated by an experienced orthopedic surgeon for irregularities. Joint motion of at least thirty degrees flexion was aimed for.

### 3 Results

Attachment of the femoral and tibial articulating distractor parts after placement of bone pins and bone pin clamps at anatomically best positions was found to be feasible, although determination of the sagittal plane of motion and positioning of the distractor parts near the axis of rotation could only be achieved by application of an additional alignment tool that secured parallelism between medial and lateral distractor parts. Range of motion was limited by dimensioning of the distractor parts to thirty degrees flexion. Interconnecting elements, of which a representation is given in figure 2B, reproduced joint motion.

### 4 Interpretation

An externally attached articulating knee distractor at anatomically optimal positions that mimics joint specific motion by manufacturing specific interconnecting elements has great potential to improve articulating knee distraction therapy. The provided method was found to be technically feasible but evaluation was performed on cadaver joints without muscle tension and joint kinematics are known to be different from in vivo kinematics.

Moreover, prescribing joint motion in only the sagittal plane of motion (flexion/extension plane) might result in a non-comfortable joint configuration for patients. Both aspects need to be evaluated in a clinically feasibility study previous to clinical application of the described setup as therapy for knee OA.

### References


Novel bone biopsy milling tool with integrated centering system and three-step surgical dressing unit for osteologic base diagnosis

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Introduction: Because of the specific structure of tissue inside human bones, diagnostic structural analyses, e.g. in the frame of iliac crest biopsy, require complete preservation of the trabecular meshwork. Existing tools for harvesting of samples cannot fulfil this requirement to the necessary extent. In the frame of the presented research, we developed a novel instrument, which significantly improves the quality of biopsy samples for osteologic diagnosis.

Methods and Materials: The functional basis of our instrument is a dedicated milling head geometry carrying a set of six different blades. By the realized force distribution over the blades and the intermeshing performance of pre-cutting and main blades, compression fractures of bone structure during sample acquisition are prevented most effectively. At the same time, load distribution over all cutting blades helps to extend the lifetime of the tool. To achieve these effects, the pre-cutting blades are aligned with highest precision during manufacturing. At the same time, these blades overtake a centering and stabilisation function during the cutting process, which enhances the geometric quality of the cylindrical samples. After extensive tests we found an angle of 70 degrees as best value for pre-cutting blades, whereas the main blades perform best with an angle of 140 degrees. The tool further comprises a round plate, supporting to find the right position and cut along the fibre direction, to stabilize the cutting process and to provide a germ barrier.

The milling tool head changes its diameter from 11mm proximal to 9,5mm distal. The so called "relief grinding" design ensures that the tool cannot stick in the bone structure during the bone harvesting procedure. Additionally, it keeps process temperatures as low as possible.

Results: Based on a fully functioning prototype tool we performed more than hundred sample harvesting tests. It could be shown that sample acquisition is possible without any additional tools. Bone chips produced during the intervention are collected by special cannels inside on the tool and flushed away by rinsing procedure.

Conclusion: Structural bone protection, minimal invasiveness and optimal conditions for sample recovery have been implemented by our new surgical tool successfully. The harvesting of high quality bone cylinders for biopsy, also for osteoporotic patients, is facilitated considerably and can be performed without major stress for the patient. By the enhanced quality of spongious structures of the samples, the diagnostic value of analyses is improved significantly.
Abstract

Using Kinect with 3Gear Systems software to determine hand and finger movement: An assessment for minimally invasive surgery applications

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1 Background

Singe- and multi-branched steerable instruments for Minimally Invasive Surgery (MIS), that allow for maneuvering towards difficult-to-reach locations as well as the execution of complex surgical tasks such as suturing and knot tying, are currently being developed [1, 2]. The emerging fields of Single Incision Laparoscopic Surgery (SILS) and Natural Orifice Transluminal Endoscopic Surgery (NOTES) use a single entry site, and therefore put size restrictions on instrumentation. Implementation of steerable instruments into surgical practice is challenging due to their difficulty in control. In many cases, the multitude of Degrees Of Freedom (DOF) requires the cooperation of two surgeons, or alternatively, one surgeon switching between control modes.

The optimal DOF configuration along the instrument shaft (and branches), their deflection ranges, actuation strategies, and control modalities are still under investigation. Striving to determine the optimal DOF configuration, and the accompanying coupling of these DOF to the surgeons hand movements, a new testing facility is introduced and evaluated, termed BI-SCoPE: Branched Instrument Simulator for Control and Performance Evaluation.

Available methods of hand motion tracking presented in literature include various types of data gloves [3] and vision based systems [4]. Recent commercial examples are Leap Motion [5] and 3Gear Systems [6]. The latter system is incorporated in BI-SCoPE and an evaluation is performed of the system’s robustness in detecting the fingers as a function of changing hand orientations.

2 Methods

The BI-SCoPE facility is intended to allow for the simulation of any type of single- or multi-branched instrument in a virtual environment and coupling of the modeled DOF to hand and/or finger movements of the surgeon. This allows us to design an instrument with any construction, simulate its movements in a virtual environment, and try out control coupling strategies before building a physical prototype.

The setup consists of two Kinect cameras, mounted on a frame, looking down from opposing angles onto a tabletop (Fig. 1). Software is implemented of 3Gear Systems (v0.9.34), allowing for detection of both the hand positions and orientations as well as the finger deflections. The 3Gear systems software is an extension of the work presented by Wang et al. [7]. Using two cameras allows for the detection of both hands, even when for one camera a hand is visually obstructed by the other hand.

An anatomically correct wooden adjustable right hand model, with length 21.35 cm, measured from wrist to tip of the middle finger, and breadth 8.3 cm, was mounted on a tripod with a 3-way pan/tilt head. Due to the slight difference in hand-size between the wooden model and the average male hand (having length 18.89 cm and breadth 8.45 cm [8]), first the Hand scale (Hs) auto-calibration algorithm that is incorporated in the 3Gear Systems software was validated. This Hs-value is a multiplication factor, ranging from 0.6 to 1.3, scaling the skeletal model in size to which the internal hand detection software algorithm optimizes, where Hs = 1.0 is equal to hand length 20.8 cm. A Hs value of 0.91 thus corresponds to the stated average sized male hand (18.89 / 20.8), and the wooden hand model Hs value is 1.02 (21.35 / 20.8). Hand and fingertip position measurements for a flat hand (palm facing down) at manually set Hs were compared to the auto-calibrated Hs results. The manually set HS spanned the entire range with step size 0.05 and the range [1.0, 1.1] with step size 0.01. At every step approximately 350 measurements were taken in 30 seconds, and the Standard Deviations (SD) of the hand and fingertip measurements were determined for the measured hand orientation as well as assessing the pitch angles. For every session the mean and SD of 10*350*7=24,500 measurements when for example one camera a hand is visually obstructed by the other hand.

The second test involved the model hand, with the fingers stretched and hand flat, being placed in varying pitch, yaw, and roll angles (ranges [30°, -60°], [-60°, 60°] and [-120°, 60°] respectively). All angles were varied at 15° intervals (while keeping the other angels constant at 0°), where at every step again approximately 350 measurements were taken in 30 seconds. Combinations of angles were not assessed. Every measurement session was repeated ten times, leading to a total of 10*350*7=24,500 measurements when for example assessing the pitch angles. For every session the mean and SD were determined for the measured hand orientation as well as the combined angular measured finger deflections of the metacarpophalangeal and (proximal) interphalangeal joints. The mean and SD were subsequently averaged across the ten sessions. Note that the fingers were not flexed during tests.
and thus we would expect to see the same result at all orientation angles of the hand.

3 Results

The SD of the hand position estimation in the x-, y- and z-coordinates is provided in Figure 2 as function of varying Hs values over the range [1.00, 1.10]. A Hs of 1.02 yielded the lowest SD from the determined mean hand position, close to the optimum Hs (opt. in Fig. 2) as determined through auto-calibration. For the fingertip positions however Hs opt. was more robust, because the middle finger with Hs 1.02 showed significantly higher SD. Hence Hs opt. will be used for subsequent testing. The SD of the overall 3D hand position is 1 mm in any given direction at its optimal estimation, and the SD of the fingers tip locations varies no more than 4 mm.

In auto-calibration modus, the mean and SD of the thumb and index deflection values as a function of pitch, yaw and roll angles are given in Fig. 3. All three angles at 0° correspond to a horizontal flat hand with the palm facing down. A positive pitch equals to an upward angled hand, a positive yaw to a sideways angled hand with the thumb pointing away from the computer screen, and a positive roll with counter-clockwise rotation of the hand with the thumb pointing down. The angles provided on the horizontal axis are the imposed orientation angles of the hand in the directions of interest.

4 Interpretation

Figure 2 shows that Hs most significantly influences the z-direction position estimation. As the hand was placed longitudinally along the z-axis in the camera fields, it is logical that this scaling factor shows the highest impact along this axis. Although the data presented in this figure does not provide insight into the accuracy of the position estimation with respect to the true hand position, it does provide an indication of the systems’ precision around its estimate. As the SD of the data associated with the systems auto-calibrated Hs is close to the lowest determined SD, and stable when accounting for fingertip location estimations, it can be stated that the internal auto-calibration algorithm is well suited for testing purposes.

The data shown in Fig. 3 is limited to the thumb and index fingers, as these are the ones of most importance. As the hand and fingers were kept passive during variation of the pitch, yaw and roll angles, one expects to see a constant mean value for the finger deflection estimation. During pitch, the mean finger deflections indeed vary only a little, although the thumb’s SD does increase at a steep upward tilted hand. The yaw angle appears to be of significant influence on the estimation. The thumb behaves erratically, and both the thumb and index finger show higher SD at larger positive yaw angles, that is, when the thumb is pointing away from the screen. As the software compares the detected hand to an internal database of pre-computed 3D images corresponding to each possible hand configuration in the workspace, it is likely that large yaw angles lie outside the scope of the database. The roll angle mostly influences the thumb estimation as compared to the index finger, and worsens at larger roll angles. In this position the thumb is sharply pointing down, making it difficult for the cameras to detect.

We showed that the Kinect – 3Gear System setup provides a consistent measurement of the hand position and orientation. However, the finger deflection estimations are dependent hand orientation, the hand’s yaw angle in particular. For future applications, motion smoothing or data fusion with other motion capture sensors, may be required.

References

Classification of Catheter Steerability within the Heart: A Review on Contemporary Technology and Future Perspectives

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1 Background

The field of interventional cardiology is a growing branch of cardiology where minimally invasive procedures are used in the treatments of e.g. coronary artery disease, congenital heart defects and heart valve diseases. Within the use of minimally invasive instruments for cardiac applications, catheters are among the most versatile and instruments. A large variety in existing catheter designs is commercially available for use in different cardiac applications, with catheters varying from simple delivery tubes to more complicated designs with additional tip functionality for tissue interaction.

Despite their growing field of application, currently existing catheter designs allow for limited functionality as a result of several difficulties. Precise positioning of the catheter tip within the heart is one of the main problematic issues, as a result of complex 3D shapes within the heart and the absence of vessel wall support. In addition to that, respiration and heartbeat lead to a constant movement of the heart and changes in blood flow within the cardiovascular system. Therefore, the use of catheters for complex interventions within the heart requires a catheter tip that can be positioned directly and precisely at the region of interest, without undesired interference of physiological conditions. [1].

Commercially available steerable catheters come in a large variety with respect to steering ability and functionality. Even though previous reviews with focus on catheter steerability have been carried out [2-4], a structured categorization of different groups and sub-groups of steerable catheters, such as will be presented in this review, has not yet been defined. Therefore, two main objectives for this review exist: (1) developing a structured classification for catheter steering and actuation possibilities, in order to provide improved understanding of the underlying technology and new design insights, and (2) providing a comparative analysis and user experience background of currently applied steerable catheters in cardiac interventions, with the purpose of informing cardiac specialists and hospital supplies management with regards to the possibilities.

2 Methods

The MedicalExpo database is consulted for an initial overview of all existing cardiac catheters and the companies producing them. Over 1200 cardiac catheters are found, offered by more than 180 different medical companies. For a further refinement and identification of steerable catheters, the resulting catheters are separated based on their ability to steer in an active manner.

Subsequently, the Web of Science digital collection of scientific literature is consulted for analysis of steerable catheters more specifically. The applied search within the database is subdivided into four categories: (1) motion, (2) medical region, (3) intervention, and (4) instrument. Within each category, a number of important search terms are defined including, inter alia, steer*, deflect*, card*, heart, electro-physiology*, ablature*, catheter, and sheath. Two to four categories are specifically combined in separate search queries, using the ‘AND’ operator to combine the categories and the ‘OR’ operator to combine the search terms in title or abstract. All currently existing cardiovascular catheters are considered within the timeframe from the 1950s to the present.

However, within the scope of this review article and for the benefit of creative new solutions, it is decided to not restrict the classification to the existing steerable catheters or scientific papers. It is therefore determined to include reviews from within the entire Espacenet patent database within the time period from the 1950s to the present. The literature search within Espacenet is executed with the integration of the aforementioned categories and keywords in the search queries, nevertheless by only combining a maximum of two categories as a result of the extensiveness of the search queries. Over 1000 patents for steerable catheters are found.

The applied classification will include both actively steerable (actuation dependent) and passively steerable (environment dependent) catheters. Steering and actuation technology are explored and existing catheters are compared. Finally, recommendation for future catheter steering in the heart will be given based on requirements and new possibilities. Additionally, attendance during a number of cardiac interventions is enabled and medical specialists, both cardiologists and cardiac surgeons, are consulted for user experience with regards to the different existing steerable catheters employed during cardiac interventions.

3 Results

Relevant nomenclature with regards to deflection range, curve type, and curve dimensions is explicitly defined in order to differentiate between different steering possibilities. Together with the results from the search queries, medically applied and patented catheter designs are classified based on steering possibilities and related DOFs.

A first classification of catheter steerability draws a borderline between (1) catheters with actuation dependent steering and (2) catheters with environment dependent steering. The former group consists of catheters that are actively actuated in order to deflect or steer towards a certain desired location of interest. The group is further subdivided into (1) internal actuation and (2) external actuation, where internal actuation describes (1) mechanic, (2) hydraulic, (3) thermal, and (4) electric actuation, whereas external actuation focuses exclusively on magnetic actuation. The latter group consists of flexible (pre-shaped) tube catheters, able to bend depending on environmental structures within the body and is further subdivided into (1) flow dependent steering, (2) structure dependent steering, and (3) opening dependent steering. Figure 1 shows a visualized summary.
Actuation dependent internal steering describes the group of (1) mechanic, (2) hydraulic, (3) thermal, and (4) electric actuation where a specific motion at the proximal end is transmitted into a deflection of the distal catheter tip. Mechanic actuation applied in steerable catheters makes use of force transmission by mechanical components. The use of pull wires within the catheter is a frequently applied solution to enable mechanic steering. Hydraulic actuation depends on the transmission of linear movement from the proximal end, causing a hydraulic pressure transmission that enables a deflection of the distal catheter end. Hydraulic tubes, as well as their number, and their shaft design occur in variable appearances. Thermal actuation depends on Shape Memory Alloys (SMAs) which possess the ability to deform based on the supply of heat, and subsequently recover their original shape. SMAs are frequently applied in micro-actuator systems due to their ability to generate large amounts of force and displacement \[5\]. Finally, electric actuation can be based on a number of processes including, inter alia, pressure related change by incorporation of piezo-electric materials and shape related change by use of electro-active polymers. Actuation dependent external steering describes solely the subgroup of magnetic steering, where external electromagnets are implemented in order to actuate the inserted catheter tip. A number of different magnetic mechanisms is applied or is still in an experimental phase.

Environment dependent steering forms an utterly different branch of steerable catheters. In contrast to actuation dependent steering, these catheters benefit from the hemodynamic principles by using flow, structures, and openings in the cardiac environment to steer their way towards the location of interest. These catheters have a wide range of applications, are made of flexible materials and deflection is provided by three means of material modifications: (1) removal of material, (2) addition of material, and (3) reinforcement of material.

![Figure 1. Primary classification of Catheter Steerability](Image)

4 Interpretation

This review provides a contemporary overview and classification of catheter steerability within the heart by focusing on actuation dependent steering in actively activated catheters as well as on environment dependent steering within flexible (pre-bent) catheters. With special focus on catheters used in cardiac interventions, the intention is to improve understanding of the differences in fundamental design, the strengths and weaknesses, and the user experience, of the different steering possibilities.

During the review process, a number of categories and subcategories were successfully identified in order to improve understanding of catheter steerability. It was suggested that novel steering possibilities can be generated not only by thinking in degrees of freedom, but by combining several fundamental categories together as well. New future designs could incorporate smart mechanics, consider miniaturization and explore material options.

With regard to the line of development in catheter steerability, an unambiguous change in functionality and necessity of steerability can be observed over the past decades. The main use of cardiac catheters in the past was in the fields of visualization and monitoring, and steerability was thus not a necessity. Towards the present, a shift in functionality can be observed where steerability is of high importance in the field of interventional cardiology. Currently, steerable catheters are gaining most interest in electro-physiology, where a number of steerable cardiac ablation catheters are already commercially available. Applying (multi-)steerable catheter technology within the field of interventional cardiology would not only provide a number of medical advantages and facilitate the procedures for both patient and medical specialist, it could lead to new possibilities in minimally invasive cardiac interventions as well, as confirmed by a number of cardiac specialists at the cardiology and cardiac surgery department of the Erasmus Medical Center in Rotterdam, the Netherlands.

References
