Design of Medical Devices – Europe Edition 2013

	Monday Oct 7		Tuesday Oct 8		Wednesday Oct 9	
08:30	Registration					
09:00	Opening		Welcome		Welcome	
	Keynote: S. Paul		Keynote: N. Navab		Keynote: A. Menciassi	
10:00	Inv. Spkr. RJ. v. Geuns	Special Session: BioInspired Technology	Inv. Spkr. M. Friebe	Special Session: Bio-photonics	Inv. Spkr. K. Cleary	Special Session: Human Factors
	Fast Forward		Fast Forward		Fast Forward	
11:00	Interactive: Endo-vascular Devices		Interactive: Computer Integrated Devices		Interactive: Hand Held Devices	
12:00	Lunch		Lunch		Lunch	
13:00	Keynote: W. van Furth		Keynote: K. Althoefer		Lab Tours TU Delft Departing from Foyer	
	Company Presentations		Company Presentations			
14:00	Inv. Spkr. V. Dubey	Special Session: Workflow Monitoring	Inv. Spkr. G. Kronreif	IMDI Session: Centers of Excellence in Imaging		
	Fast Forward		Fast Forward			
15:00	Interactive: Prostheses Ortheses Exoskeletons		Interactive: Robotic Devices		Closing	
16:00	Coffee Break		Coffee Break			
	IMDI Session: (Inter)national Developments in R&D Collaboration		Boston Scientific Session: Medical Device Innovation Consortium			
17:00						
18:00						
	19:30-22:00 | Diner at Brasserie Delft		19:30-22:00 | Drinks at Lambert van Meerten			

TU AULA LOCATIONS:

- Entrance hall (orange)
- Foyer (green)
- Senaatszaal (blue)
- Commissiekamer 3 (light blue)

Sunday Oct 6

17:30-19:00 | Reception at Old Town Hall, Delft

Endovascular devices

Tip Actuated Guidewire for Endovascular Interventions Under MRI Guidance

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John J. van den Dobbelsteen

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Abstract

Conventional endovascular instruments have limited shapes and flexibility and, therefore, are difficult to steer and control. Consequently, catheter and guidewire are exchanged frequently to change stiffness, diameter, or tip shape. To support the navigation process, a 1.6m long and 0.035” diameter polymer-based guidewire with a bendable tip was designed. The tip could be oriented in angles from 30° to 250°. The materials were selected so that the instrument could be used under Magnetic Resonance Imaging (MRI) guidance, which, unlike x-ray, does not use ionizing radiations. The tip was driven using a detachable handle that incorporated a slider. With the current design it was possible to slide conventional 0.035”–compatible catheters over the guidewire. Further, the guidewire was imaged in a 1.5T MRI without producing artifacts that would have shaded the anatomy.

Intravascular Catheter for Photoacoustic Imaging of Coronary Atherosclerosis

Gijs van Soest
Krista Jansen
Min Wu
Geert Springeling
Antonius FW van der Steen

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Intravascular optical coherence tomography imaging at 3200 frames per second

Tianshi Wang [1]
Wolfgang Wieser [2]
Geert Springeling [1]
Robert Beurskens [1]
Charles T. Lancee [1]
Tom Pfeiffer [2]
Antonius F. W. van der Steen [1]
Robert Huber [2]
Gijs van Soest [1]

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Abstract

We demonstrate intravascular optical coherence tomography (OCT) imaging with frame rate up to 3.2 kHz (192,000 rpm scanning). This was achieved by using a custom-built catheter in which the circumferential scanning was actuated by a 1.0 mm diameter synchronous motor. The OCT system, with an imaging depth of 3.7 mm (in air), is based on a Fourier domain mode locked laser operating at an A-line rate of 1.6 MHz. The diameter of the catheter is 1.1 mm at the tip. Ex vivo images of human coronary artery (78.4 mm length) were acquired at a pullback speed of 100 mm/s. True 3D volumetric imaging of the entire artery, with dense and isotropic sampling in all dimensions, was performed in less than 1 second acquisition time.

Maneuvering devices inside the bloodvessels - guiding endovascular procedures by integration of navigation technology - An update from the Trondheim research group

Geir Arne Tangen, MSc [1,2,3,4]
Frode Manstad-Hulaas, MD, PhD [1,2,4,5]
Asbjørn Ødegård, MD [1,2,5]
Toril A.N. Hernes [1,2,3,4]

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Abstract

In several studies we have tested the feasibility of position tracking devices and navigation technology in endovascular procedures. This technology can improve these procedures by making the maneuvering of catheters and tools easier for the operator. Three-dimensional visualization combined with real-time position indication of the catheter/tool, presents an intuitive view to the operator. Other potential improvements using this technology are reduced radiation to the patient and medical personnel, reduced use of contrast agents and increased safety when performing image-guided interventions. This paper is a summary of some important sub studies and aspects related to the integration of navigation technology for smart guidance of medical devices during endovascular interventions.

FPGA based electromagnetic tracking system for fast catheter Navigation

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Georg Rose

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Abstract
An experimental setup of an electromagnetic tracking system (EMTS) has been developed to perform fast catheter navigation for minimally invasive surgery (MIS). The algorithm for the position and orientation (P&O) calculation is implemented in MATLAB while the whole EMTS is programmed and controlled by LabVIEW. The system utilizes a field programmable gate array (FPGA) for signal generation, acquisition and filtering. With the frequency division multiplexing (FDM) and FPGA infinite impulse response (IIR) filter technology, the developed system is able to track P&O of the catheter tip 35 times per second in five degrees of freedom (DOF). A phantom experiment has been performed to evaluate the performance of the EMTS. After calibration, the positional accuracy of the EMTS is 1.4mm inside the region of interest (ROI).

Saving Twins: A Hemodynamic Model of the Fetoplacental Circulation for Validating New Instruments and Techniques

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Sjoerd van Tuijl [2]
John van den Dobbelsteen [3]
Dick Oepkes [1]

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Abstract

Twin-to-twin transfusion syndrome is a monochorionic twin pregnancy condition with poor perinatal survival if left untreated. Current intrauterine laser treatment has increased survival significantly, yet room for improvement still exists. In order to validate new instruments and techniques a realistic human placenta model is required since an animal model is not available. A term singleton placenta was casted in a gelatin solution leaving the fetal side exposed. A syringe pump with a heparinized sodium chloride solution was connected to the umbilical arteries. Four different arterial flow settings between 6.0ml/min and 26.6ml/min were used and venous outflow was measured. Also arterial pressure measurements were taken.

The outflow/inflow ratio was 100% at 6.0ml/min, dropping to 93% at 26.6ml/min.

We successfully developed an ex-vivo model of the fetoplacental circulation. This unique model is an essential step in the development of new laser- and other treatment devices for intrauterine treatment of twin-totwin transfusion syndrome.

Optimization of a Shape Sensing Needle

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Abstract
Robotic needle steering requires accurate spatial information about the needle tip. Presumably, fiber Bragg gratings (FBGs) can provide this. We quantified the accuracy of needle shape sensing with FBGs by means of simulation. The number of sensors and their distribution along the needle were varied in order to optimize the needle design. In addition, different interpolation models were investigated. The simulations show that interpolation by means of fitting a spline results in lowest errors. Adding sensors increases the accuracy of estimated tip position. The placement of the sensors can be optimized for each specific loading situation, but this is not practicable because of the variation of forces that act on the needle during insertion. Based on these results, a shape sensing needle was manufactured, which was calibrated in an experimental set-up. According to the simulations, interpolation introduces an average error in estimated deflection of 0.15 mm. However, subsequent measurements show that other factors influence the accuracy as well, which include drift of the interrogator and the precision of manufacturing.

Prostheses, orthoses, exoskeletons

A Novel Non-fusion Scoliosis Correction System

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Abstract
Scoliosis is a 3-D deformity of the spine, which occurs mostly in young girls and is characterised by a lateral deviation and axial rotation of the spine. Current treatment includes a metal rod that is fixed to the spine.

However, this results in a stiff spine, because the rod is rigid and the vertebrae will fuse (grow together). Moreover, due to the fusion of vertebrae, the length growth of the patient stops, so surgery is performed at a late stage, at which time the deformities are more severe.

Recently a non-fusion scoliosis correction device was designed that corrects scoliosis completely ithout causing vertebral fusion, because it keeps the spine flexible. It also allows growth of the spine, so it can be used at an earlier age, and can be removed after use, leaving a healthy and straight spine. The system was successfully tested for strength and on functioning in animals.

A New Osseointegrated Fixation Implant for Amputated Patients

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Abstract

Leg amputation has a big impact on patients' mobility and quality of life. Traditional stump-socket fixations introduce soft-tissue problems, gait control and fitting difficulties.

Alternatively, a direct osseointegrated attachment of an artificial limb to the skeletal system overcomes skin and fitting problems, provides a better prosthetic control and increased mobility. However, bone loss around the prosthesis, bone and implant failures and infections restrain applications of the current osseointegrated implants.

To solve these problems, a new fixation system was developed that could restore the natural load transfer in the femur and allow implantations in short stumps. The system is composed of a metallic core sliding in an elastic sleeve to reduce bone failure risk and bone loss.

Finite element analysis and experimental techniques showed that the novel concept produced a more physiological stress and strain distribution in the bone, reduced failure risk and minimized long-term bone loss.

Attendant driving tactile interface for electric wheelchairs or trolleys

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Abstract
This paper introduces a novel device based on a tactile interface to replace the attendant joystick in electric wheelchairs. It also can be used in other vehicles like shopping trolleys. Its use allows intuitive driving that requires little or no training, so its usability is high. This is achieved by a tactile sensor located on the handlebar of the chair or trolley and the processing of the information provided by it. This proposal aims to help disabled people and prolong the personal autonomy in a context of population aging.

Evaluation of an arm support with unrestricted trunk motion

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Abstract

Due to progressive muscle weakness, arm function in boys with Duchenne Muscular Dystrophy (DMD) reduces. Existing arm supports are wheelchair-bound, which restrict the ability to make trunk movements. To simulate the function of a body-bound arm support a linear guide has been added to an existing arm support, so that trunk movements are allowed. To examine the effect of this device, video analysis of single joint movement and activities of daily living were performed with and without the device. The arm function of three out of four patients improved. Patients with the least arm function benefitted the most from the arm support and all patients reported a positive effect when performing upward movements. The effect of a body-bound device with unrestricted trunk motion was perceived as important. It increased the range of motion for some movements, and also allowed compensatory movements that patients still use to minimize the required energy.

Evaluation of EMG, Force and Joystick as Control Interfaces for Active Upper-Extremity Movement-Assistive Devices.

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A.Q.L. Keemink [1]
Arno H.A. Stienen [1, 2]
A.C. Schouten [1, 3]
P.H. Veltink [4]
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Abstract
The selection of the control interface to operate an active movement-assistive device in response to each user's needs and capabilities is crucial for the usability and proper functioning of the device. Currently, many control interfaces exist and it remains unclear which strategy is most suited to each type of impairment and task. The goal of this study was to quantitatively evaluate the performance of EMG-, force- and hand joystick-based interfaces. The human operator abilities were tested in 8 healthy subjects using a screen-based one-dimensional position-tracking task, where the interface signal was mapped to the velocity of the cursor and the target was moving according to a multi-sine signal with a flat velocity spectrum. The performance of the control interface was evaluated in terms of tracking error, human-operator bandwidth and information transmission rate.

A Novel Self-Aligning Mechanism to Decouple Force and Torques for a Planar Exoskeleton Joint

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Abstract
The design of exoskeletons is a popular and promising area of research both for restoring lost function and rehabilitation, and for augmentation in military and industrial applications. A major practical challenge to the comfort and usability for exoskeletons is the need to avoid misalignment of the exo-skeletal joint with the underlying human joint. Alignment mismatches are difficult to prevent due to large inter-subject variability, and can create large stresses on the attachment system and underlying human anatomy. Previous self-aligning systems have been proposed in literature, which can compensate for muscle forces, but leave large residual forces passed directly to the skeletal system. In this paper we propose a new mechanism to reduce misalignment complications. A decoupling approach is proposed which allows large forces to be carried by the exo-skeletal system while allowing both the muscle and skeletal joint force presented to the user to be compensated to any desired degree.

The Delft Cylinder Hand, design of a lightweight hydraulic hand prosthesis

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F.C.T. van der Helm

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Abstract
Users of prosthetic hands indicate that mass reduction of the prosthetic device is the most important design criteria. Despite this clear demand current prosthetic hands are too heavy and their mass has increased over the past decades. Current hands require an uncomfortably high user effort to operate the hand and they have stiff fingers. To meet the demands of the users, a new prosthetic hand prototype has been developed: The Delft Cylinder Hand. This hand prototype has articulating fingers and is anthropomorphic, slender, fast, efficient and silent. The hand mass is 68% lower than the lightest commercially available articulating hand. The hand requires a lower effort from the user. This hand prototype is the first prosthetic hand that combines a very low mass, fast and easy control and an anthropomorphic appearance in one prosthetic device.

Computer Integrated Devices

Evaluation, Screening and Research Device: Nutrition, Undernutrition and Obesity

Tiago Andrade [1]
Manuel Rodrigues Quintas [1,2]
Maria Teresa Restivo [1,2]
Maria de Fátima Chouzal [1,2]
Carlos Moreira da Silva [1,2]
Teresa F. Amaral [1,3]

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Intrauterine navigation using a dynamic range camera for the fetoscopic treatment of twin-to-twin transfusion syndrome.

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Boris Lenseigne [2]
Pieter Jonker [2]
Dick Oepkes [1]

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Abstract

Twin-to-twin-transfusion syndrome is a major complication in a group of twin pregnancies due to vascular connections on a shared placenta. Fetoscopic laser surgery during pregnancy is considered treatment of choice.

In this study we investigated the advantages of high dynamic range imaging to improve visualization of the vascular network during surgery. For this experiment we used a high-fidelity simulator model and a conventional endoscope mounted on a HDR camera.

This technique appears to greatly improve image quality and opens the gate for advanced visualization and navigation techniques, an essential element in the treatment of twin-to-twin-transfusion syndrome.

A Method for Contactless Measurement of the Human Eye Parameters by Fiber Optic Low Coherence Interferometry

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Milos Tomicb [2]
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Christoph Kmenta [1]

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Abstract
In this paper we present a fiber optic sensing technique based on low coherence interferometry that provides a remote and contactless measurement of ocular biometric parameters such as central corneal thickness (CCT) anterior chamber depth (ACD), lens thickness (LT), axial length of the eye (AL) and assures a possibility to make a correlation between these parameters and intraocular pressure (IOP). The technique is a promising platform for making a light and wearable diagnostic device capable for 24 hours eyes monitoring and glaucoma detection. The technique is ergonomically designed being allows mounting of the miniaturized sensing probe over the glass frame aiming the patient's eye.

Differences in abdominal force between conventional and single port laparoscopy

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Tim Horeman

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Abstract

In laparoendoscopic single-site surgery (LESS), only one single incision is used to introduce all instruments into the abdominal cavity. The introduction of multi-channel single-port devices enabled insertion of laparoscopic instruments and laparoscope through one single entry point instead of multiple entry points in conventional laparoscopic surgery (CLS). From recent studies is known that the distance between instruments influences the force exerted on tissue during manipulation. To investigate whether this force difference can also be found on the abdominal wall, a two-dimensional force measurement mechanism was designed and incorporated in a standard trainer box. The sensors were used to measure the abdominal force exerted by either the standard trocar or the single-port device on the artificial skin that mimics the abdominal wall. A randomized crossover study consisted of 16 students and three experienced surgeons was conducted. The subjects were asked to perform a task with two different instrument configurations (CLS and LESS) in randomized order. The results showed that when performing a force-related task with LESS configuration, the maximum abdominal force was significantly higher compared with the conventional twoport CLS configuration.

Design of a Rectal Probe for Diffuse Optical Spectroscopy Imaging for Chemotherapy and Radiotherapy Monitoring

Martijn van de Giessen [1,2]
Robert Wilson [3]
Ylenia Santoro [3]
Soroush Mirzaei Zarandi [3]
Alessio Pigazzi [4]
Albert E. Cerussi [3]
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Abstract

Diffuse optical spectroscopy imaging (DOSI) has shown great potential for the early detection of non-responding tumors during neoadjuvant chemotherapy in breast cancer, already one day after therapy starts. Patients with rectal cancer receive similar chemotherapy treatment. The rectum geometry and tissue properties of healthy and tumor tissue in the rectum and the requirement of surface contact impose constraints on the probe design. In this work we present the design of a DOSI probe with the aim of early chemotherapy/radiotherapy effectiveness detection in rectal tumors. We show using Monte Carlo simulations and phantom measurements that the colon tissue can be characterized reliably using a source-detector separation in the order of 10 mm. We present a design and rapid prototype of a probe for DOSI measurements that can be mounted on a standard laparoscope and that fits through a standard rectoscope. Using predominantly clinically approved components we aim at fast clinical translation.

Optimizing imaging of cartilage defects in the ankle using ultrasound

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Maaike Terra[2]
Christian Askeland[3]
Gino Kerkhoffs[1]
Gabriëlle Tuijthof[14]

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Micromechatronic drive concepts for surgical instruments

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Jonathan Schaechtele
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Abstract

To enable novel surgical techniques, the instruments need to be adapted. The novel instruments are required to be flexible and highly dexterous as well as intuitive to control and able to transmit forces similar to current laparoscopic instruments. This investigation focused on hydraulic and pneumatic actuation concepts based on these requirements. Three actuator types were examined: piston cylinders, bellows, and artificial muscles. For each variety, prototypes were developed and tested. The miniaturized piston cylinder model with a diameter of 2.7mm was shown to withstand pressures up to 200 bar with minimal friction. The other actuators models similarly showed promising results. Concepts to integrate sensors were also considered: a coil designed to be part of an artificial muscle that would change in length and diameter with the actuator. The experiments confirmed that the displacement could be derived from the change in inductance.

Robotic Devices

A Mechanical Drive System for Enhancing Flexible Endoscopy

Linan Zhang [1,2]
Rahul Khare [1]
Emmanuel Wilson [1]
Craig A. Peters [1]
Kevin Cleary [1]

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Abstract
Uretero-renoscopy is used widely with flexible ureteroscopes for inspection, access, and manipulation in the ureter and kidney. The ureteroscope includes a fiberoptic endoscope along with a working channel, with both embedded in a small diameter flexible cable. However, existing endoscope designs rely on decades-old manual controls for translation, rotation, and tip flexion. The development of a more intuitive and userfriendly control system has the potential to greatly enhance the safety, efficacy, and efficiency of these instruments. Based on a first generation prototype, our lab designed an ergonomically enhanced flexible endoscopy robotic system, including a new robotic drive system, control system and a system assessment software platform. The drive system was designed to enable the surgeon to operate the endoscope through a low cost game controller. The initial evaluations show the feasibility of this approach.

Design of a Dedicated 5 DoF MRICompatible Robot for Image Guided Prostate Interventions

Longquan Chen [1]
Torben Pätz [1]
Scheherazade Kraß [1]
Jumana Al Issawi [1]
Darko Ojdanic [1]
Stefan Kraß [1]
Gerrit Tigelaar [2]
Jan Sabisch [2]
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Abstract
In order to improve the current clinical application of MR-guided prostate biopsies, a new, fully MRIcompatible solution has been developed. This solution consists of a five degree of freedom (DoF) robot, a programmable logic controller (PLC) and a software application for visualization and robot control. For the calibration the robots needle guide is used to calibrate the geometrical position of the robot with the 3D coordinate system of the MR scan. The software application supports the calibration with graphic overlays and guides the user through the interventional planning process. After selecting a target point the application will calculate the needed adjustment and an automatic execution can be done. In case of further adjustments the software also allows for manual control of the robot, to position the needle guide according to the acquired MR-images.

The Development of Medical Devices for Interventional MRI: Challenges, Strategies and Current Achievements

Mandy Kaiser
Johannes W. Krug
Georg Rose

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Abstract
Within the last decades, magnetic resonance imaging proved to be a well-suited imaging modality during minimally invasive interventions. However, the development of MR specific medical devices fur such interventions is still remaining challenge. Hence, this paper addresses the design process of such devices. It is illustrated as a common Plan-Do-Check-Act cycle. The main focus thereby is the evaluation of medical devices within the MR environment. Furthermore, this paper presents a selection of medical devices which have been developed especially for interventional MRI (iMRI) applications. Besides others, these devices include electronic hardware for patient monitoring, specialized catheters or biopsy related equipment. Based on the specific challenges and the current developments, several reasons for the impeded establishment of iMRI procedures will be discussed.

Robot-assisted needle steering by a cable driven tip actuator

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Abstract
A new tip-steered needle positioning method is presented to perform local diagnosis or treatment on deep seated structures. The steering robustness was validated from a mechanical viewpoint in air, gel, and ex-vivo liver. Feed forward steering was assessed by measuring the lateral needle deflection with a camera or ultrasound probe. A linear relation was found between the servo input and the produced tip angle. In gel phantoms, the needle curvature increases with the servo input, but the lateral displacement was found to level off as the needle workspace describes part of a sphere. In liver tissue, there were too many uncertainties to make solid statements on feed forward needle steering. Needle steering is often assessed on gel. This study shows the need for more complex and realistic models (preferably ex-vivo or in-vitro). Current developments for our steerable needle focus on mechanical improvements and the incorporation of system feedback.

Effects of Needle Reuse on Puncture Force Characteristics

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Abstract
Needle reuse is common in needle insertion experiments, industrial applications, and in clinical practice, and is known to increase overall insertion force. However, little is known about the influence of reuse on characteristic force metrics for specific needle tip geometries. This paper investigates the effect of reuse on force metrics for a specific type of bevel tip. To this end, results from four separate experiments are compared. In each experiment a single needle was used to perform 18 punctures of a polyurethane membrane. The following metrics are considered: force at incision start, force at incision end, and maximum wedging force. All three metrics were found to increase with reuse. At 0:05N per insertion, which is 6:5% of the peak force for a new needle, the force at the end of incision showed the largest rate of increase. The rate of increase appears to decline slowly for both incision force metrics, but not for the wedging force metric.

An Articulated Handle to Improve the Ergonomic Performance of Robotic Dextrous Instruments for Laparoscopic Surgery

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Alain Devreker
Florian Richer
Ali Hassan Zahraee
Jérôme Szewczyk [2]

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Abstract

Hand-held robotic instruments with dextrous endeffectors offer increased accessibility and gesture precision in minimally invasive laparoscopic surgery. They combine advantages of both intuitive but large, complex, and expensive telesurgery systems, and much cheaper but less user-friendly steerable mechanical instruments. However, ergonomics of such instruments still need improvement in order to decrease surgeon discomfort. Based on the results of former experimental studies, a handle connected to the instrument shaft through a lockable ball joint was designed. An experimental assessment of ergonomic and gesture performance was performed on a custom virtual reality simulator. Results show that this solution improves ergonomics, demanding less wrist flexion and deviation and elbow elevation, while offering gesture performance similar to a robotic dextrous instrument with standard pistol-like handle configuration.

The Method for Minimizing the Rolling Joint Play in the Steerable Laparoscopic Instrument Prototype – DragonFlex

Filip Jelínek
Sander Dobbenga
Geert van de Jagt
Davey Kreeft
Annemijn Smid
Rob Pessers
Paul Breedveld

Department of Biomechanical Engineering,
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Abstract

The recently developed steerable laparoscopic instrument prototype, DragonFlex, utilizes specialized cable guiding profiles to maximize the cable bending radius to the achievable limits, thus increasing their fatigue resistance. These cable guiding profiles are used in conjunction with

geared rolling joints which serve to equalize the cable moment arms and hence the force requirements on both cables. Despite being superior to hinged joints, the perfectly circular rolling joint design does not entirely eliminate the mechanism play. As a result, the enabled joint backlash tends to undermine the joints' bending stiffness. The original playcompensating mechanism, a shaft-embedded compression spring, proved unsatisfactory. Therefore, a new prototype with an optimized rolling joint curvature was designed. The new design was evaluated by testing its tip deflection with respect to the original prototype. In conclusion, the optimized curvature does significantly lower the play and thus is a major improvement in comparison with the original design.

Hand Held Devices

Disposable pulling force sensor for force measurements in surgical Sutures

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Abstract

The tension in a suture is an important factor in the process of wound healing. If there is too much tension in the suture, the blood flow is restricted and necrosis can occur. If the tension is too low, the incision opens up and cannot heal properly. The purpose of this paper is to describe an highly affordable disposable pulling force sensor to be used in the operation room to measure the pulling force on a suture thread. The accuracy and sensitivity of this sensor is high enough to determine the most important differences in performance. In a pilot study, a continuous suture of 7 stitches was applied on porcine abdomen for validation. The results show that the lowest average max force in of 6 (SD 1.2) newton was found in the second stitch and highest (8.3 SD 1.8) newton in the last stitch. This study indicates that the simple affordable sensor can be attached easily to the thread for accurate pulling force measurements. Since it is disposable it can be easily used on the operation room after gamma serialization to inform the surgeon about the ideal pulling force during closure of complex incisions.

Crown Cutter – The Impact of Tooth Quantity and Bevel Type on Tissue Deformation and Penetration Forces

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Abstract

Current laparoscopic biopsy devices are very ungainly, inaccurate and limited in application. The bio-inspired springloaded biopsy harvester, developed at TU Delft, was designed to facilitate peripheral cancerous tissue detection and resection at high speed and accuracy. This paper focuses on the optimization of the harvester's cutting tool, the crown cutter, with regard to different tooth quantity and bevel type. Various designs of crown cutters were evaluated using a high speed camera and a universal testing machine, with respect to the tissue deformation and the penetration forces respectively. Unlike changes to the bevel type, the different tooth quantity revealed significant differences with respect to the tissue deformation in-between 4 versus 6-teeth and 10 versus 6-teeth cutters. As for the penetration forces, the significant difference was found only between 10 and 6-teeth cutters. Overall, the 4-teeth cutter exerted the lowest forces. Differing the cutter bevel type was found to have negligible influence.

Preliminary report: Design, Prototyping and Evaluation of a Trans-Vaginal Morcellator for Total Laparoscopic Hysterectomy

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Abstract
Morcellation is the minimally invasive dissection and removal of a large tissue mass from the abdominal cavity. Various morcellators for use during Total Laparoscopic Hysterectomy (TLH) are available on the market. These function through one of the minimal incision sites created during minimally invasive surgery, and allow the surgeon to remove a fully resected uterus from the intra-abdominal area. This process takes a long time as relatively small pieces of tissue are repetitively removed from the main tissue mass. Moreover, the process is associated with large tissue spread which leads to a long inspection and irrigation phase for the removal of tissue debris. In order to address these issues, a novel transvaginal morcellator for TLH has been designed, prototyped and a proof-of-principle evaluation performed. It has been shown that, when developed further, this instrument will remove larger tissue pieces and function faster with less tissue spread, compared to the current standard morcellators.

EndoPathController: a manual control interface for maneuverable surgical instruments

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Abstract
For surgeries carried out transluminally or through instrument-created pathways (i.e., pathway surgery), instruments with multiple steerable segments (manoeuvrable instruments) have been introduced, but their controllability (e.g., dexterous steering and performance effectiveness) remains unexplored. A research platform, EndoPathController is designed for investigating manual controllability of manoeuvrable instruments. Current study investigate which control method, thumb or wrist, and which mapping, parallel or inverse, leads to more dexterous steering in an orientation task for pathways surgery. 24 Subjects were asked to use EndoPathController to guide a virtual instrument without collisions toward a target located at the end of an animated curved tunnel. The performance of subjects was compared with regard to time, path length travelled by the virtual tip along the curved tunnel, number of warning/collisions, subjective workload and questionnaire results. The measured results did not differ significantly between two control methods. Yet the measured time, path length, number of warning, and subjective workload were significantly lower from subjects using parallel mapping than using inverse mapping. Our study revealed that wrist control and thumb control did not have a significant effect on the performance but parallel control mapping significantly improved the novice subjects' performance.

Development of Surgical Tool To Aid in Component Positioning of THA Surgeries

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Abstract

Improper component positioning during total hip arthroplasties is the most common surgical error that takes place during the procedure. Though developments in the individual components have taken place, the positioning of these components during the surgery continues to be a challenge for surgeons, resulting in dislocations with a frequency between 1-10 % [1,2,3]. A practical and elegant solution in the form of a guidance tool was developed to be used by surgeons during placement of the acetabular cup component. The tool accounts for differing patient anatomy and patient position.

Soft Pneumatic Gripper Device

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Abstract
Traditional hard rigid robots or tools have been widely adopted in surgery; however challenges still exist for the surgeons when using these traditional technologies to handle delicate soft tissues during surgery. In this study, a soft pneumatic gripper device was designed to aid in manipulation of delicate thin tissues. Compared to current laparoscopic graspers that require a complex multicomponent mechanical structure, the soft gripper involves very simple design and control to generate actuation. It was fabricated from silicone rubber using a modified soft lithography technique, and consists of a gripper component that is made up of two gripper arms, with a wire-sized pneumatic channel in each arm, and a chamber component. The pneumatic channels are positioned close to the outer wall of the gripper arms and were connected to the chamber. Upon compression of the chamber, the pneumatic channels inflate towards the outer walls, which thus bends the gripper arms and results in a closed gripping posture. This soft gripper can be used to pick up objects of size ranging from 0.5mm to 2mm.

The Influence of Waterjet Diameter and Bone Structural Properties on the Efficiency of Pure Waterjet Drilling in Porcine Bone

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Abstract
Using waterjets in orthopedic surgery can be beneficial due to the absence of thermal damage and the always sharp cut. To minimize operating time and the volume of water that is used, the efficiency of the waterjet should be maximized. The open trabecular structure can cause the efficiency to vary between different waterjet diameters. In this study, 86 holes were drilled in porcine bone with nozzles of 0.3, 0.4, 0.5 and 0.6 mm at 700 MPa during 5 seconds. MicroCT scans were made to measure the removed bone volume and the bone structural properties. No significant differences were found for the material removal rates per added volume of water for the waterjet diameters, nor any influence on the efficiency was seen caused by bone structural properties. The total volume of added water is a leading measure for the drilling capacity, which provides freedom in the development of waterjet instruments.

The Smooth SetOn Applier for Per- Anal Fistels

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Abstract

Anal fistula are abnormal, inflammatory tracts from the colon or rectum to the perianal skin and are commonly seen in patients with Crohn’s desease. Seton rings are placed in these ‘Fistula tracts’ to keep them open and to prevent the forming of Peri-anal abscesses. The Seton threads used today are sutured or knotted together to form a ring. This knot causes complications, pain and discomfort to the patient. In the presented study a hand held applier is presented. This tool enables a surgeon to create a Seton with smooth surface by melting the two ends of a polyuretane (PU) tube together within 0.7 seconds, with an RF sealing tool. Before the ends of the new PU Seton are welded together, a round insert was placed in the hollow ends of the tube for a better fit and smoother surface. The results from the pilot tests indicate that if inserts are used from PU or Stainless Steel, and the tube ends overlap each other, the strongest connection is accomplished (on average 19N and 18 N respectively) . Therefore RF welding is a suitable and fast way to join the ends of a PU tube together and can be efficiently used for the creation of smooth Setons.

Special session:

Human Factors

A Pilot Study of Pen-Tablet interaction for contouring in radiotherapy treatment planning using orthogonal and non-orthogonal views.

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Abstract

With advancements in technology, human-computer interaction (HCI) in healthcare is flourishing. However, in the field of radiotherapy not many advances have happened in HCI. This paper describes a pilot study of two prototypes, which have been designed for aiding in contouring as part of radiotherapy treatment planning. The main aim of this paper is to evaluate the prototypes in terms of functional purpose and physical form. The functional purpose refers to how the clinical task is performed, and the physical form is related to the hardware that allows for user input. Expert feedback indicated that pen-tablet interaction was much appreciated. Interaction with one of the prototypes was cognitively demanding. To enable interpretation of anatomy and contouring in non-orthogonal plane using a pen-tablet user interaction should be optimized. This usability study provided directions for future research.

1 Background

The radiotherapy workflow is an extensive process and the physicians do not have the possibility to spend much time on a single specific task. Rapid and accurate delineation of tumor volumes and organs at risk is highly important in radiotherapy treatment planning and this key step influences the subsequent steps in the radiotherapy workflow (1,2). Physicians taking part in our research project have reported that most time is spent on contouring in radiotherapy planning. Currently, there are many automatic segmentation software applications available that enable much more rapid tumor and organ contouring than the expert clinicians. However, it is mentioned in the study by Whitfield et al. that automatic segmentation does not yet match the accuracy of the expert clinician. In order to attain reliable contours, user input is still essential, also in combination with automated contouring (3). Therefore, the focus of this study is on human-computer interaction (HCI) for semi-automatic contouring in radiotherapy. This research is carried out as part of a multidisciplinary project (4). The automatic contouring part is being done by our technical partners. The ultimate goal of the project is to design a semi-automatic contouring tool for radiotherapy.

The field of HCI has seen a number of advances in recent years. It has emerged as a highly successful area which blends fundamental studies in cognitive psychology with applied work in design (5). Prior to this pilot study, a literature survey on several different interaction and input devices used in radiotherapy contouring was performed. From this survey it was concluded that the focus of HCI research in radiotherapy is only on comparing the mouse with the pen for contouring. This comparison has provided some interesting results. It was found that the accuracy and speed of contouring with the pen is higher as compared to using a mouse (6). A muscular load analysis study of pen and mouse based interaction was done by Kentaro et al. (7), and found that there is reduced muscular load using a pen-tablet.

Tablet PC is the general platform for pen interaction as it provides a natural way to interact with the computer (8). Writing on a tablet is similar to writing on a paper using a pen. Even users with minimal or no experience with computers can use this interaction in a very efficient way (8). The tablet PC in general is rather vague term as it is used by individuals to refer to devices of varied sizes in their respective fields. For instance, many radiotherapists use the word to refer to a screen as big as 21 inches. In radiology the tablet (with sizes less than or equal to 10 inches) is generally used for direct storage of the patient data, for diagnostic reading, and for efficient communication between personnel (8, 9). Freudenthal et al have used the concept of pen-tablet to design a new interface for drawing/marking on imaging datasets (10).

Elliott et al. reported that drawing stacks of contours in radiotherapy to get a complete three-dimensional (3D) volume is a very time consuming task. Hence, there is a clear requirement for any system to enable quick 3D volume contouring (3). Generally, physicians use orthogonal slices of volumetric datasets while inspecting medical imaging data. Orthogonal planes are the standard planes which assess the orientation of the body. Being able to navigate in multiple directions can be advantageous in both creating and inspecting 3D contouring results. Hinckley has used the concept of direct navigation through a doll's head in different orientations, while holding a plate on his other hand (11). Freudenthal et al used the same concept of navigation in medical image data (10). Instead of the plate, a tablet was used to navigate through the dataset which was visualized on the screen. The concept of navigation in non-orthogonal planes for interventional radiology was further investigated by Varga et al. (12). In this study a prototype was designed which was used to view oblique images which differ from the traditional orthogonal images in terms of orientation. The oblique slices were cognitively demanding for the users, as they were used to viewing orthogonal images. Selecting non-orthogonal planes has been used previously in radiotherapy contouring (13, 14). In our research we considered the use of non-orthogonal slices as 1) the physicians of our research group had expressed their desire to visualize the tumor in the direction of its largest diameter 2) they were interested in an easier and faster method for contouring, and 3) were interested in contouring the tumor as a volume and not as stack by stack.

The goal of this pilot study was to evaluate our prototypes in terms of functional purpose and physical form. The functional purpose refers to the way the clinical task is performed (free view technique, volume contouring instead of slice by slice) and the physical form is related to the hardware that allows for user input (e.g.: pen-tablet interaction). The research questions that we addressed in our work are: 1) What is the difference in interpretation of the anatomy with the orthogonal views and non-orthogonal views? 2) Is it feasible to contour using the non-orthogonal view? 3) What are required steps for implementing pen-tablet interaction in radiotherapy contouring?

2 Methods

2.1 Approach

In this pilot study we did not go for a full design but instead designed a vertical prototype with the functions that were needed for the test. With regard to these functions, the prototypes were considered as high –fidelity prototypes (15).

2.2 Materials

2.2.1 Prototype 1

Prototype 1 was a Wacom CintiQ 21UX screen with a pen input. The screen had its own pen-stylus. The screen was connected to a laptop which ran the software. The interface had the option to contour the images either on the axial plane or the user was able to switch to all the three orthogonal planes (axial, sagittal, coronal) and could contour in any of these planes. Also, there was an option to visualize the 3D volume that was generated based on the contours, or alternatively fill in the 2D contour in the 3D view to enable a better interpretation of the 3D anatomy (Figure1).

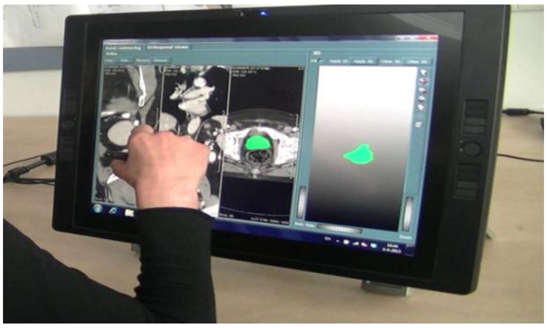

Figure 1: Contouring on Prototype 1 :

The last sub window with a green colour indicates the 3D contour filled volume without any anatomy. So either 2 or 4 sub-windows with axial and 3D contour volume sub-windows or axial, coronal, sagittal and 3D volume sub-windows were shown.

2.2.2 Prototype 2

Prototype 2 was a Windows 7 tablet of 10 inches and was also connected to a 13.3 inch computer screen. The tablet had a pen input but in this case it was a common type of pen which could be used in all tablets. As the tablet had a touch screen the users could use their fingers for contouring. Both the tablet screen and PC showed three sub-windows; the first visualized the plane which the user selects; the second one was for viewing the 3D image volume and the third one visualize the 3D contoured volume. Both the prototypes had Mevislab 2.2.1 as the platform for programming. Prototype 2 used NDI Aurora technology for tracking (16). A sensor was attached to the tablet, which enables the user to select different planes on the tablet by rotating. Upon finding a desired plane, the user was able to stop the navigation mode lay down the tablet on the table for contouring. The tablet was connected to the computer screen such that the images on the tablet appear on the screen as well, for better visualization of the images. Two different anonymised patient datasets were used for each prototype. Prototype 1 had whole CT data from the brain till feet. The other dataset were restricted only to the abdominal region. Prototype2 had the same interface options as Prototype 1.

Figure 2: Contouring on Prototype 2

2.2.3 Participants

Two annotators participated in this study. The first one was a radiation oncologist with 15 years of experience in contouring of CT images. She is a specialist in paediatric oncology. Participant 2 was a medical physician who is in her final year of medicine education and doing research in liver tumor contouring in CT images. She has only few months of experience in contouring, however, in these months she contoured hundreds of datasets. Both physicians had only previous experience in contouring orthogonal views, mostly in the axial view.

2.3 Method

2.3.1 Experimental task

Task1 was to manually contour the prostate using Prototype 1. The participants had to contour on the prostate images in whichever manner they liked. The second task was to segment the bladder using Prototype 2. The reason for selecting the bladder was that it is one of the organs which could be easily contoured on any plane which the physicians have never used before because of its spherical shape. They were explained how to use the prototype and instructed to use a small number of oblique planes for contouring.

2.3.2 Test setup & protocol:

The test was conducted in a large meeting room, where the prototypes were placed in the opposite ends of the room far from each other. There were two test leaders assigned to the two participants. Both participants performed both tasks switching places. Thinking aloud, semi-structured interviews and guided expert discussion were used as testing methods. Video-recording was used for detailed analysis of the study.

Before performing the tasks participants were given a very short demonstration of the two prototypes in which their functionality was explained and questions were addressed. Each task took 10 minutes on average and the whole study with breaks and end discussion took approximately an hour.

3 Results

1)Analysis of anatomy

Prototype 1	Prototype 2
Quite easy to understand the anatomy in 2D planes because the viewing of slices was similar to that of daily routine. But the users had to mentally reconstruct the 3D anatomy because only the 3D filled contours were visualized on the screen and not surrounding structures.	Easy to understand the anatomy in orthogonal planes. But subjects had to imagine on their mind about the non-orthogonal planes, to understand the anatomy. 3D volume window helped the users to select the plane in the non-orthogonal view.

2) Contouring

Prototype 1	Prototype 2
Very confident and easy contouring in all 3 orthogonal planes. Participant 1 expected interpolation of contours on the next slice which was not provided. Contour filling was much appreciated.	Easy contouring in standard view. Even though it was difficult to understand the anatomy in non-axial views, both users managed to contour in 2 slices. Participant 1 expected to select a single contouring plane direction and to contour that plane, which was not an option in our prototype.

3) Interactions

Prototype 1	Prototype 2
Use of pen and screen is very intuitive. The users preferred the 2D and 3D images with contours, on the same screen. Filling of contour volumes was seen only in axial plane, but the users expected it to appear in all the 3 orthogonal images.	Concept of tablet was much appreciated by user 1. User 1 prefered to use her finger for contouring over using a pen. Cannot discuss anything about contour filling because both the users did not reach to that point as the task time was restricted to 10mins.

4 Interpretation

From the results it could be seen that Pen-Tablet interaction is a good starting point in radiotherapy contouring. Even though physicians gave preference to Prototype 1, the concept of Prototype 2 also had several advantages.

4.1.1 Interpretation of the anatomy

Normally, physicians use orthogonal slices of CT datasets to check the tumor and to see which slices need to be included for contouring. The use of non-orthogonal planes was cognitively demanding as the users often had to mentally reconstruct the 3D picture. Both participants started with the axial slice and then tried to rotate to get different planes in view. The reason for starting with axial plane might be that both users are used to view the images only in the axial plane. It has been found from the study by Varga et al. that the main strategy of physicians at first is to select an orthogonal slice which they are familiar with as a basis and then rotate to an oblique slices. But then it was assumed that rotation angles further away from well-known planes are more challenging (12).

4.1.2 Contouring

Both users found it very intuitive to contour on Prototype 1. User 1 expected the extrapolation of the contours on the every next slice. Prototype 2: it was assumed by the author that the user could visualize the tumor on the screen in any direction in 2D slice and could find the largest diameter of the targeted organ easier to contour on it. However, user 1 started with the same idea but she expected that the design might be similar to the study by Sowell et al. where the user could select a largest diameter plane and freeze it and could navigate back and front on the same plane. This might help the users to interpret the anatomy well and the contours easily. The 3D contoured tumor volume was cognitively demanding because the participants had to mentally imagine the anatomy around the volume. However, we believe that this problem can be resolved by better interaction design as well as by training.

4.1.3 Interaction

Both of our participants are used to contour with mouse and they had no experience in contouring with a pen. As both of the prototypes used pen contouring, the physicians preferred the pen which came with the Wacom tablet as it had a fine tip and it was easy to use. Physicians suggested that they prefer to have many options like contrast adjustments, zooming, panning etc., which may be controlled by pen, instead of going to the menu on screen and clicking on the screen every time. User 1 who has many years of experience in contouring with a mouse, preferred the concept of the tablet-pen and finger interaction. More testing will be done with the pen and finger interaction, to test the accuracy while contouring.

4.1.4 Reflections on the study

Different behaviours were observed when comparing the two participants, which is probably related to their experience. The participant who had more experience, was less explorative with the prototypes and to search functions. She was searching for user interface elements which she uses in her daily practice. On the other hand, the less experienced participant was more explorative and found all the functions by herself.

4.1.5 Future research

As this was a pilot study of the prototype, not much practice sessions were given to the users and also the number of users and number of cases was very limited. And also we used a vertical prototype and not a complete design. Hence, our future research will focus on conducting a proper usability trial after improving the prototype design, with a few minutes demonstration of the basic functions and also including some of the ideas given by the participants like selecting a single plane and contouring in that plane, using tablet-pen and tablet-finger contouring etc.

4.1.6 Conclusions

From our study it was obvious that interpretation of anatomy with orthogonal plane was very easy because the participants use this in their daily routine. But still interpretation of anatomy and contouring in non-orthogonal plane using a pen-tablet is possible if enough practise might be given to the users. Thus this usability study provided insight for our future research.

4.1.7 Acknowledgement

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What is Sensemaking in the Context of External Radiotherapy Treatment Planning?

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Abstract

The external beam radiotherapy (RT) is one of the medical treatments against cancer, which is changing rapidly in these years as a result of technological advancements. Despite the expected benefits of integrating new technologies, often it results in increased cognitive workload for the user. This paper describes the (a) current clinical context of external radiotherapy from the perspective of defining tumorous volumes; (b) the concepts of problem solving, decision making and sensemaking; and (c) the main cognitive processes while defining tumorous volumes in the frame of user-system-environment interaction.

1 Background

External radiotherapy (RT) is one of the medical treatments against cancer, which is to a large extent built on technology – both hardware and software. Although the importance of software solutions is increasing in healthcare [1], the current technological solutions are not always fitting to the clinical situations and they also have usability flaws [2].

One of the critical tasks for a good treatment plan is to identify the tumor "correctly". Unfortunately the outcomes depend strongly on the skills of the physician and until now there is no other gold standard [3]. As a result, for some types of tumors there is large inter-observer variability (expressed by metrics such as volume comparison, center of the volume, concordance index etc. [4]) between experts.

In order to precisely identify the tumor, the physician has to build a good understanding of the characteristics of the tumor and the anatomy of the patient, based on medical images, which inherently have a high level of uncertainty. In terms of RT treatment planning the location and the shape of the tumor is identified by different target volumes (see Figure 1): macroscopic spread of the tumor as the gross target volume (GTV); microscopic spread of the tumor as the clinical target volume (CTV); the predicted movement of the tumor inside the patient's body during treatment session as the internal target volume (ITV); and the predicted deviation of patient's position during treatment session compared to the planning position as the planning target volume (PTV).

Morphological (CT, MRI) and functional (PET) images – acquired from the patient's body – are used in order to identify these different volumes. Even though the technology has advanced significantly in the recent years, the borders/edges of these volumes are still not always clear on these images.

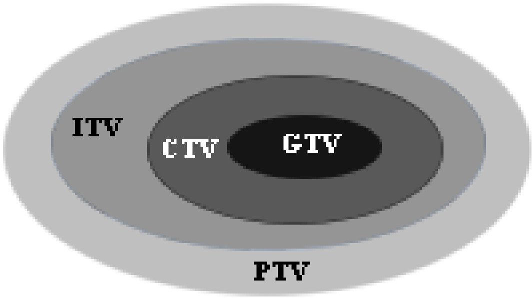

Figure 1 Target volumes in relation to one-another in 2D view

The medical knowledge regarding tumors is constantly growing and new strategies for better treatment planning and dose delivery are researched (e.g., adaptive radiotherapy, "dose painting by numbers" [5]). This creates a situation where already complex treatment planning, including the process of defining target volumes, is becoming even more complex and the existing solutions are no longer sufficient to support the radiotherapy team in a usable way. The SUMMER project aims to "blend the information in a comprehensible way, and to provide control of multi-modalities in one location" solution [6].

The basis of the radiotherapy treatment planning is defining precisely the target volumes and also the relevant organs at risk (OARs). While the organs can be mostly identified based on the anatomical knowledge, identifying the target volumes requires much more cognitive work since there are significantly more variables for the clinician to take into consideration. A well-designed ergonomic software solution is needed in order to decrease the cognitive workload. Such solution should increase the accuracy of the target volume, the user satisfaction, support decision making and consequently improve the patient outcomes. Therefore the main design question is how to support the sensemaking of existing data in order to identify the relevant target volumes through design.

2 Methods

Ethnographic studies were conducted in combination with workflow analysis in order to identify the context for design. Selective literature review was conducted to bring in theoretical knowledge from cognitive science

Ethnographic studies were conducted in the form of naturalistic observations (~40h) in a radiotherapy department of a French hospital and semi-structured interviews were held with various RT team members. The field notes and interviews were then used as an input for **workflow analysis**.

The first step of workflow analysis was to create a visual representation of the current tasks which was then presented to the medical staff of the same hospital and the project members and improved iteratively. As part of the workflow analysis, hierarchical task analysis [7] was conducted, starting with the high level tasks.

Selective literature review primarily focused on two aspects:

- Problem solving and decision making mostly in clinical context. (*Scopus: (TITLE-ABS-KEY("decision making") AND TITLE-ABS-KEY(health OR medical OR medicine OR clinical)* returns 200'200+ results) and problem solving (*Scopus: (TITLE-ABS-KEY("problem solving") AND TITLE-ABS-KEY(health OR medical OR medicine OR clinical))* returns 24'100+ results)
- Identifying leading theories of sensemaking. (*Scopus: TITLE-ABS-KEY(sensemaking OR sense-making) returns 2'300+ results*)

The results were explored by publication date, citation count and subject area, based on which the most influential publications were reviewed further. In addition Google

Scholar was used to search for other types of publications (e.g., books, conference papers).

3 Results

Ethnographic studies

From the ethnographic studies the understanding of the working environment was built. Some of the most important aspects related to the task of identifying the target volumes are following:

- At the time of defining the target volumes and also the OARs, all the relevant data about the patient is already gathered.
- The tasks of defining the target volumes and OARs are divided based on the skills required for the specific case (e.g., medical resident or attending physician) and organizational set-up (e.g., technician or physician).
- Validating (checking and accepting) the outcome of each task is of high importance for patient safety management.
- The tasks are performed either individually (initial volumes definitions) or collaboratively (discussion on where the volumes need corrections).
- At any given time there may be interruptions. For instance radiation oncologists often carry their telephones with them and may be called to treatment room or may be called to consult about another patient.
- Multiple software solutions may be used in order to perform tasks in the most efficient way.

Workflow analysis

The RT treatment planning process consists of multiple linear steps, for several of them the time-efficiency and the effectiveness leave much room for improvement [8].

In order to define target volumes and OARs, some of the main cognitive tasks, which in turn will require physical actions, were defined as:

- Building mental image of the body based on the medical images;
- Processing all information from reports;
- Understanding the visible macroscopic area of the tumor in order to define the GTV;
- Understanding the microscopic spread of the tumor, which is not visible on the medical images but is known from medical research (and the resulting publications) in order to define the CTV;
- Understanding the potential movement of the tumor within the patient's body in order to define the ITV,
- Deciding on the required margins in order to compensate for the treatment positioning uncertainties, in order to define the PTV;
- Identifying the (volumes of) the organs at risk which need to be spared from irradiation as much as possible;

The cognitively difficult part in defining these various volumes is not gathering the needed information, but it is in understanding the relevant parts of all this information.

Currently in clinical practice, volumes are mostly defined by contouring the volume borders on multiple 2D slices from the 3D images set. There are different tools in different software solutions to support this tedious process (e.g., 3D ball, interpolation between slices, atlas-based automatic segmentation) but they have not been sufficient to reduce the time-efficiency to a satisfactory level.

Decision making and problem solving

The two most researched cognitive processes in the context of healthcare are decision making and problem solving. In order to support these cognitive processes with a design solution a full understanding of them in the design context is needed.

In the view of human as an information processing system, problem solving has been defined as the search in the problem space (consisting of an initial state of knowledge, a set of elements, a set of operators and the total knowledge available) in order to reach the goal state [9]. A more general understanding is that problem solving is the process of finding possible solutions. At the same time decision making is about judging the possible solutions and choosing one of them. As such, problem solving typically culminates with decision making.

Problem solving research in healthcare was initially focused on describing the reasoning by expert physicians [10] while decision making research was mainly focused on identifying the deviation from the optimal solution [11] by analyzing the reasoning process.

Sensemaking

The selective literature review identified the leading theories in sensemaking. Sensemaking is researched in different domains since 1980's, which results in different views and understandings in what is the definition of sensemaking. The most referred theories come from the communication/knowledge management and organizational science.

- Organization science - Weick [12] defined sensemaking as "the making of sense" and defined it with seven characteristics: "grounded in identity construction"; "retrospective"; "enactive of sensible environments"; "social"; "ongoing"; "focused on and by extracted cues" and "driven by plausibility rather than accuracy".
- Communication/knowledge management - Dervin [13] developed Sense-making framework which is built on the assumption that "humans live in a world of gaps: a reality that changes across time and space." Furthermore "the Sense-making metaphor forces us to attend the possibility of change [and] this forces our attention to human flexibilities and fluidities as well as their habits and rigidities."

The main theories rooted in the domain of computer science are:

- Decision making/artificial intelligence - Klein et al. [14] developed a Data/Frame theory of sensemaking: "frames [*stories, maps, etc.*] shape and define the relevant data, and data mandate that frames change in non-trivial ways."
- Human-computer interaction – Russell et al. [15] define sensemaking as "finding a representation that organizes information to reduce the cost of an operation in an information task. The product of learning loop is the representation and encodon [*instantiated schema*] set".

4 Interpretation

Applying the knowledge from cognitive science or any other domain to solve a specific design problem is not a trivial task. In the previous section a brief overview of relevant cognitive theories for the task of defining target volumes and surrounding organs' volumes have been described.

The identification of the target volumes is an ill-defined problem. Even though the end goal is clear there are several paths to a solution and there can be several different outcomes depending on the problem solver. In contrary, a well-defined problem would have only one solution (e.g., solving a puzzle). Furthermore, the problem solving task defining target volumes happens at different levels, on individual level as well as on collaborative level while taking into consideration organizational and other existing regulations.

Newell and Simon's [9] model of problem solving, finding a solution strategy by choosing between operators in order to move from one state to another within a problem space, does not encompass the concept of comprehension building. In such a view of problem solving, the comprehension is seen as a preceding process to problem solving and decision making [16]. Even though this information processing theory is clear when it comes to well-defined problems with one outcome as solution, it is not that obviously with ill-defined problems [17].

A wider view on problem solving defines the core activities of complex problem solving as "data ordeals", "wayfinding" and "sensemaking" [18]. Similarly problem solving has been described as a combination of "information foraging loops" (processes aimed at seeking information, searching and filtering it, and reading and extracting information possibly into some schema [19]) and "sensemaking loops" to perform a task [20].

To the contrary to the usual ill-defined problems, in target volumes' identification the difficulty for the user is not in gathering the right data, but it is in understanding the existing data and making "good" sense out of it. Providing the relevant data in the right way and at the right moment is the biggest design challenge. Previously mentioned theories of sensemaking help the designer to think of different aspects while designing an ergonomic solution, but in their original form they are not easily applicable for such a specific design problem.

Sensemaking as a cognitive process has not been clearly defined – in some views sensemaking and information seeking have been coupled for years, but recent advancements identify that information seeking and sensemaking are separate though interconnected processes [21]. Figure 2 attempts to position the cognitive process of individual sensemaking of ill-defined problems. Previously mentioned sensemaking theories describe both external as well as internal aspects (e.g., "being retrospective") of sensemaking. In this paper the internal aspects will not be covered.

User-system-environment interaction from sensemaking perspective

Ergonomics (or human factors) is the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system [22]. In the context of radiotherapy treatment planning, the interaction is between one or more users and software-hardware system. The soft-ware-hardware system often consists of multiple software solutions and many of them require a separate set of hardware (e.g., PC, keyboard, mouse).

Usability has become an essential requirement for any product design, unfortunately it seems that there is still room for improvement within healthcare systems [23]. One of the reason for usability problems is the mismatch between the designers intent and the user's goals - the gulfs of execution and evaluation [24]. Therefore in order to design the system fitting with the user, knowledge is needed on each aspects of use – cognitive aspects as well as physical and environmental aspects.

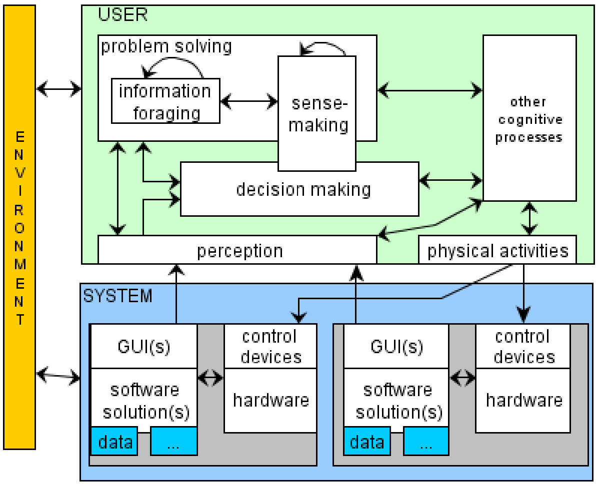

Figure 2 External aspects of individual sensemaking

In the task defining target volumes within the context of external radiotherapy treatment planning, the key cognitive processes which need support are problem solving (consisting of information foraging and sensemaking loops) as well as decision making. For instance, the cognitive aspects can be described with the following actions:

- Information foraging – reading the images of the patient and manipulating the display of them (e.g., changing contrast level), creating mental images of the perceived data, cognitively combining information from different sources into mental images and models. The main user intent is to have the right information.
- Sensemaking – interpreting the medical images and textual reports based on the mental images and models, hypothesis generation of the target volume border location, evidence finding to evaluate the hypothesis. The main user intent is to understand the information in a right way.
- Decision making – choosing where to contour, deciding if the contours need adjustments. The course of action can be either to take no action (contours are accepted), look for further information (return to information foraging) or by contouring (matching the contour to the hypothesis made by physical action). The main user intent is to decide on the right course of action.

As these cognitive processes have different user intents, they also need different design approaches. In order to support the information foraging, best practices and knowledge from information seeking and presentation theories are needed (e.g., the control devices need to support intuitive retrieval of data as well as fast way to manipulate how the data is shown). At the same time, the way the information is shown on the GUI contributes significantly to how sense is made out of the data. Moreover the software-hardware system has to support taking proper intended physical action (e.g., drawing the contours exactly where intended).

The user is part of the working environment and as such the surrounding working atmosphere has its influences. In addition quite often there is collaboration happening between colleagues in order to perform the task. As such further investigation is needed on how collaborative sensemaking influences the individual sensemaking and how design can support both in order to achieve the best outcomes in defining the target volumes and organs at risk.

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Cognitive task analysis and prioritization to improve image guidance of TIPS.

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Abstract

TIPS placement is one of the most technically challenging procedures in interventional radiology. During TIPS, limited image guidance (IG) is provided, especially during the intrahepatic puncture. To develop a suitable IG system, the aim of this study was (1) to know what parts of the procedure developers need to focus to contribute to a successful TIPS placement and (2) to find possible solutions for the IG system. Action research and co-design methods were applied to define a list of 18 prioritized steps and possible solutions. All seemed to be related to the intrahepatic puncture. The results allow developers to create a system which provides complete and required support to improve TIPS. It shows that prioritizing steps with the end-user makes a development process efficient and will increase the impact of developing new medical technology.

1 Background

Interventional radiology is a medical specialisation. During an interventional procedure, the interventional radiologist (IR) makes little incisions in the patient's neck or groin to insert long, thin instruments in the patient's body. To operate, the instruments are navigated through the patient's body. Radiological images (e.g., fluoroscopy) are used to guide the IR during the procedure. Even though the interventions have a minimal invasive character, the support from the image guidance (IG) can be very limited, making the procedures extremely challenging and causing a lot of (unnecessary) risks. Especially for transjugular intrahepatic portosystemic shunt placement (TIPS), an improvement of the IG systems is needed. TIPS is a lifesaving procedure, but also one of the most technically difficult procedures in interventional radiology. During the procedure, a shunt is created between the two veins in the liver (portal vein (PV), hepatic vein (HV)) to decrease high blood pressure in the PV. Mainly when puncturing through the liver into the target PV, physicians have difficulties to see where to puncture [1].
Our multidisciplinary research team consists of engineers, human factor experts and physicians. The team aims to improve IG during TIPS using real-time three-dimensional ultrasound (real-time 3D US) as the main modality [2]. To facilitate better guidance during TIPS, our team should know what to improve and how to improve the new IG system. Unfortunately, the minimal invasive character of TIPS makes observing and understanding the complex procedure difficult. The procedure is primarily performed inside the covered body of the

patient and decisions are made inside the physician's head. As a result, the required system improvements are hard to unveil [3].
The team applies action research [4] to unveil the system improvements. In previous research, a detailed task analysis of TIPS was conducted [3]. During the analysis macro steps were distinguished. A macro step is, for instance, the step 'catheterize the HV'. The steps can be observed and verbally identified. The building blocks of macro steps are micro steps. A micro step can be a micro questions in the mind of an IR (e.g., what is the position of the needle relative to PV?) or a micro action performed by the IR (e.g., position the needle towards the PV). Micro steps are elementary, small, hard-to-express, unobservable steps [3]. Micro steps form a comprehensive set. Overall, to execute safe navigation and treatment within the patient's body no micro step can be eliminated. Unfortunately, to several of these micro questions the current IG systems do not provide answers. Cuijpers et al (2012) revealed 64 mental micro questions for TIPS, and discovered that for 26 out of 64 questions, the IR can find the proper information to answer the question. For 31 of the questions no answers can be found at all, and for the rest support is limited. This means that IRs are often forced to base decisions on their own knowledge of the anatomy and procedure. In the same study the puncture from the HV to the PV (called intrahepatic puncture) was identified as the most crucial, but complex macro step [3]. This is also the step in which most complications do occur [5].

To develop a support for all the 38 identified and poorly supported micro questions at once would be too ambitious. Therefore, we decided to prioritize the micro questions. As mentioned by Freudenthal et al (2008), improving one part first and gradually expanding the improvements allows medical professionals to steer the system in the desired direction and it thus allows developers to make a suitable solution. We wanted to know which part of the procedure should be improved first for maximal impact regarding patient safety (Patient safety being effective treatment as well as avoiding any unnecessary complications). Unfortunately, an overview of priorities was unavailable. Therefore, the aim of this study was (1) to know on what micro questions developers need to focus to contribute to a successful TIPS placement and (2) to find possible solutions to create a suitable IG system.

2 Methods

Methods were used to (a) expose the macro steps and related micro questions; (b) prioritize the micro questions; and (c) generate possible solutions.

(a) Ethnographic techniques are commonly used by designers for task analysis [6]. The techniques help to gain understanding of the procedure, context and users (see [3][6]). The techniques were used during 42 interventional procedures, of which 8 TIPS procedures.

(a) Generative sessions were conducted with six IRs of four different hospitals. The session gave insights in physicians' tacit knowledge [7]. The sessions made considerations, needs, and values more explicit and open to discussion (see [3]).

(a) From the results of the generative session a list of all recognized micro questions of the intra-operative procedure was created (also see [3]). The micro questions were divided in five macro steps, one cluster of macro steps and a 'general' step:

- (1) Navigate from the jugular vein to the HV;

- (2) Catheterize the HV;

- (3) Intrahepatic puncture: puncture from HV to PV;

- (4) Control the intrahepatic puncture;

- (5) Catheterize the PV;

- Balloon placement, stent placement, check and closure;

- General

Some macro steps were clustered, because they do occur after the intrahepatic puncture and when stable access to the PV has already been gained. For these macro steps, a clear protocol is available. To perform the steps before the cluster is more challenging and requires more experience. The 'general step' involves all micro questions which are more or less performed throughout the whole procedure. For each defined question, the researcher wrote down if support is currently provided and sometimes extra remarks.

(a) Validation list: the list was sent to an IR who had experience of performing TIPS. He was asked to check the list, add comments, and to provide input for unclear parts. Based on his feedback, the list was revised and completed. When comments remained unclear or contradictory, the IR was reconsulted.

(b/c) Prioritize: one workshop and several discussions were held. These were held to validate the most critical part(s) of the workflow, to prioritize the micro questions, and to understand what and how support could be provided for the micro questions.

- Workshop: the researcher visualized the workflow (macro steps) on an A0 sheet. The micro questions which urgently need help were added as well. During the workshop the workflow was discussed with the multidisciplinary research team. Missing micro questions were added and the members were asked to define the macro steps or micro questions for which most improvement is needed. Subsequently, the participants had to pick a defined step or question and create possible solutions. Finally, the team discussed the outcomes. The results helped the researcher to validate and prioritize the micro questions and to define preliminary ideas.

- Discussions: held with multidisciplinary team and two additional IRs. During the discussions the focus points were validated and possible solutions for the micro questions were discussed. The outcomes were used to complement the list.

(b/c) Final validation: based on the outcomes of the workshop and discussions, a list of prioritized micro questions and possible solutions was created. For final improvements, this list was sent (together with the original, complete list) to the interventionist in training (member of the team, and has experience of performing TIPS).

3 Results

The list (table 1) shows that 18 of the 64 questions most urgently need help. For five questions, information is available, but could be improved or made more easily available (column 3 and 4, table 1). This subset was chosen with the idea that support can be provided without changing the whole procedure. Especially the IRs emphasised the need to only improve a distinct part of the procedure and leave most of the intervention unchanged (for now).

To improve TIPS in particular the micro question(s) of the steps *(3) Intrahepatic puncture* and *(4) Control the intrahepatic puncture* and of *General* should be improved first. These steps are the most crucial, but involve little information. This makes completing them very challenging. All need to be improved to provide complete guidance during the intrahepatic puncture.

Possible solutions to support the micro questions (in bold the solutions from column 5, table 1):

- Trajectory Planning: the IR can pre-operatively plan TIPS placement (by assigning **navigation landmarks** in the user interface (UI) and choose a suitable puncture **trajectory.** The trajectory should be visualized on the UI of the IG system. **Details** about critical **structures**, cirrhosis, and distances etcetera should be presented as well. Computed tomography (CT) or US can be used to provide those details.
- Free Selectable Plane: Real-time 3D US was chosen because it allows to select any **free plane** in a generated 3D volume (see [2]). Furthermore, US visualizes the veins (which are key in TIPS) and **anatomy** and the **instruments** in **real-time.** Before the procedure (e.g., during trajectory planning), IRs should be able to freely select the planes they desire to see during the procedure. During the procedure, the system should be able to visualize these planes when needed, in the -for IRs- preferred way. Catheters need to be tracked (e.g., electromagnetic tracking) or redeveloped to make them visible under US. The IR should always be able to interact with the planes; for example to tune the planes and to re-plan the procedure. If desired, artificial **landmarks** or required elements from CT or other pre-operative image could be **added** to the US planes.
- Intra- operative workflow alterations: To visualize desired planes, the 3D US probe will not be manually controlled by an additional IR (see [2]), but alternatively by a probe holder. The planes will not be generated by hand movements, but will be calculated in the US cone. The benefit of this is that visualization of planes become less operator dependent, the operating physician controls what is visualized while being able to solely focus on the procedure (not on acquiring suitable information).
- Instruments: Some problems could be solved by improving the TIPS **instruments** (e.g., steerable or predictable needles).

4 Interpretation

The results show for which macro steps and which of their micro questions sufficient support is needed to improve TIPS in the most efficient way. The physicians and the multidisciplinary team defined 18 micro questions of two macro steps (i.e., intrahepatic puncture, control the intrahepatic puncture) and a general step. By improving all 18 micro questions, the IR will be able to effectively puncture in the PV and the puncture becomes less challenging. The new IG system can be applied during these two macro steps and the remaining steps can still be conducted in the conventional way. Future research may see how much improvement can be gained from applying IG in the other steps.

Several research groups tried to improve the IG for the intrahepatic puncture. However, these IG systems answer only a few of the micro questions that are needed to perform the puncture. For example, Adamus et al. (2009) aimed to guide the puncture from HV to PV. They used two two-dimensional projections to create 3D path planning on real-time fluoroscopy. The solution helps to answer questions as 'What is the position of the needle relative to PV? and 'What is the best place to puncture the PV?' However, according to Maleux (2010) the solution does not include essential anatomical information and therefore injury may still occur. This indicates that the solution is incomplete since questions such as 'What is the 3D position of materials in relation to veins, environment of veins, structures?' and 'Will/ did I not cause collateral damage?' remain unanswered. Also for other groups (e.g., [10]) the same seems to happen (e.g., not supports the micro question 'what is the best place to puncture the PV?'). This confirms the need to improve more than only a few micro steps. It presumes that providing support for all listed micro questions of table 1 is essential, to facilitate an effective puncture, fast recovery after miss puncture, and to safeguard patient safety. The result of this paper can help research groups to make solutions more complete.

The list also contains micro questions which cannot be solved by improving the IG alone. For example, to sufficiently control the needle is challenging due to the current instrumentation. This suggests that also additional improvements are needed. A new IG system will benefit the navigation process, but additional help (e.g., improved needle) will benefit the procedure even more. Unfortunately, during our research project, we will not be able to redesign additional aids. Though, we trust other research teams to develop this idea further.

Next to a list of prioritized micro questions, the results also provide innovative solutions for each micro question in order to improve the puncture. For example, solutions which require planning do exist (e.g., [8]), but to freely select a plane is a new and promising solution. The planes will be very informative, match the needs of the IR and will probably improve the efficiency during the procedure. Technical possibilities to create the solutions are already available, making the possibility of creating the innovative solutions highly likely. For example, automatic registration between real-time 3D US and pre-operative CT can be successfully achieved (e.g., [11]). Also, registration of 3D US volumes to intra-operatively visualize the planned US planes is possible [12]. The option to track instruments on 3D US is already researched for other interventional procedures [13] and we thus expect that applying this in TIPS will be possible as well.

Although the intrahepatic puncture was defined as the most complex step [3][5], we did not research this macro step alone. Nevertheless, while 64 questions were originally unveiled [3], this paper claims that developers should focus on 18 micro questions which are all related to the intrahepatic puncture. There are several reasons for this extensive analysis. First of all, we did not want to overlook important micro questions. With the complete list we were able to judge if other micro questions could really be left out (the results show that this is not the case). Secondly, we desired to let IRs indicate the focus for system improvement. They know best for which parts of the procedure support is most essential. Furthermore, the analysis provides in depth understanding of the whole procedure (e.g., actions, thoughts, concerns, teamwork, materials used) and all small steps. As mentioned in the introduction, having an overview of all small steps and gradually improving them (e.g., by constantly checking), suits the common approach in medicine [4].

Overall, prioritizing steps seems essential during the development process. It allows creating an IG system which provides the required support. Prioritizing prevents developers to just build a fancy technological solution which is incomplete, or has functions which are superfluous. However, this process would not have been possible without applying action research and co-design. When developing new medical technology for complex procedures, the methods allow the development process to be efficient and to increase clinical impact.

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Table 1. The selected critical micro questions of TIPS. These micro questions, as a complete set, should be supported most urgently.

Macro step/task	*Relevant Micro question*	*Information available to IR?*	*Remarks*	*Possible Solutions, e.g.;*
1. Navigate from jugular vein to the HV				
2. Catheterize the HV				
3. Intrahepatic puncture (puncture from HV to PV)	8.Where is the target vein positioned in 3D?	*Limited*	*If a radiopaque marker was used, the 3D position can be required by rotation of the C-arm.*	*Free plane, landmarks*
	9.What is the position of the needle relative to PV?	*Limited*	*2D position known when using PV visualization tools. Turning the C-arm, shows 3D position*	*Free plane, real-time, landmarks, details structures, trajectory*
	10.What is the real-time 3D position of materials compared to veins, environment of veins, structures?	*No*		*Free plane, real-time, landmarks, trajectory, details structures*
	11.What is the best place to puncture the PV?	*No*	*Only based on estimation.*	*Free Plane , landmarks, details structures*
	12.What is the desired catheter shape and direction to arrive correctly at the target point??	*Limited*	*Can be estimated if aid to visualize PV is used/ the c-arm is rotated for 3D information. Otherwise, based on estimation, experience, and trial & error and only clear afterwards, when gained PV access.*	*Trajectory*
	14.How much force should be applied on the needle?	*Yes*	*- anticipate on severity of cirrhosis* *- Needle bends/curves, pops away , shoots through, or complications occur (harm to patient)*	*Trajectory, landmarks added, details structures, real-time instruments*
	15.Do I puncture in a fluent line, without a kink?	*Yes*	*- Angle of needle to PV axis* *- Angiography when stent is placed*	*Trajectory, real-time instruments*
	17.Will I sufficiently control the instrument when puncturing to the PV?	*Limited*	*-Before procedure: see cirrhosis on CT.* *-During procedure: needle movement visible on fluoroscopy provides feedback on actual density and needle behavior.* *-Anesthetist will tell if blood rate drops.* *-Blood in ascites drain* *After first puncture, acquired knowledge will help to estimate needle behavior.*	*Trajectory, real-time, instruments, details structures*
	18.How will the needle move, during each puncture?	*No*	*Estimate on experience*	*real-time instruments, instruments*
	19.Will I not puncture outside the liver?	*No*	*Estimation*	*Trajectory, free plane, real- time, added*

				landmarks
	20. Will/ did I not cause collateral damage?	*Yes*	*- Materials: shoot away* *-Anesthetist will tell the IR if blood rate of the patient drops.* *-blood in ascites drain*	*Trajectory, instruments, landmarks, real-time*
	22.How to handle complications? *Note: not thoroughly researched* Possible questions are: Where is the damage? How to repair the damage?	*Yes*	*Complications afterwards, contrast dye to find a leak, and to repair damage. If it is serious and leak cannot be found; surgeon will operate the patient and tell the IR what happened*	*Real-time, free plane*
4. Control the intrahepatic puncture	23.Did I puncture inside the PV?	*Yes*	*Feel resistance, blood aspiration, contrast dye* *- DSA with CD to see anatomy/PV*	*Free plane, details structures, real-time*
	24.Did I puncture on the edge of PV?	*No*	*guess*	*Details structures, real-time, free plane*
	26.Do I puncture the PV 1-3 cm above the PV bifurcation?	*No*		*Real-time, landmarks, trajectory*
	27.Why did I not puncture the PV?	*No*	*Guess*	*Free plane, trajectory*
	28.How can I improve my puncture?	*No*	*Estimation and background knowledge*	*Free plane, trajectory*
5. Catheterize the PV				
Place stent etc.				
General	44.What is the safest route? E.g., in case of large tumor?	*No*	*CT will help to plan*	*Free plane, trajectory, landmarks added, details structures*