

Mediate

Patient Friendly Medical Intervention

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State of the art in Interventional Therapies



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State of the Art In Interventional Therapies



Mediate: Patient Friendly Medical Intervention



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1 Introduction

1.1 Aim of activity

The goal of this document is to create a starting point for the Mediate project. For that purpose it describes the current state of the art in a number of specific Image Guided Interventional Therapies (IGIT) that are targeted by the project. The intention of Mediate is to develop new technologies that address some of the clinical problems and clinical needs that exist in the current day practice of these procedures.

Every of the targeted interventions is described in a standardized way. In the first section, a short introduction is given that provides the background & context of the procedure. The second section describes the existing way of working and the third section sheds some light on the problems that clinicians face while performing these procedures as well as the at present unmet clinical needs. Finally the last section provides a list of the clinical experts that were interviewed to collect the information that formed the basis of this document.

1.2 Contributors

Several authors contributed to the production of this document. Each of those authors was responsible for a one of the targeted procedures.

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2 Executive summary

This document provides the “State of the Art” for the clinical procedures that are targeted by the Mediate project. The goal of Mediate is to develop technologies that solve a number of problems and clinical needs.

In total 9 procedures are addressed:

- Cardiac RF ablations
- Transcatheter Aortic Valve Implantation
- Percutaneous Coronary Interventions
- Minimally Invasive Treatment: Needle Ablation
- Non-Invasive Treatment: MR-guided HIFU
- Bone tumor navigation
- Corrective osteotomy
- Innovative user interfaces in minimally invasive treatment
- Single Incision Laparoscopic surgery (SILS)

All these procedures are described in a standard way.

From an interventional perspective, 3 of these procedures are within the domain of endovascular (or transcatheter) interventions, 2 in the domain of needle punctures, 1 in the domain of planning & alignment, 1 on laparoscopic procedures and 1 in the domain of non-invasive ablations. In addition, there are more generic technology related topics. From a more clinical view, 3 of the procedures are cardio related, 4 tumor related and 1 orthopaedic. As such, the spectrum of selected topics cover a broad range of IGIT based procedures.



3 Glossary

3DRA	3 Dimensional Rotational Angiography
ADC	Apparent Diffusion Coefficient
CABG	Coronary Artery Bypass Graft(ing)
CT	Computer Tomography
CFR	Coronary Flow Reserve
CTA	Computed Tomography Angiography
CTO	Chronic Total Occlusion
DWI	Diffusion Weighted Imaging
FFR	Fractional Flow Reserve
Fr	French, a catheter scale: 1 Fr = 0.33 mm
GUI	Graphical User Interface
HMI	Human Machine Interfaces
IGIT	Image Guided Interventional Therapy
IVUS	IntraVascular UltraSound
LGE-MRI	Late Gadolinium Enhancement MRI
Mediate	patient friendly MEDicAI inTErvention
MRI	Magnetic Resonance Imaging
MR-HIFU	MRI-guided High Intensity Focused
MW	MicroWave
NOTES	Natural Orifice Transluminal Endoscopic Surgery
NSS	nephron-sparing surgery
OCT	Optical Coherence Tomography
OR	Operating Room
ORF	Operating Room of the Future
PCI	Percutaneous Coronary Intervention
PEI	Percutaneous Ethanol Injection
QCA	Quantitative Coronary Angiography
RF	RadioFrequent
RN	radical nephrectomy
SILS	Single-Incision Laparoscopic Surgery
SPECT	Single Photon Emission Computed Tomography
SSS	Symptom Severity Score
TAVI	Transcatheter Aortic Valve Implantation
US	UltraSound



4 References

None.



5 Clinical Procedures

5.1 Cardiac RF ablations

(Boudewijn Lelieveldt)

5.1.1 Introduction

Pathological disturbances of electrical activation of the heart are an important cause and consequence of cardiovascular diseases. For instance, atrial fibrillation is the most commonly encountered arrhythmia frequently initiated by atrial premature beats originating in the pulmonary veins. This may lead to less efficient contraction of the heart and thus decrease of cardiac function. It can also cause formation of blood clots in the cardiac atria. Sudden release of these blood clots in the circulation is an important cause of stroke. Spontaneous arrhythmias in the cardiac chambers (ventricles) are often caused by the presence of scar tissue due to prior myocardial infarction. These scars may disturb and slow the propagation of the electrical activation wavefront through the chambers. Ventricular tachycardias are caused by an electrical “short-circuit” through scarred tissue resulting in a disturbed and often faster electrical activation of the ventricles which may lead to reduced contraction and cardiac arrest in some patients.

Both atrial and ventricular arrhythmias may be difficult to control using medication, and therefore in many cases require treatment using catheter ablation. The main goal of these interventions is either to isolate the electrically active areas in the pulmonary veins (atrial fibrillation), or to break the electrical conduction circuit through the scar area (ventricular tachycardia). This is done by targeted heating of parts of the cardiac muscle using a catheter, with which small patches of the heart muscle can be selectively heated and thus destroyed, by depositing radiofrequent (RF) energy in the tissue. This way, the sites that cause the arrhythmia may be electrically isolated from the heart or re-entrant circuits may be prevented from occurring.

5.1.2 Current State of the Art

During RF ablation, catheters are inserted in the heart through an artery or vein in the groin, which can be followed under X-ray guidance. Both types of ablation are complicated procedures for the following reasons:

- In VT ablation, first an electrical map of the ventricle and the scar areas needs to be constructed using a mapping catheter. This mapping process is highly complicated, as it requires maneuvering the mapping catheter to many positions at the ventricular wall to measure the voltage changes in the tissue during the cardiac contraction. This is done to identify the boundaries of the scar areas, which cause the electrical short circuit in the ventricle. Only after mapping out the scar areas, the interventionalist can decide on which parts of the scar boundaries should be ablated. As in atrial ablation procedures, this mapping process is cumbersome and time consuming, leading to very long intervention times (3-8 hours). Due to the heuristic nature of the procedure, success rate greatly depends on the experience of the interventionalist to identify the ablation sites.



- In RF ablation of atrial fibrillation, the pulmonary veins need to be electrically isolated by ablating a ring around the attachment of the pulmonary veins to the atria. Due to the complex anatomy of the atria, identifying the exact location of the ablation site is highly complicated. As such, a CT scan made prior to the intervention is used to study the individual geometry of the patients' atria. This pre-intervention CT data may serve as a roadmap for identification of the exact ablation sites. The CT data is mapped to the patient anatomy based on a number of clear anatomical landmarks (coronary arteries, pulmonary veins). After registration, the catheter position can be visualized with respect to anatomy, this all in 3D. For verification of the registration, X-ray is used. This entire process is a cumbersome and time-consuming process, as a result of which the duration of an intervention may easily amount to 3-5 hours.

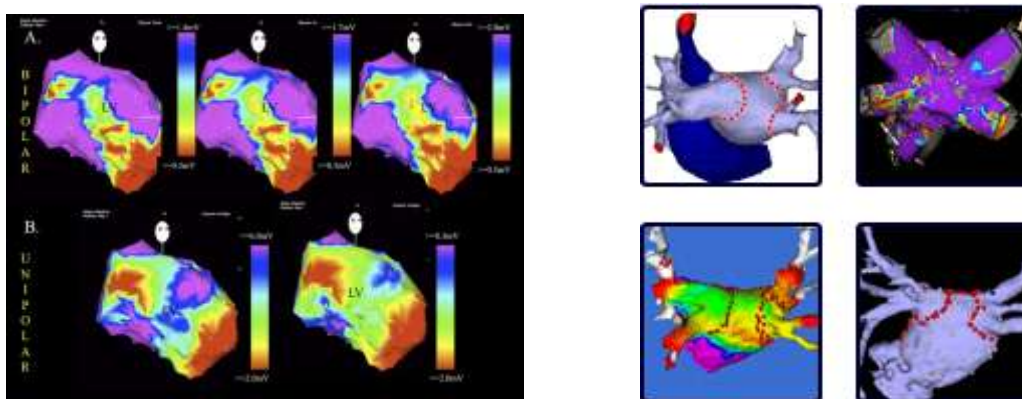


Figure 1: Example of RF ablation procedure.
Left: Electro-anatomical map constructed during VT ablation that is used to decide on the ablation sites (image courtesy LUMC).
Right: Visualization of pre-operative CT with RF ablation sites overlaid as red dots (image courtesy www.afsymposium.com)

5.1.3 Existing Problems and Unmet Clinical Needs

Due to the high complexity of both types of cardiac RF ablations, there is a great need for navigational aids that help the cardiologist in finding the proper ablation sites. For atrial fibrillation, this involves relating a model of the atria derived from pre-operative CT data to the actual patient anatomy during the procedure by registering it to interventional X-ray or rotational angiography. By overlaying this anatomical information on the X-ray, the identification and localization of the pulmonary veins may be greatly facilitated. For ventricular tachycardias, the use of pre-operative MR imaging that clearly depict the scar areas (Late Gadolinium Enhancement MRI, LGE-MRI) in the ventricles may greatly facilitate localization of the candidate ablation sites in the ventricle. Potentially, the mapping of the pre-operative LGE-MRI to the interventional X-ray images may replace the time-consuming electrical mapping of the scar areas in the ventricle. In addition, there is a great need for reliable registration and motion tracking that enables relating the pre-operative CT data to the per-operative X-ray.



5.1.4 Clinical consultants

Name	Institute
Dr K. Zeppenfeld	LUMC

5.2 Transcatheter Aortic Valve Implantation

(Pascal Haigron)

5.2.1 Introduction

Aortic stenosis is the most common valvular lesion occurring among elderly patients and has become extremely frequent because of changing demographics in industrialised countries. Surgical risk after the age of 70 has increased. Transcatheter aortic valve implantation (TAVI) has emerged as a promising alternative to conventional aortic valve replacement for patients with severe, symptomatic aortic stenosis who are otherwise left untreated due to the perceived high risk of operative mortality.

First in man TAVI procedure was performed in 2002. Approximately 14000 procedures will be performed in 2011. Today one randomized study is currently used as a clinical reference: the PARTNER study. It showed that the rate of death from any cause at 1 year among patients treated with TAVI was appreciatively 25 %.

5.2.2 Current State of the Art

Presently two TAVI devices are under post-marketing surveyance in Europe: the balloon expandable Edwards Sapien prosthesis (Edwards Lifescience, CA) and the self expandable CoreValve revolving prosthesis (Medtronic Inc, MN).

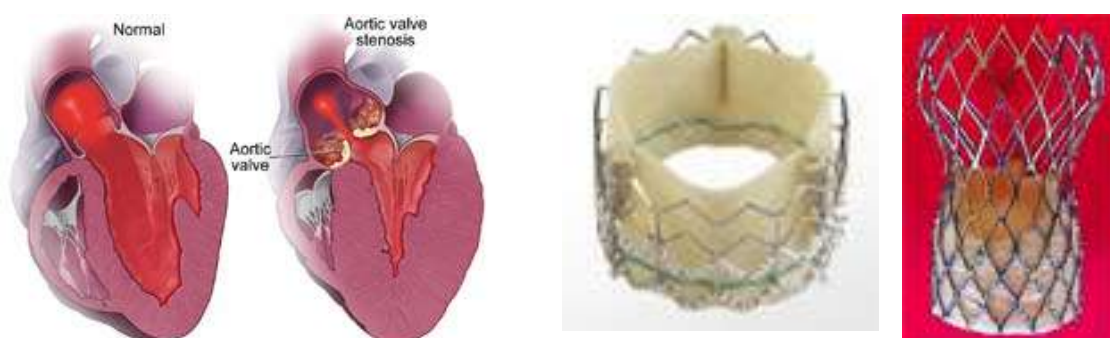


Figure 2: Aortic valve, Aortic stents: (a) Edwards Sapien; (b) CoreValve ReValving



Three accesses catheterization are described:

- the transfemoral access, the most used and applicable independently with Sapien device or CoreValve device, in a 18 Fr sheath by either a percutaneous approach or surgically,
- the transaxillary artery access using CoreValve device (18 Fr),
- and finally the transapical access using a specific Sapien device.

We focus on the transfemoral artery procedure. It is performed in a sterile environment, catheterization laboratory or operating room, with the patient under neuroleptanalgesia. Following prior catheterization to insert the stimulation lead and the rigid guidewire through a femoral access, the overall procedure consists of introducing the transcatheter valve passing through successively the descending, the ascending aorta and the native valve to finally perform the deployment of the aortic valve bioprosthesis. Characterization of the vascular access, native aortic valve and coronary arteries is currently performed interactively and carefully from pre-interventional imaging. Moreover stent valve positioning, deployment and implantation, under 2D fluoroscopy/angiography intra-operative imaging are critical and complex operations.

Today there do not exist commercial CDSS (Clinical Decision Support Systems) to support knowledge based decisions during minimally invasive surgery and other interventional procedures as it happens to support diagnosis, treatment and/or long term care. Actual support systems are more oriented to provide real-time image guidance and task automation support while the clinician is performing the intra-operative tasks.

Tendencies in interventional and surgical DSS consider the necessity to center the design on OR-workflows and context adaptability. An OR-workflow combines the information flow with the interventional process (which has to be defined or modelled). Workflow monitoring is the mechanism to continuously recognise the actual situation during an intervention with respect to the expected workflow execution.

Interventional DSS have to provide significant information, for decision making, according to current situation during the workflow execution. At this point a Case-based Reasoning (CBR) approach can be very convenient to design the DSS based on the exploitation of experiences collected during previous interventions. Under a general point of view a CBR is a problem solving methodology that consists of four basic tasks: RETRIEVE the most similar case or cases according to the actual situation (problem description), REUSE the information and knowledge in the retrieved cases to solve the problem, REVISE the proposed solution and finally RETAIN the parts of this experience likely to be useful for future problem solving. This last task gives to CBR an on-line learning capability (lazy learning) not always available in other approaches. So, cases have to be defined as previously informed interventions during the corresponding workflow execution.

5.2.3 Existing Problems and Unmet Clinical Needs

The development of this highly technical interventional practice, based on the use of flexible instruments interacting with vascular structures, imposes new demands in terms of training, planning, manipulation (reduced manoeuvrability and from a distance, intensive visual monitoring, reduced tactile feedback) and ergonomics.



Technical and clinical challenges have still to be faced including the development of efficient computer/robot assistance solutions at the early stage of the development of the endovascular interventional procedure. Computer-aided and augmented reality based planning, steering and placement of endovascular devices with flexible body is a challenging objective that may contribute to make more secure and reliable the TAVI procedure. Difficulties lie here in taking into account the deformable and moving nature of soft tissues with complex issues related to the behaviour of anatomical structures in the presence of endovascular device.

The planning phase relies on pre-interventional imaging potentially including different modalities (CT, angiography, US, MRI). It has still to be supported by operational tools to perform efficiently and objectively the analysis, quantification, measurement, and characterization of anatomical structures of interest. It is a question of segmentation of the aortic arch, heart, coronary ostia, annulus and commissures with characterization of arterial wall (calcifications) for valve sizing and therapy decision making aid including the determination of the optimal annulus plan pose.

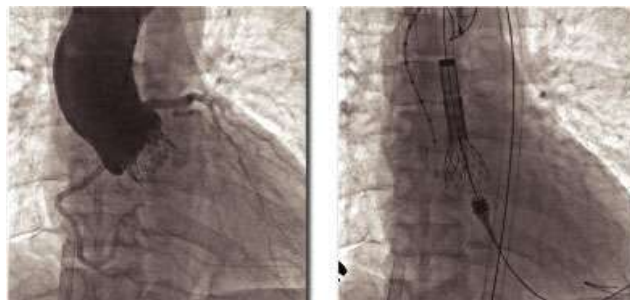


Figure 3: Placement of an aortic valve
Left: Controlled expansion of the prosthesis
Right: Control angiogram after a successful ReValving procedure

In the intra-operative phase, Angiography - Fluoroscopy is the reference technique for guiding TAVI. Nevertheless several angiographic injections are often required due to the lack of navigation tools. The objective is thus to develop efficient tools coping with difficulties in obtaining an optimal view of the native valve and the absence of reference, in navigating the transcatheter valve through the native valve and positioning and deploying the valve prosthesis precisely regarding an optimal target location.

The design of a CBR based DSS for TAVI requires a definition (modelling) of the interventional workflow and available information for monitoring. Critical stages and relevant information used in the decision making process during interventions is required to codify cases and to define metrics to implement retrieval mechanisms. Finally, CBR is based on the existence of a minimal set of cases, well documented (expertise on their interpretation for correct exploitation) and support on the identification of relevant information and feature extraction to define the appropriate metrics and CBR mechanisms.

5.2.4 Clinical consultants

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5.3 Percutaneous Coronary Interventions

(Theo van Walsum)

5.3.1 Introduction

Coronary artery disease is the major cause of death in the Western world. The main cause is atherosclerosis, i.e. a thickening of the coronary artery vessel wall. This process of build-up of fatty deposits in the vessel wall may already start in young adulthood, and continue afterwards. The continued build-up of these plaques may eventually lead to a narrowing or occlusion of the coronary lumen, causing ischemia (lack of blood supply) and angina (chest pain) symptoms. Alternatively, a coronary plaque may rupture and release its contents in the artery, causing blood clots and a sudden occlusion, potentially leading to an acute myocardial infarction (heart attack). There are several risk factors associated with the development of premature ischemic heart disease and acute myocardial infarction, such as smoking, age, diabetes, hypertension and obesity.

Percutaneous coronary intervention (PCI) is one of the treatment options for patients with chronic stable angina (chest pain due to ischemia of the heart muscle). Other options are medication, and coronary artery bypass graft (CABG). Whereas PCI is less invasive than CABG, and thus seems favorable for patients, the preferred treatment depends on various issues, such as patient characteristics and classification of a lesion, and is still subject to investigations and debate. The interventions do not cure the coronary heart disease but they are carried out to alleviate the symptoms and both have some survival benefit. For acute patients, CABG and PCI are associated with significant short- and long-term mortality benefit.

Diagnostic preoperative imaging of patients with cardiac problems involves X-ray angiography, which visualizes the lumen of coronary arteries. In this procedure, contrast agent is introduced in the left or right coronary tree, by advancing a catheter via the femoral arteries and aorta into the coronary ostium. X-ray angiography allows the quantitative assessment of the narrowing of the coronary lumen (stenosis). Coronary X-ray angiography currently is the standard modality for assessing coronary lesions, and a 50% diameter stenosis (75% area) is considered a significant lesion. However, the hemodynamic significance of a coronary lesion does not correlate well with stenosis measurements. Therefore other quantitative measurements and imaging techniques, both before the intervention (CTA, SPECT, perfusion MRI, stress echo) and during the intervention (FFR, OCT, IVUS), are nowadays investigated and employed to decide whether a lesion needs treatment.

5.3.2 Current State of the Art

The purpose of PCI is to restore the vascularization of the heart muscle by widening stenotic lesions in coronary arteries. To this end, a stent is placed in the coronary



artery, possibly after prior dilation with a balloon. The procedure is performed minimally invasively, often via the femoral artery (but also via brachial or radial artery). First a guide catheter is introduced, such that the distal tip of the guide catheter is in coronary tree, to provide a safe access of the guide wires and catheters to the coronary arteries. Subsequently, a guide wire is inserted through this catheter, and advanced beyond the lesion. Optionally, additional intravascular imaging or measurements (IVUS/OCT/CFR/FFR) may be performed to assess the hemodynamic significance of the lesion or the composition of the plaque. Next, if dilation of the lesion before stent placement is needed, a balloon catheter is advanced over the guide wire, positioned at the lesion spot in the coronary artery and inflated to dilate the artery. After dilation, a catheter with a balloon-mounted stent is advanced over the guide wire. When the stent is located at the lesion spot, the balloon is inflated to deploy the stent. After stent deployment, the balloon catheter is removed.

Image guidance during the procedure is performed by mono- or biplane fluoroscopy (see Figure 4), which visualizes the guide wires and catheters (some of which have additional markers for improved visibility). The coronary arteries are visualized by injections of contrast agent, which result in a transient visualization of the vessels. Optionally after the stent placements, the stent deployment is checked by using IVUS or OCT. If struts are not positioned correctly against the lumen wall, a second balloon inflation might be needed to place the struts correctly for a better end result of the procedure.

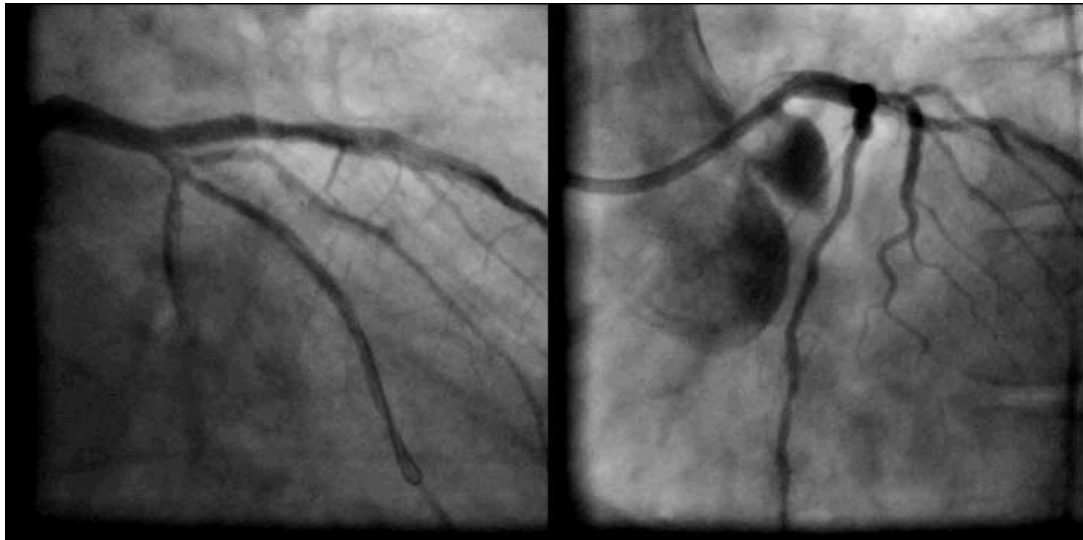


Figure 4: Biplane image of coronary intervention (Image courtesy Erasmus MC)



5.3.3 Existing Problems and Unmet Clinical Needs

There are still several challenges in the treatment of coronary lesions via PCI. The first challenge is related to the diagnosis and planning of the therapy. Several patients with advanced coronary artery disease have multiple lesions. Currently, the reference standard for determining the significance of a lesion is a stenosis measurement on angiographic images QCA. However, this is a morphological measurement on projection images, which does not always associate well with the hemodynamic significance of a lesion, i.e. it does not always predict well whether treatment of the lesion will reduce the symptoms. Additionally, revascularization of myocardium is not relevant if it is not viable anymore. Several imaging technologies are being explored to provide improved classification of the lesions, both by pre-operative imaging (MRI, CTA) as well as during the intervention (Rotational X-ray, FFR, Doppler CFR).

Another challenge is to determine the characteristics of the plaque: vulnerable plaques, i.e. plaques that may easily rupture and cause acute myocardial infarction, are more in need of treatment, whereas stable plaques are less dangerous. Also here the value of various pre-operative and interventional imaging modalities is under investigation (CTA, 3D Rotational X-ray, OCT, IVUS).

A third challenge is the guidance during the intervention. Whereas the success rates of normal PCIs are very high, there are still several factors that may dramatically reduce the success rates. The most important difficulty is the treatment of chronic total occlusions (CTOs). Interventional treatment of these lesions is difficult, as it is hard to move the guide wire across the lesion. Also the lesion itself cannot be visualized adequately during the intervention, as contrast agent will not flow into such an occlusion. Interventional treatment of these lesions is associated with a significantly higher radiation dose and use of contrast agent. Heavily calcified lesions and lesions at bifurcations or with sharp bends are more complicated and also have lower success rates. In all these cases, it is expected that improved guidance, e.g. by providing 3D information on the vasculature, plaques and calcifications during the intervention, may improve procedural outcomes, and additionally reduce both contrast usage and radiation dose. Techniques to integrate these types of information from pre-operative 3D images are currently being investigated.

5.3.4 Clinical consultants

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Robert-Jan van Geuns, MD, PhD	Erasmus MC

5.4 Minimally Invasive Treatment: Needle Ablation

(Niels Noordhoek)

5.4.1 Introduction

Tumor ablation is still associated to a relatively high recurrence rate when compared to surgical resection. The two main challenges are in the treatment of intermediate



and large tumors and in the achievement of accurate and reproducible applicator placement. These procedures provide a great opportunity for imaging and device companies to improve tumor targeting and treatment monitoring.

Ablation will also be used in combination with other therapies (i.e. with external beam radiation for lung lesions) and its competitive role with respect to surgery will continuously be subject of debate. New platforms such as microwave ablation will aim at overcoming the main limitations of early RF ablation technologies, including heat sink effect, seeding and tumor size (>3cm).

5.4.2 Current State of the Art

A number of ablation types currently exist:

- Radiofrequency (RF) ablation: RF ablation involves the use of electrical currents in the range of RF waves through a needle that heats and destroys cancer cells. The objective is to ablate the tumor and a rim of normal tissue around its edges.
- Microwave (MW) ablation: MW ablation induces thermal coagulation of tissue using microwaves. The ablation diameter is less than with RF ablation but multiple needles can be used to achieve larger ablation volumes. Tissue ablation is achieved in shorter time when compared to RF.
- Cryoablation: cryoablation is the use of freezing gas circulating within a needle in a tumor to kill cancer cells in freeze/thaw cycles. Several needles can be used in parallel and the development of the ablative ice ball can be monitored with CT/MR/cone-beam CT.
- Percutaneous ethanol injection (PEI): PEI involves the percutaneous injection of pure alcohol to kill cancer cells. Alcohol induces tumor destruction by drawing water out of tumor and thereby altering the structure of cellular proteins.

The typical steps in tumor ablation are reported in the following diagram.

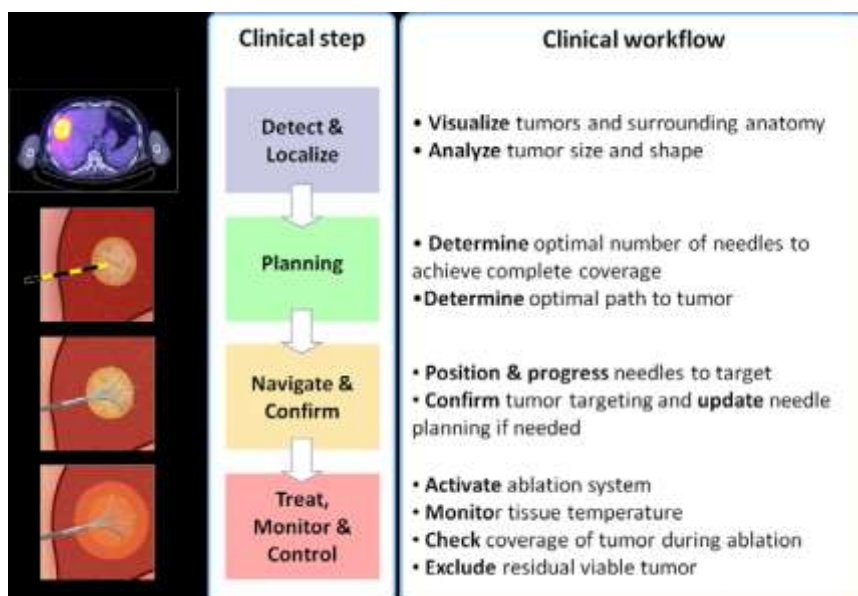


Figure 5: Workflow diagram of tumor ablation procedures



Ablation are mostly used on tumors in liver, lung, kidney, bone, prostate.

5.4.3 Existing Problems and Unmet Clinical Needs

The most prominent problems and unmet needs are presented in the following diagram.

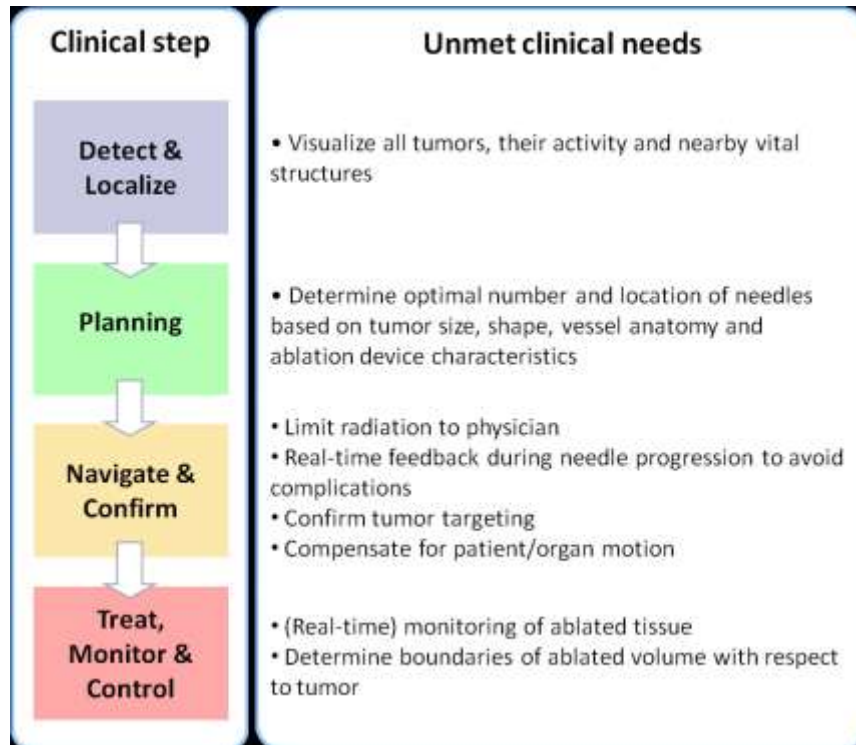


Figure 6: Unmet clinical needs in tumor ablation procedures

5.4.4 Clinical consultants

These data have been obtained through the network of Philips Healthcare Clinical Science, consulting key opinion leaders and by clinical and marketing literature studies.

5.5 Non-Invasive Treatment: MR-guided HIFU

(Koen Vincken)

5.5.1 Introduction

High Intensity Focused Ultrasound is one of the first fully non-invasive procedures for tumor ablation. In MRI-guided High Intensity Focused Ultrasound (MR-HIFU), the



ultrasound energy generated by the transducer is focused into a small volume at specific target locations inside the tissue (see Figure 7). Outside the focus, the ultrasound beam penetrates through soft tissue without causing tissue damage, but within the focus the ultrasound energy density is so high that high temperatures (55°C to 70°C) can be reached. In this way, a thermal dose which causes irreversible cell damage and coagulative necrosis can be delivered precisely to the target. In MR-HIFU, MRI is used for accurate treatment planning, for guidance of ablations using MR thermometry and for evaluation of treatment results.

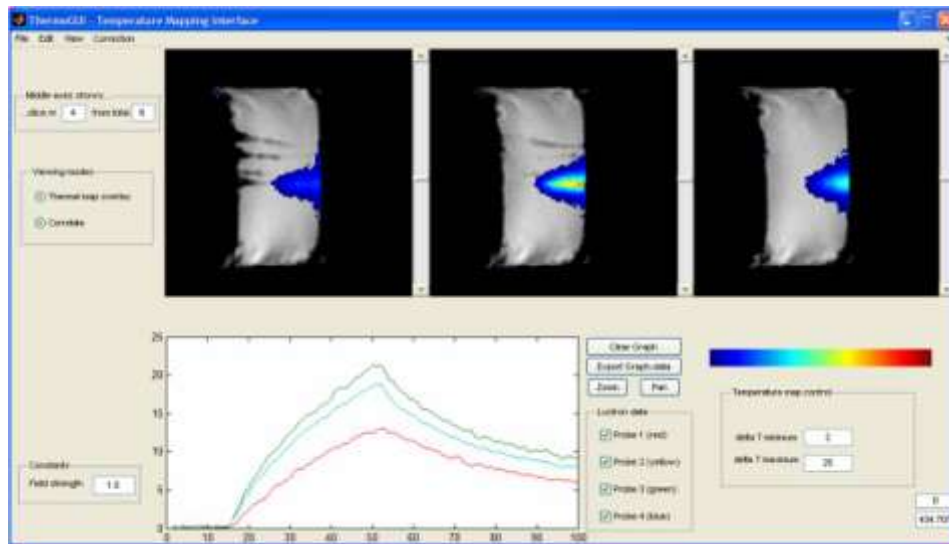


Figure 7: Example of a HIFU temperature map

Promising results have been obtained with MR-HIFU for selected clinical indications, such as the ablation of uterine leiomyomas and bone metastases. Currently, technology is being developed aimed at the treatment of tumours in the liver and the breast.

In this part of the project, we will focus on the improvement of MR-HIFU treatment of uterine leiomyomas. Uterine leiomyomas or fibroids are the most common benign tumor in pre-menopausal women. Fibroids occur in 20-50% of women over 30 years of age, and with increasing size produce pain, menorrhagia, pressure, bloating and urinary and bowel compression symptoms. Fibroids may also cause infertility. Uterine leiomyomas are benign tumors originating from smooth muscle cells of the uterus and occasionally the smooth muscle of uterine blood vessels. Symptomatic fibroids impact health and well-being of the female including lost work hours and reduced quality of life.

5.5.2 Current State of the Art

Current medical treatments include invasive removal of the fibroid (hysterectomy, myomectomy), drug therapy or treatments causing necrosis of the fibroid tissue such as ablation (freezing or heating) or embolisation. In the Netherlands, 13,000 hysterectomies are performed per year, and around 60% are conducted due to fibroids. For the relief of symptoms, women wishing to preserve the uterus may choose between invasive procedures of myomectomy, Uterine Artery Embolisation



(UAE), ablation or cryotherapy. The surgically invasive procedures require anaesthesia, hospital stays, and long recovery periods.

HIFU ablation of a fibroid requires treatment planning, targeting of the ultrasound (US) beam to desired locations, monitoring of the energy delivery and post-treatment imaging of ablation results. In principle, diagnostic ultrasound imaging can be used for image guidance of HIFU treatment. While diagnostic US provides some anatomical details and helps with procedure planning and treatment targeting, it does not provide 3D planning, means for measuring the temperature increase generated by HIFU, nor metrics for quantifying the energy/dose delivered to the treatment zone. Currently, only MR imaging can provide real-time non-invasive temperature measurements and thermal dose quantification in the treated tissue. Furthermore, MR thermometry can be used to control the delivery of HIFU energy in a feedback control system, which ensures optimal temperature profiles to the target locations. The Philips MR-HIFU system (See Figure 8) uses the volumetric heating approach which is based upon electronic steering of the focus using phased-array transducers under real-time temperature-based feedback control. Recent advances in MR temperature mapping make it possible to achieve temperature accuracy of 2-3°C in moderately moving tissue like liver, and of about 1°C in stationary tissue.



Figure 8: Overview of the Philips MR-HIFU system

Symptomatic uterine leiomyomas can cause excessive menstrual bleeding, pelvic pressure, urinary frequency, and back and pelvic discomfort (bulk symptoms). These symptoms are subjective in nature and are difficult to quantify objectively. In previous studies, The Symptom Severity Score (SSS) from the Uterine Fibroid Symptom and Quality of Life Questionnaire developed by Spies et al. was used to assess subjective symptom improvement of menorrhagia, pelvic pressure, increased urinary frequency, bulk symptoms of back and pelvic discomfort and quality of life from the patient's perspective. With MR-HIFU treatment, the reduction in the SSS has been shown to be correlated with the percentage of fibroid tissue successfully treated. Specifically, if MR



imaging showed that greater than 20% of targeted fibroids was successfully ablated, then the SSS and primary symptoms were significantly reduced.

Current practice is to treat only women that fulfill a minimum set of requirements. This involves position, size and nature of the myoma (e.g. so-called white fibroids are not suited for HIFU treatment owing to perfusion problems, which hamper the heating process), and the absence of scars (e.g. caused by a caesarean).

5.5.3 Existing Problems and Unmet Clinical Needs

A HIFU treatment procedure starts with treatment planning. First of all, it has to be decided whether the acoustic window on the target region inside the patient, which may vary from day to day due to changes in location of the intestines, is acceptable for HIFU therapy. This requires the manual identification of critical structures that may not be hit by the beam, like air-filled bowel, scars, and the pubic bone. Next, the ideal position and angulation of the beam has to be determined, which is now also a manual task. The next step is to plan the ablation cells inside the target volume. For each cell, care should be taken that no critical structures are in the near or far field (beyond the focus) of the ultrasound beam. Again, this involves a time-consuming inspection of the projected beam onto the patient's anatomy. Furthermore, a problem is to find the optimal distribution of cells, cell sizes, ablation powers, and the ablation order which ensures the shortest possible total procedure time.

Also in the post-treatment evaluation stage, an important clinical need remains unmet. Although MRI scans allow visual inspection of treatment results (e.g. non-perfused volumes in contrast-enhanced MRI or lesion sizes measured on DWI or ADC maps), there are currently no means for proper quantitative evaluation of the ablated volume during or directly after treatment.

5.5.4 Clinical consultants

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Marianne Voogt, MD	UMC Utrecht
Maurice van den Bosch, MD, PhD	UMC Utrecht

5.6 Bone tumor navigation

(Eric Stindel)

5.6.1 Introduction

Computer assisted surgery is widely used in orthopaedics since the end of the 90'. Numerous papers have demonstrated its efficiency in terms of precision and accuracy for total knee and hip arthroplasties, high tibial osteotomies, or ACL replacement [7]. However, computer assisted management of bone tumor is an emerging field. Very few papers exist in the literature. Most of them are focalized on percutaneous treatment of benign tumors or metastasis.



5.6.2 Current State of the Art

Concerning the field, two categories can be identified. : A) Percutaneous treatment of benign tumors (osteoid osteoma) or metastases. B) Navigation of bone tumors (pelvic or long bones tumors).

5.6.2.1 Percutaneous treatment of benign tumors

This category is the most developed area. The tumor removal, also called ablation, is performed using several cells destructions techniques. For each technique a specific destructive agent is used to destroy the target. They are usually used when conventional therapies (radiotherapy, chemotherapy, open surgery, hormone therapy, systemic radiopharmaceuticals and bisphosphonate) are unsuccessful.

- a) Percutaneous **ethanol therapy** has been initially used providing a 75% rate of success [9]. However some complications appeared linked to ethanol diffusion to nerves which were close to the tumor.
- b) **Percutaneous laser yag** is useful for destruction of small lesion. It has been used under CT guidance [9].
- c) **Cryobalation** is one of the most diffused technique, and one of the older. In this case, Argon is used to create ice balls which are destroying the tumor. The size of the ball limits the volume of the tumor which can be destroyed during each treatment. However, it is possible of using several probes to increase the size [9]. Cryo application was initially limited by the size of the probes, the cost of the equipment and the time required for each treatment (close to 30 minutes). In 2003, Popken described in [13] miniature cryoprobes which can push the initial limitation of the size.
Trans or intra articular therapy may also be permitted thanks to the aspect of the preservation of the extra-cellular matrix and more specifically the collagen matrix.
- d) **Radiofrequency ablation**: RF energy is the most familiar heat source for tissue ablation. [5] The cellular damage is obtained by the conversion of radio waves into heat. Small size probes can be used for percutaneous treatment, and several needles may be combined to treat large lesion.
The RFA probes are placed under CT guidance, and may be used for by metastasis treatment. Initially dedicated to spine lesions, RFA has also been used for ribs, pubis or shoulder metastases, or benign tumors such as osteoid osteoma [22]. Multiplanar images are used to localize the probes.
Tumors up to 5 to 6 cm can be destroyed in one application of the heat. 3 tumors can be treated at the same time. [23] The trajectory of the probe is also thermo coagulated to avoid migration of cells.
Limits: RF diffusion in bones is limited by the low conductivity of bony structures and their poor thermal conduction. Therefore some authors are now developing microwave based techniques [5].
- e) **Microwaves**: 900 to 2450 Mhz length waves are used to provide 120° to 140°. Large volume can be destroyed thanks to the deeper penetration of the microwaves with respect to RF waves. However, thermal injuries to adjacent organs have been described.
- f) **Plasma mediate radiofrequency ablation**: represents a new generation of techniques for ablation of bone lesions. It consists of electricity liable to create a field of ionized particles that break the bonds within organic soft tissue. The result is dissolution of tissues and the formation of a cavity. The temperature is



lower than with RFA or Cryoablation (around 40°-70°) and the diffusion volume can be controlled precisely. Therefore this approach is less painful and allows faster recovery.

- g) **Extracorporeal focused ultra-sound:** is an absolutely noninvasive technique which use ultrasound energy to heat and destroy the tissues. MR imaging is used to target the tumor and MRI based thermometry is used to control energy deposition. Evidence regarding its use to treat bone metastases is limited but promising.

There is a consensus in the literature to say that image-guided percutaneous ablation of bone tumors is safe, effective, durable and repeatable. All authors agree that, if all these techniques are efficient, no one of them is superior to the others.

5.6.2.2 Navigation of bone tumors

Compared to arthroplasty surgery, the literature on navigation of bone tumors is very limited. First experiences are reported by Krettek in 2004. But in 2011, there is still no software design specifically for surgery of the long bone tumors or pelvic tumors. Initial experiences were achieved with software designed for spine surgery.

In 2007, the first 3D ultrasound based navigation system for tumors resection was described. In this paper a 3D ultrasound probe is used to track the needle which is inserted into the tumor. Dedicated to tumor resection, this software was never used for bone applications.

In 2008, first results combining electromagnetic navigation and intraoperative CT is reported, but this approach was also limited to percutaneous surgery.

In 2010, Cho reported on 6 cases of bone tumor resection based on MR imaging. A paired-point registration technique was used with a mean error of 0.98 mm. All this approach was used since MRI is considered to be the best method for defining the extent of marrow involvement for bone tumors and for planning resection in bone tumor surgery. Two papers from 2010 reported also on the use of MRI + CT fusion applied to navigated assisted bone tumor surgery [Cho 2009 – Wong 2008].

5.6.3 Existing Problems and Unmet Clinical Needs

One of the common problems in the ablation procedures described above is the observation of and control over the extent of the ablation site. It would be of great benefit for instance in cryoablation that one can actively observe the formation of the iceball and control it size during the treatment [12]. Interventional MRI can be used to visualize the position of the probe and allow, near real time, optimization of the frozen parameters. Multiplanar images are used to control the location of the probe and its relationship to the target. MRI is also useful to assess the post-operative results [17]. Similar requirements apply to RF ablation, where monitoring of temperature distribution is essential for bone tumor removal. However, MR guidance of RFA is limited by the interaction between the magnetic field and the RF waves. Therefore MR suits more to cryoablation approach than RF ones. US guidance has also been tested for cryablation of bone tumors. But a shadowing phenomenon limits the visualization of the posterior part of the iceball.

To date, little to no navigation devices exist nowadays for planning and monitoring of ablations. One must recognize that a very low number of papers has been published published on the topic of bone tumor ablation planning. There is a real



need from the surgical community since it concerns technically demanding surgery in which tumor free resection margins are difficult to achieve. Efforts should be put by developers on specific tools dedicated to plan the procedure. These models should be specific of the patient tissues and include diffusion heat models. They should probably be MR based in order to visualize the soft tissues surrounding the bones.

5.6.4 Clinical consultants

Pr Stindel is orthopedic surgeon and will act as clinical consultant for the use case. Additional information from other clinical partners will be collected if needed

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5.7 Corrective osteotomy

(Geert Streekstra)

5.7.1 Introduction



The annual occurrence of distal radius fractures is about 0.3% of the population. These cases are diagnosed with X-ray and mostly treated by aligning the bone segments followed by plaster application. The two bone segments malunite in approximately 5% of the cases. Malunion after distal radius fracture results in an incorrect position of the distal bone segment with respect to the proximal bone segment. This misalignment may lead to reduced function of the hand, early osteoarthritis and chronic pain. An established treatment option is a corrective osteotomy. In this procedure the bone is cut at, or near, the fracture site and a bony wedge is removed (closed wedge osteotomy) or inserted (open wedge osteotomy) between the bone segments for alignment correction. In case of pure axial misalignment, only rotating the distal segment suffices. Repositioning of the bone segments is usually done by inserting Kirschner wires or fixation pins into the bone that are used during extraction (open wedge osteotomy) of the tissue to enable wedge insertion.



Figure 9: Inserting a bony wedge for repositioning

(Image courtesy: Academic Medical Center)

Two-dimensional fluoroscopy is used intraoperatively to check for alignment. Finally, the bone segments are fixated (osteosynthesis) either internally, using a plate and screws, or externally using a mechanical device (external fixator).

5.7.2 Current State of the Art

Standard planning of osteotomy surgery for the distal radius is based on plain X-ray images. Preoperatively, the shape of the wedge is estimated from two orthogonal radiographs, and comprises its length and two inclination angles. To this end the radial inclination, the palmar tilt and the ulnar variance are measured and compared, either with the contralateral side, or with average values of these parameters considering population-based data. However, 2-D images for planning and evaluation hide rotations about the longitudinal axis, possibly causing a misinterpretation of the corrective parameters. In fact, optimal pose correction of the articular surface in 3-D requires restoring six parameters: three displacements and three rotations.

During conventional treatment, an incision is made at the palmar or dorsal side, depending on the preferred approach. The incision is relatively large and, after



dissection and osteotomy, allows fixation of the bone segments using a plate and screws (osteosynthesis). Different types of plates are commercially available: T-shaped, L-shaped and anatomically shaped plates are available for bones in the upper and lower limbs, which are supposed to fit every individual. The actual osteotomy cut is performed using an oscillating saw. The bony wedge, usually harvested from the hip, is inserted for repositioning. Fluoroscopy is finally used to check for alignment before applying osteosynthesis. In the likely case that repositioning is suboptimal, 2-D fluoroscopy is practically limited and requires an iterative way of visual evaluation at different angles (usually 90°) and further reduction of the deformity.



Figure 10: Planning and evaluation using 2-D X-ray

(Image courtesy: Academic Medical Center)

5.7.3 Existing Problems and Unmet Clinical Needs

Conventional planning of a corrective osteotomy is based in 2-D radiographs, which hide rotations about the axial bone axis. There is a tendency towards 3-D planning of the osteotomy based on CT-scans of the affected and healthy contralateral bone (reference). Three-dimensional systems would be able to correct the malunion in all six degrees of freedom, including three displacements along, and three rotations about three orthogonal axes in 3-D space. Recent 3-D methods mainly distinguish in the way intraoperative repositioning is achieved. In some methods intraoperative tracking is used for orienting the cutting blade and for navigating the bone to the new position. Most methods still use 2-D evaluation which hampers judging the end result.

The osteotomy procedure with internal plate fixation is rather invasive. Alternatively, external fixation can be utilized which requires inserting pins into the bone segments. These pins, and thus the bones, are fixed in 3-D space to improve positioning, using an external clamping mechanism (external fixator). Minimally invasive methods are lacking but would most probably shorten the healing phase which is beneficial for the patient and for the society.

5.7.4 Clinical consultants

<i>Name</i>	<i>Institute</i>
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5.8 Innovative user interfaces in minimally invasive treatment

(Kris Hermans)

5.8.1 Introduction

The objective of this package is to use innovative UI concepts & technologies to optimize the interaction of the users with the system. Very often those devices are not well adapted to the working conditions of physicians, especially at the table side. In addition multiple systems need to be controlled by the hospital staff in an interventional environment. Those systems are not integrated and each system has its own UI devices with its own user interaction model. Over the years the expanded functionality leads to an increased complexity and user handlings. New approaches are required to keep the operation of systems easy, intuitive and, for the physician.

Currently, physicians have to work under suboptimal conditions, for example coping with an overload of data, working under dimmed light, standing for hours wearing a lead apron, and limited access to the patient. In order to address these difficulties, solutions which present the necessary information at the right time in a concise way, combined with physical improvements in the OR environment, can reduce the strain on the surgeon and with benefit to the patient.

In order to improve the situation for the physicians, several specific challenges need to be addressed. The first challenge is to develop new technologies and solutions for optimizing the workflow and interfaces of multi-vendor systems, without the need to re-engineer the core OR equipment. The second challenge is to investigate new ways to improve the decision-making and ergonomic conditions at the OR table-side. The third challenge is to provide new technologies for innovative intervention devices to allow surgeons achieving mini invasive surgical operation reducing the trauma for the patient and, in the future, enlarge the field of endoscopic surgical operation to NOTES or maybe even other applications.

5.8.2 Current State of the Art

The "OR 2020 Workshop: Operating Room of the Future" was held on March 18-20, 2004, at Turf Valley Conference Center in Ellicott City near Baltimore, Maryland (ref. http://or2020.org/OR2020_REPORT/OR2020%20Annual%20Report.pdf). The general objective of the workshop was to identify the clinical and technical requirements for deploying advanced computer-assisted and robotic technologies and biomedical modeling in next generation operating rooms and interventional suites. Integrated systems and the general character of the Operating Room of the Future (ORF) were defined, with the year 2020 used as a target timeframe.



There were a number of common themes that were identified during the workshop and they are noted as follows:

- Standards for devices and their use in the operating room (OR) are sorely needed. Every aspect of OR activity today is affected by their absence, from non-standardized and incomplete patient records, to varied and un-standardized imaging formats of visual information that is needed during surgeries, to varied and sometimes imprecise language used in communicating among surgical team members.
- Interoperability of devices is needed for development of a smoothly operating OR as well as for improved surgeries. Currently, most devices and computer systems function as stand-alone islands of information and their use requires a great deal of surgeons' time and effort.
- Surgical robotics continues to develop and its role in the Operating Room of the future is still being defined. Improvements in surgical robotics are needed to build on their unique capabilities such as precision, accuracy, ability to withstand ionizing radiation, and dexterity in small spaces inside of the human body.
- Improved, surgery-specific image processing and display are needed for effective use in the OR. The two-dimensional (2D) static images that are typically available in today's OR do not accommodate the 3D and real-time imaging needs of surgeons in most specialty disciplines.
- Communications issues must be addressed and aim toward attaining a common language, training requirements, and protocols for effectively performing advanced surgeries and using telecommunications-ready tools as needed.

To a large extent, interoperability is linked not only to the consolidation of the underlying technology backbone but also to the consistency and ease of use of the user interfaces that expose those underlying technologies to the various users. Too often, user interfaces in use today are technology centric rather than user centric, they should the possibilities of the technology, and the complexities thereof, rather than asking what the user would like to do under ever changing conditions.

Current state of the art systems are not truly fulfilling the user's basic needs. They are too cumbersome to use, difficult to learn... Obviously the medical use cases also need to cover specific requirements such as ensuring sterility, patient safety ...

Newer systems emerging also exist:

- Kinect in the operating room - Surgeons use XBox to keep hands sterile before surgery - <http://www.healthzone.ca/health/newsfeatures/article/960393--surgeons-use-xbox-to-keep-hands-sterile-before-surgery>
- Head control - <http://www.youtube.com/watch?v=OkWOj48iqcc>

Most new systems are derived from applications that are mostly focusing on typical consumer market applications.

5.8.3 Existing Problems and Unmet Clinical Needs

Three main human functions (ref Surgeon's cockpit: A research program to improve safety in the operating room – Lessons learned after 3 years by Goossens and van



Veelen) can be distinguished that play a role in human-product interaction. A human function is defined as a human system/mechanism that is necessary to perform a task with a product. The following functions are distinguished:

1. Perception
2. Cognition
3. Action

Perception is concerned with the human conditions of selection, organization, and interpretation of stimuli, and is influenced by internal factors such as motivational states, emotions, expectations, and past experience. Roughly speaking, perception is the attachment of meaning to sensation. Both the human and the environment contribute to perception. The environment is the source of informational cues, but the perceiver decides which cues to pay attention to and use.

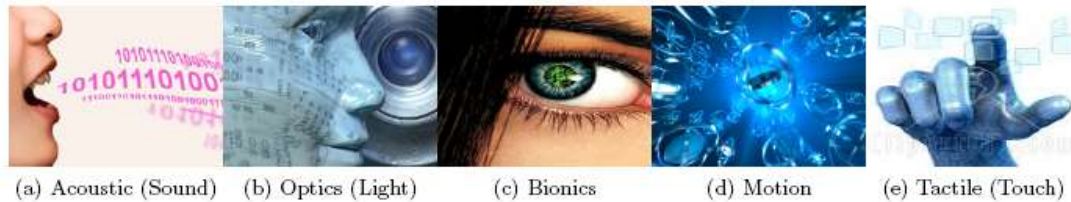
Cognition comes from the Latin word *cognoscere* (to know) and is applied to anything that refers to knowledge and knowledge processing. In this thesis cognition is defined as the mental activity that involves the acquisition, storage, retrieval and use of knowledge.

Actions are those operations which occur as a consequence of the decisions that are made. These functions fall roughly into 2 classes: physical control action (e.g., the activation of certain control mechanisms or the handling, movement, modification, or alteration of materials or objects), and communication action (e.g., speaking). The ability of people to perform physical activities is based on the structure of the body (the skeleton), the skeletal muscles, the nervous system, and the physiological features that control metabolism.

There are a number of simple question one can ask to understand the overall performance of any user interface (ref <http://usability.gov/basics/index.html>):

- **Ease of learning** - How fast can a user who has never seen the user interface before learn it sufficiently well to accomplish basic tasks?
- **Efficiency of use** - Once an experienced user has learned to use the system, how fast can he or she accomplish tasks?
- **Memorability** - If a user has used the system before, can he or she remember enough to use it effectively the next time or does the user have to start over again learning everything?
- **Error frequency and severity** - How often do users make errors while using the system, how serious are these errors, and how do users recover from these errors?
- **Subjective satisfaction** - How much does the user like using the system? This could also include for instance 'ownership', i.e. how does a surgeon appreciate the system given the ownership it provides him over the overall system.

An interesting overview of HMI (Human Machine Interfaces) has been described in Human-Machine Interaction (HMI): A Survey - Technical Report: CES-508 by Cannan and Hu. They describe 5 broad categories of HMI.



Status of current user interface systems:

- Centralized user control via a GUI – to date probably still the most commonly used. Sometimes difficult to use and never give the surgeon the full control over his environment.
- Voice control – there are some systems in the field but overall acceptance seems fairly low given the relatively low success rate of any voice recognition system.
- Keyboard and mouse functionality – the traditional PC approach, not giving the user the overall control he would like to want.

Current systems just don't do the trick. None of them meet all of the 5 criteria to measure UI performance outlined above. Clinical needs however are strong and evolving further to giving the end-user full control of his/her environment.

5.8.4 Clinical consultants

We are still in the process of establishing our clinical reference database. A lot of information has been collected through direct user observations in the past and from literature on this particular subject.

5.9 Single Incision Laparoscopic surgery (SILS)

(Sebastian Berthier)

5.9.1 Introduction

Nowadays, with the accuracy of the modern imaging techniques, the diagnosis of incidental renal tumors has become increasingly frequent. In this case, it has been showed¹ that there is a benefit for the patient to undergo nephron-sparing surgery (NSS) instead of radical nephrectomy (RN). In RN the surgeon removes the whole kidney and the tissue around it, while in NSS the surgeon removes the cancer and part of the kidney surrounding it so that the patient still has some working kidney left after the operation.

These tumors are often small in size and minimally invasive procedures (laparoscopies) represent an optimal indication to perform nephron-sparing surgery (NSS). Laparoscopic surgeries have major benefits to the patient in terms of reduced post operative pain, increased post operative comfort, reduced hospital stay, quicker return to normal physical activities and ultimately a quicker return to work. Improved cosmesis and reduced wound complications associated with large scars are also

¹

Uzzo RG, Novick AC Department of Urology, Cleveland Clinic Foundation, Cleveland, Ohio, USA (2001) *Nephron sparing surgery for renal tumors: indications, techniques and outcomes.* J Urol 2001 Jul;166(1):6-1.



major advantages associated with this technique. In addition, the oncological results are comparable to the open approach.

Recent reports have suggested that single-port or single-incision laparoscopic surgery (SILS) is technically feasible. Some studies² have compared SILS and conventional laparoscopic nephrectomy with respect to peri-operative outcomes and short-term measures of convalescence. The results show that SILS nephrectomy is feasible with peri-operative outcomes and short-term measures of convalescence comparable to conventional laparoscopic nephrectomy. Although SILS may offer a subjective cosmetic advantage.

But among all surgeries, only a few are laparoscopies (about 15% in the USA - Figure 11, less in other countries). And among laparoscopies, only a few are performed using SILS (estimation: less than 1%).

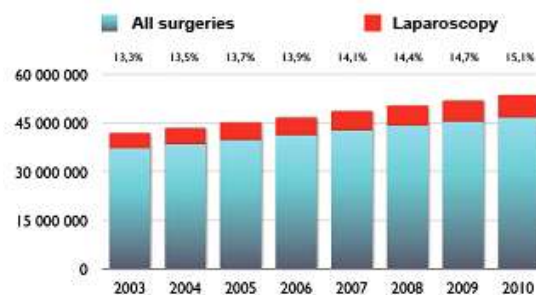


Figure 11 : Surgical procedures evolution (US)

These figures reflect the difficulty induced by minimally invasive technologies. Laparoscopy is more complex than laparotomy, and SILS is more complex than laparoscopic surgery. Therefore laparotomy is more indicated than laparoscopy, which is more indicated than SILS (Figure 12).

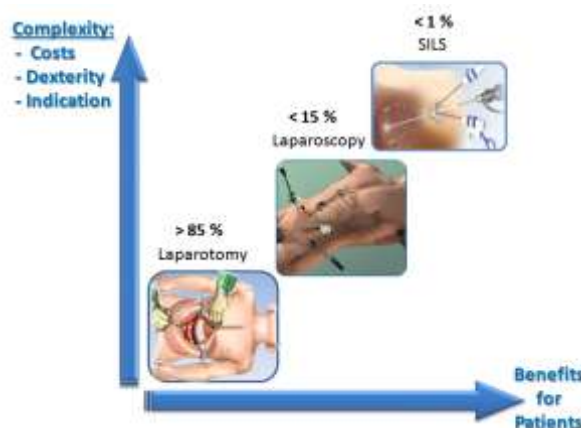


Figure 12 : Complexity of the different surgeries vs benefits for the patients

² Raman, J. D., Bagrodia, A., & Cadeddu, J. A. (2008). Single-Incision, Umbilical Laparoscopic versus Conventional Laparoscopic Nephrectomy: A Comparison of Perioperative Outcomes and Short-Term Measures of Convalescence. *Eur Urol*, doi:10.1016/j.euro.2008.08.019.



This difficult for indicating laparoscopy and SILS can be explained by different factors: dexterity, costs, and relevance for specific cases. These factors could be reduced by using a new generation of instruments.

5.9.2 Current State of the Art

Today, there are a numbers of tools dedicated for SILS (Figure 13). These tools are of great help compared to traditional instruments because they offer additional degrees of freedom in the patient's abdomen. However, due to the relative novelty of SILS in clinical routine, the number of tools developed for SILS is still limited.



Figure 13 : Current SILS tools (manual)

The robotized tools used in laparoscopy, such as the Da Vinci[®] from Intuitive Surgical, cannot be used easily in SILS because they cannot make all the required movements and the diameter of the instruments is too big (8-10mm).

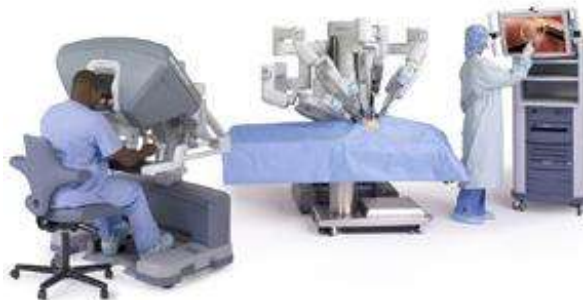


Figure 14 : Da Vinci[®] system

A new generation of instruments will be launched by EndoControl at the endo of year 2011 (JAiMY[®] - Figure 15). This new generation combines the ease of use of the current SILS manual tools with a robotized command interface.

This kind of products will ease the use of laparoscopic surgeries and SILS, but it is still far from being ideal. The form factor is still very rectilinear and a lot of surgeries cannot be performed using SILS technics.



Figure 15 : JAiMY[®] system

5.9.3 Existing Problems and Unmet Clinical Needs

To overcome the limitations induced by the current tools, a new generation of tools must be developed to increase indication of laparoscopy and SILS. These limitations are the fact that the different movements are controlled manually, and current tools do not provide the same comfort of use than instruments used in laparotomy. Moreover, their form factor, which is very rectilinear, deprives the surgeon of the ease of movement, thus limiting SILS indication when the movements to perform are too complex.

Novel tools to be developed specifically for SILS must enlarge the area that can be reached with the surgical instruments. They should ease the access to laparoscopic techniques, by offering better feelings for surgeon, to avoid having a long and costly learning curve. The goal of this use-case is to develop a new generation of tools to increase indication of laparoscopy and SILS. These tools must enlarge the area which can be reached with the surgical instruments. They should ease the access to laparoscopic technics, by offering better tactile feedback for surgeon, to avoid having a long and costly learning curve. They should also allow more complex movements to increase SILS indication. And they should allow more complex movements to increase SILS indication.

5.9.4 Clinical consultants

Clinical contacts in the framework of this project will be established in the next phase of the project.