Virtual Reality and Haptic Training Simulator for Sacral Neuromodulation Surgery

BY

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THESIS

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Ever tried, ever failed, no matter.

Try again, fail again,fail better.

Samuel Beckett

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LC

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

LIST OF FIGURES

LIST OF ABBREVIATIONS

2D	2 Dimensional
3D	3 Dimensional
AP	Antero-Posterior
API	Application Programming Interface
AS	Ascension
CE	Cost Effective
CNS	Central Nervous System
CT	Computerized Tomography
DICOM	Digital Imaging and Communication in Medicine
DOF	Degrees Of Force
DoF	Degrees of Freedom
FDA	Food and Drug Administration
GUI	Graphic User Interface
LUTS	Lower Urinary Tract Symptoms
OAB	Overactive Bladder
PCA	Percutaneous Access
QoF	Quality of Life

LIST OF ABBREVIATIONS (continued)

QH	QuickHaptics™
ROI	Region of Interest
SN	Sacral Nerve
SNM	Sacral Neuromodulation
SNS	Sacral Neurostimulation
TURP	Transurethral Prostate Resection
UI	Urinary Incontinence
VL	Visualization Library
VR	Virtual Reality

SUMMARY

Virtual Reality and Haptics Training Simulator for Sacral Neuromodulation Surgery project aims to design and develop an efficient, valuable and economically viable tool for training surgeons, residents and medical students on the procedure to implant a Neuromodulator on the sacral nerve, to treat problems in the overactive bladder spectrum. Through the exploitation of Virtual Reality and Haptics technologies, it will be possible for medical personnel to learn and practice on the most important tasks to be performed in such a surgery, mastering their eye-hand coordination while managing the C-arm to handle the fluoroscopy imaging; this features also allow the trainee to understand how to rely on 2D imaging to move in the 3D space.

The application's intent is to fill the void in the field of medical training for what concerns Sacral Neuromodulation, since no other relevant tools are specifically designed to learn and practice on this task, although the number of cases is estimated to be continuously rising, and, with the progression of technology, the current most common way for students and residents to become acquainted with surgical procedures, i.e. relying on direct experience, hands on a patient, is being left behind, at least in the first phases of education, in order to increase patient safety and contain costs.

CHAPTER 1

INTRODUCTION

Patients with symptoms comprised in the spectrum of overactive bladder, if not responsive to the first and less invasive therapies prescribed, have the possibility to undergo Sacral Neuromodulation (SNM). SNM is surgical procedure performed on sedated (hence, not anesthetized) patients, under fluoroscopy guidance from X-Ray imaging obtained through a C-arm; when it is performed minimally invasively, which is currently the standard, it consist in the percutaneous access of the sacral nerve to implant an electrode lead, which gives electrical pulses that modulate the activity and restore the correct communication between the brain and the bladder, so that incontinence and urgency events are severly waned and quality of life is significantly improved for the patient.

Quality of life is often one of the biggest concerns for patients with OAB syndrome. It is not, in fact, a deadly disease or a threat for life in any way, but its a chronic condition that constantly stress people who suffer from it with symptoms that severely affect one's freedom, undermining self confidence, sociality and private life. These symptoms may include either urinary or fecal incontinence, non obstructive urinary retention, urgency, and in general an increased micturition frequency. Psychological drawbacks are important in these people, because cases of depression and excessive stress directly correlated to OAB symptoms are well documented in literature. However, several studies on its efficacy report that SNM is a suitable procedure to treat this condition, with huge improvements on the quality of life in patient.

Two are the main drawback of SNM: first one is that its side effects, and the frequency they occur which, are significantly more relevant than other therapies, which means that patient have to be carefully selected and general routine involves at least two other levels before getting to SNM. This directly leads to the second main drawback, which is cost: resources needed to perform a surgery are widely larger than for behavioral therapy or drugs. Moreover, it is not so rare to incur in errors and problems after intervention, which usually require re-operation, resulting in a menace for the economical viability of the therapy. For these reasons, it is important to have well trained and experienced medical personnel who, thanks to their acquired skills, are able to operate almost risks free.

This puts the focus on medical education: the trend nowadays is to reduce the number of hours spent in direct training for residents, with the aim of lowering the costs and, most important, to prevent excessive extended shifts that would affect doctors decision making abilities. The drawback is that trainees have less opportunities to become acquaintance to operations in general, fact worsened by the increasing amount of different techniques and technologies emerging. It is important, then, to have suitable instruments for them to safely and extensively training, in order to compensate for the hours lost. For what regards SNM, no specific training tools exist and it is common practice to develop the necessary skills to perform it on low fidelity manikins and bench models. To have the possibility to train on a specifically designed system would most likely help to more quickly overcome the learning curve and gaining some experience that is going to be valuable in the OR. as it is proved that trained surgeons perform better, at least in the first phases. A training system developed and designed with a certain surgery in mind, would be an important tool for soon-to-be surgeons aiming to become experts in that field, as they would be able to improve their outcomes from the very first times in the OR, lowering risks for patients and likely costs.

CHAPTER 2

BACKGROUND

2.1 Overactive Bladder

From the International Continence Society definitions, Overactive Bladder(OAB) is a chronics pathological condition [5] which diagnosis is usually symptomatic, based on the occurrence of identified symptoms such as frequency of micturitions, urgency, urge incontinence, not explainable through local pathologies, like stones, tumors, cystitis, or methabolic diseases like diabetes [6] [7]. Neurological causes leading to such symptoms are included in OAB. Lower Urinary Tracts Symptoms (LUTS) are among the most prevalent pathological conditions either in the US and worldwide, affecting hundreds of million of people, with incidence increasing with age and no relevant difference between males and females, except for the occurrence of symptoms and their relevance [1] [8] with the respect to the quality of life. An increasing trend has also been highlighted, with more and more people being affected by this kind of problems in the future [9],mainly because of the mean age of population raising thanks to the improvement of health and life conditions. [10].

Studies claim that in 2018, people affected by general LUTS in general are about 2.1 billions [1], with a slightly higher incidence in women than man (46% vs 44%). Furthermore, anticipations for OAB are to reach more than 500 millions of people, with a difference of 2% in favor of men. Data about prevalence rfom studies are shown in Figure 1 and Figure 2.

2.1.1 Symptoms and quality of life

Being the diagnosis symptomatic, it is important to correctly state and analyze events occurring the patient, and contextualize them with the respect to the amount of invalidation they cause to the patient. It happens, in facts, that many people presenting this kind of symptoms can still conduct a normal life, not requiring extensive and invasive treatments, whereas others must undergo specific therapeutic pathways to gain the chance to see their quality of life restore [11]. It has been evidenced that not only urge incontinence, but also frequency and urgency are extremely invalidating symptoms, that strongly affect the patients' life. A considerable percentage of people presenting the symptoms (32%), show episodes of depression, while approximately 28% feels stressed by the bladder activities and for another 28% the symptoms ar of some considerable concern. Obviously, people affected by OAB and incontinence are more likely to report serious problems conducting a normal life than the once without it. However, more than 70% of this kind of patient is really uncomfortable with his/her symptoms and requires some treatment [12].

2.1.2 Therapies

For the reasons above, it is of fundamental importance to have ready and adaptable treatments for every patient presenting OAB symptoms. Most common therapies in the past (up to 2006) were distinguished between drug based and non drug based ones, with some better outcomes using the previous, anticholinergics in particular [13]. More recently, antimuscarinis became the first-to-go solution for treatment [14]. One of the most important thing to consider when treating OAB, perhaps, is that, not being a real disease and not being a life threat at all,

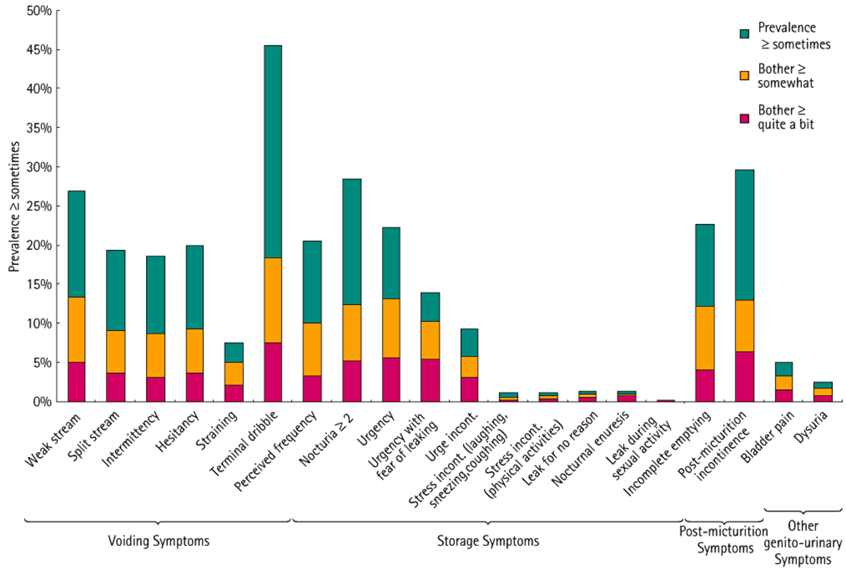

Figure 1: Histogram showing prevalence of LUTS symptoms among men [1]

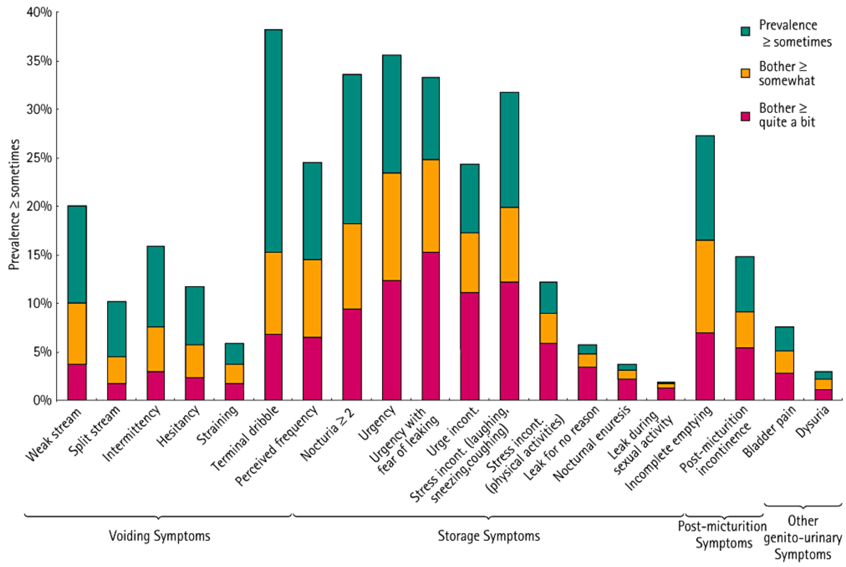

Figure 2: Histogram showing prevalence of LUTS symptoms among women [1]

patient not witnessing significant improvements should not keep on undergoing a therapy, with the risk of incurring in side effects, and surely creating excessive costs [15]. In [15], a framework to be followed to shape the most useful treatment on a certain patient is stated, with three levels identified, as the invasiveness and power of the solution increases:

- **Behavioral approach**; first treatment to be considered is the risk-free and tailorable training of a certain patient, changing his/her habits or environment, or teaching him/her to improve his/her management of bladder voiding. Literature shows how many patient, thus not completely eliminating symptoms, can see a significant improvement with both bladder [16] and behavioral [17] therapy. The substantial absence of adverse events (AEs) and the economical viability, makes this the first choice.
- **Anti-Muscarinics**; oral administration of drugs is the second-line therapy suggested in the paper, to be used where no considerable improvements in the quality of life of the subject is observable with the first try. Patient with severe symptoms are often observed to remit quite well, while a small portion of subjects, the ones with mild events occurring, can have their normal life completely restored. Sides of this treatments are the presence of AEs, though not life threatening.
- **Neuromodulation (SNM)**; when no other treatment suits the needings of the patient, surgery is often the last chance. In particular, Sacral Neuromodulation happens to be the most effective treatment to improve the conditions of a patient, even if not exempt a lot of AEs, due to his surgical nature.

Figure 3: Representation of an Interstim®system implanted

2.2 Sacral Neuromodulation

As previously said, SNM is the last treatment to be considered when trying to restore a normal QoF for a patient with OAB. It has been approved as a general treatment by FDA since 1999 [2]. Perhaps, the only approved commercially available device for SNM is InterStim®, by Medtronic(Minneapolis, MN)[18]; the device basically delivers mild electrical pulses to the roots of the third sacral nerve (SN), as shown in Figure 3, allowing for communication with the portion of nervous system controlling the adjacent organs, i.e. the ones relative to urinary functions. In particular, the sphincter and the bladder itself.

Result, partially shown in Figure 4, with the respect to QoF of SNM on patients are found to be usually way better than the outcomes of standard medical therapies [2] despite the frequent AEs; patients treated with InterStim®usually report several and significant improvement in sleeping, sexual functions and sociality, feeling more self confident and less stressed, without the concern of urgency and frequency, often almost completely regaining total continence. The drawback of this surgery is that bad outcomes are not rare, and it is fairly common that patients have to undergo a second surgery step, due to the device becoming an unbearable, useless or ineffective foreign body [19]. Most common failures in SNM include [20]:

- Migration, meaning that the device has moved away from it implant site; this can drive to it becoming useless, painful or to stimulate the wrong anatomical structure, triggering unexpected body response and needing immediate revision.
- Infection, when the implant causes infection in the device site. Obviously it has to be reimplanted.
- Adverse stimulation, causing painful events to the subjects and resulting in a
- change in the local impedence, driving the pulses to be almost completely ineffective.
- battery depletion.

In general all of these problems can be solved through explant and substitution of the device, or the battery, with successful follow ups. However, it is generally considered that with proper surgery it is possible to avoid or at least reduce the occurrence of failures due to for instance migration and sepsis, since they are mainly due to some errors during the procedure. The objective of the improvement of the implant technique, to reduce as much as possible these events, and reach better outcomes, has been pursued by several works, among which [21] and [22].

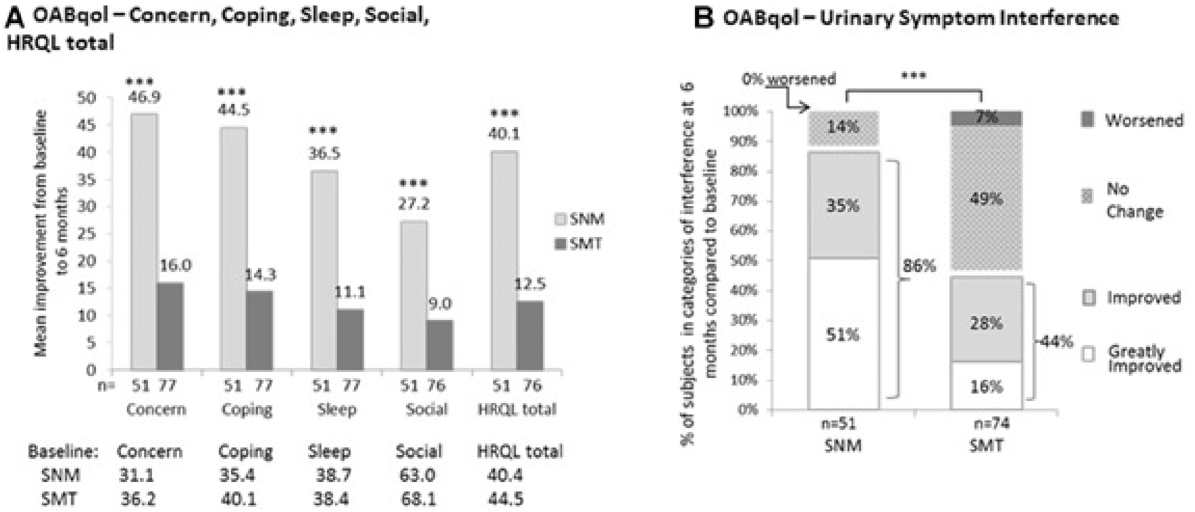

Figure 4: Patients follow-up at six months from the implant, compared to tibial stimulation[2]

2.2.1 State-of-the-Art procedure

In [3], a precise guideline to perform the procedure has been defined with the main purpose to avoid failures due to bad practice, taking into consideration the difficulties in performing such a procedure. In the cited article, a percutaneous access to the sacrum is considered, fact that makes it very suitable as a blueprint for the simulation developed with the work. The surgery is performed under fluoroscopy guidance, because minimal invasive percutaneous access does not allow the surgeon to clearly see where is he going with the instrument. General goal is to place the InterStim®electrode lead through the S3 foramen, in the sacrum, as near as possible to the roots of the SN, following its processes. This is going to stimulate the nerve through mild electrical pulses and restore the communication between CNS and bladder, improving the symptoms. This procedure can not be performed under total anesthesia, because it is necessary to test the correct positioning of the instruments sending pulses, intra operatively, and checking that the patient gives the correct response; if he/she was under total anesthesia, no response could be detected at all. It may be, indeed, a painful procedure, because of repeated touches of the periostheum, which is richly innervated, and therefore causes very strong pain when touched.

The procedure consists in the identification of the correct spot where to enter the skin; this is done with AP fluoroscopy imaging, which allow to identify the right foramen, and lateral fluoroscopy, to find the right angle Figure 5 Figure 7 Figure 6 Figure 8. Then, the position of the foramen needle is tested, connecting a plug through which electrical pulses are given, and the response of the patient is observed: what the surgeon wants to see is the toe bending and the anal sphincter contraction, because that means that the right nerve is being stimulated, and the stimulation is effective. Later on, a guidewire is placed in position of the needle, with a radiomarker to avoid excessive penetration. Next, the actual lead is moved through the guide to be inserted, taking care to give it the most suitable bending to lie along the SN roots Figure 9; the lead position is tested again, and the same response is wanted, in order for the surgeon to consider the placement successful. Eventually, the device is deepened in a suitable pocket in the buttock, and this is usually quite an easy task.

Possible errors in the placement of the foramen needle would induce one of the following scenarios:

- Foot rotation; if when testing giving electrical pulses the foot rotates instead of bending the toe, usually what happened is that the wrong foramen has been accessed, in particular S2.
- Ipsilateral gluteus contraction; the cause of this unexpected contraction is usually an excessive depth of the needle, which stimulates the muscle directly, and not the nerve.
- no response or poor response to pulses; the reason may be a non-ideal placement, as well as problems with the instruments.

Figure 5: Marks on the lower back of the patients to identify the entry point [3]

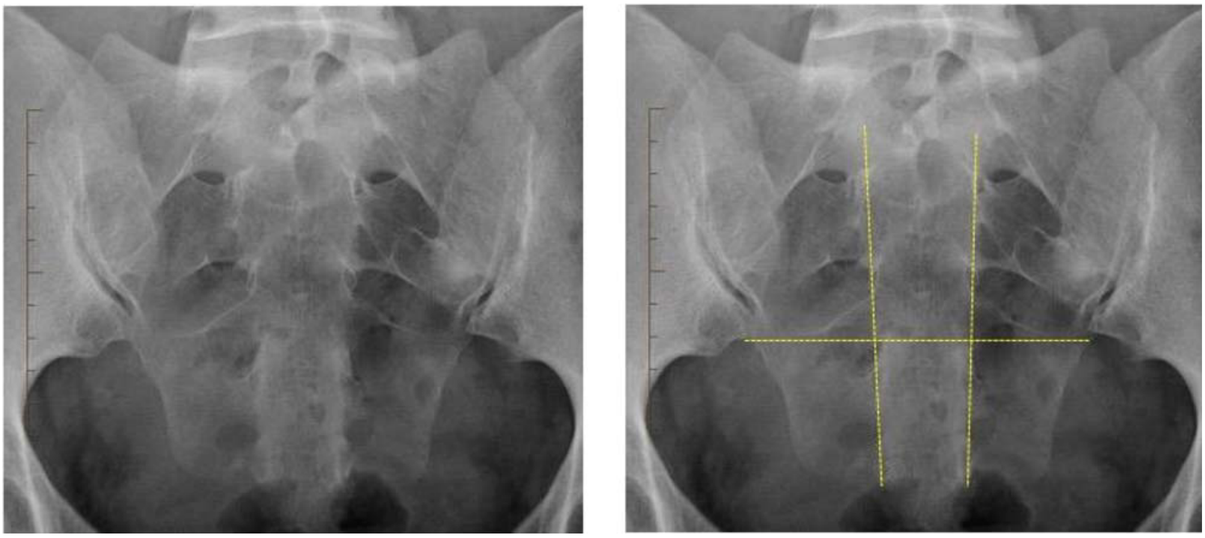

Figure 6: Fluoroscopy imaging to identify the correct foramen and mark the skin [3]

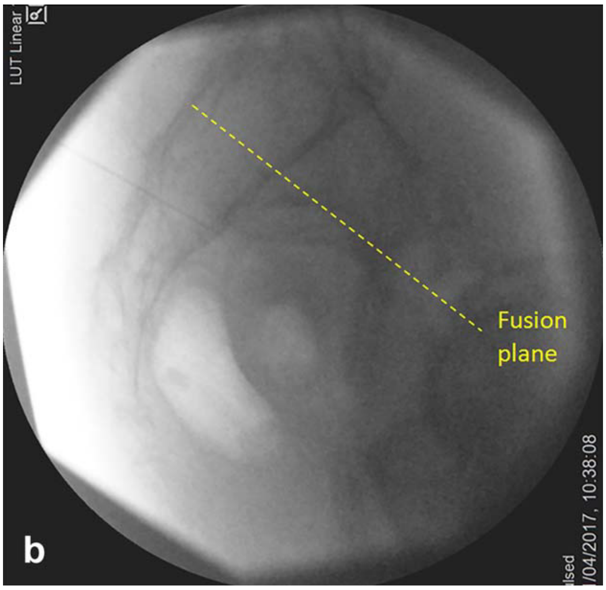

Figure 7: Fluoroscopy imaging to identify the correct angle to access the foramen [3]

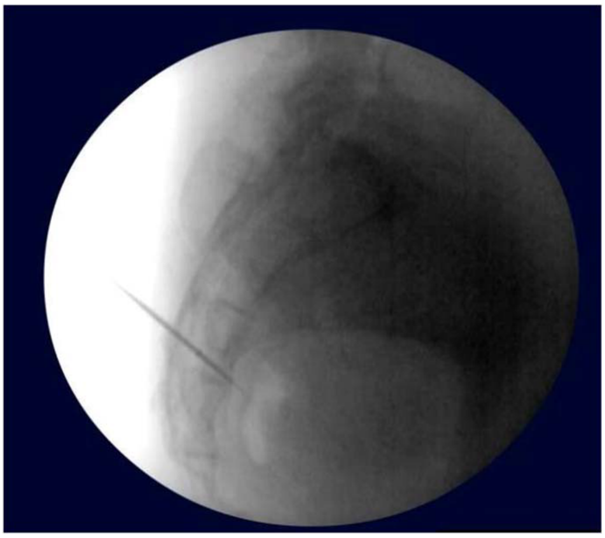

Figure 8: Fluoroscopy imaging to identify the right spot while inserting the needle [3]

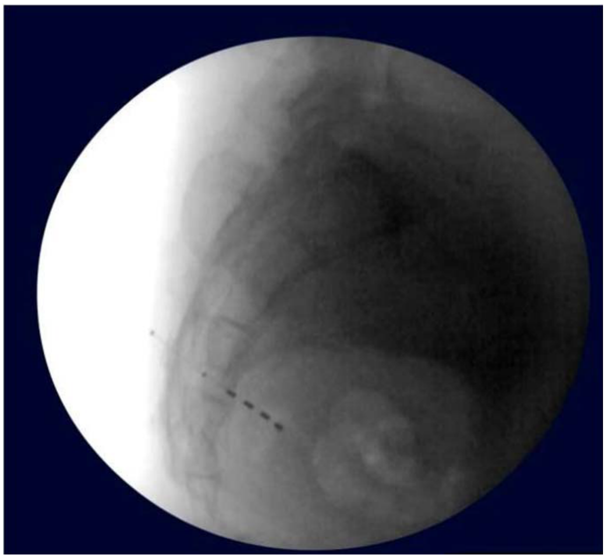

Figure 9: Fluoroscopy imaging of a correctly implanted electrode lead [3]

2.2.2 Costs associated

In [23] and [4] in analyzed cost effectiveness of SNM, stating that the procedure, although seemingly not CE in a span of 2 years [24], is, in fact, as can be seen in Figure 10. This, combined with the very good general outcomes observed with this treatment, drives SNM to be a quite widely spread procedure. Cost effectiveness, though, is related to the success of the surgery: all the cited paper evidence how, in particular during the first years of implant, the costs are higher than other treatments, mainly because of the device costs itself. Failure would, hence, significanly lower the economical viability, because of the resources needed to implant another device and to perform another surgery, even if kept minimally invasive.

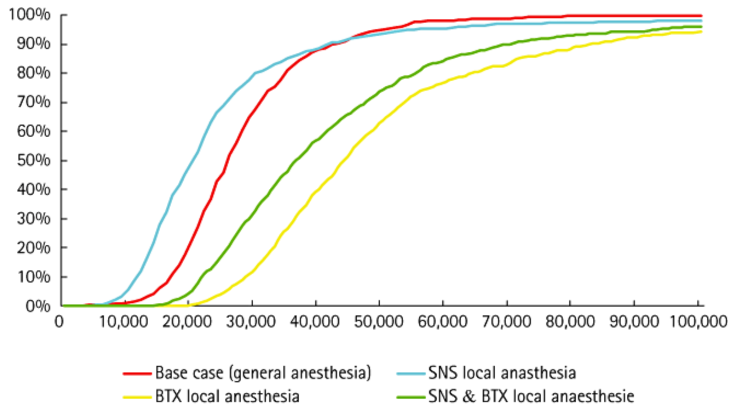

Figure 10: Cost effectiveness of SNM with the respect to other procedure, measured in quality-adjusted life-years [4]

It is indeed absolutely necessary that the performer (i.e. the surgeon in charge of the procedure) is well trained enough to master the procedure and not incur in big mistakes which would result in possible injuries to the patient, excessive pain, or, in the worst case scenario, even in a failure, depleting all the advantages of SNM. This puts the focus on surgical training, more than on the procedure itself.

2.3 Surgical Training

One of the main problems in surgical training in general is the lack of a specific and extensively validated pathway to be followed to rapidly and effectively climbing the learning curve, for a particular procedure or in terms of general skills [25]. Plus, the increasing number of new technologies and techniques, together with the decreasing mentoring opportunities, due to the most diverse reasons, are driving to the necessity of other ways to teach and train a surgeon

[26]. Several models can be used for training, with different characteristics, with advantages and disadvantages each. Categories can include [27]:

- **Animal models**: quite diffuse, they present the advantage of some realism, in particular due to blood flowing, and trying on something real that can be injured, or can give a feedback; it can also be followed to understand the outcomes, giving the chance to give an evaluation to the surgeon. In urology, for instance, pig models are used to train residents on kidneys related surgeries, such as nephrolitotomy [28]. Problems that occur with animal model are usually in terms of ethics, mainly; some difficulties using this training method may arise with the respect to their cost, and not immediate availability; cost issues also include the necessity to additional expert personnel, like veterinarians, to anesthetize the animals, if in vivo approach is used.
- **Bench model**: bench models find extensive use in surgical training because of the many choices and the great variety they present. They can be high fidelity, expensive but with accurate anatomy, or low fidelity, cheaper, less accurate. Despite their immediate availability, absence of ethical concerns, and amount of possible solutions, they do not provide the trainee with a satisfying enough experience, and are not something on which the training can be based on. Also, they tend to be pretty unreliable in terms of cost effectiveness, meaning that low fidelity cheap models can be as good (or, from a different perspective, bad) as the high fidelity ones, while their price can differ by orders of magnitude [29].
- **Cadavers**: the most ancient solution, and one of the most reliable, because present many of the advantages that an ideal training set presents; they are highly accurate and not

much expensive, but they are very difficult to be found, other than being in some way disposable. They offer also the possibility to measure the performance.

- **Virtual Reality Simulation**: the most modern and promising models are those built "in silico". They offer the advantages of others, without ethical concerns, problems of maintenance or reproducibility. Next sections will go through these models more extensively.

- **Real patients**: it is still the most common and though to be reliable method to train surgeons and medical personnel in general. The leitmotiv is "See one, do one, teach one", meaning that witnessing real operation, thus learning from experts, is the best way to learn a surgical procedure. It is an old approach, still valid, even though some may rise some concerns about it [27]. It is nowadays considered that learning on real patient is not the ideal way, first of all because of ethical concerns, related to them undergoing a higher risks procedure, augmenting the probability of injuries; costs issues may arise in this case also, because, for instance, if a trainee is learning to perform SNM and the outcome is a failure, reoperation is an additional (high) cost, other than a huge discomfort for the patient. It is also a matter of time: in procedure like SNM, performend under fluoroscopy guidance, time is important because the less the patient and the OR staff is exposed to radiation, the better is. Moreover, being performed under local anesthesia, the discomfort with excessive time required would be higher.

Performances of different models can be found in literature; general belief is that training with models is better than only theoretical preparation. In [30], after training different groups of medical students with different sets (cadavers, bench models, theoretical), it is observed that groups with some physical model training performed better, even though no significant differences between the two groups could be evidenced, meaning that bench models and cadavers can be substantially equal in adding value to education. The concept of distributed simulation is gaining increasingly consents int the education field: it is a method that combines models, like bench models, with an immersive and realistic environment, giving the trainee the same feeling he would have in an OR. It has been demonstrated how in this kind of simulated OR, there is not only the chance to learn technical skills, but, equally important, other non-technical skills [31], like verbal communication, crisis management, teamwork, that are absolutely fundamental for medical personnel; studies show how many of the errors and failures occurring during operations, are actually attributable to this kind of deficiencies more than technical ones [32]. Moreover, in setups like these, expertized personnel is find to outperform novices [31] when in comes to reproduce a real intervention; this ones is an important parameter to be considered, because it gives a measure of the realism of the simulation, and constitutes a strong validation of the method.

2.3.1 VR in surgical training

In many professional field there is an extensive and validated use of simulator, at the point that it may be required to start the training on the real job. For example, in aeronautics, it is nowadays necessary for pilots to have a certain number of simulated flight hours in order for them to be allowed to train on real planes and be granted a flight patent. In motor sports, like Formula1, due to the restricted possibilities to test the car on a real track, pilots are often training on simulators. Questions are arising on why such a technology driven field like medicine still has not a protocol to its professionals to undergo before actually entering an OR. Reasons can be multiple, mainly related with costs of newest sets and lack of consistent validation with randomized controlled trials on high number of subjects [25] that state the objective usefulness of the models. Many times, when trying to validate surgical simulators, researchers tend to rely on rule-of-thumb judgment parameters, which differ from time to time, for instance expertize of personnel is usually not very clear, because some consider an expert a surgeon with 100 procedure under his/her belt, whereas for other more than 1000 are required. These limitation can be some of the reasons for simulators to be still not wide spread and commonly included in surgical and medical training. VR environments, on the other hand, present great advantages with the respect to other training sets, including:

- **Measurable performances**: being entirely built in a virtual environment and controlled by a computer, what happens is that the developer has always the control of the simulator, meaning that everything can be tuned and customized; records of everything that happens in the environment can be kept, and inferences can be done on these records; the virtual simulation allows to an extensive data recording, because of the complete control on the setup; differences between VR models and, for instance, bench models are evident; in the latter, consideration have to be done to evaluate the performance, and generally a post-operation analysis has to be performed, often using external tools, like pressure sensors; furthermore, parameters are not always clear and reproducible, because it degrades with use, or breaks. VR simulator make possible to precisely compute certain parameters to be evaluated, giving a precise feedback on a task and allowing to consistently compare among different users.

- **Reproducibility**: one of the huge advantages of VR is that the exact same task can be performed over and over without any difference, degradation, defects occurring on the simulator. The importance of such a property lies on the comparison that a trainer wants to check how the trainee is improving, and this can be clearly inquired only with repeated trials, if particular if the aim is to learn a specific task. It is so of great relevance to provide tools with high reproducibility, tackling the necessity of inferring on the learning curve of trainees, and possibly distinguish among good-to-be surgeons, and medical students who better follow other pathways.
- **Adaptability**: another feature of VR setups is the virtually infinite choice of simulation and patients. A characteristic like this becomes relevant when considering how various can be human body, and how many differences can exist among different people, in terms of shape, dimensions, anatomy; because of this, trivial procedures on patients of mean average and weight may become extremely arduous on obese individuals, or people with malformations, or affected by some particular pathologies. For these reasons, it is important to differentiate training to be able to compel with the most diverse needs possible, in order to be at least experienced with more conditions.
- **High Fidelity**: extensive advancements reached in the computer graphics industry, including features from the videogames world, can be exploited in VR simulation to create extremely precise and high fidelity models, giving the trainee a precise and comfortable

environment; this is important because the feeling of a low fidelity model, being it ballistic gel or something similar, is way worse, even sometimes still valuable, because it requires abstraction from the trainee. Obviously, on the other hand, newer technology and high fidelity training sets always increse the costs.

- **Economical viability**: this is of a great concern when taking into consideration the training of surgeons and medical personnel in general. What happens is, in fact, that because of the past extensive supposed reliability on "see one, do one, teach one", the main thing considered when the necessity to buy a training set is pure cost of the tools, not considering how actually CE it can be. Several training hours might, other than improving the skills of medical personnel, would reduce avoidable injuries to the patient that would otherwise be used fo the purpose, containing medico–legal costs as well as improving outcomes. Considering VR, high fidelity simulators and systems can be extremely costly, with esteems of even tents of times a rapid prototyped 3D printed and hundreds of times a biological one [33].

VIrtual Reality simulations are widely considered effective in general [34] whether it comes to predict skills [35] or improve performances. As technology progresses, they present the advantages to overcome problems in medical education, as they are validated and included in curricula as necessary.

2.3.2 VR in Urology

For what concern Urology, many simulations, mainly due to the extensive use of minimally invasive surgery, with laparoscopic techniques [27], that lends itself quite well to both mechanical and virtual toolsets; also, correct managing of tools in laparoscopy is often arduous, because of the necessity to coordinate 3D motion of the hands with the 2D imaging usually used, while dealing with being practically blind on the site.

Most relevant current simulations for Urology procedures are related to TURP, Cytoscopy and Uretoscopy, PCA, and laparoscopy. Among these, most relevant VR sets are:

- PERC Mentor™; 3D Systems's device [36] device is designed to let a trainee learn PCA with a diverse patient choice, managing the tools used in a real OR with the help of a manikin, with the possibility to perform the entire procedure. It is also one of the fews consistently validated [37]. Main disadvantage is the cost.
- URO Mentor™; another 3D Systems' device[38], intended to teach basics endourological skills to inexperienced medical students. Studies shows how this set is valuable to predict skills among medical students and low experienced residents [39], improving their performances, while its effect on already well capable surgeons is negligible. [40] inquire the relevance of the UROMentor™ in training, assessing that improved results are noticeable among performers trained with it.
- LAP Mentor™; [41] similar platform as URO Mentor™ and PERC Mentor™, but for laparoscopic intervention. This one also features a mixed reality headset, to let the trainee experience a fully immersive virtual OR, giving him an even more realistic and comprehensive training tool. However, this system only allows practice on simple procedures.
- Haptic and Virtual Reality Surgical Simulator for Training in Percutaneous Renal Access; [42], [43], this is the prototype of a completely different work, designed to be way cheaper

than other solutions, with low experienced medical students and residents in mind, to create an affordable, reliable and economically viable and relevant simulator for PCA, combining light software and hardware components, that do not necessitate of excessive amount of resources to be used, but offers a valuable tool to get trainee involved in the first steps of learning, allowing them to practice on basic skills.

It is evident how new advanced technologies, such as VR and mixed reality, are usually costly, and many institution simply can not afford to purchase one of them, having to rely on different solution.

2.3.3 Haptics in surgical training

Haptics means interaction involving touch. In this work, technologies intended to give the user a tactile feedback from a device touching a virtual scene is intended. In the medical field, many researches are trying to involve the sense of touch to augment their fidelity; medical and surgical training is one of those, since diagnosis and many treatment heavily rely in this sense. In particular, when operating, is important to have the tactile perception of the tissues and the structures being touched, to avoid excessive pressure and, thus, injuries to the patient. The necessity of some physical presence in simulation is required to achieve what is called "suspension of disbelief" [44], which is basically the need of something to touch in order to get a realistic feedback. In [45], an extensive and complete review on haptic devices and haptics in medical education is provided. Many different types of haptic devices are nowadays commercially available; the most relevant difference between them are Dof and DOF; 6 DoF devices are fairly common and their costs is not excessive, in comparison with less free models;

however, 6 DOF devices are way more expensive, because of the more difficult design to create 6 degrees force feedback and render it in the correct way. Most common devices present 6 DOF and 3 Dof, meaning only positional force feedback. Another way to distinguish between different devices is hw they provide forces:

- Admittance: the force feedback is computed through the force applied by the user, which is transformed in relative distance, representing how to base the force feedback on. These devices tend to be extremely complicated and because of this, very big.
- Impedance: the software paired with the device computes the force to be applied at a certain momento, with the respect to the position of the proxy in a certain moment. Easier and smaller device are built in this way, increasing their diffusion. Phantom®(Geomagic®) and Falcon®by Novint Technologies Inc.®are the most common haptic devices of this kind.

One of the reason that haptics in medical education is not so common is the difficulty of force rendering with the respect to visual rendering and costs associated, even though there are some companies producing extremely nice simulators. Human visual system works in fact at slower rate than the tactile perception: 30Hz are enough to perceive a sequence of images as a video, whereas the same can not be said for haptic, because it is commonly accepted that an at least 1000Hz rendering is accepted to feel continuous tactile sensation.This means that a lot of computational power is required to give a suitable feedback; for this reason haptic technologies are unable to follow the progresses in graphics. Tasks reproduced with haptic devices include: stitching procedures, palpation, simple dental procedures, endoscopic and laparoscopic procedures, orthopedics, biopses, needle insertions, punctures. In general, somehow geometrically simple procedures are suitable to be reproduced with not very expensive haptic devices, like, as mentioned, needle insertion, biopses and some laparoscopics.

CHAPTER 3

APPROACH

3.1 Motivation

SNM was initially approved by the FDA as a therapy for the treatment of refractory bladder voiding in 1990. Later on, clearance for using it in UI was given in 1997 and acceptance for non-obstructive urinary retention two years later. From 2009, it has also been approved for fecal incontinence and bowel control.

In such a scenario, and considering the number of people presenting symptoms of the OAB spectrum, together with their estimated increment [1], it is evident how the number of devices implanted is going to constantly rise. Generally, in western countries, prevalence of OAB is already huge: from 8-9% of the people in Canada to 15-17% in Sweden [46]. This, combined with costs that varies in a range of 300-1000 per person per year, evidences how of an impact is this condition in the healthcare. Annual total costs are in the order of billions of dollars More and more patient means that more professionals are going to be of a need, and so it is very important to develop a class of well trained medical personnel, able to perform the procedure with the least risks possible for patient. Injuries occurring during this operation, though not mortal or directly life-threatening, usually result in the necessity to re operate the patient, meaning a big jump forward in the total resources needed. Moreover, significant discomforts for the patients would be present as well, which is always to be avoided because of the ones that the usual OAD patient already presents.

The most difficult part of the procedure is for sure the percutaneous accesso to the foramen, because of the small cut that does not allow the surgeon to see inside (otherwise the procedure could not be considered minimally invasive) and different anatomies of patient that can result in higher difficulties in the procedure. The main risk when accessing the sacrum with the foramen needle are multiple, and can drive to different outcomes; excessive touch and pressure on the periostheum are going to deliver extreme pain to the patient, creating so an excessive amount of discomfort; errors in the positioning may lead to migration, hence, failure, of the operation; sometimes happens that the surgery fails due to the wrong foramen accessed, because it can be challenging to understand which is the correct one. Another relevant issue with this intervention is the fluoroscopy guidance. It is obviously a very useful and reliable tool, essential when it comes to minimally invasive surgeries like this, but what the C-Arm basically does is deliver radiation to the patient, to create the X-Ray imaging. To be exposed to an even low amount of radiation is always inadvisable, fro the well known multiple reasons. Radiation exposure is of a concern in particular in young patient. An expert surgeon, after gaining the skills to perform the procedure, is expected to keep the fluoroscopy time as low as possible, for his/her own sake, for the staff in the OR and for the patient. Conversely, not much expert personnel is more likely to fall into more mistakes, exposing himself and the patient to a higher risk, with the chance to procure overheads.

No specific and generalized training tool exist for student, trainees, surgeons to gain confidence with SNM. The only reported training set, other than on real patients, is built with manikins falling in the category of bench models. IN this case it reportedly low fidelity and not the ideal standard to learn the procedure. What happens currently in the process of learning SNM is, hence, mainly amenable to the common motto "*see one, do one, teach one*", meaning mentoring by expertize medical personnel and training on actual cases, with all the risks above mentioned. Urological training is hence lacking a valuable tool specifically designed for SNM training, at least in the initial phases of the surgeons' careers.

3.2 Proposed Solution

A solution to vacancy can be created through VR and Haptics. It has been described in the previous section how this two technologies are successfully exploited in medical education, and as new devices and new system are commercially available, they get a more and more relevant share of the field. In order to fill this void in a suitable way, the necessity is to develop a system that is completely designed and shaped toward SNM, with the help of medical experts that help to identify the hidden challenges behind such a procedure.

High level specifications of the ideal solution are have been identified:

- **Anatomical accuracy**: the system has to offer the trainee a well defined and high fidelity model, from which he can clearly recognize the anatomical structures and then directly be able to transpose the knowledge gained during training on the real patient, learning how to deal with for instance anatomical markers and to understand his/her position while inside the body

- **Realism**: it is important that the user gets the most realistic feeling possible when he/she is learning, in order to get accustomed to the OR before entering it, and focus on the right aspects. Moreover, he/she must be able to sense the patient in his/her completeness, and perceive the instruments as they where on a real case.
- **Adaptability**: inter patient differences are extremely relevant when it comes to surgery, because a standard shape, when referring to human body, is often not applicable. Different patient have different shaped anatomical structures, that can severely affect the easiness of an operation. It is absolutely fundamental, then, that the system is able to differentiate the training, offering a range of situations in which the trainee can gain familiarity, so that when he will be facing an obese patient, for instance, he knows what to do.
- **User friendliness**: the system must be complete, intuitive and ready to be used as it comes, without difficult settings or additional knowledge to make it work. Also, the interface has to be clear and readable, so to be easily understandable.
- **Performance feedback**: once the procedure has been finished, it is fundamental to compute parameters that state how the user performed, and, possibly, what he has to improve on. Give an evaluation, or at least parameters upon which an evaluation can be conducted, is very important because otherwise, in particular with VR tools, would be hard to understand what are the weaknesses of someone, and what should the focus put on.
- **Reproducibility**: another fundamental feature for a training tool is how many times can a procedure be repeated with the same settings; this is mainly because in this way,

the trainee has the real chance to learn from his/her errors instead of performing one and having to transpose everything to another set immediately. In this way, the learning curve is climbed gradually and efficiently.

- **Safety**: a safe training environment in medical education mainly means that patients are involved as low as possible. In SNM, a safe training set has been identified as without patient, to avoid injuries and risks, and also without fluoroscopy, i.e. with no radiation exposure, neither for the surgeon, nor for the patient himself. This means that both have to be somehow simulated, because, obviously, without them the system would not make much sense.

- **Economical viability and relevance**: the costs/benefits ratio has to be effective with the respect to other products already available in order to carry out a sensible solution. This means that to high costs, have to directly correspond even higher performances. It is not reasonable to not consider economical viability by any product specification.

Chosen solution, in order to fulfill as much as possible the specifications, is a VR and Haptics simulator, targeting at least the initial phases of the learning curve, in which the trainee has to accustom him/herself to the procedure and how to approach it. The system has been thought to be low cost, in order to be, once properly realized and tested, affordable by many institution, without much concern, but still being able to deliver a great educational value. Hardware and software parts were chosen so that the experience is comprehensive of graphics that allows to render accurate models, 3D rendering, extensive possibility when it comes to create force fields and effects.

CHAPTER 4

METHODS

The main purpose of the project is to develop a solution that offers all the specification identified in the previous chapter: anatomical accuracy, realism, adaptability, safety, user-friendliness and commercial viability and relevance. To do so, the application is needed to replicate the feeling of a surgeon in the OR; thus, 3D models and virtual tools must be as precise as possible, both visually and haptically speaking, to provide the trainee with the most realistic experience possible and make the application an actually valuable and usable tool to be introduced in curricular medical education, trying to improve the efficiency of surgical training.

With the requirements clear in mind, the process to fulfill all of them as accurately as possible, includes the following steps: first of all, collecting a set of DICOM medical images and reconstruct a volume from them; performing segmentation on said volume, to identify and isolate the relevant anatomical structure; from segmented data, creating the meshes which will be displayed in the virtual scene; since meshes straight out of segmentation are usually rough, a refinement step is required; eventually, programming to create the virtual environment is the final step.

4.1 Anatomical models

Well designed 3D models are crucial to the success of the project, since they influence the perception of the trainee on the scene, and define how accurate can the simulation be. Rough, poorly designed or inaccurate models would result in imprecisions, affecting the relevancy for training purposes of the application.

The initial dataset used to extract anatomical structures and develop precise 3D models is a volume reconstructed from a thoracic CT scan easily accessible online, from the NIH website [47].

4.1.1 Dataset processing

The CT scan set used is pretty gross, in terms of axial resolution, since the spacing between the images is $5mm$, and in terms of noise as well, so the voxels are too big to perform a suitable segmentation, and to reconstruct the meshes without needing further heavy modeling session would be hard, other than wasting a lot of time later in modeling. Plus, the volume is used to simulate the fluoroscopy, and since the surgeon needs a well definite and precise image, it is necessary to have something more accurate. To get to this, it has been performed some pre-processing, using Matlab®[48].

First step of pre-processing has been to reduce the noise. Most efficient way is to apply linear filter that eliminate the high frequency components, resulting in more clean and definite images set. To have an even better result, a Wiener filter has been applied to every slice, which helped to reduce blurring and to enhance the structures morphology. Another task to improve how the volume is visualized, and make more efficient the live adjusting through the transfer function further implemented, all the voxels with gray values below the 20% of the gray scale range were saturated to the lowest value. This eliminates all the gray-ish mist surrounding the regions of interest and can be done since, being the dataset from a CT scan, bone and relevant tissues will have high values. Afterwards, to get a better axial resolution, the slices have been interpolated, creating a more dense dataset. However, this process makes the volume way heavier, since a lot of data is added. To make it slightly lighter, other than making it compatible with LACE, it is possible to cast the voxels, passing from data type *short* to *unsignedchar*. To avoid very high loss of resolution in this step, manual rescaling of the gray scale values has been perform, clamping them between 0 and 255.

4.1.2 Segmentation

The process of clustering the pixels of an image or the voxels of a volume to identify groups is called segmentation. Different areas are distinguished and grouped together, to identify the different components of an image or a volume. This process is fundamental in the development of a model from a CT scan, because given the images and reconstructed the volume from them, it makes possible to extract the anatomical structures.

Two kinds of segmentation can be performed: manual and automatic. The former is usually thought to be more precise, but it is extremely time consuming, because it requires the user to go through every slice of the volume and identify the region of interest, to be included in the final result; the latter, conversely, is way faster because algorithms that analyzes the images and distinguish between the region of interest and te background are implemented and choose the pixels instead of the user, but can result in low precision and create artifacts, which affect the final result. automatic is the chosen method, because segmentation is not the main purpose of the work and the result would have undergo further processing anyway, so it was way more efficient.

The method used relies on thresholds to distinguish among the different pixels through their gray level and recognize so the groups with similar color. Here the main purpose is to recognize and extract the spine and the skin, since they are the two main tissues the trainee will interact with, and since their absorption properties are way different one another, it is not the most difficult task.

Two softwares have been used to perform segmentation: the first choice was ITK-Snap™ [49], an open source tool based on ITK/VTK frameworks and is commonly used to perform medical image segmentation. Since the result were not quite as good as expected, in terms of precision of the models and realistic outcome of the organs, it has been decided to move on and try something else; in particular, the most common problem was with internal organs, whose 3D graphic properties were strongly affected by the low resolution of the scan, despite pre-processing. Despite low resolution, perhaps, rough 3D models of skin, spine and pelvis extracted with ITK-Snap™ have been used to build the initial raw application and start developing. Second choice to perform in improved segmentation was Mimics™ [50], a software by Materialise®. With its more advanced algorithms, which rely on not only threshold, but also clustering, the outcome are way better and more easy to be handled with than what comes out of ITK-Snap™, in terms of graphics, smoothness and anatomical accuracy, not to mention a lower evidence of artifacts and imprecisions. Thanks to this, it has been possible to build an improved 3D model of the lower back, to respect the requirements of anatomical accuracy and realism.

4.1.3 Models post-processing

The outcome of said softwares are usually files in .STL format, which is the most common format in virtual and rapid prototyping. Files of this kind contain information about the 3D structures of an object, allowing to represent the correspondent mesh. In the .STL, data uniquely identifying the triangles composing said mesh are stored: for every basic shape, vertices and normal to the surface are stored, resulting in twelve data for each shape (i.e., three coordinates in a xyz space for every vertex and three for the normal); every triangle is connected with the one next to him whilst necessarily sharing two vertexes.

The biggest challenge to be faced while reconstructing 3D meshes from medical images is the considerable roughness that is usually encountered after extracting a mesh through segmentation. This is mostly due to the fact that, although softwares are optimized and algorithms are made more efficient, human body's internal tissues are similar in terms of absorbance of X-Rays, so, while it can be easy for an expert to precisely distinguish among different organs and tissue, it can be challenging for a software. To overcome this problems, post processing is fundamental.

This step has to do with editing the 3D meshes to create smooth, polished, and accurate models to represent the anatomy of the virtual patient in the environment. Multiple softwares are available to perform this in the correct way; the ones used to refine the meshes out of the segmentation are AutoDesk™ 3DSMax®[51], that comes free in its student package; ParaView™ [52], an open source software including powerful and effective algorithms to apply filters and improve visualization, such as contour polygons and decimation; ZBrush®[53], an efficient, precise and user friendly sotfware to sculpt 3D object, like 3D meshes, modify shape, smooth them, and enhance their visualization.

First thing to do with the .STL file out of the segmentation software is try to eliminate all the artifacts. This can be done with 3DSMax™, selecting the polygons that must excluded by the mesh and erasing them. A mesh with a lot of artifact is not only bad looking, because the shape would be distorted in some points, and some sort of dust may be visible around it, affecting the working environment, but is also harmful for the haptic properties of the application; polygons from artifacts, which may bee unseen, are subject to the risk that the collision detection algorithms of QuickHaptics™ fails on those small particles; since those would be loaded as part of the mesh, the haptic properties would be very poor, because touching one of the particles would be like touching the expected mesh, messing up the results. For instance, if the application is designed so that it counts the number of times the trainee hits the wrong organ with a needle during a biopsy, but said organ is modeled with a poor mesh with a lot of artifacts, the system may give a wrong feedback because every time one of the artifacts is touched, the counter would be increased, even though the expected organ remains untouched. taking out all the artifacts is so the first step; going through the improving of the mesh without first cleaning it, in facts, would cause to edit the artifacts also; this increases the computational time for the procedures, because the softwares have to edit also the useless parts; second reason to avoid straight up editing is that it is possible that at the end of the process, when it's time to eliminate the artifacts, the mesh is again affected and requires to undergo another 3D modeling session, with a huge waste of time.

Second step is smoothing the surface. As written before, meshes straight out of segmentation are very rough. A good way to smooth the surface is to take advantage of 3DSMax™'s modifiers, relying on their automatic techniques and high efficiency, even though they are usually expensive in terms of computational resources. This software is also useful to adjust the position of different meshes with the respect to each other, as it is easily possible to drag them and fix them where wanted. However, after segmenting from the same dataset, this should not be required.

To operate on the models more heavily, Biomedical Visualization students suggested to use Zbrush™, together with a Wacom®Intuos™ device. The software is indeed intended to digitally reshape, carve and sculpt a model. With such tools, it is possible to modify the mesh to make it more realistic and accurate, as well as designing missing parts, edit inaccuracies and adjust portions erased together with artifacts because shadowed by them. This happens to be really important, since the collision detection algorithms rely on the normals of the polygons composing the mesh, and have a smooth and homogeneous model is important to lighter the computations and enhance the feedback itself. The dataset used comes from a CT scan, so the patient was laying down on a table. Because of this, it happened that reconstructing the skin through segmentation, the result was pretty good on the belly and chest, but really poor on the back, because everything was flattened. Since the access to the sacrum in SNS is percutaneous, from the back, it would have been absolutely impossible to use such a messy mesh in the application, even if completely smoothed, because all the anatomical references would be absent, and the shape of a body, from the back, would be hardly recognizable. This is the main reason this step is necessary: the model needs a strong reshaping to restore the complete anatomy of a normal body and recreate the right shape on which a trainee can operate.

The last step is decimation. A mesh is usually created with basic polygonal shapes, among which triangles are the most used, because of how simple they are, and how easily they can be represented. Obviously, the bigger is the mesh, the higher is the number of polygons, and so the number of faces and vertices. The haptic rendering of a shape, in general, is highly expensive in terms of computational power. This is due to the fact that every shape is rendered as a group of polygons, and the collision detection algorithm implemented in QuickHaptics relies on the normals. For these reasons, having big and high polygonal meshes to be rendered both graphically and haptically is absolutely not advisable if the aim is to have a smooth and fluent interaction between the user and the scene. Anatomical structures tend to be very complicated with the respect to basic shapes, and so, to be rendered precisely they usually need a lot of polygons and faces, resulting in extremely heavy models. Furthermore, processing and refinement often result in increasing the number, because for instance, to smooth an object, it is required that some edges are rendered with more vertices in order to be less sharp, so some precautions must be taken before throwing the models in the application. Decimation is the process of reducing the number of samples in a dataset and it is fundamental to combine both accuracy of the visuals and smoothness of the application. A lagging application in surgical training would be totally useless, because of the high precision that surgery in general requires. In the case of meshes, this means reducing vertexes and faces. Obviously, a strict requirement is to keep the shape as coherent as possible with the original one, even though a reduction of precision is physiological in the process. To perform this, both 3DSMax™ and ParaView™ were used, since they both have powerful algorithms aiming to reduce the number of vertexes and faces without affecting the topology. The result is a simpler and lighter mesh, which can still be extensively used for the purpose of the application.

4.2 Software features development

In this project, the requirements include integration between robust and accurate graphic models, showing the most relevant anatomical structures, and tactile feedback when these models are touched through the haptic device, to provide the trainee with a realistic feeling and let him learn how to manage the procedure. It is indeed necessary to rely on specifically built development kits for visualization and haptic rendering. This tools are included in a C++ middleware called LACE [42] [54] [55] [56] developed in a collaboration between NearLab at Politecnico di Milano and Mixed Reality Laboratory at University of Illinois, which allows to concurrently handle extensive and advanced graphic tools in an OpenGL environment as well as a robust haptic rendering with the QuickHaptics™microAPI.

4.2.1 LACE Library

The implementation of such a tool, in the form of API, comes from the needs of better graphics capabilities than the ones included in QuickHaptics only, with the possibility to implement shaders and visualize volumetric data, as well as the fact of including more features in an application, like electromagnetic tracking.

LACE Library components, as shown in Figure 11 and Figure 12:

- Visualization Library (VL) [57]; an OpenGL based framework, open-source library developed for 2D and 3D graphic application, It is a light and very effective object oriented library to develop with the power of OpenGL, but retaining a certain user-friendliness that allows to develop in a more easily environment. It features GL Shading Language, volume rendering, interpolation and many other extremely useful features when developing a Virtual Reality application.
- QuickHaptics™ [58]; as previously outlined, it is the microAPI built upon OpenHaptics. It is originally intended develop softwares to be used with 3DSystems™ haptic devices. It is here used to handle the tactile feedback provided to the user through the device. It make possible for the user to choose among the default force effects to be included in the application, or define it's own self, to better represent some more complicated features which can not be modeled with simple damping, friction or a constant force.
- Wykobi Library [59]; a C++ open source library to perform geometric computation, 3D and 2D, in a light, fast and efficient way.
- Ascension 3D Guidance; Electromagnetic tracker, to manage the communication with a 3D guidance system through its API.

LACE is designed in such a way that graphic and haptic renderings are performed in two separate threads. Two GLUT windows are opened, one always by the VL thread, to show the models and the shapes with the advanced graphics, and the other, if activated, by QuickHaptics™, where haptic rendering happens. Communication between all the features is handled through LACE API, which make sure every object is correctly mapped both in the QuickHaptics™ and in the VL one. LACE API can be grouped in four types:

- Renderables; this includes the classes to display, manage and modify shapes, meshes and volume. The design for this type of classes is done in such a way that a base class, LACE_Object, groups the common function to every possible other object which can be represented in the scene.
- LACE Forces; special force effects are included. In particular, the ones to create the force effects associated with the LACE_Volume class and the LACE_Extrusion.
- Renderings; these section is designed to provide multiple ways to visualize the scene. Through the class LACE_Rendering it is possible to add multiple subwindows to the main one, to better organize the scene. LACE_CuttingPlane, otherwise, allows to virtually cut the objects.
- Tracking system; this is to customize the use of electromagnetic tracking with the classes LACE_Sensor and LACE_Transmitter and make them communicate with Ascension.

The class used to handle every other instance is LACE_Class, which must always be defined in every application. It manages processes, creates the threads, load the variables and enhance user customization. This class contains also the methods necessary to initialize the application, activate the libraries and initiate the program, entering the GLUT loop, which is the actual starting point of a program based on OpenGL.

Every object created in a LACE application has two sides: his QH and his VL side. The first one is obviously important for what concerns his haptics-related attributes and methods; in this part is set, for instance, its stiffness, the roughness of its surface, its popthrough value and other properties that can be perceived when it is touched. This attributes and methods are accessed by the developer through its QH_Geometry pointer, which is basically the portal to its QH life. Its counter part, the VL one, otherwise, is accessed through all the attributes usually present in a VL object to be visualized, namely the aspect that an object must fulfill to be correctly visualized in such an environment; these object include a transform, VL_Transform, where the 3D spacial settings are stored, a geometry, VL_Geometry, which describe the geometrical properties, an effect, VL_Effect, including for instance light, shadows, surface aesthetic, and an actor, VL_Actor, which group all the VL attributes together to identify the object. QH and VL sides of an object share informations and communicate mainly through their transform, i.e. their attributes VL_Transform and QH_Transform; these two are in facts set to make the position in the GLUT window to be displayed on the screen correspondent to the position and orientation in the QH environment, and so coherent with the haptic device.

4.2.2 Implementation

The application is generally designed to try to exploit the available tools in the most efficient way possible, taking advantage of the already existing LACE API where convenient, and develop new methods and classes when necessary.

The scene Figure 13, Figure 14, presented to the user is so that it has an a main portion of the screen where he can interact with the models through the stylus of the haptic device.

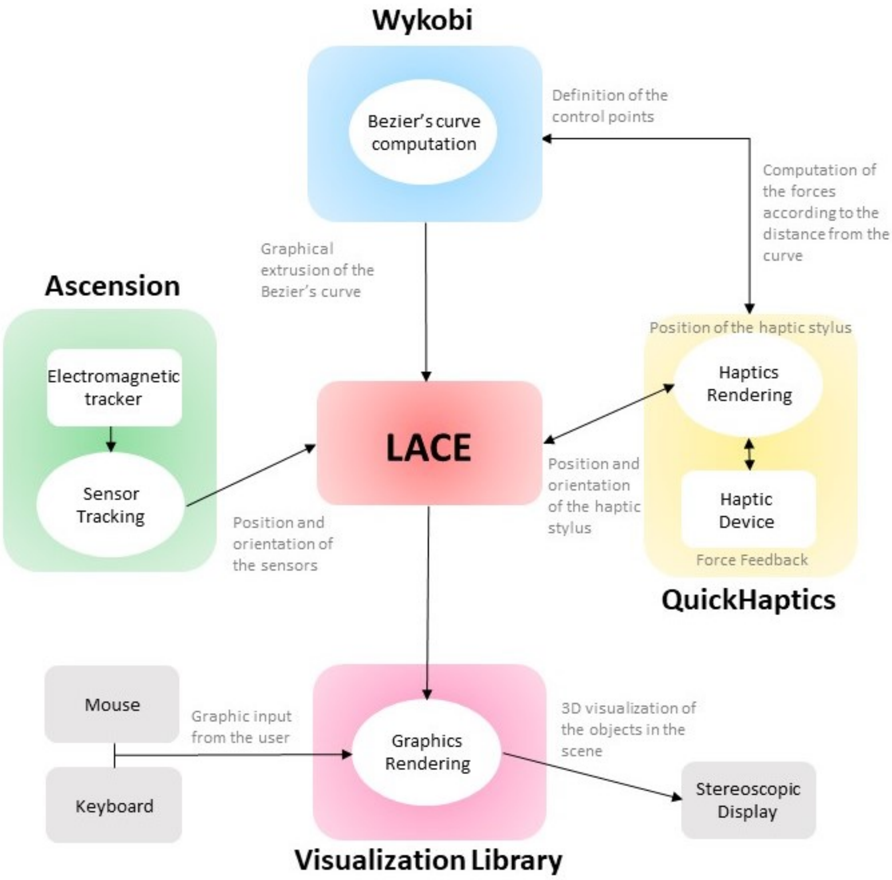

Figure 11: General scheme of LACE Library

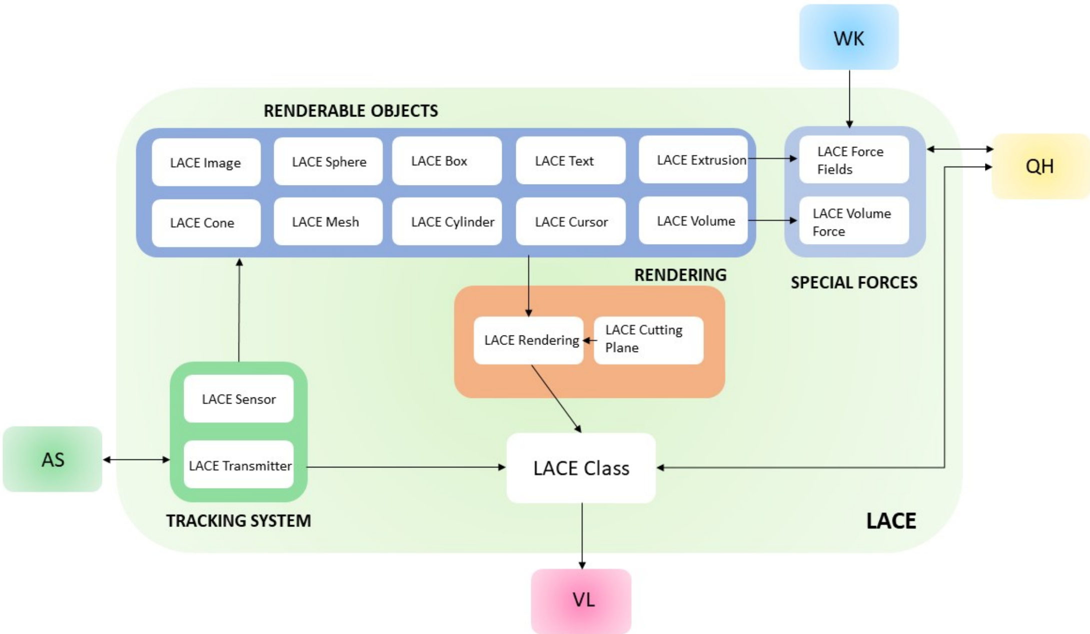

Figure 12: Classes in LACE

Another part with utilities to replicate the tools available in an operating room, to test the correct positioning, to activate or deactivate the C-arm, move it, or simply select the step one wants to perform. A third part is composed by the visual feedback that a surgeon relies on when performing the procedure, namely the fluoroscopy guidance, the toe bending and the anal sphincter contraction.

The work flow of the simulation is designed in such a way that the trainee can go through the most relevant steps of the procedure, repeating as many times as he wants every step, and getting a final evaluation. Three steps have been identified as the most relevant to be simulated,

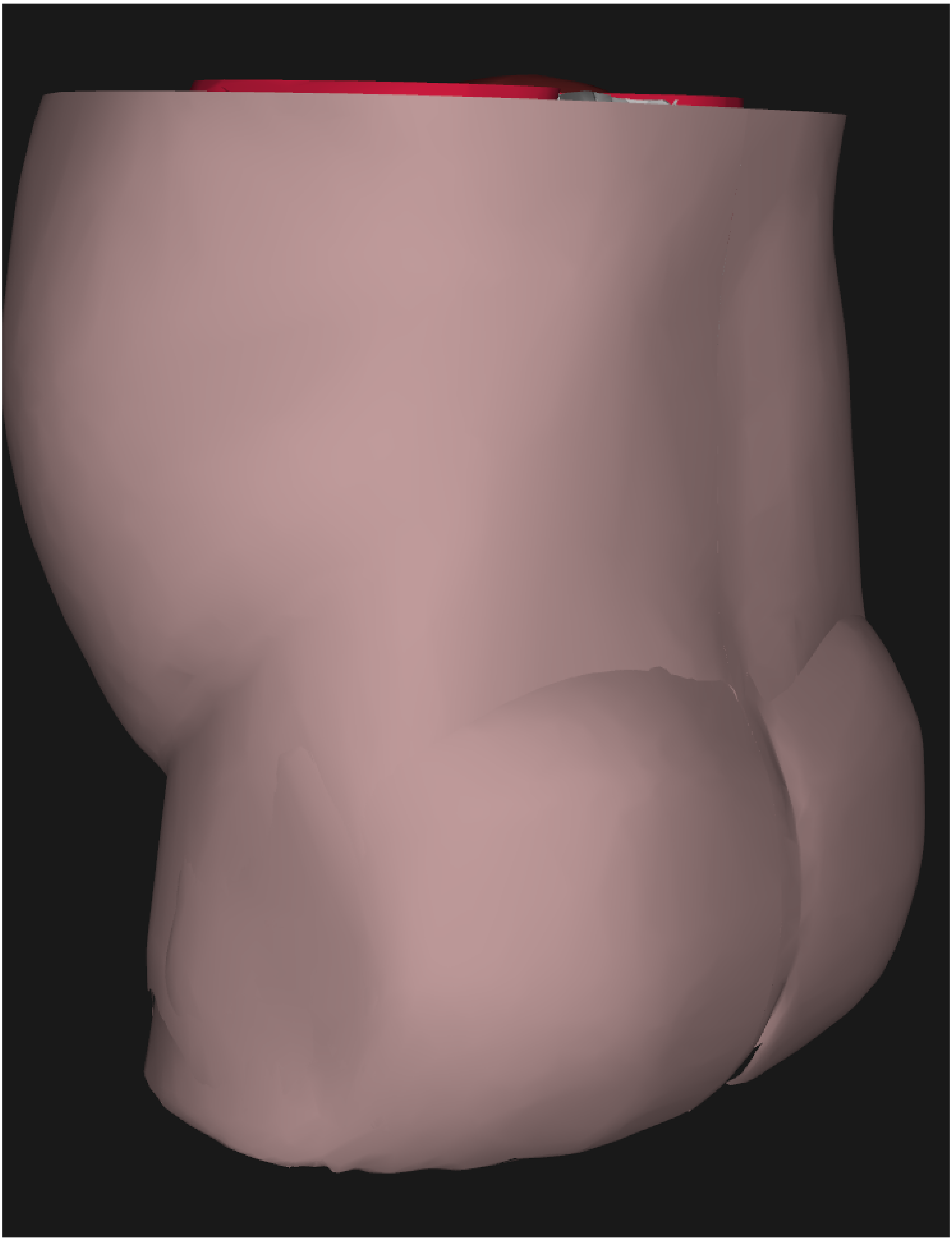

Figure 13: The anatomical models in the environment - skin

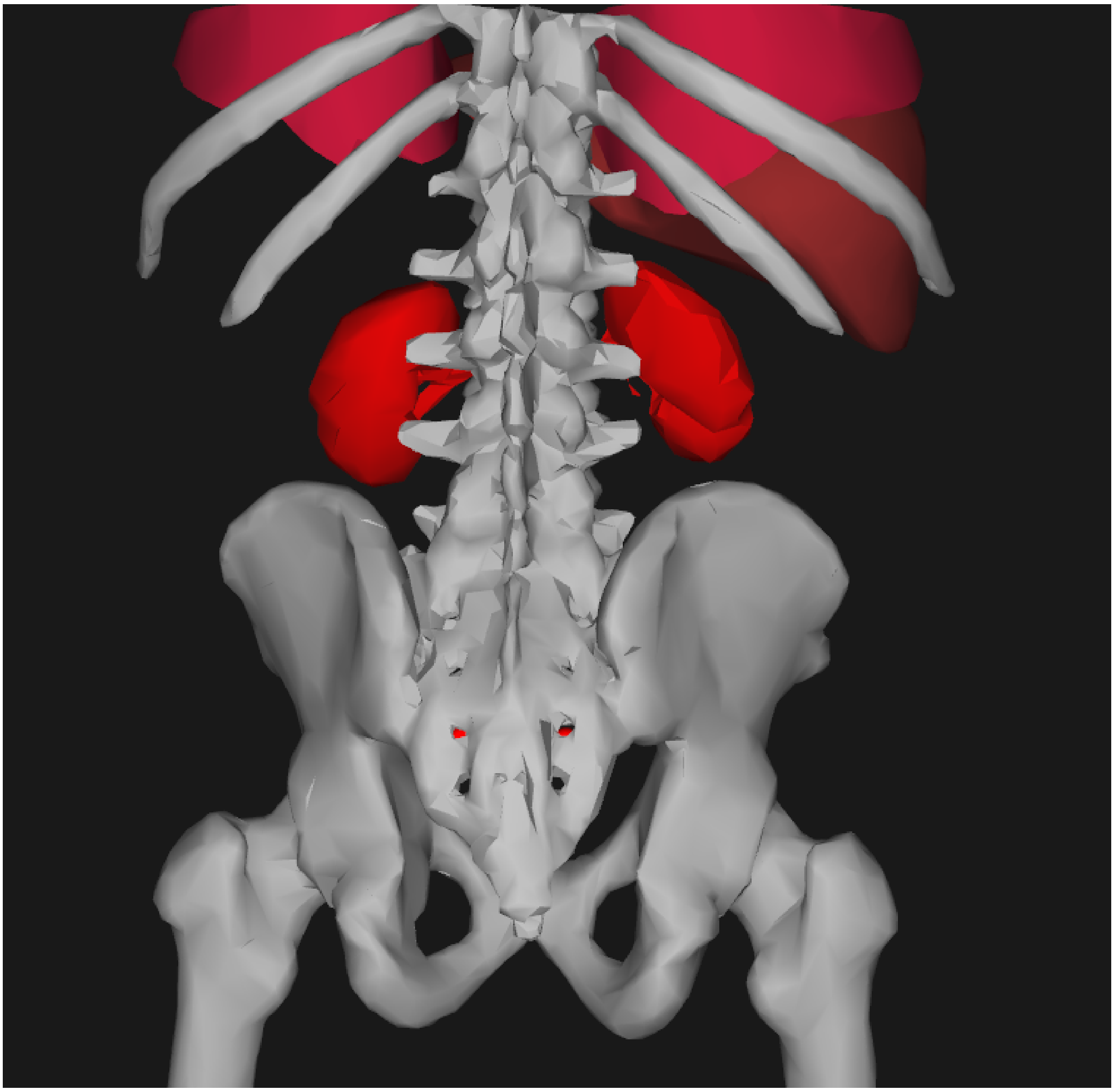

Figure 14: The anatomical models in the environment - bones and internal organs

because those are basically the ones that the surgeon has to master and that can cause over exposure to radiations or injuries to the patient, as well as excessive pain:

1. **Needle insertion**; this first step is by far the most challenging and difficult to perform, and it is the most important for the outcomes. It is necessary that the trainee is allowed to deeply understand how to manage the instrument to find the correct foramen and fix it in the correct position, how to test the position and recognize a well done placement.

2. **Guide placement**; this second step is possibly the easiest one, according to expert surgeon who often operate to implant neuromodulators. It basically consist in placing the guide inserting it around the needle, taking care that the radio marker is in the most suitable position. This task usually requires just a few minutes, and it is important to be as quick as possible to reduce the fluoroscopy time.

3. **Electrode positioning**; last highlight identified is the actual placement of the electrode inside the guide. The electrode, after exiting the guide below the foramen, can bend to reach the exact correct spot. Once the placement is done, the device has to be tested, taking time to ensure that all the electrode are working correctly, carefully activating each one to see if they work with the correct current. This is the last step of the simulation.

After the trainee has performed all the tasks, the application provides some feedback to evaluate the performance and let him understand where he should improve. It is designed to record previous performances by the same trainee, in order to monitor how the learning curve is affected. Every step can be repeated, and the system gives multiple evaluations, one each time the step is performed.

4.2.3 Graphic User Interface

Utilities for the user are available through a Graphic User Interface (GUI) built with the GUI framework from the OpenGL context, GLUI. This allows to create essential user interfaces, featuring buttons, scrollbar, panels, and other basics tools to build a simple but intuitive tool for the user. Choice fell to GLUI for multiple reasons: first of all, it is easy to be integrated with a GLUT window, since it is part of the same toolkit, it is based on C++, and it is fairly easy to implement. It is also convenient to let him set some parameters as he feels comfortable with, like tuning the fluoroscopy transfer function which changes his visualization.

4.2.4 Fluoroscopy guidance simulation

As mentioned in the background, Sacral Neuromodulation is performed under fluoroscopy guidance. It is indeed strictly required for the application to be coherent to what is available in an operating room to include a simulation of a C-arm. The C-arm is a unit present in operating rooms when fluoroscopy is required, and it is basically a robotic arm which can be moved by the OR staff to take snapshots or set the live imaging display. It is usually designed in such a way that the surgeon is allowed to have a broad choice of angles from which he can visualize what is happening inside the body. Usually, during a procedure like SNS, two point of views are used: antero-posterior, to see where the foramens are and to choose the access point, and sagittal, to find the best angle to correctly enter the hole.

The surgeon is so allowed to move the arm and see the whole body of its patient. This means that it is not possible to fulfill the requirement of a fluoroscopy simulation with a simple image, or just changing images. It is way better to use the volume reconstructed from the data set, the same segmented to reconstruct the 3D models. The explanation to use a computationally heavy object like a volume is immediate: first of all, with the volume it is possible to visualize the whole portion of interest, from different angles, as an image, the same thing that happens in the real operation; a second reason is that the models are built from that volume, which means that the imaging is actually correct. Plus, the raycasting technique used to visualized the volume represents the said volume as a 2D image on the screen, which is even more accurate in the representation of reality.

Two separate subwindows have been used to visualize two different views. Each needs a camera pointed on the scene, to display the correct point of view. The positions of every object in the renderings and in the main scene are coherent; this is fundamental, because an object in the center of the coordinate system of the main window, if displayed also in a separate rendering, will be in the same position with the respect to that rendering's coordinate system. So, it is fairly easy to place the models in the principal window, which is the one with the user interacts with, and the volumes in the same position in the renderings, in order to make them stay coherent. The cameras are put in a way that they point to the volume from the back and from the side, displaying it in the views needed to assist the procedure. Since the meshes can be moved and have their position adjusted to haev the right perspective on the scene, everything is adjusted with the help of the transform of the cursor, resulting in keeping the scene together.

To better simulate a C-arm, the user has the possibility to adjust the view on the volumes through the keyboard, with W, A, S and D to move the arm respectively up, left, down and right. What actually happens in the scene is that the cameras are moved, and the point of view together with them.

4.2.5 Patient's responses reproduction

As mentioned in the description of the procedure, the surgeon has to test the position of the needle, to ensure that he didn't choose the wrong foramen or that he reached the correct point on the nerve. As previously explained a full bellow contraction, together with the toe bending inward are sings of a correct position, meaning that the instrument has reached the right spot to allow modulation. The real device can give current with different intensities, usually in a range of 1 to 4 mA, and the provider suggests to tune the placement in such a way that the body responses occur at 2.1mA or less. With the electrode, the test is basically the same, the only difference is to test that all the four electrodes trigger the correct response.

To implement this test and get the trainee to learn how to interpret and recognize the right signs, two other renderings are created, one for the toe and another for the anal sphincter. In the GUI, a panel is dedicated to the settings of the test: the user can tune the intensity of the pulse, in a range from 1 to 4 mA, and activate the current through a button. What happens is that in the renderings, the bellow and the foot supposed to move are displayed, and a function computes the amount of motion that must be triggered, in the bellow and in the toe. In this way, the trainee has to infer on the contraction he sees, understanding if the position is correct or not.

This part of the application is designed in a simple, yet effective way: an array of images is loaded when the application starts; these images cover the ideal range of motion triggered by a correct stimulation. When the current is activated by the user, with the button in the GUI, a function computes a range, which is basically a percentage of the images to be shown. The array is streamed in this range and the result is the partial or full motion of the foot and bellow.

To further explain:

$$N, i, d$$

are respectively the number of images in the array, representing the maximum range of motion, the current chosen for the pulse and the distance of the instrument from the target; let's state that, given d_0 the maximum distance possible from the target to trigger a response and $n_{i,d}$ the range of motion related to a given condition:

$$n_{i,d} \propto \frac{1}{d}$$

$$n_{i,d} \propto i, d \leq d_0$$

$$n_{i,d} = n(i, d)$$

that directly lead to the function:

$$n(i,d) = \begin{cases} 0 & \text{if: } d \leq d_0 \\ \dfrac{i}{d}\alpha & \text{if: } 0 < d \leq d_0 \\ N & \text{if: } d = 0 \end{cases}$$

Which is the function used to compute the range in which the motion is to be displayed. The array is streamed up to this range, back and forth, to display a natural motion, repeated as long as the test is on. The parameter α is computed in such a way to better fit the images sets used.

4.2.6 Haptic force effects

To give the trainee a full experience during the practice, ça va sans dire, it is absolutely necessary to provide the same tactile feedback he would encounter in an OR. This is, perhaps, one of the main features of the application, and it is provided through the haptic device. It is important that the tactile sensation provided is as accurate as possible, because, in a procedure like this, the feeling of the needle inside the body is what he surgeon has to rely on to perform his task.

There are basically two types of haptic effects in the application:

- **Shape related haptic effects**; these are the ones directly linked to the 3D models and their topology; the user can actually touch them, and perceive their texture and their stiffness through the stylus. All the models can have an haptic effect, but since the topic of this simulation is mainly linked to the tactile sensations provided by a needle penetrating the skin and trying to avoid as much as possible the contact with the bone, there is only the strict necessity to well tune the spine, in its sacrum portion, and the skin, to allow the soaking. Other models, such as the kidneys, the liver, the lungs, are just included for the sake of completeness, in order to create a more realistic and comfortable environment for the trainee, who is allowed to make the skin transparent to see the insides, and it would not feel familiar for him/her to see an empty body. So, the spine model is rendered as stiff as the device and QuickHaptics allow to. The skin, on the other hand, is soft and smooth, with a superficial damping effect that makes it more realistic; it has a popthrough effect, which is a sort of threshold that if overcome while pushing against the object, allows to enter it. This is to emulate the needle piercing.

- **Event related effects**; these effects are not related to an object in particular, but are triggered when a specific action is performed by the trainee. This is the case that occurs when the skin is penetrated with the needle and the inner layer are entered; the popthrough threshold, when overcome, make the program enabling damping and friction effect, which represent the difficulty of moving under the skin; also, when the needle is inside, there is the constraint of the entry point, which makes hard to shift the instrument, while leaving a substantial freedom of movement around said point; to simulate this, a custom fulcrum effect , which is later explained, is created. In the second and third step, the fulcrum effect is substituted by a line effect, to simulate the constraint of the guide over the needle and the guide around the electrode, eventually.

The above mentioned fulcrum and line effect are custom effect created expoiting the servo loop callback of QuickHaptics, which allows the developer to create his own force effects. Further explanations on the fulcrum effect follow: as said, it is intended to recreate the constraint of the entry point in the skin, letting freeom of movement of the top and the bottom of the needle. Is created in the following way:

$$f, \overrightarrow{Q} = \begin{bmatrix} qw \\ qx \\ qy \\ qz \end{bmatrix}$$

are respectively the entrance point and the quaternion with the orientation of the needle in a certain moment. Exploiting the axis of the quaternion:

$$f^1 = f + (qx, qy, qz)$$

and a line passing for f and f^1 is created. Given the position of the cursor p, and p^1 its projections on the line, the force effect is computed as:

$$\overrightarrow{F} = (p^1 - p)\alpha$$

where alpha is a parameter set to adjust the force. Since those point are vectors, as well as the force, the direction will be directed to the line and just needs to be adjusted in terms of magnitude. This is the blueprint for the line effect as well, the big difference is that in the fulcrum, the orientation of the line is constantly updated, whereas in the line the line stays still. In the application, the line for the line effect is set when the placement of the needle is confirmed by the user, and will remain there for the rest of the procedure.

4.2.7 Feedback on the user's performance

The ideal performance for a procedure like SNS is a fast and precise access to the S3 foramen, without touching the spine, placing the needle on the sacral nerve, test the device to see the right response from the body; in this way, the fluoroscopy time would be minimized, and so the radiation exposure for surgeon, patient and for everyone in general in the OR; the risk of injuries is minimized as well, together with the pain for the patient.

Considering this, the application has to give useful feedbacks to the trainee in terms of time and access. Three main feedback are hence provided:

- **Fluoroscopy time**; only the continuous fluoroscopy time is considered. Every interval is recorded, and the total time is updated on the scene after every usage.
- **Surgery time**; the application computes the total time the trainee requires to perform the procedure. This counter is updated every time a step is completed.
- **Accuracy of the access**; the accuracy of the access is thought in terms of number of times the bone is touched. The goal is to avoid touching the bone as much as possible, exploiting the guidance to enter in the right spot and with the right angle.
- **Accuracy of the placement**; together with an expert, a target is defined, as an ideal position, considering the anatomy of the model. The trainee is intended to learn to

recognize the correct spot and to be able to get to it as precisely as possible. To compute this indicator, once the placement has been done, the distance of the needle from the target is easily found.

To implement in the software the task regarding the time, a custom class, Chronometer, has been specifically designed, to easily allow the computation of time, accessing the clock of the machine used, and to keep record of every interval, like every time fluoroscopy is used, every step, to keep track of every aspect of the performance.

4.2.8 Virtual electrode lead properties

Since the electrode, when it enters the body through the guide and reaches the correct spot, can bend, this property had to be included in the application. To implement this in a light and effective way, the class LACE_Extrusion has been modified. Originally this class was intended to create Bezier curves only, but the requirement of this work did not comply well with a mathematical object like this, so the necessity of something else arose. The choice fell upon a Catmull-Rom spline; Catmull-Rom spline are known to be smoother than usual cubic spline, and for this reason very suitable to be used to recreate the natural bending of something like the electrode. At least four control points are required to create a curve like this, and to avoid unnatural behavior it is strictly suggested to avoid aligning three points. Obviously, the higher is the number of control points the smoother is the curve, but it increases also the computational requirements to elaborate the extrusion. Two modes are used when the user is managing the electrode:

- When the user is freely moving the electrode, outside the body or in the first part through the guide, all the four points are aligned with the orientation of the cursor, taken through a quaternion. Although has just been stated that a situation with three points aligned is to be avoided, it has to be considered that this is a completely different situation, because in this case the electrode is intended to be like a stick, straight and rigid.
- On the other hand, when it is placed through the guide and the point is reached, a small bending occurs. The fours points in this case are computed in a different way: one point is placed on the cursor, another along the guide, a third at the end of the guide and the last one, that is the most difficult to be placed, is put under the line connecting the point on the cursor and the one at the end of the guide. What happens in this case, is that as the surgeon moved the cursor, he is no more moving the extrusion as a whole, but the last point only, while the others are adjusted with the respect to that one, and the one at the end of the guide. The one along the guide slides on the line created to keep the length of the electrode constant; the last one is constantly computed and adjusted to confere to the extrusion the correct smoothness.

Further explaination on the Catmull-Rom spline are provided in the Appendix.

4.3 Hardware components

Software elements are paired with hardware requirements for haptic and visual rendering. The first one is the 3D monitor; with the proper glasses, it allows to conceive 3 dimensionality to the scene, giving the trainee the possibility to perceive the depth of the scene and move with the respect to, conferring so a greater and more immersive experience in the virtual environment.

Figure 15: The haptics device used

Type	Touch 3D Stylus
Positional Feedback	6 (complete pose)
Force Feedback	Dof 3 (position only)
Force Feedback workspace (WxHxD)	10.45 x 9.5 x 3.5"
Maximum Force	3.4 N
Nominal position resolution	0.084 mm

Figure 16: Device specifications

The second element is the haptic device, shown in Figure 15; Touch™ 3D Stylus by 3DSystems Geomagic®is the model used in this project. It features 6 DoF and 3 DOF. Basic technical sheet is in figure. Choice fell in this because of its availability and cheapness, which is of great value for the aim pursued. 6 DOF devices would result in a better result, but the cost would increase a lot as well, reducing economical viability.

CHAPTER 5

DISCUSSION

The purpose of the work was to develop a reliable tool for medical students, residents and urologist to train on Sacral Neuromodulation. The acquisition of the necessary skills to perform a well resulting procedures are currently only learnt through practice on real patient, with many additional risks with the respect to the procedure performed by expertized personnel. Due to constantly reduced training hours, residents and medical students do not have the chance to be involved in extensive curricular training that covers all the aspects of their specialization; moreover, thanks to the advancing of technology and, hence, the birth of new techniques, it is always more difficult for low expertize to master the several procedures available, and most of all more procedures means fewer chances to practice on one in particular.

For these reasons, it will be more and more important to take advantage of the technology available to build tools and systems to achieve the goal of providing comprehensive facilities to residences, medical student, and physicians in order for them to train at least on the most relevant procedures in the most appropriate condition, which can be identified as the specification of medical training system mentioned in 3.2. Furthermore, simulator respecting said specifications, are proved to develop more rapidly the skills of and apprentice, decreasing the time needed to climb on the learning curve, even though it is a steep one.

The application described and developed in this work offers an instrument designed to meet these requirements, intended to be a suitable tool to learn the surgery procedure used to implant neuromodulators. Safety of everyone normally involved in the operation is preserved, since no radiation are used, and no patient is going to be under a greater risk than the normal. Unlike available bench model, the advanced 3D graphics are tailored for the procedure, to confer the highest accuracy possible and to respect the real anatomy, in order to give the trainee the sensation to operate on something that is directly related to what he will perform in a real OR; this is neglected in both artificial and biological bench models, because of the materials used in the previous, and the different anatomy of the latter. Plus, it offers a greater possibility to evaluate the procedure, thanks to the parameters given by the computer once the procedure is completed. Another great advantage offered by the VR-haptic simulator is the reproducibility of the task: the user can try to succeed as many times as he wants, keeping track of his performances and addressing the accomplishment of a well mastered procedure within multiple training sessions. The same can not be said neither with bench models in general, nor with cadavers or real patient, because all of these other methods are subject to degradation, and about of real patient, the procedure has to be repeated only if something goes really wrong, which obviously must not be the case.

No other specific SNM training tool exist, so a comparison with a specific other system can not be done, even though some other VR sets to train in urology related procedures exist, like the URO Mentor®, which, even though very well built, due to their very high costs can not be extensively applied and wide spread. Plus, the haptics feedback is not present. The VR-haptic system, conversely, is cheap, provides tactile feedback and can also be improved and tuned with the advice of experts, who can test it and suggest how to tune the tactile feedback, and what to include in the application to extend its potentiality. The economical viability of such a system are also related to the hardware required to make it function; the only non so common thing in the setup is the haptic device, and it is the only special tool necessary. The 3D monitor is actually a plus, to perform the simulation in more immersive environment and to give the perception of depth, but it is not stricly required to run the simulation as the application perfectly works with a normal screen. However, the value of the 3D rendering of the scene is important, because in such a way, the comprehensive simulation would give the possibility to learn eye-hand coordination, as well as how to correctly use the C-Arm, relying on 2D imaging to move in a 3D space, which is one of the most relevant skill for a surgeon that has to perform fluoroscopy guided surgery.

CHAPTER 6

CONCLUSIONS

The application is thought to provide a valuable tool where no other solution were available, filling the gap between SNM and other more popular procedures in terms of training, like PCA or laparoscopy. The application, after undergoing testing, validation, and refinement reflecting the results, can be included in the curricular training of residents and medical students, as well as be part of insitutions' facilities in general, to address any practice necessities occurring from time to time.

For what concerns the core of the software elements of the application, the LACE library API, general contribution has been brought to the development, after the first implementation done last year in the works cited in 4.2.1. In particular, a certain amount of generalization has been conceived to some classes initially intended for a specific application, and some methods have been refined to better meet the needs encountered during the development. Moreover, extensive usage has mandatorily driven through a necessary debugging work, which helped to put the focus on some improvement that could be useful for future developers and users. LACE remains an extremely valuable and consistent tool to develop rich and complete visuo-haptic applications, and it will be important to push it further, creating a more and more efficient platform.

As is, the application is working and provides the blueprint for a valuable tool, but it can be improved and expanded to give better feedbacks; most immediate future development may include:

- Tests, involving medical students, residents and expert physicians, that can provide a wise evaluation on the work done, helping to improve it. This is currently planned to be pursued at Politecnico di Milano, as a fulfillment of the developer's Master thesis.
- Inclusion of Head Mounted Display; 3D monitor techology is doomed to be substituted by mixed reality headsets in its entirety, for multiple reasons, out of the scope of this thesis. Include such a device would be of great importance, because it would give the possibility to create not only a virtual patient, but n entire virtual OR in which the experience would be even better.
- An automated process in which, loading a volume, the application would undergo by itself through the segmentation and the creation of a mesh. This would project the system out of the training field, encountering also the possibility to plan an intervention thank to the data given by the simulator.
- Some information on the angle that the needle should assume when puncturing the skin, in order for the trainee to learn how to position it with the respect to the fluoroscopy and the sacrum. This, in combination with the second improvement, would result in an extremely useful tool to be used also intra operatively.

Undeniably, the use of better hardware solution would also affect the performance and the experience in a positive way. Should be kept in account, thus, that those features would increase the costs of the system, making it less appealing and less spreadable as a training tool.

APPENDIX

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PROJECTS

- VIRTUAL REALITY AND HAPTICS TRAINING SIMULATOR FOR SACRAL NEUROMODULATION SURGERY - University of Illinois
  A VR and Haptics application to train medical students on Sacral Neurostimulation Surgery.
  - Segmentation and Virtual Prototyping to create the 3D models.
  - OpenGl enviromnent and in-house sw framework development to handle visualization and haptic features, respectively through Visualization Library and OpenHaptics.
  - C++
- MOLECURAR ANALYSIS OF AMYLOID FIBRILS - Politecnico di Milano
  A computational study to understand the molecular mechanisms that drive the folding of human Calcitonin, generating amyloid fibrils, correlated with Medullary thyroid cancer, through Molecular Dynamics simulations in an aqueous enviromnent.

WORK EXPERIENCE

Graduate Research Fellow at *Mixed Reality Laboratory*, University of Illinois at Chicago Working on 3D modeling, mixed and virtual reality and haptic applications	JAN 2018 - MAY 2018

VOLUNTEERING AND MEMBERSHIPS

Founder and Member of BEA - BIOMEDICAL ENGINEERING ASSOCIATION Students association of Politecnico di Milano, finalized to develop a network between students and Academics, promoting activities, projects and mutual collaboration, with an eye on opportunities from industry	MAY 2017 - *Current*
Volunteering, Department of Orthopaedics, Civil Hospital of Legnano(Italy) Activities consisted in providing support to the patient when no relatives showed, organizing entertaining activities to improve their period of hospitalization	2012

SKILLS

NUMERICAL/FEM/PROCESSING: MathWorks MATLAB, FreeFEM, ADINA VIRTUAL PROTOTYPING/SEGMENTATION: OpenHaptics, Autodesk 3DSMax, ZBrush, Mimics, ITK/VTK Packages IDE: Microsoft Visual Studio (2010, 2017), Python IDLE, Code::Blocks Microsoft Office Package (Word, Excel, PowerPoint) LaTeX	SOFTWARE AND APPLICATIONS
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