Politecnico di Milano

SCUOLA DI INGEGNERIA INDUSTRIALE E DELL'INFORMAZIONE
Corso di Laurea Magistrale in Ingegneria Biomedica

Tesi di Laurea Magistrale

Haptic Virtual Reality Training Simulator for Sacral Neuromodulation Surgery: a Feasibility Study

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Anno Accademico 2017–2018

Ever tried, ever failed, no matter.
Try again, fail again,fail better.
Samuel Beckett

Ringraziamenti

Innanzi tutto, un sentito ringraziamento a tutti coloro che hanno contribuito alla realizzazione di questo progetto; innanzi tutto, da lla University of Illinois at Chciago, il Professor Luciano, con cui è partito tutto e che è sempre stato presente nella supervisione dei primi mesi, durante la maggior parte dello sviluppo; dopodichè tutto il gruppo dello UR*Lab, tra cui in particolare il Dr. Niederberger ed il Dr. Kocjancic, che sono stati fondamentali, con la loro esperienza nell'ambito dell'urologia; infine tutto il Mixed Reality Lab; dopodichè, da Milano, la Professoressa De Momi, per aver promosso la continuazione del progetto al NearLab.

In secondo luogo, Martina, Greta, Marco ed Elena, i miei compagni di viaggio nella Windy City, nonchè coinquilini, ma soprattutto amici, poichè è grazie a loro che si è creato l'ambiente familiare che tanto mi manca da quando siamo tornati.

Dopodiché, un enorme ringraziamento va alla mia famiglia, perchè è grazie a loro e ad i loro sacrifici che ho potuto vivere l'esperienza dell'università ed in particolare un intero anno negli Stati Uniti. Uno degli obiettivi futuri sarà fare per loro almeno la metà di quello che è stato fatto per me, poichè proprio a loro devo tutto quello che ho ma soprattutto che sono.

Infine, un grazie non può che andare al PoliMi, che negli anni mi ha stressato parecchio e reso la vita difficile, ma ha anche saputo rendermi estremamente orgoglioso di averne fatto parte, mi ha permesso di crescere, di conoscere persone fantastice, e tutto sommato alla fine mi mancherà.

Milano, Dicembre 2018 L. C.

Sommario

Nel seguente lavoro viene presentato un sistema aptico di simulazione in realtà virtuale per training chirugico sull'impianto di dispositivi di neuromodulazione sacrale per via percutanea. Lo scopo del progetto, portato avanti tra il Mixed Reality Laboratory della University of Illinois at Chicago, in collaborazione con il Dipartimento di Urologia della suddetta, ed il Neuroengineering and Robotics Laboratory del Politecnico di Milano, è quello di contribuire al campo dell'educazione medica e chirurgica sviluppando un sistema che renda possibile la simulazione in ambiente virtuale di una procedura di impianto di un neuromodulatore sacrale, utilizzando un dispostivo che permetta all'utente di percepire una retroazione tattile del modello virtuale di paziente con cui sta interagendo, laddove esiste una lacuna: al momento infatti non sono descritti in letteratura dispositivi o applicazioni pensati in modo specifico per imparare tale operazione.

L'intervento consiste, con paziente sedato, nell'accesso percutaneo al nervo sacro attraverso un forame anteriore di S3, dopodichè viene praticata una piccola incisione e sopra l'ago viene infilata una guida con un radio marker che ne guiderà il posizionamento; infine l'ago è estratto dalla guida ed è inserito l'elettrodo. L'accesso tramite ago richiede notevole capacità di valutare il corretto punto da cui partire ma soprattutto il corretto angolo che permetta di seguire il decorso del forame ed arrivare al corretto punto sul nervo, evitando accuratamente di toccare il periostio. Per verificare che l'ago sia posizionato in modo opportuno, il chirurgo invia impulsi elettrici che, se la posizione è corretta, generano due reazioni nel paziente: la contrazione dello sfintere anale e la flessione dell'alluce. Sta al chirurgo valutare che la risposta sia adeguata o meno. Stessa procedura è necessaria dopo aver introdotto l'elettrodo.

Grazie alla versatilità della realtà virtuale è infatti possibile creare dei modelli di paziente da immagini anatomiche volumetriche come TAC, soluzione usata in questo progetto, o risonanze magnetiche, in modo da avere la possibilità di creare un ambiente di allenamento sicuro, potenzialmente infinitamente vario e ripetibile. A ciò si aggiunge l'utilizzo di un dispositivo aptico, che permettendo all'utente di

percepire la rigidezza e le proprietà dei modelli con cui sta interagento, fornisce un'ulteriore grado di realismo al sistema.

Precedentemente allo sviluppo vero e proprio sono state identificate delle specifiche che un sistema con tali obiettivi ed in generale un sistema progettato per il training chirurgico; questo comprendono: accuratezza anatomica dei modelli; realismo del sistema, ovvero l'utente deve poter direttamente trasferire ciò che impara in una sitazione reale; sicurezza per paziente, apprendista ed insegnante, con il rischio di infortunio ed esposizione a situazioni di pericolo minimizzati; versatilità, in termini di diversificazione del training su diversi pazienti; facilità di utilizzo da parte dell'utente; capacità di fornire un riscontro sulla performance; riproducibilità delle sessioni senza degradazioni; rapporto costi/qualità del sistema favorevole. Per la realizzazione dell'ambiente virtuale è stato utilizzata una libreria, LACE_Library, precedentemente sviluppata in una collaborazione tra i due laboratori citati poco sopra, che consente di sviluppare applicazioni in realtà virtuale che includano dispositivi aptici. Un contributo al miglioramento di questo strumento è stato fornito durante il lavoro, soprattutto a livello di debugging. L'applicazione è scritta in linguaggio C++. Il dispositivo aptico utilizzato è un Touch™3DSystems®, con 3 gradi di libertà per quanto riguarda il feedback tattile e 6 per il posizionamento.

Il flusso di lavoro dell'utente che utilizza l'applicazione è diviso in tre fasi: accesso percutaneo alla radice del nervo, inserimento della guida e posizionamento del vettore di elettrodi. La prima, secondo il parere degli esperti urologi che hanno partecipato al progetto, è quella che presenta le maggiori criticità. Per ricreare un'esperienza il più simile possibile all'operazione reale, l'applicazione presenta: una simulazione della fluoroscopia, con viste sagittale ed antero-posteriore, che permettono di trovare il corretto punto di accesso ed il corretto angolo; una simulazione delle reazioni del paziente alla stimolazione test, basata su intensità dell'impulso elettrico e la distanza dal punto corretto di applicazione; un'interfaccia grafica che permette all'apprendista di regolare alcuni aspetti grafici e funzionali come l'intensità dell'impulso; output che permettono di valutare la prestazione dell'utente, come tempo impiegato, tempo di utilizzo della fluoroscopia, numero di interazioni con il periostio adiacente alla zona da accedere, distanza dal posizionamento ideale.

Per testare il risultato dello sviluppo, quindici studenti del corso magistrale di ingegneria biomedica sono stati coinvolti con il fine di far provare l'applicazione a soggetti inesperti ed analizzare le loro performance, oltre che collezionare le loro valutazioni tramite un test standard volto a valutare l'usabilità del sistema. I risultati ottenuti dopo due osservazioni della stessa procedura per ogni soggetto mostrano un miglioramento generale nella seconda ripetizione, quando la familiarità con il sistema aumenta.

Il risultato finale del lavoro è dunque un sistema che permette di simulare tutti gli aspetti rilevanti dell'operazione, cercando di rispettare le specifiche identificate prima dello sviluppo. Dai risultati dei test si può evincere come gli aspetti di forza sono l'implementazione degli strumenti di ausilio alla procedura e la coerenza con ciò che viene fatto nell'operazione reale, mentre è da migliorare la facilità d'uso.

In conclusione, il sistema sviluppato si configura come un prototipo funzionante ed immediatamente utilizzabile, che però necessità ulteriore lavoro prima di poter essere inserito all'interno di un programma curricolare di educazione medica specialistica. Fornisce però la possibilità di sviluppi futuri di ampio raggio, potendo anche essere sfruttato per la programmazione di interventi oppure usato come base per lo sviluppo di simulatori simili.

Abstract

In this work a virtual reality and haptic simulator for training in Sacral Neuromodulation is preseted. The aim of the project, developed between the Mixed Reality Laboratory (University of Illinois at Chicago), in collaboration with the Department of Urology (School of Medicine - University of Illinois at Chicago), and the Neuroengineering and Robotics Laboratory (Politecnico di Milano), is to contribute to the medical and surgical education field, which lacks a system specifically designed to train student and residents on Sacral Neuromodulation, with a system that allows to work in a safe and realistic environment exploiting virtual reality and tactile feedback from an haptic device.

The surgical operation consists in the percutaneous access to the sacral nerve root with a needle on a sedated patient, through the anterior foramen of S3, the third vertebra of the sacrum. After the access, a small incision in made to let a rigid guide be inserted along the needle, with its position checked through a radiomarker. Later, the needle is extracted and the electrode lead of the device is inserted through the guide, aiming to lay it along the nerve. The first access is the critical phase, because it requires a lot of skill by the surgeon to find the correct entrance spot and angle to reach the nerve root; everything is done under fluoroscopy guidance, in particular the insertion of the needle, which is radio-opaque. To check if the position of the needle is correct, after the insertion, electrical pulses are delivered through it; if the access is successful, the patient's body will react bending the toe and contracting its anal sphincter. It will be the surgeon's job to evaluate the patient's response to understand if the spot reached is correct.

Thanks to the versatility of virtual reality it is possible to create anatomical models from volumetric images like CT (used in this project) or magnetic resonance and insert them in an environment to have a safe and reproducible training facility. Combining this with an haptic device that let the user interact with it, the realism of this facility is increased because the trainee can actually touch the virtual objects. Before the development, high level specifications of a system for medical training were identified: anatomical accuracy of the model; realism, to give the trainee a

similar feeling to a real operative room; safety for patient, trainer and trainee; user friendliness; measurable performance; reproducibility of the sessions; economical viability and relevancy. The cornerstone for the development of the application is LACE_Library, a C++ library that allow to handle graphic and haptic parts in an application developed between the above mentioned laboratories. Contribution to the library has been brought mostly in terms of debugging and improvements of some features. The haptic device used is the Touch™by 3DSystems®, with 3 degrees of freedom for the force (it can't apply torque) and 6 for the position.

The user workflow in the application is designed in three phases that reproduce the real operation, even though the main focus is on the first phase, i.e. the access with the needle. These phases are the percutaneous access, the insertion of the guide and the insertion of the electrode lead. To reproduce as closely as possible the real operation, the application features also: a simulation of the fluoroscopy imaging, with both sagittal and antero-posterior views; a simulation of the test to check the position of the needle and the electrode delivering electrical pulses, interpreting the patient's reactions; a graphic user interface, to tune graphical and functional properties, like the intensity of the pulses delivered to test the position; outputs with the performance of the trainee, in terms of total time of the procedure, fluoroscopy time, touches on the periosteum, distance from the ideal spot.

To test the application, 15 biomedical engineering master student has been recruited. They has been asked to perform some tasks with the application, focusing on the percutaneous access. The test has been repeated twice for each subject, their performance has been recorded twice and eventually they have been submitted a questionnaire to evaluate the system. The results obtained from the records show a general better performance during the second repetition.

The outcome of the work is hence a system that allows to simulate the relevant aspects of the procedure respecting as much as possible the specifications identified. From the results of the tests it can be seen how the major strengths are the implementation of the environment and the tools available to the trainee, like the fluoroscopy and the simulation of the test. However, some aspects need to be improved, in particular the user friendliness.

In conclusion, the system developed offers a first prototype of the a working system, immediately usable, that perhaps requires some other work before being included in the curricular training of urologists. It also present the possibility to be a valuable basis for the development of other systems, like similar simulators for different surgical operations or for surgical planning of sacral neuromodulation.

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Chapter 1

Background and State of the Art

1.1 Overactive Bladder

From the International Continence Society's definitions, Overactive Bladder(OAB) is a chronic pathological condition [3] which diagnosis is usually symptomatic, based on the occurrence of identified events such as frequency of micturitions, urgency, urge incontinence, not explainable through local pathologies, like kidney stones, tumors, cystitis, or methabolic diseases like diabetes [1] [61]. Neurological causes leading to such symptoms are included in the OAB spectrum. Lower Urinary Tracts Symptoms (LUTS) are the most prevalent pathological conditions either in the US and worldwide, affecting hundreds of million of people, with increasing incidence with age and no relevant difference between males and females, except for the occurrence of events and their relevance [13] [54] 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 [23] because of the mean age of population raising thanks to the improvement of health and life conditions. [25].

Studies claim that in 2018, people affected by LUTS in general are about 2.1 billions [13], with a slightly higher incidence in women than man (46% vs 44% of the population) Data about prevalence from studies are shown in figures 1.1 and 1.2.

1.1.1 Symptoms and quality of life

Being the diagnosis symptomatic, it is important to correctly state and analyze events occurring to 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, without requiring extensive and invasive treatments, whereas others must undergo specific

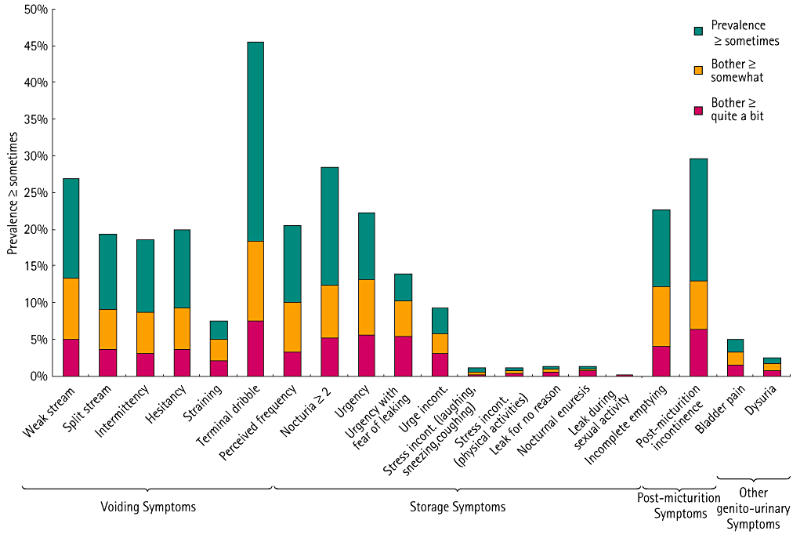

Figure 1.1: Histogram showing prevalence of LUTS symptoms among men [13]

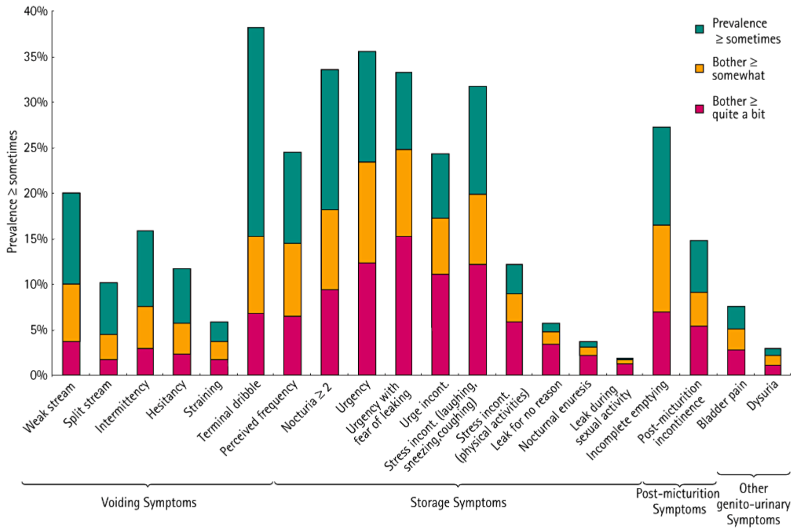

Figure 1.2: Histogram showing prevalence of LUTS symptoms among women [13]

therapeutic pathways to gain the chance to see their quality of life restored [2]. It has been evidenced how not only urge incontinence, but also frequency and urgency are extremely invalidating. 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 are 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. Anyway, more than 70% of patients requires some treatment [22].

1.1.2 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. Better outcomes are highlighted in literature with pharmacological treatments, with anticholinergic drugs in particular [4]. More recently, antimuscarinis became the first-to-go drug choice [31]. However, one of the most important aspects to be considered when treating OAB, is that, not being a specific disease and not being a life threat at all, patient not witnessing significant improvements should not continue the therapy indefinitely, with the risk of incurring in side effects, and creating excessive costs [19]. In [19], a framework to be followed to shape the most effective treatment on a certain patient is defined, with three therapy levels identified, as the invasiveness of the solution increases:

- **Behavioral approach**; first try is the risk-free and tailorable behavioral training, changing the patient's habits or environment, or teaching how to improve the management of bladder voiding. Literature shows how many patient, thus not completely eliminating symptoms, can see a significant improvement [28] [11]. The substantial absence of adverse events (AEs) and the economical viability, makes this an obvious choice to start with.

- **Anti-Muscarinics**; administration of drugs (usually oral) is the second-line therapy which should be considered, to be used where no considerable improvements in the quality of life of the subject is observable with behavioral therapy. Patients with severe symptoms are often observed to remit quite well, while a small portion of subjects, the ones with mild events occurring, might have their normal life completely restored. Sides of this treatments are the presence of AEs, although usually not life threatening.

- **Neuromodulation (SNM)**; when no other treatment suits the patient's needing, surgery is 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 its own surgical nature, other than sharply increased costs.

Figure 1.3: Representation of an Interstim®system implanted

1.2 Sacral Neuromodulation (SNM)

As previously said, SNM is the last treatment 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 [51]. Perhaps, the only approved commercially available device for SNM is InterStim®, by Medtronic(Minneapolis, MN)[46]; Interstim®device delivers mild electrical pulses to the roots of the third sacral nerve (SN), as shown in figure 1.3, 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.

As partially shown in figure 1.4,the outcomes of SNM with the respect to QoF on patients are found to be usually way better than the ones of standard medical therapies [51] despite the frequent AEs; patients treated with InterStim®usually report a 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 [21] to be removed. Most common failures[15] in SNM include:

- Migration; the device can in fact move from its implant site. This may trigger responses from the wrong anatomical site, for instance make the glutesu contract, or cause pain to the patient, while also stopping being effective in treating the symptoms. In such a case, explant is required.

- Infection; sepsis fenomena are always a possibility when a surgical operation is

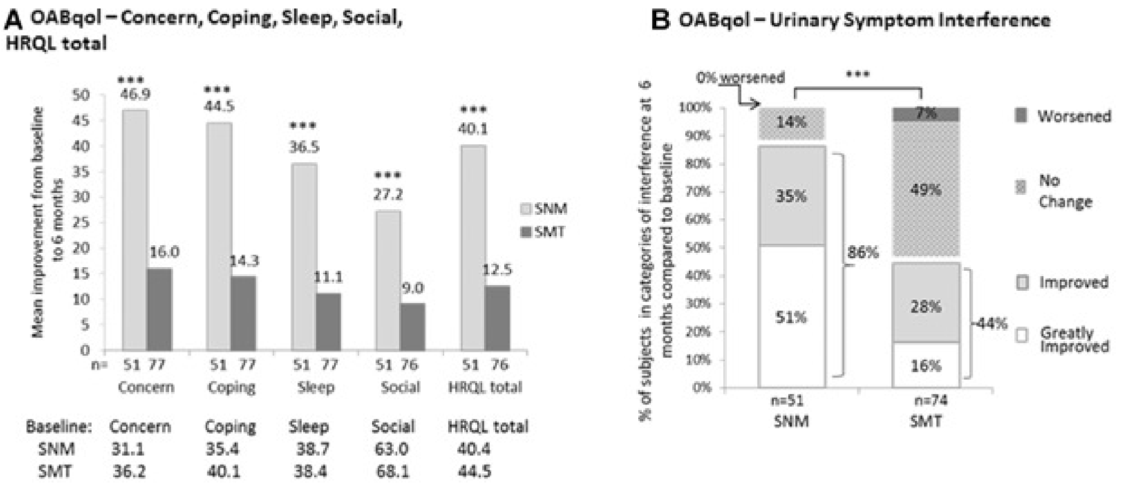

Figure 1.4: Patients follow-up at six months from the implant, compared to standard medical therapy (SMT). It is very clear how SNM outscores SMT in every category, in terms of outcomes. Left: the histogram compares the improvements reported by the patients in different aspects of their life. Right: reported outcomes of the therapy among the subjects[51]

required and can be caused by multiple reasons; bacterial problems necessarily lead to failure.

- 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. This is mainly due to the patient's characteristics and it is less predictable.
- battery depletion; it may be linked to some device's malfunction if it runs out before the terms.

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 errors during the procedure. The aim 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 [52] and [53].

1.2.1 State-of-the-Art procedure

In [35] a precise guideline to the procedure has been perfected addressing the most common and relevant problems occurring during the operation. In the cited article, a percutaneous access to the sacrum is considered, in order to keep the operation the less invasive possible, fact that makes it 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 see where is he going around the instrument and inside the body. The goal is to place the InterStim®electrode lead through the S3 foramen, in the sacrum, as close as possible to the roots of the SN, following its processes. This is going to stimulate the nerve delivering the electrical pulses to restore the communication, which is the reason why it has to be close to the target; as said in the previous section, a wrong position of the lead usually causes failure. 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 the patient is 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 strong pain if inadvertently touched.

The procedure consists in the identification of an appropriate entrance spot on the skin figure 1.5; this is done with AP fluoroscopy imaging through a C-arm, which allow to identify the right foramen, and lateral fluoroscopy, to find the right angle, in figure 1.7 1.6 and 1.8. The needle is then inserted through the skin trying to follow the identified path. This is the most difficult part of the operation, because the surgeon has to avoid to touch the bone, while sensing when to stop once the nerve has been reached. Then, the position of the foramen needle is tested, connecting it to a special plug through which electrical pulses are given; the response of the patient is observed: what the surgeon wants to see here is the toe bending and the anal sphincter contracting, which means that the right nerve is being stimulated, and the stimulation is effective. Later on, a guide wire with a radiomarker is placed in position of the needle; the radiomarker allows the guide to be seen in the imaging to check his suitable advancing. Next, the actual lead is moved through the guide, taking care to give it the most suitable bending to lie along the SN roots,as in figure 1.9; the lead position is tested again, and the same response is wanted, in order for the surgeon to consider the placement successful. All the four electrodes must be checked. Eventually, the device is deepened in a suitable pocket in the buttock and connected to the lead.

Given a working device, errors in the insertion of the foramen needle would induce one of the following scenarios when the tests are delivered:

- Foot rotation; if the pulses make foot rotates instead of just causing the toe

Figure 1.5: Marks on the lower back of the patients to identify the entry point [35]

to bend, 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 directly stimulates the adjacent muscle, and not the nerve.
- no response or poor response to pulses; the reason may be a non-ideal placement, usually it means that the tip is too far from the nerve root and the signal can not be delivered.

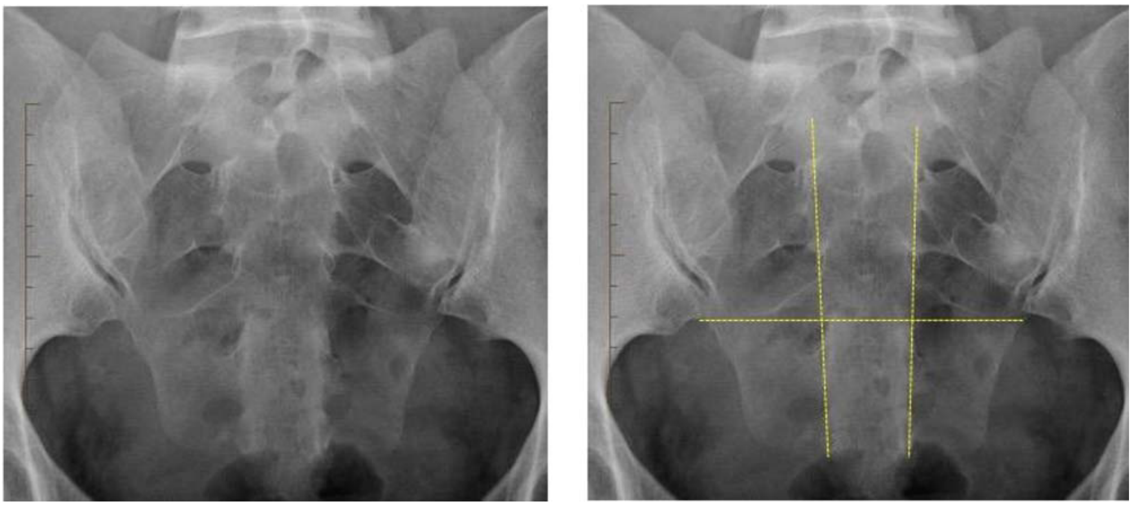

Figure 1.6: Fluoroscopy imaging to identify the correct foramen and mark the skin [35]

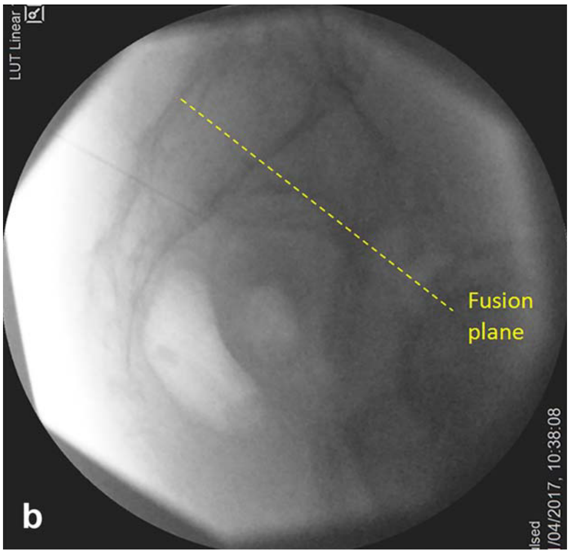

Figure 1.7: Fluoroscopy imaging to identify the correct angle to access the foramen [35]

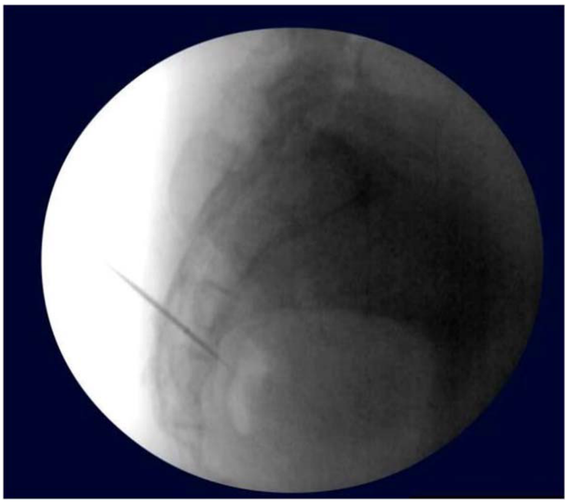

Figure 1.8: Fluoroscopy imaging to identify the right spot while inserting the needle [35]

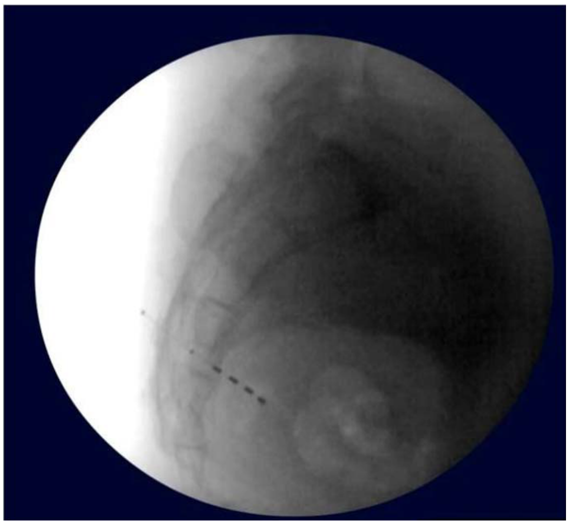

Figure 1.9: Fluoroscopy imaging of a correctly implanted electrode lead [35]

1.2.2 Costs associated

In [6] and [30] cost effectiveness of SNM is analyzed, stating that the procedure, despite seemingly not commercially viable in a span of 2 years [50], is, in fact, considering long term follow-ups. 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: the literature evidence how the costs are significantly higher than other treatments, because of the device costs itself and the nature of the procedure. Failure would, hence, meaningfully lower the economical viability, because of the resources needed to implant another device and to perform another surgery, even if kept minimally invasive.

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.

1.3 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 [48]. 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 [47]. Several models can be used for training, with different characteristics, with advantages and disadvantages each. Categories can include [63]:

- **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 [45]. 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 [33].

- **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 [63]. 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 [5], 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 [9], 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 [18]. Moreover, in setups like these, expertized personnel is find to outperform novices [9] 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.

1.3.1 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 [48] 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 [39].

VIrtual Reality simulations are widely considered effective in general [49] whether it comes to predict skills [40] 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.

1.3.2 VR in Urology

For what concern Urology, many simulations, mainly due to the extensive use of minimally invasive surgery, with laparoscopic techniques [63], 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$^{\text{TM}}$; 3D Systems's device [43] 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^{TM}; another 3D Systems' device[59], 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 [27], improving their performances, while its effect on already well capable surgeons is negligible. [34] inquire the relevance of the UROMentor^{TM} in training, assessing that improved results are noticeable among performers trained with it.

- LAP Mentor^{TM}; [29] similar platform as URO Mentor^{TM} and PERC Mentor^{TM}, 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; [14], [58], 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.

1.3.3 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" [20], which is basically the need of something to touch in order to get a realistic feedback. In [12], 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 [62] is how they provide forces:

- Admittance: the force applied by the user is sensed and motion is fed back to give the tactile effect. Devices relying on this principle are usually very complex and expensive.
- Impedance: the user's motion is sensed and corresponding force is fed back to him in response. Devices with this working principle tend to be cheaper and smaller. 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 2

Motivation and Approach

2.1 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 [13], 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 [24], as highlighted in 2.1. This, combined with costs that varies in a range of 300-1000 Euro per person per year [24], evidences how of an impact is this condition in the healthcare. Annual total costs are in the order of billions of dollars.

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 less amount of 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 need to be taken into account as well.

According to experts, the most difficult part of the procedure is the percutaneous access to the foramen [35], because of the small cut that does not allow the surgeon to clearly see what he is doing (otherwise the procedure would not be minimally invasive) and different anatomies of patient that may result in higher difficulties in

Country	Gender	Prevalence of OAB	Total estimated no. of individuals with OAB	Prevalence of UUI	Total estimated no. of individuals with UUI
Sweden	Men	13.2	469 137	2.8	100 795
	Women	19.6	719 927	9.9	365 241
Italy	Men	10.7	2 374 404	1.7	374 578
	Women	11.6	2 833 623	3.3	811 728
Canada	Men	8.0	1 009 365	2.5	312 311
	Women	8.9	1 173 465	4.4	572 514
Germany	Men	11.3	3 637 717	1.5	489 037
	Women	13.0	4 473 031	3.0	1 042 873
UK	Men	8.7	2 005 732	1.8	427 432
	Women	10.2	2 536 578	4.5	1 116 763
Spain	Men	10.8	1 804 645	1.8	243 048
	Women	12.8	2 412 726	3.9	536 547
Total	Total	11.8	25 221 033	2.9	6 365 266

Figure 2.1: Prevalence of OAB and UI in six western Countries, with estimated number of people affected

the procedure. The main risk when accessing the sacrum with the foramen needle are several, and can lead to different outcomes:

- the periostheum is very richly innervated, therefore it is sensitive to an external instrument touching it. In order to avoid delivering extreme pain to the patient, contact with the surface of the bone must be avoided as much as possible.

- Errors while positioning the electrode lead may bring to migration and, hence, failure of the operation.

- Sometimes happens that the surgery fails due to the wrong foramen being accessed, because it may be sometimes challenging to distinguish among foramina, even with fluoroscopy. This should be checked giving pulses though the needle intra operatively, because accessing the wrong foramen triggers a different respnse.

- Fluoroscopy is obviously a very useful and reliable tool, essential when it comes to minimally invasive surgery, like in this case, but what the C-Arm basically does is to deliver ionizing radiations to the patient, to create the X-Ray imaging. Being exposed to ionizing radiations, even though it is a low dose, is always inadvisable, from the well known reasons. X-Ray exposure is of some concern in particular when treating young patient.

An expert surgeon who masters th 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, other than bing able to keep the oddity under control. Conversely, inexpert personnel is more likely to fall into some mistake, exposing himself and the patient to problems, also causing overheads.

No specific and generalized training tool are found in literature for 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 is 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 only is relied on, together with training on actual cases, with all the risks above mentioned. Urological training is hence lacking a valuable training tool specifically designed for SNM.

2.2 Proposed Solution

A solution to this vacancy may be created through VR and Haptics. It has been described in the previous section how this two technologies are nowadays 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.

With the help of the Department of Urology of the University of Illinois at Chicago, 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, the trainee 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 not applicable. Different patient have differently shaped anatomical structures, that may 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 is well aware of the critical issues and how to deal with them.

- **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 and helpful for the user.

- **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 a procedure can 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.

- **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 bring 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.

In the following chapters it will be presented how the system has been implemented, and also how a preliminary evaluation test has been designed, with the results and their analyses.

The main development of the application has been carried on at the Mixed Reality Laboratory, in the Department of Bioengineering of the University of Illinois at Chicago, while the remainder of the work at the Neuroengineering and Robotics Laboratory at Politecnico di Milano.

Chapter 3

Methods

The main purpose of the project is to develop a solution that fulfills as much as possible the specification identified in the previous chapters. To do so, the application is required to replicate the feeling of a surgeon in the OR; thus, 3D models and virtual tools must accurately rendered, both visually and haptically, to provide the trainee with a realistic experience and make the application a valuable tool that may actually be included in curricular education for urologists.

With the requirements clear in mind, the process toward the development includes the following steps: to reconstruct a volume from a set of DICOM images; to segment the resulting volumetric data to identify and to isolate the relevant anatomical structure; from segmented data, to create the meshes which will be displayed in the virtual scene; a mesh refinement step is required to improve the 3D models; to create the virtual environment including the models; program the haptic in order to use it to operate on the virtual patient.

3.1 Anatomical models

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

As mentioned before, the initial dataset is a volume reconstructed from a whole thoracic CT scan. One dataset only has been provided to

3.1.1 Dataset processing

The CT scan provided is pretty gross, in terms of axial resolution, since the spacing between images is $5mm$ and the images are quite noisy themselves, so the voxels are too spaced to perform a suitable segmentation, and to reconstruct the meshes without needing heavy modeling session would be hard, other than wasting a lot of time. Plus, the volume is used to simulate the fluoroscopy (later explained in details), 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 [32].

First step of pre-processing has been to reduce the noise, done by applying a linear filter that eliminates the high frequency components, resulting in a cleaner images set. To improve the result, a Wiener filter has been applied to each slice, which helped to reduce blurring and to enhance the structures' morphology. Another way to improve how the volume is visualized in the virtual scene (later explained more in detail), 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, being more radio opaque. Afterwards, to improve 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.

3.1.2 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 to extract suitable 3D models for the most relevant organs.

Two kinds of segmentation can be performed: manual and automatic. The former is sometimes 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 manually identifying the region of interest; the latter, conversely, is way faster because algorithms that analyzes the images and distinguish between the regions of interest and the background are implemented and choose the pixels instead of the user, but can result in low precision and create artifacts, in particular with low resolution images. Automatic is the chosen method, because segmentation is not the main purpose of the work and the result would have underwent further processing anyway, hence it was 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 value. 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 fairly simple.

To perform segmentation, Materialise®'s Mimics™ [36] has been used, a commercial software to manage medical images, provided by the Department of Medicine of the University of Illinois at Chicago. Thanks to this, it has been possible to easily extract smooth 3D models of the organs from the volume, to respect the requirements of anatomical accuracy and realism.

3.1.3 Models post-processing

Performance, in an application like the one presented here, is crucial. To have the application perform in a way that allows it to bring value to the field, it is necessary to have light and smooth meshes, with, ideally, are like an external membrane of the shape to represent, without internal artifacts. This is even more relevant with an haptic application, because of the computational heaviness of the 1kHZ update rate necessary to have a suitable tactile rendering. One of the main problems with meshes reconstructed from anatomical images is in fact that they usually are rich of small artifacts, which must be eliminated before using them in the application.

The goal of the editing is to create smooth, polished, but still accurate models. Multiple softwares are available to perform this; the ones used to refine the meshes are AutoDesk™'s 3DStudioMax®[8]; ParaView™ [42], an open source software with effective functions to apply filters and improve visualization; Pixologix's ZBrush®[65], a 3D sculpting tool, usually used by illustrators and designers. All were provided by the Department of Medicine of the UIC as well.

Artifacts have been removed with 3DSMax™, selecting the polygons that had to be excluded from the mesh and erasing them. This helps to reduce the memory occupied by the mesh because some data is removed, but mainly avoids that the collision detection algorithms of the haptic library may detect them and give a wrong tactile feedback. Reducing the number of polygons also reduce the computational time to process very big meshes, speeding up the post processing.

Smoothing the surface of the meshes is another crucial point of post processing aiming to improve the haptic rendering. The collision detection algorithms in fact, rely on the normals of the polygons composing the mesh, which are the vectors perpendicular to the plane identified by those polygons. Having a smooth surface means that tho those normals do not have sudden changes in their directions, giving a robust tactile feedback. 3DStudioMax®is the suitable software to perform this task, exploiting its modifiers.

Being the initial data from a thoracic CT scan, segmenting the skin and creating a usable anatomical model from it is quite hard without heavily manually modifying the mesh, because the patient is laying down and the reconstructed shape is very messed up. This is a risky procedure, because there is the chance to alter the morphology of the virtual patient with the respect to the volume with the data. Keeping this in mind, the software used to reshape the skin is ZBrush®. The method used to avoid the displacement with the respect to the volume was to load the skin mesh together with the bone, keeping their original positions and editing it being careful not to alter them.

As mentioned before, a 3D mesh object is usually composed of a set of vertexes and triangles. Obviously, the bigger is the mesh, the higher is the number of polygons, and so the number of faces and vertices. Anatomical structures tend to be very complex, plus, the necessity to have anatomical accuracy makes it difficult to have models with a low number of polygons. Moreover, a lagging application or poorly accurate models in surgical training system like this one would completely cancel its relevancy with the respect to low fidelity bench models. Decimation, the last step to have usable models, is the process of reducing the number of samples in a dataset and it is fundamental to combine accuracy with a fluid rendering, both from the graphic and haptic standpoint. In the case of meshes, this means reducing vertexes and faces withouth affecting the morphology of the model. 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.

3.2 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

Figure 3.1: The final anatomical model of the skin from the back

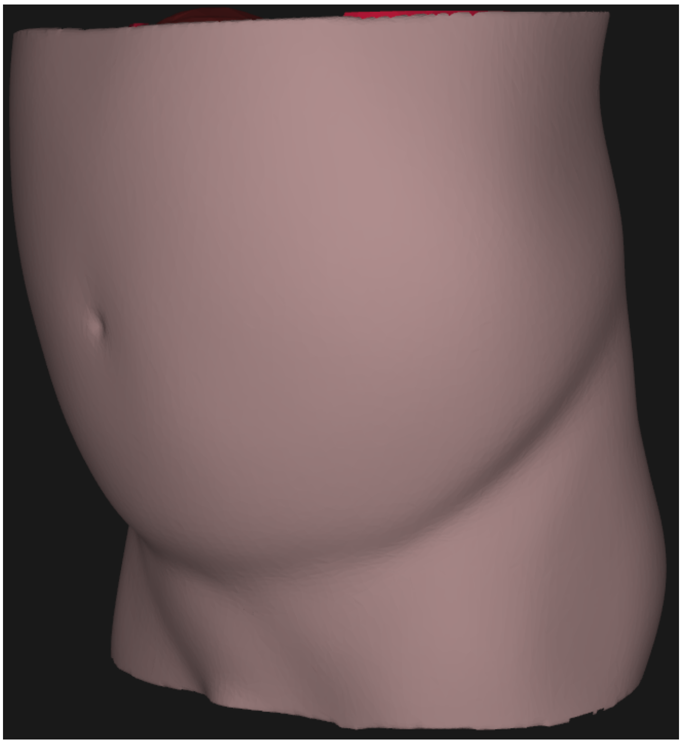

Figure 3.2: The final anatomical model of the skin from the front

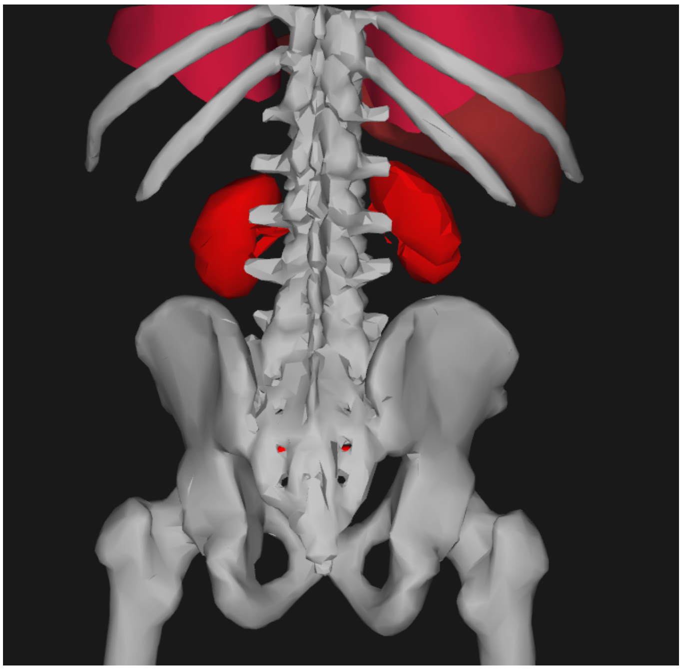

Figure 3.3: The anatomical models in the environment - bones and internal organs

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 toolkits for visualization and haptic rendering. This tools are included in a C++ library called LACE_Library [14] [17] [44] [56] developed in a collaboration between NearLab and Mixed Reality Laboratory, which allows to concurrently handle extensive and advanced graphic tools in an OpenGL environment as well as a robust haptic rendering with the QuickHaptics^{TM}microAPI built upon the OpenHaptics SDK.

3.2.1 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 3.4 and 3.5:

- Visualization Library (VL) [60]; 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^{TM} [41]; as previously outlined, it is the microAPI built upon OpenHaptics. It is originally intended develop softwares to be used with 3DSystems^{TM} 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 [64]; 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, not required for this project.

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^{TM}, 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^{TM} 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 sub-windows 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 since it is the one managing the threads. This class contains also the methods necessary to initialize the application, activate the needed libraries and start the program entering the GLUT loop, which is the actual starting point of a program based on OpenGL, i.e. the thread were the graphics run.

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 (the value at which the object is trespassed by the proxy) 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; these 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.

LACE_Library is a recent development kit and it has not been used for many applications yet. It was also originally designed to meet the needs of the specific application cited above([17], [14], [56], [44]), so some of the classes are created with to serve a specific function. Also, with a more extensive usage it is easier to highlight bugs and issues. During the development of the haptic VR simulator, some of these has come out and have been fixed. The most extensive modification, however, have been brought to the LACE_Extrusion class. In [17], it was used to create trajectories to be followed with the haptic device, and therefore it was strictly linked to the force field applied (LACE_ForceField); the two are now detached, and the extrusion features the possibility to be created along a Catmull-Rom spline, necessary to create the virtual electrode lead, described in the following sections,

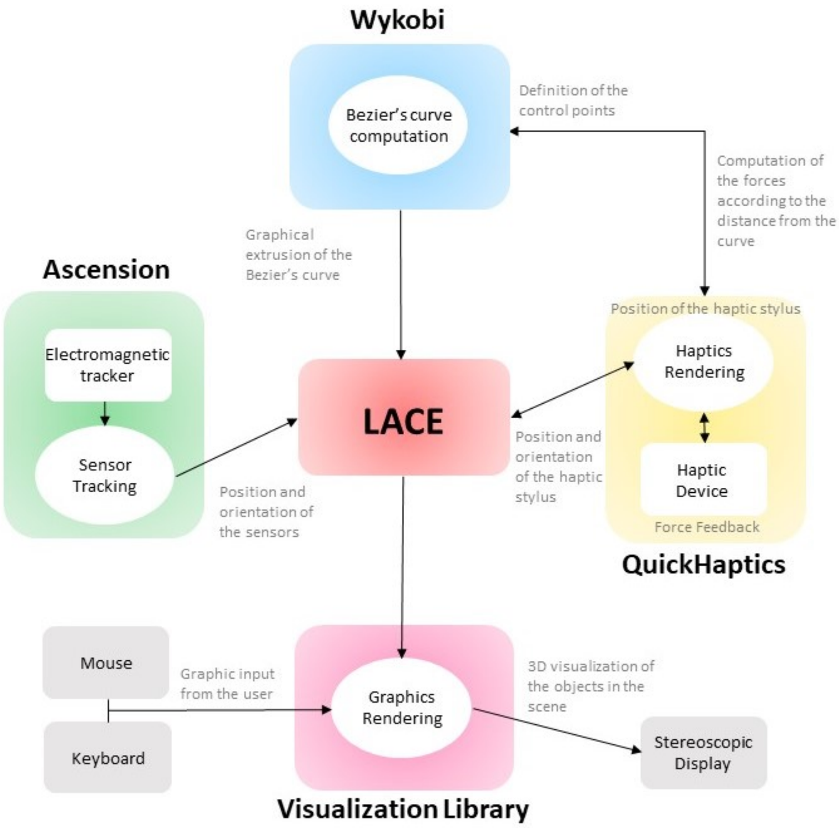

Figure 3.4: Representation of the design behind LACE Library

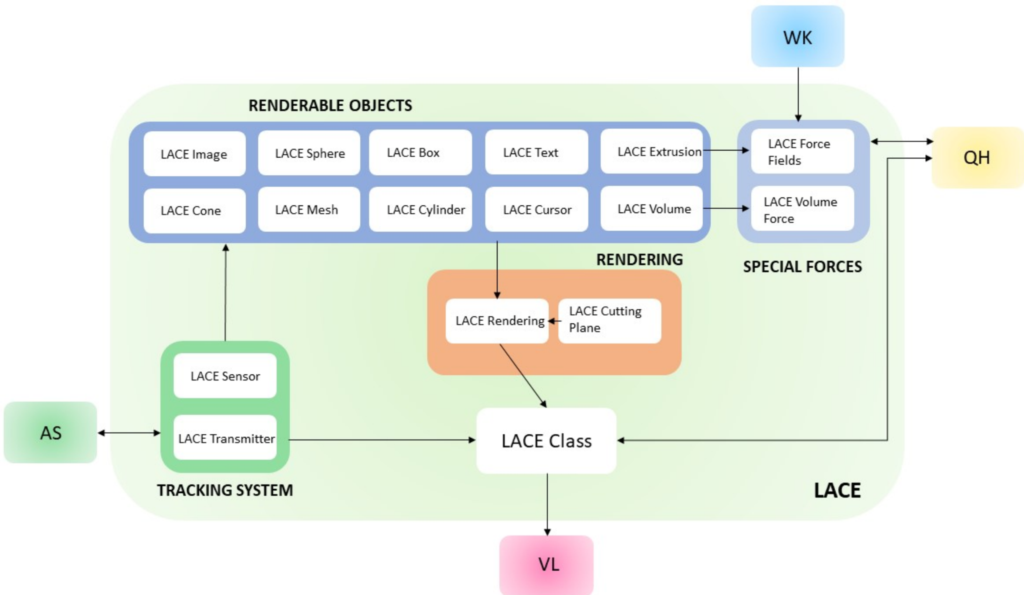

Figure 3.5: Summary of the classes in LACE

with a custom number of control points. Obviously, with a lot of control points, the computations may be quite heavy and slow down the application. On the other hand, debug mainly affected the base class LACE_Object, from whom the renderable objects (LACE_Mesh, LACE_Box, ..., as can be seen in figure 3.5) inherit, where many of the getter/setter functions have been revised to be more intuitive from the user's standpoint and coherent, avoiding redundancies highlighting differences among similar ones.

3.2.2 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, but developing new methods and classes when necessary.

The scene 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. Another part with utilities to replicate the tools available in an operating room, to test the correct positioning, to activate or deactivate the virtual C-arm, move it, reset the scene. A third part is composed by the visual feedback that a surgeon relies on when performing the procedure, 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, 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:

1. **Needle insertion**; As described in section 1.2.1 this first step is by far the most challenging and difficult to perform and it is the most important for the outcome of the operation. It is necessary that the trainee is allowed to deeply understand how to manage the instrument to find the correct foramen and fix the needle it in the correct position, how to test the position and recognize a well done placement through the patient's response.

2. **Guide placement**; this second step is possibly the easiest one, according to the surgeon of the Department of Urology. It basically consist in placing the guide inserting it over the needle, taking care that the radio marker is in the most suitable position. This task usually requires just a few minutes, and the

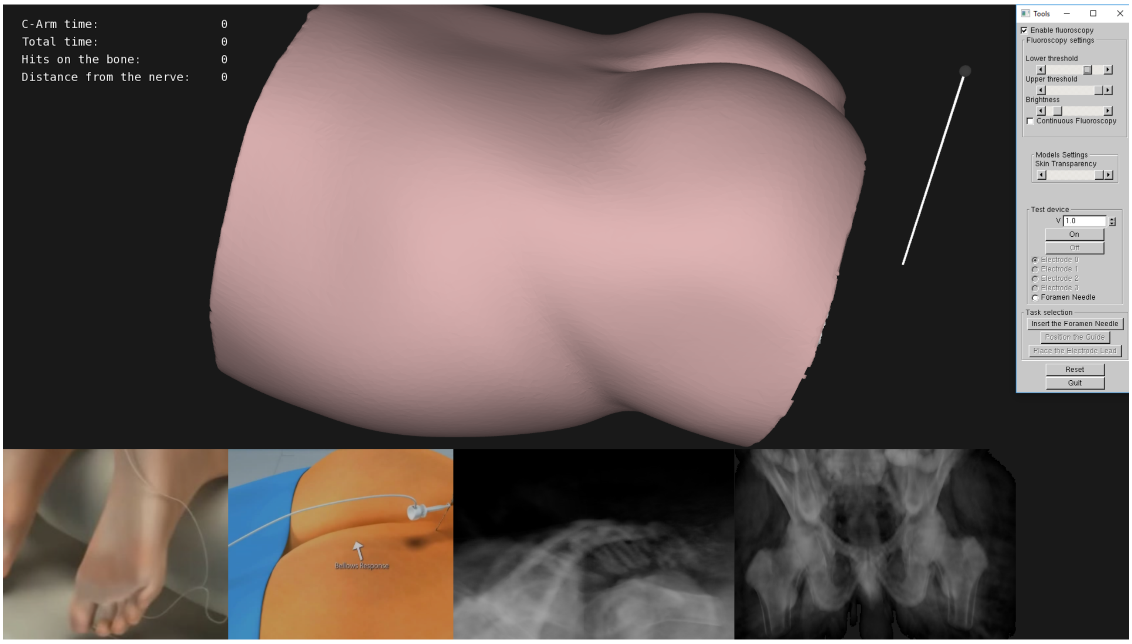

Figure 3.6: The virtual scene in the application

only criticism is to be as quick as possible in order 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 electrodes are working correctly, carefully activating each, one at a time, to see if they all work with the correct current, which is stated in [35]. This is the last step of the simulation.

After the trainee has performed all the tasks, the application provides the user with data 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 being affected. Every step can be repeated, and the system gives multiple evaluations, one each time the step is performed. The scene presented to the trainee when the application starts is shown in figure 3.6. From left to right, from above to below, it feaures: the live parameters about the performance: total time, C-arm (fluoroscopy) time, interactions with the periosteum and distance from the target; the virtual patient; the virtual needle; the graphical user interact; the two LACE_Renderings for the test, with the toe and the anal sphincter; the two LACE_Renderings for the fluoroscopy.

3.2.3 Graphical User Interface

Intra operative tool are available to the user that can control them through a Graphical User Interface (GUI) built with the GUI framework from OpenGL, 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 framework and it is based on C++. It is also convenient to let the user set some parameters as he feels comfortable with, like tuning the volume's transfer function which changes his visualization in the scene, in order to be able to reproduce something as realistic as possible.

3.2.4 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, it is basically an arm which can be moved by the OR staff to take fluoroscopy images and display them on the screens. It has the capability to show continuous imaging, to see the movement of a radio opaque object like the needle moving in the body. Obviously, in order to produce such images, it delivers ionizing radiations (X-Rays). It is usually designed in such a way that the surgeon is allowed to choose the angle from which he wants to visualize the internal structure of the body. Usually, during a SNM procedure, 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 build the 3D models. The explanation to use a memory-wise 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, just moving the virtual camera, which is 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 the same. The rendering technique used for the volume is volume raycasting; the main difference between a CT and a fluoroscopy image is, that the fluoroscopy is a 2D representation of a 3D object, being in fact a projection, whereas the CT keeps the volumetric data. With raycasting what happens is that the volumetric 3D data from an object is projected on a 2D image, exactly like it happens with fluoroscopy imaging. The raycasting algorithm consists in four steps:

1. casting: a line is cast from each pixels of the 2D image through the volume;
2. sampling: equally distant points along the casted line are taken as sample. If a sample falls in between voxels, these are interpolated to produce a valid sample;
3. shading: a transfer function retrieves an $RGB\alpha$ value and the illumination gradient for the point, which is then colored according to them. The scrollbar in the user interface affect the threshold of this transfer function, changing the $RGB\alpha$ representation of the sample;
4. composition: the sampled points are composed to create the color of the pixel showed in the 2D image.

Two separate subwindows (LACE_Rendering) have been used to visualize two different views. Each one needs a camera pointed on the scene, to display the correct point of view. The reference system of each rendering is the same to the one in the main window; 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 transform in the LACE_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 virtual patient can be moved in the virtual environment, and it is necessary to have their position adjusted to keep the right perspective on the scene, when the patient is moved, the cameras pointing to it to display the fluoroscopy are moved jointly, as well as the volume, expoiting the transform of the cursor, that is moved according to the proxy position of the device. However, 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 keys to move the arm respectively up, left, down and right. What actually happens in the scene is that the cameras are moved around the models, and the point of view together with them.

3.2.5 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 anal sphincter contraction, together with the toe bending inward are signs of a correct position of the needle, meaning that the instrument has reached the right spot under the foramen. The correct spot in the scene has been identified to be right under S3, with the help of the physicians of the Department of Urology of the School of Medicine of the University of Illinois, and marked with a red ball that moves coherently with the virtual patient. To compute the accuracy of the position of the needle, the distance between said target and the tip of the needle is computed as:

$$d = \sqrt{(x_{target} - x_{tip})^2 + (y_{target} - y_{tip})^2 + (z_{target} - z_{tip})^2} \tag{3.1}$$

The real device can give current with different intensities, usually in a range from 1 to $4mA$, and the provider suggests to tune the placement in such a way that the body responses occur at 2.1mA or less [35]. 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 *LACE_ Rendering* are created, one for the toe and another for the anal sphincter representation. 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 array length, i.e. the number of images to be shown. The array is streamed back and fort in this range, like a flip book, and the result is a partial or full motion of the foot and bellow. Exploiting the graphic update loop of Visualization Library to update the image shown, running from $30Hz$ to $60Hz$, the motion is fluid.

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 with the maximum pulse intensity and $n_{i,d} \leq N$ the range related to a given condition:

$$n_{i,d} \propto \frac{1}{d} \tag{3.2}$$

$$n_{i,d} \propto i, d \leq d_0 \tag{3.3}$$

$$n_{i,d} = n(i, d) \tag{3.4}$$

that directly lead to the function:

$$n(i,d) = \begin{cases} 0 & \text{if: } d \geq d_0 \\ \dfrac{i}{d}\alpha & \text{if: } 0 < d \leq d_0 \\ N & \text{if: } d = 0 \end{cases} \tag{3.5}$$

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 number of image used.

3.2.6 Haptic force effects

To give the trainee a full experience during the practice, it is 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 exploiting 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 freedom of movement of the top and the bottom of the needle. Therefore the effect is such that the stylus is free to rotate around the fucrum point but it is limited while trying to translate orthogonally to itself. Is created in the following way:

$$\overrightarrow{f}, Q = \begin{bmatrix} qw \\ qx \\ qy \\ qz \end{bmatrix} \tag{3.6}$$

are respectively the entrance point ($\overrightarrow{f}$) and the quaternion with the orientation of the needle, updated every (haptic) frame. Exploiting the axis identified by the quaternion, a point $\overrightarrow{f^1}$ is created on a line passing for $\overrightarrow{f}$ and parallel to the axis identified by Q, represented by the vector (qx, qy, qz), composed by the last three components of Q:

$$\overrightarrow{f^1} = \overrightarrow{f} + (qx, qy, qz) \tag{3.7}$$

The line passing for $\overrightarrow{f}$ and $\overrightarrow{f^1}$, l, is created. Given the haptic stylus proxy position $\overrightarrow{P}$ and $\overrightarrow{P^1}$, both updated every frame, its projections on the line l, the vector $\overrightarrow{F}$ applied to create the force effect is computed as:

$$\overrightarrow{F} = (\overrightarrow{P^1} - \overrightarrow{P})\alpha \tag{3.8}$$

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. A scheme of the fulcrum effect is shown in figures 3.7 and 3.8. This is the blueprint for the line effect as well, with the difference that in the fulcrum, the orientation of the line is updated every frame, whereas in the line effect it is computed when the effect starts and kept until the effect is stopped.

3.2.7 Performance Feedback

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. Four main indicators 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

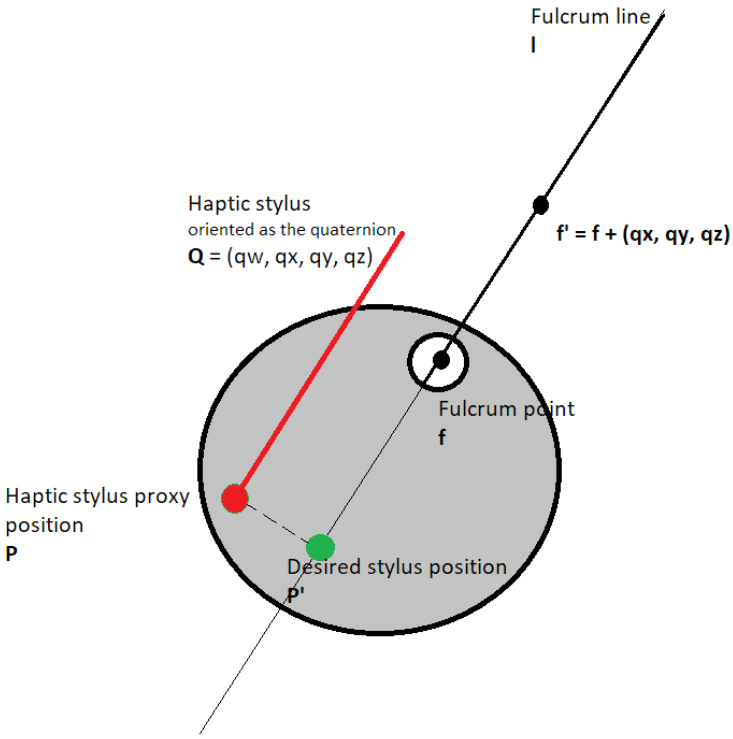

Figure 3.7: Schematic representation of how the fulcrum effect is designed. The fulcrum point, the line parallel to the stylus, the proxy position and its projection on the line are highlighted

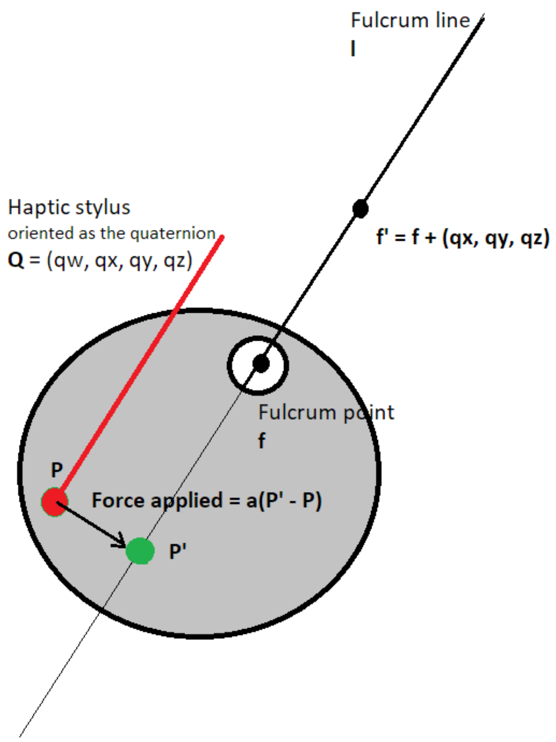

Figure 3.8: Schematic representation of how the fulcrum effect is designed. The applied force is highlighted

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.

3.2.8 Virtual electrode lead properties

Since the electrode can bend to better follow the nerve processes, when it enters the body through the guide and reaches the correct spot, this property has to be included. 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 has risen. The choice fell upon a Catmull-Rom spline; Catmull-Rom spline are known to be smoother curves 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. 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 give to the extrusion the correct smoothness.

3.3 Hardware components

The PC used to develop the application featured an Intel Core i5-2500K processor, with CPU running at 3.3GHz, a graphic card NVIDIA Quadro K600 and 8GB RAM. At PoliMi the setup was slightly different but more performant, featuring an Intel Core i7 - 6800K (3.4GHz) processor, a 16 GB RAM and a NvIDIA Titan Xp graphic card. In the development phase at the University of Illinois at Chicago a 3D monitor has been used; with the proper glasses, it 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. This feature is not available at Politecnico di Milano, so the tests have been performed with a standard 2D screen. The second element is the haptic device, shown in 3.9; 3dSystems' Touch^{TM} is the model used in this project. It features 6 degrees of freedom and 3 degrees of force. Technical specifications are in tab 3.10. Choice fell on this because of its availability and cheapness, which is of great value for the aim pursued. 6 degrees of force devices would obviously result in a far better result, but the cost would increase a lot as well, reducing economical viability.

3.4 Experimental Protocol

To have a preliminary evaluation of the application, 15 biomedical engineering students have been recruited to participate in the study testing the application. These students were solicited to perform the most relevant tasks in the virtual environment,

Figure 3.9: The haptics device used in the application

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 3.10: Device specifications

their performance has been recorded through the output of the application and their feedback was collected with a questionnaire that is described in details in the following sections. The user was asked to perform the tasks twice and paired data has been generated in this way; obviously, the questionnaire has only bee submitted once. No one of the subjects had previous experience, neither with haptic application, nor with surgical training, but the feedback from people with a technical background has been thought to be useful to help to improve the system. The application is in fact intended to target people with no or very limited experience on SNM, which is also likely to have no experience dealing with haptic devices. The subjects were asked to:

- run the application and get familiar with the user interface;
- understand how to move the virtual C-arm and display the continuous fluoroscopy;
- find the correct spot in the skin to access S3 foramen
- find the correct angle to access it with the right slope
- access the foramen relying on the spot on the skin and the angle
- fix the needle and test the correct position through the electrical pulses, taking care to understand if the response from the virtual patient is suitable

An explanation of the functions of the application has been provided before the testing and the session has been planned as follows:

- The subjects sits before the screen and adjusts the haptic device to its comfort.
- The application is run, the subject can move the virtual needle in an empty environment, in order to gain confidence about the workspace of the device.
- The virtual patient is spawn in the scene, the subject can freely move it and interact with it
- The test actually starts, together with the total time record.
- Once the subject has completed the task, i.e. the target has successfully been reached and the position has been checked, time is stopped and the indicators, total time, fluoroscopy time, interactions with the periosteum and final distance from the target are recorded.
- The procedure is then repeated, after a while, to collect data for the second observation.

3.4.1 Performance

As explained in 3.2.7, the application is able to compute and provide some data summarizing the performance of the subject. After every performance, these data have been collected and analyzed in terms of basic statistical quantities; mean (m), variance (σ^2) and standard deviation (σ) have been extracted.

$$m = \frac{\sum_i^N (x_i)}{N} \tag{3.9}$$

$$\sigma^2 = \frac{\sum_i^N (m - x_i)^2}{N} \tag{3.10}$$

$$\sigma = \sqrt{(\sigma^2)} \tag{3.11}$$

A Wilcoxon signed rank test ($\alpha = 0.05$) has been used to compare the paired samples composed of the two observations for each parameter, to understand if the difference between the first and the second is statistically significant or not. Such a test is suitable for this kind of data because they are composed of independent paired couples of ranked indicators. A difference δ can be computed for each couple and analyzed. Moreover, being the number of samples quite small, it is safer to use a

Wilcoxon signed rank instead of a t-test. The null hypothesis considered is that the differences between the first and the second observation are due to chance, therefore no statistically significant differences are evidenced. This test has the property that with a sufficient number of subjects(n), the distribution of the statistic parameter T is normal, with values:

$$mean : \mu = \frac{n(n+1)}{4} \tag{3.12}$$

$$variance : \sigma^2 = \frac{\mu(2n+1)}{6} \tag{3.13}$$

$$z_{score} = \frac{|(T-\mu)|}{\sigma} \tag{3.14}$$

where z_score represents how far is the value of the observations from the average in terms of standard deviations, value that can be used with at least $n > 10$.

The purpose of this test is to have a first overview about how the interaction of an inexpert subject changes with repetitions, how people adjust while getting familiar with the haptic device and the virtual environment, and a general idea about how difficult may be for someone completely new to deal with the system.

3.4.2 User feedback

A simple qualitative evaluation has been used to assess the user friendliness and how likely someone be interested in use the application. System Usability Scale (SUS) is a widely used ten item Likert attitude test presented in [10] that gives a score in the range 1-100, where 100 is the maximum value, representing the usability of a system, based on the users' reviews. The trainee has to indicate a value in the range 1-5 for each item, where 1 stands for a strong disagreement and 5 stands for a strong agreement; mid values are shades ranging between the extremes. The score is computed as follows:

$$SUS_{score} = 2.5\sum_{i=0}^{4}[(5-q_{2i}) + (q_{2i+1}-1)] + (5-q_{10}) \tag{3.15}$$

where q_i is the i-th question (or item). As can be seen in the formula, odd items carry a positive value with them, while even ones give a negative opinion on some aspects. The ten items can be found in 3.11. Every subject has to compile the questionnaire after both repetitions, in order to have a deeper knowledge of the application and the system and be able to evaluate it more coherently. There

N	Statement
1	I think that I would like to use this system frequently.
2	I found the system unnecessarily complex.
3	I felt very confident using the system.
4	I found the various functions in this system were well integrated.
5	I thought the system was easy to use.
6	I thought there was too much inconsistency in this system.
7	I found the system very cumbersome to use.
8	I would imagine that most people would learn to use this system very quickly.
9	I think that I would need the support of a technical person to be able to use this system.
10	I needed to learn a lot of things before I could get going with this system.

Figure 3.11: Items of the SUS questionnaire

will be a SUS_{score} for each trainee; these scores are averaged and the final result represented in terms of mean and standard deviation. The meaning of such a test is to understand how someone who does not know anything about the system, yet, having a technical and technology oriented background, feels like while interacting for the first time with the haptic device and the application in general. Moreover, students can usually give very interesting hints toward some improvement.

Chapter 4

Results

The results of the first evaluation are presented in this chapter. As mentioned in 3.4.1, both a qualitative and quantitative test have been performed.

4.1 Trainees performances

The null hypothesis of the test, stating that the differences between the two observation were only due to chance, has been confirmed only for the data on the unwanted interactions with the periosteum, while the other three quantities analyzed presented a diminishing trend, even though slightly less evident in the distance from the target. Data are reported in 4.1.

As above mentioned, from the tab is evident how both fluoroscopy and total time significantly decrease in the second observation. P-value are in fact, respectively, 0.010 and 0.024. Therefore, the null hypothesis has to be rejected and it can be said that the difference between these two couple is significant. Conversely, the indicator for the interactions with the bone shows a p-value of 0.77 and the one for

Indicator	**1st attempt**	**2nd attempt**
Total time [s]	135 ± 19	126 ± 13
Fluoroscopy time [s]	126 ± 15	119 ± 12
Interactions w/ bone	55 ± 12	54 ± 13
Distance from target [mm]	2.9 ± 1.4	2.8 ± 1.2

Table 4.1: Tab with the values extracted from the performances of the subjects. All the values are reported as $Mean \pm SD$. Decimals are omitted for the first three rows because not relevant for the time, and meaningless for the interactions

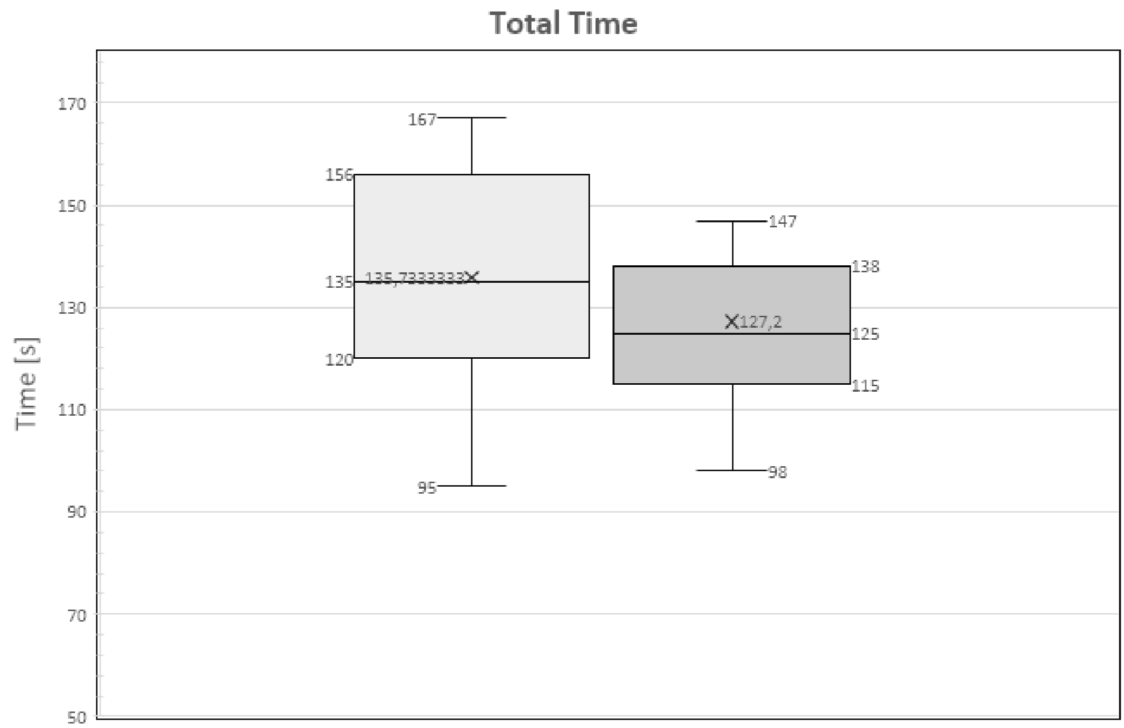

Figure 4.1: Box plot showing data from the total time indicator. First observation (first repetition) on the left, second on the right

the distance from the target of 0.97 which allow us to firmly claim the absence of statistical significance in the difference between the couple, rejecting the hypothesis. Box plots with all the statistical values are presented in 4.1, 4.2, , 4.3, 4.4.

4.2 SUS results

The averaged SUS_{score} computed is 60.67 ± 15. As evident in the following pie charts, the principal strengths are the application's likeability to be utilized, the lack of inconsistencies and the well integrated features. However, it is still quite week in terms of user friendliness, as many felt the need of a supervisor to be able to correctly use the system. A significant number of subject also felt the need to learn a lot of things before being able to use it. From figure 4.5 to figure 4.14 the pie charts with all the data from the items of the SUS questionnaire are shown. The percentage value are relative to the population, which comprehends 15 subjects.

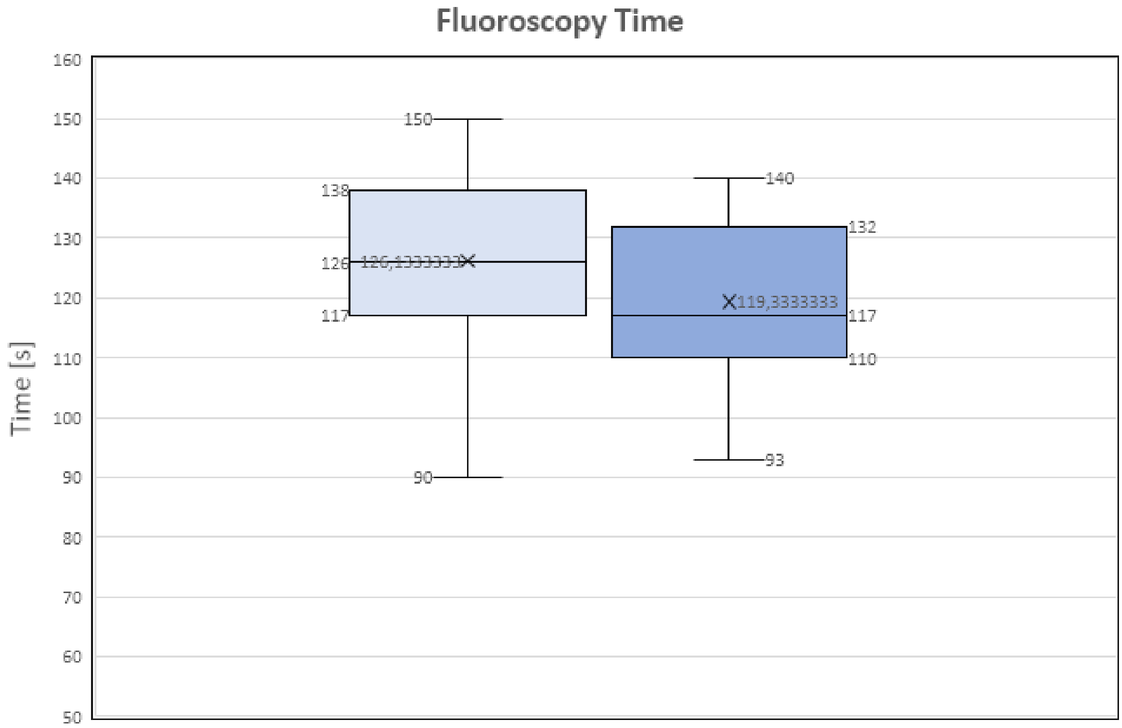

Figure 4.2: Box plot showing data from the fluoroscopy time indicator. First observation (first repetition) on the left, second on the right

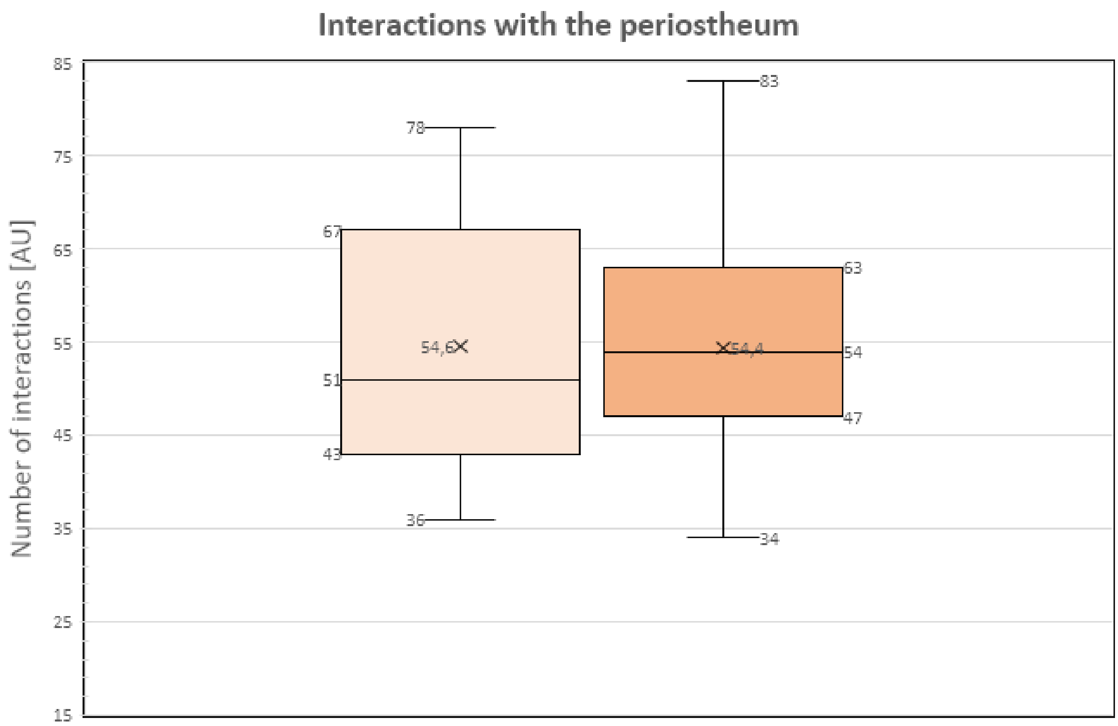

Figure 4.3: Box plot showing data from the interaction with the periosteum indicator. First observation (first repetition) on the left, second on the right

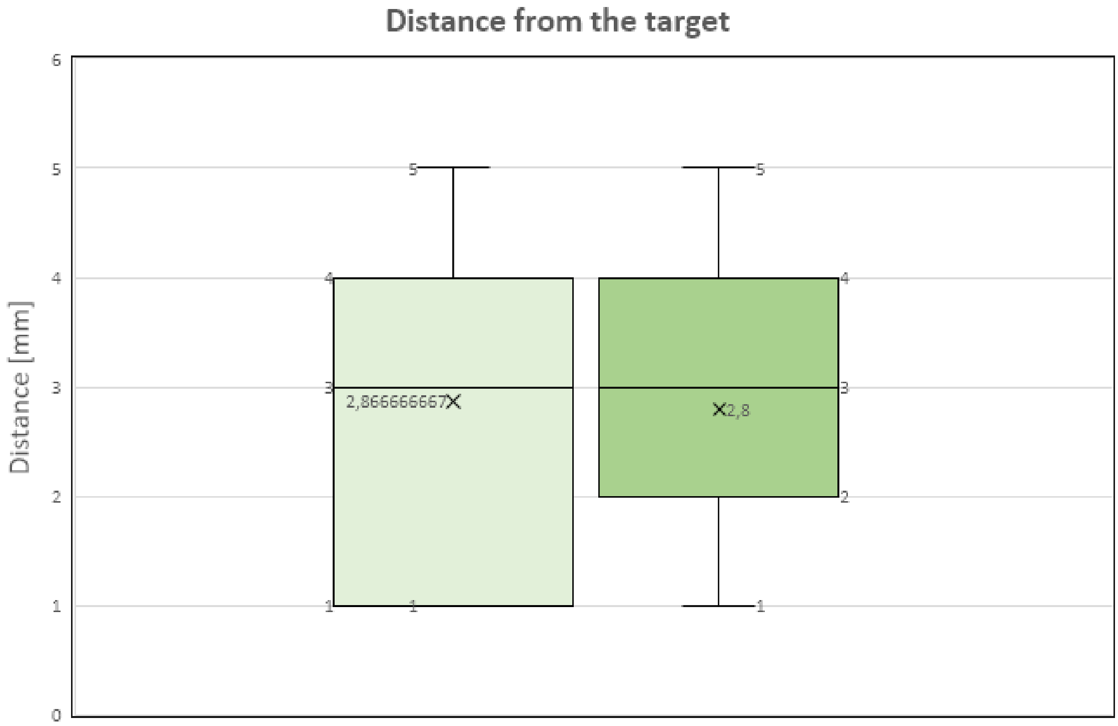

Figure 4.4: Box plot showing data from the distance from the target indicator. First observation (first repetition) on the left, second on the right

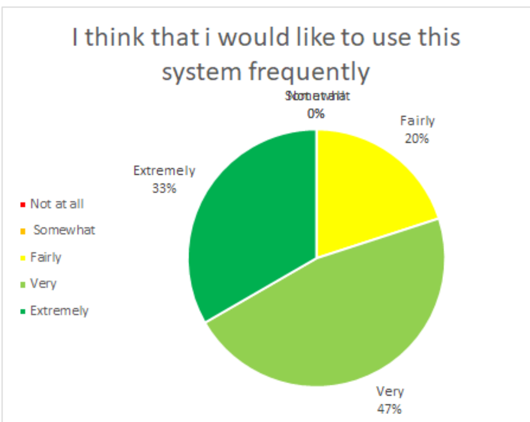

Figure 4.5: Answers to item 1 of the SUS test

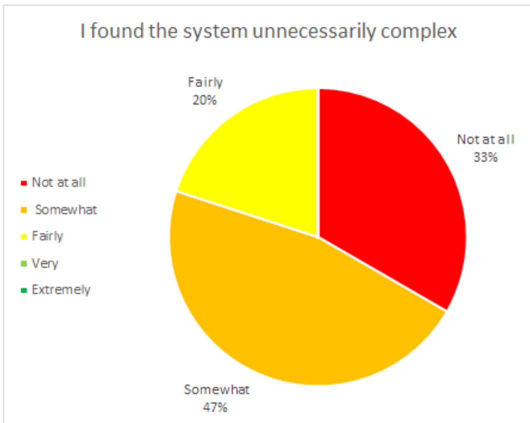

Figure 4.6: Answers to item 2 of the SUS test

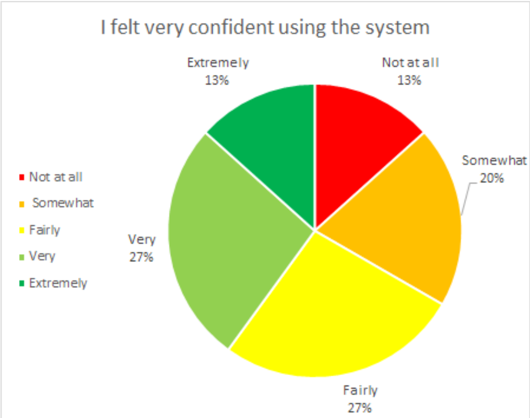

Figure 4.7: Answers to item 3 of the SUS test

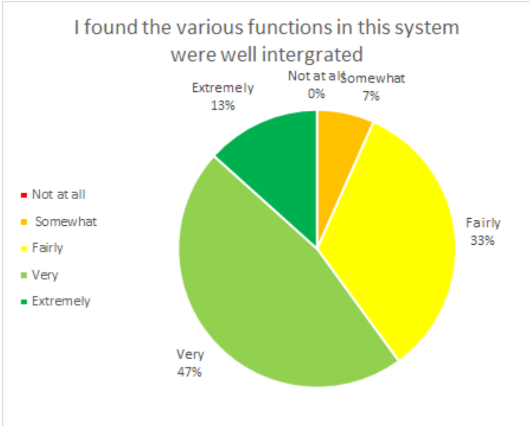

Figure 4.8: Answers to item 4 of the SUS test

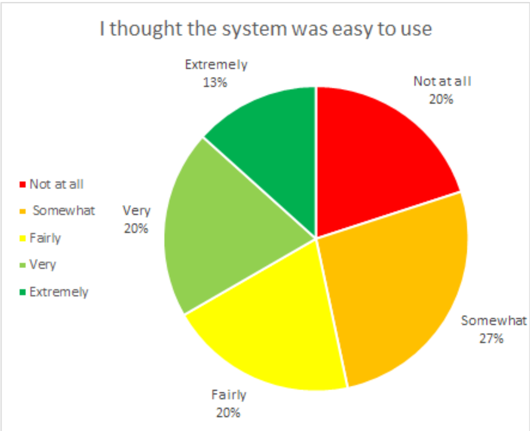

Figure 4.9: Answers to item 5 of the SUS test

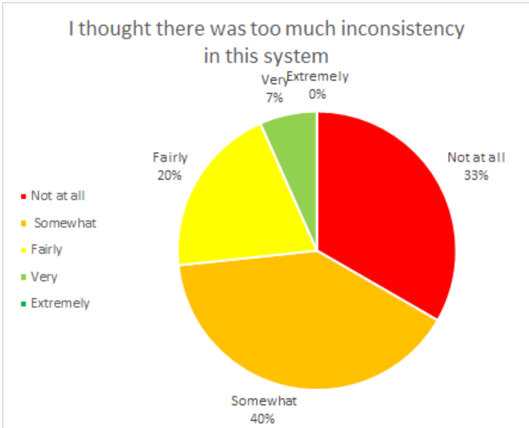

Figure 4.10: Answers to item 6 of the SUS test

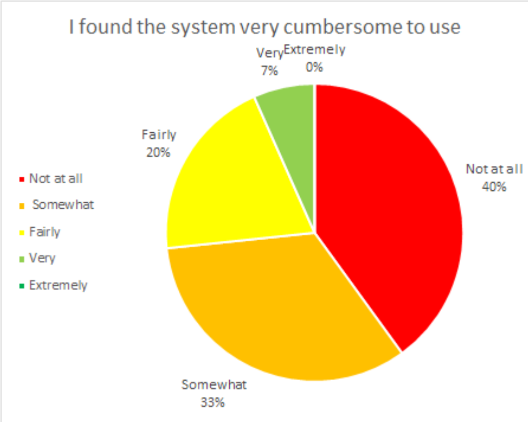

Figure 4.11: Answers to item 7 of the SUS test

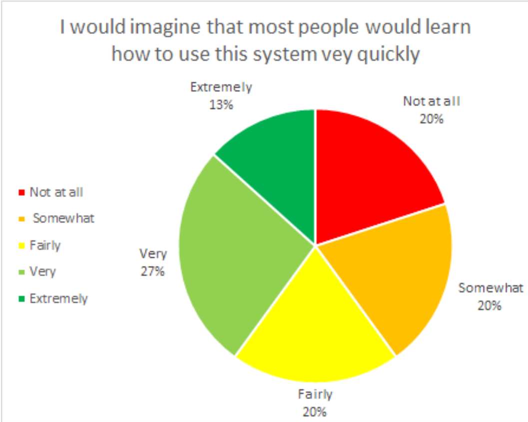

Figure 4.12: Answers to item 8 of the SUS test

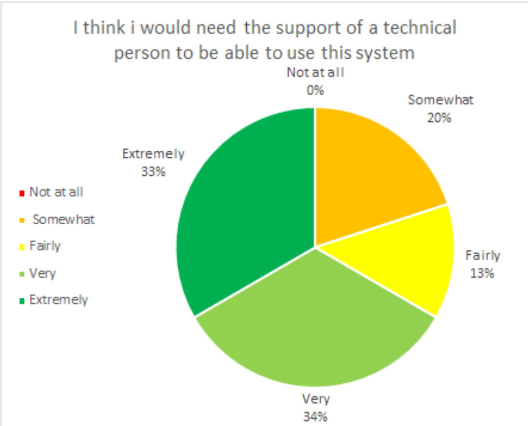

Figure 4.13: Answers to item 9 of the SUS test

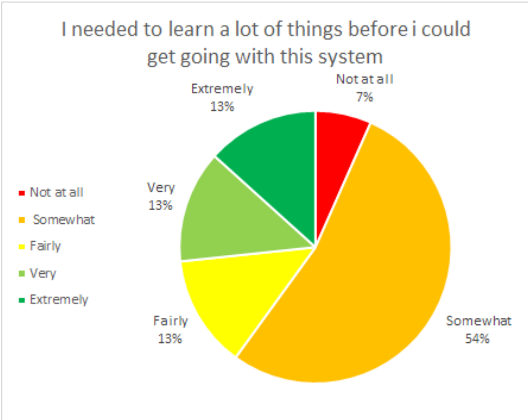

Figure 4.14: Answers to item 10 of the SUS test

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 learned 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 procedures and techniques, it is even more difficult for low expertized personnel to master the quantity of procedures available, with even lower chances to specialize in a specific one.

For these reasons, it will be more and more important to take advantage of the technology available to build tools and systems to provide comprehensive facilities to the trainees 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 2.2. Furthermore, simulator respecting said specifications are proved to develop more rapidly the skills of an apprentice (as explained in 1.3), decreasing the time needed to climb on the learning curve, even when it is a steep one.

The application described and developed in this work offers a system designed to meet the mentioned requirements, intended to be a suitable tool to learn the surgical 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 exploited to tailor the application 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 is the reproducibility of the task: the user can try as many times as he's needed, 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.

Moreover, 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 are commercially available, like the URO Mentor®, which, even though very well built, due to their very high costs can not be widely spread. Plus, the haptics feedback is not a feature. The VR-haptic system, conversely, is cheap and provides tactile feedback, other than offering the possibility to include more virtual patients if needed. The economical viability of such a system are also related to the hardware required to make it work; the only not-so-common tool in the setup is the haptic device. The 3D monitor is in fact a plus, to perform the simulation in a more immersive environment and to give a better perception of depth, but it is not stricly required to run the simulation as the application perfectly works with a normal screen, as the one used in the tests. However, the value of the 3D rendering of the scene is important, because in such a way, the simulation gives the possibility to improve eye-hand coordination, as well as how to correctly use the C-Arm, relying on 2D imaging for a 3D virtual patient, which is one of the most relevant skill for a surgeon that has to perform fluoroscopy guided surgery.

For what concerns the results of the test, it is evident that the population is limited. However, some inference may still be done. From the quantitative data provided by the simulator it can be seen that a repeated trial drives to some significant improvements, in particular about the time-related aspects of the operation. Despite time is an important feature, it is important to keep the focus on the good outcome of the application, without making it a sort of time attack where the subjects try to rush the tasks without taking care of avoiding the spine surface; this is likely to happen when more people is tested together; some of the results, in particular regarding the number of hits on the periosteum and the accuracy of the placement may in fact be negatively affected by this. Data on the interactions with the bone may also be altered by some buggy behavior of the haptic device when interacting with big meshes, or not running at the proper update rate ($1kHz$); sometimes in facts, it happens that it spot more collisions with a single actual touch, due to some delays in the renderings. Another possible alteration is relative to the distance to the target: since the position of the needle has to be tested intra operatively, triggering virtual pulses, the subject who does not encounter a suitable response must try the positioning again, until the correct response from the virtual patient is reached. For this reason, it is very likely that the distance from the target will be small anyway, and in general not much affected by the experience, at least in the first phases of the training. This process however, increases both the time of the procedure and the number of interactions with the bone, therefore a correlation between long time and high number of hits is likely to be found, analyzing bigger numbers.

Regarding the qualitative data found with the SUS_{score} computed from the questionnaires, it can be seen that the value is not very high, other than having a significant variation among the subjects. Analyzing the pie charts, there are some certainly positive features, like the fact that many people showed enthusiasm about the application, the lack of inconsistencies spotted, and a not very high complexity, but there are some even more flaws for what concerns its user friendliness; many people pinpointed that they did not felt very confident while managing the device and that they feel to need some mentoring to be able to effectively run it. This can be seen as a sort of apprehension about using the system, or seeing it somehow distant from the task they are trying to perform, and it would be very important to clear these points out.

Chapter 6

Conclusions

The application is thought to provide a valuable tool where no other solution are available, filling the gap between SNM and other more popular procedures in terms of training, like PCA or laparoscopy. The application, after undergoing further testing, and refinement, aims to be included in the curricular training of residents and medical students, as well as to be part of institutions' facilities in general, to address any practice necessities occurring, while being the basis for similar systems intended for other surgical procedures. With the respect to the specifications identified in section 1.3, the application is found to fulfill them as follows:

- **Anatomical accuracy:** 3D models have been extracted from a real CT scan, therefore reproduce a real patient respecting in details its anatomy.
- **Realism:** the trainee has every tool available during the main phases of the real operation; no significant inconsistencies have been identified during the tests, and the fluoroscopic images are composed with the real X-Ray images of the virtual patient, that can be taken from every point of view keeping their coherence.
- **Adaptability:** up to now the application only includes one virtual patient, being only one dataset available, but it is designed in such a way that other models and datasets can be easily added, creating a library of virtual patients.
- **User friendliness:** it has been evidenced from the tests that the user friendliness may be improved, in particular because some of the subjects felt the need of some support during the use. However, it can be expected that this need expires with the usage.
- **Performance feedback:** the application gives some direct performance feedback to the user, once the task has been performed. Moreover, it saves

said parameter for each user so that they can be analyzed after some sessions to understand the improvements.

- **Reproducibility:** being a software application, it can be reproduced as many times as needed in with the same setup.

- **Safety:** no ionizing radiations are used during the training sessions, no patient can be injured and no relevant risks in general have been encountered during the tests nor hypothesized during the development. Thus, the system can be considered absolutely safe.

- **Economical viability:** the system is more affordable than the similar tool sets described in section 1.3.1 and developed to be able to bring more value than bench model, hence it can be said to be economically viable.

For what concerns the software core 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 3.2.1. In particular, a certain amount of generalization has been apported 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 driven through a necessary debugging work, which helped to put the focus on some improvement that might be useful for future developers and users. LACE remains an extremely valuable and useful tool to develop rich and complete visuo-haptic applications, and it will be interesting to push it further, to create an efficient and, possibly, widespread platform.

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

- Continue with the development, in view of the tests performed and the critical issues found.

- New tests, involving medical students,or better residents and expert physicians, that can provide a medical point of view, helping to tune the system to meet the requirements of its actual final users.

- Inclusion of Head Mounted Display; 3D monitor technology is doomed to be substituted by mixed reality headsets in its entirety, for multiple reasons, out of the scope here. Include such a device would be of great value, because it would give the possibility to create not only a virtual patient, but an 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.

- Information about 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 previous improvement, may project the system to an application in surgical planning rather than education only.

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.

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