Development and evaluation of hand-held robotic technology for safe and successful peripheral intravenous catheterization on pediatric patients

by

Zhuoqi Cheng

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Abstract

Peripheral IntraVenous Catheterization (PIVC) is often required in hospitals to fulfil urgent needs of blood sampling or fluid/medication administration. Despite of the importance of a high success rate, the conventional PIVC operation suffers from low insertion accuracy especially on young pediatric patients. On average, each pediatric patient is submitted to 2.1 attempts before venous access is obtained, with around 50% failure for the first attempt. The risks of such multiple attempts can be severe and life-threatening as they can cause serious extravasation injuries. Given the levels of precision and controllability needed for PIVC, robotic systems show a good potential to effectively assist the operation and improve its success rate.

Therefore, this study aims to provide such robotic assistance by focusing on the most challenging and error-prone parts of the operation. In order to understand the difficulties of a pediatric PIVC, a survey investigation is conducted with specialists at the beginning of this research. The feedbacks from this survey indicates an urgent need of a hand-held robot to assist in the catheter insertion control to precisely access the target vein.

To achieve the above goal, a novel venipuncture detection system based on sensing the electrical impedance of the contacting tissue at the needle tip has been proposed and developed. Then several ex-vivo and in-vivo experiments were conducted to assess this detection system. Experimental results show that this system can be highly effective to detect venipuncture.

Subsequently, based on this venipuncture detection system, four different hand-held robots have been developed to provide different levels of autonomy and assistance while executing a PIVC insertion:

1. SVEI, short for 'Smart Venous Enter Indicator', is the simplest device without actuation. The user needs to do the whole PIVC operation, and this device only provides an indication of venipuncture by lighting up an LED.

2. SAID, short for 'Semi-Autonomous Intravenous access Device', integrates a motor to control the catheter insertion. The user is required to hold the device still and target it to a vein site. He/She then activates the device. The device inserts the catheter automatically and stops it when venipuncture is detected.

3. SDOP, short for 'Smart hand-held Device for Over-puncture Prevention', integrates a latch-based disengage mechanism to prevent over-puncture during PIVC. The user can keep the conventional way of operation and do the insertion manually. At the moment of venipuncture, the device automatically activates the disengage mechanism to stop further advancement of the catheter.

4. CathBot represents 'hand-held roBot for peripheral intravenous Catheterization'. The device uses a crank-slider mechanism and a solenoid actuator to convert the complicated intravenous catheterization motion to a simple linear forward motion. The user just needs to push the device's handle forwards and the device completes the whole PIVC insertion procedure automatically.

All the devices were characterized to ensure they can satisfy the design specifications. Then a series of comparative experiments were conducted to assess each of them. In the first experiment, 25 naïve subjects were invited to perform 10 trials of PIVC on a realistic baby arm phantom. The subjects were divided into 5 groups, and each group was asked to do the PIVC with one device only (SVEI, SAID, SDOP, CathBot and regular iv catheter). The experimental results show that all devices can provide the needed assistance to significantly facilitate and improve the success rates compared to the conventional method. People who have no experience of PIVC operation before can achieve considerably high success rates in robot-assisted PIVC (86% with SVEI, 80% with SAID, 78% with SDOP and 84% with CathBot) compared to the control group (12%) who used a regular iv catheter. Also, all 5 subjects using SVEI, 3 out of 5 subjects using SAID, 2 out of 5 subjects using SDOP and 4 out of 5 subjects using CathBot were able to successfully catheterize the baby arm phantom on their first attempt, while no subjects in the control group succeeded in their first attempts.

Since SVEI showed the best results, it was selected for the second round of evaluation. In the second experiment, clinicians including both PIVC experts and general clinicians were invited to perform PIVC on a realistic baby arm phantom with 3 trials using SVEI and 3 trials in the conventional way. The results demonstrate that SVEI can bring great benefits to both specialists and general clinicians. The average success rates were found to be significantly improved from 48.3% to 71.7% when SVEI was used. The experimental results reveal that all experts achieved better or equal results with SVEI compared to the conventional method, and 9 out of 12 non-experts also had better or equal performance when SVEI was used.

Finally, subjective feedback acquired through post-trial questionnaires showed that all devices were highly rated in terms of usability. Overall, the results of this doctoral research support continued investment in the technology to bring the hand-held robotic devices closer to clinical use.

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S. Mattos. "Modelling needle forces during insertion into soft tissue." 37th IEEE Annual International Conference of the Engineering in Medicine and Biology Society (EMBC), pp. 4840-4844. 2015.

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Patent

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Contents

List of Figures

List of Tables

Chapter 1

Introduction

1.1 Peripheral intravenous catheterization

Peripheral intravenous catheterization (PIVC) is one of the most common procedures carried out in hospitals with over 1 billion IV insertions taking place in the United States annually [50]. During a PIVC procedure, the cannula initially surrounds a needle that punctures the wall of a vein so that the cannula can be slid off the needle and into the vein, whereupon the needle is removed (Figure 1-1(A)). Through this cannula healthcare professionals can inject fluids, blood products and medicines directly into a patient's bloodstream. This enables rapid absorption and precise control over the dosage of the substance administered, which is vital for a variety of medical procedures, including giving fluids to treat dehydration, blood transfusions or issuing antibiotic treatment.

The traditional method of percutaneous intravenous access is done freehand, and the likelihood of success depends heavily on the patient's physiology and the practitioner's experience. The Infusion Nurses Society set standards regarding vascular access preparation and device placement, stating "no more than 2 attempts at vascular access placement should be made by any 1 nurse" [22]. In contrast to this highly demanding first-stick accuracy, the success rate reported for these procedures is actually low, around 77% on average. Additionally, younger and less experienced nurses have significantly lower success rates than their senior counterparts, as it requires years

of practice to become an expert in this operation. Studies have shown that PIVC success rates are higher for nurses specifically trained in infusion therapy (91%) than for staff nurses without specialized training, or for those who do not routinely place IV catheters (53% - 65%) [27]. Brown [7] also found that IV nurse specialists were more successful at IV insertion than non-IV nurse specialists (83% and 50%, respectively). Frey's study [33] reported the Registered Nurse staff have a 44% success rate compared to physicians (95%) and IV nurse specialists (98%). Therefore, it seems that using IV specialists is the only way to improve PIVC quality currently. However, acquiring IV skills is not easy and may take years of training to become a specialist [43, 17]. Also, funding and maintaining an IV specialist team is not always feasible for all clinical centers [20].

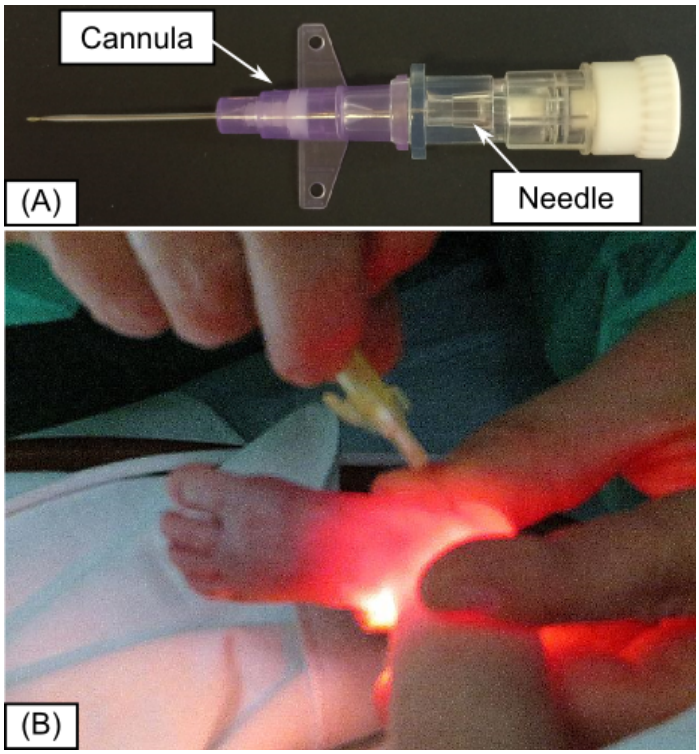

Figure 1-1: (A) For an ordinary IV catheter, initially there is a hollow hypodermic needle surrounded by a catheter cannula, and the needle is used to puncture the vein wall and introduce the cannula into the vein; (B) Peripheral intravenous catheterization on infants is highly challenging as their veins are very small and fragile.

In addition to the above, for special patients, such as infants or young children (Figure 1-1(B)), since their veins are smaller, more fragile and readily rupture, suc-

cessful IV catheter placement is even more challenging [18, 12, 49]. In addition, the percentage of subcutaneous fat in children younger than 2 years old is often high. This fat layer further decreases the visibility of peripheral veins, complicating catheterization. The estimation of vein depth is also very challenging and often requires assistive systems such as an ultrasound transducer [23, 49]. As reported in [36, 39], only 53% of PIVCs are successful on the first attempt, and about 10% of them require more than 4 attempts. A similar failure rate on the first attempt (58%) is reported in [20]. Also, PIVC performed on preterm babies is strictly required to be completed in a short time so that they can enter the incubator as fast as possible. However, this is not often the case as IV catheter placement requires an average of 2 venipunctures over 28 minutes [39].

Apart from causing pain, multiple attempts of PIVC insertions can cause several critical consequences such as extravasation, hematoma, vascular perforation, hemorrhage, and phlebitis [21]. The injecting fluid can leak into the extravascular tissues, potentially cause cellular toxicity and edema. Extravasation injuries in infant can even lead to life-threatening issues such as skin necrosis. Study [71] reported about 4% of neonates sustain cosmetically or functionally significant scars due to skin necrosis caused by extravasation injuries. These injuries are often a result of wrong placement of the catheter and, unfortunately, there is still no consensus on their management [58]. In addition, the catheterization of femoral veins, which are traditionally favored in very young children to avoid intrathoracic complications, is also frequently associated with a significant risk due to inadvertent puncture of the femoral artery when attempting the cannulation [70].

1.2 Research objectives

The current situation constitutes a great opportunity for science and innovation to improve the PIVC procedure. The goal of this research work is to develop a hand-held robot which can deskill the pediatric PIVC and increase the success rates. This particular ambition directs the efforts to approaches and solutions that should be as simple

as possible yet resist the stringent clinical requirements imposed by the specific application of pediatric PIVC. Specifically, the design aims to construct a human-robot cooperation surgery: On one hand, the robot only offers necessary assistance to one or some difficult and error-prone steps during a PIVC operation; on the other hand, the robot allows the practitioner to be always in control throughout the operation. In addition, the desire to translate this technology into a clinical solution permeates the conducted efforts during the robot development. This directs the development to focus on more practical clinical needs. For instance, the robot can allow the user to perform PIVC on flexible insertion sites (arm, leg, or scalp), and it can provide a comfortable way of manipulation requiring less learning effort for clinician.

1.3 Design procedure

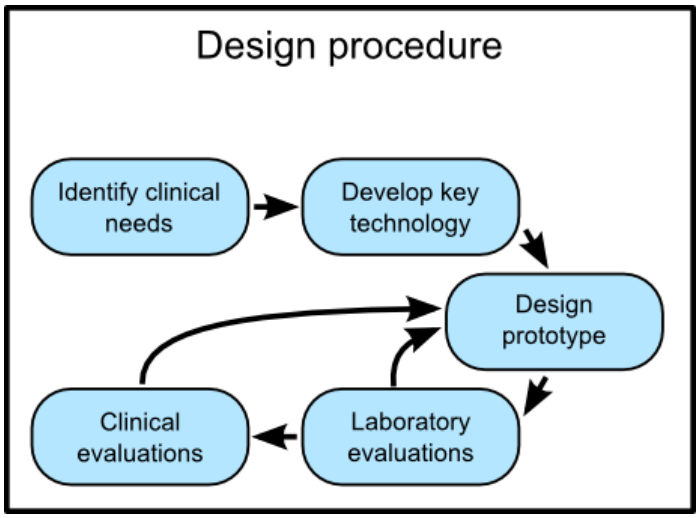

Figure 1-2: Design procedure of hand-held robotic devices for pediatric PIVC.

This research work follows a methodical development procedure for medical device [47] as shown in Figure 1-2. The development procedure starts with investigating similar products in use and identifying user needs from potential customers. In this step, a literature review is conducted, and the state-of-the-art designs are carefully evaluated and compared. Apart from that, in order to have a better understanding of the clinical challenge, a survey investigation was conducted with specialists in a

hospital. Based on the suggestions from the specialists, the target specification of the perspective design is established to be a hand-held robotic device for accurately inserting the catheter into a peripheral vein on pediatric patients. At the development stage, the author firstly focuses on addressing key technological barriers which in this case could be the sensing technology for venipuncture detection and the control actuation system for inserting the catheter. Through the process of evaluation and tradeoffs among different attributes, a novel venous entry detection system based on electrical impedance sensing is developed. This detection system has been carefully characterized and validated to ensure that it can meet all the requirements of the target specifications. Subsequently, based on the detection system, different actuation solutions are implemented for the robotic systems. Several prototypes have been built. Through a series of experiments these prototypes have been evaluated and validated. According to the evaluation results, the design can be optimized by rolling back to refine the specifications and redesign new prototypes. Subsequent user trial with potential users (clinicians) would be very helpful and give rise to further design specifications. The process of device development is cyclical and iterative as ideas are prototyped, tested, improved, re-tested, optimized and finalized.

1.4 Outline of the dissertation

The dissertation comprises nine chapters. After this introductory chapter, the following topics will be treated in the different chapters:

Chapter 2 presents the technological background and summarizes the state-of-the-art robots and clinical devices designed for assisting PIVC.

Chapter 3 describes an interview carried out in the hospital to understand the difficulties of PIVC on young babies from the specialists' point of view. The feedbacks from the investigation point out a strong need to have a robotic system assisting in the depth control during catheter insertion.

Chapter 4 introduces the PIVC environment and the derived design criteria according to clinical requirements. In addition, three realistic phantoms used in this

study are described.

Chapter 5 reviews different available sensing methods used for venipuncture detection. Further, a novel venipuncture detection system through sensing the electrical impedance at the needle tip is proposed, developed and evaluated.

Chapter 6 elaborates on the development of four hand-held robotic devices on the basis of the developed venipuncture detection system. For each device, a different mechanism is designed and integrated. The mechatronic design and characterization of the devices are provided in this chapter.

Chapter 7 focuses on the pre-clinical validation of the presented devices. Experiments are designed based on a realistic pediatric PIVC scenario. Subjects without any PIVC experience are invited to perform PIVC with one of the designed devices or a regular IV catheter. Quantitative experimental results and subjective feedback from the subjects are collected during the experiments to acquire a better understanding of the effectiveness of the proposed devices and user's appreciation.

Chapter 8 extends the evaluation of the developed technology by involving potential users (clinicians) to perform PIVC on a realistic pediatric arm phantom with one of the robotic devices and a regular IV catheter. Again, quantitative experimental results and subjective feedback from the subjects are collected and analysed.

Chapter 9 concludes this dissertation with some general conclusions and recommendations for future work.

Chapter 2

Robot-assisted surgery

2.1 Surgical robotic systems and their application

The field of surgical robotics emerged in the 1980s when an industrial robot was firstly applied to insert a needle for a brain biopsy guided by CT scanning, showing greater efficiency and precision compared to the manual intervention [37]. The publication of this work heralded the explosion of research on surgical robotics. Gradually, the first special-purpose surgical robot called PROBOT was developed by Davies *et al.* in 1988 to perform prostatic surgery. In April 1991 this robot conducted the world's first pure robotic surgery to remove quantities of prostatic tissue from a human patient [25].

In the last decades, surgical robots have been developed to assist medical practitioners in a wide range of surgical interventions, including orthopedic [28], neurosurgery [45], endoscopy [55, 64], and brachytherapy [56]. Compared to conventional surgery, robot-assisted surgery improves the surgical procedure with enhanced precision, repeatability, dexterity and control during the operation. Thanks to the use of robotic systems, the patient can benefit from fewer complications, shorter operation time, less pain and blood loss.

2.2 State-of-the-art robotic technologies for improving PIVC accuracy

The development of robotic technology to improve the PIVC operation is not a new research area. BloodBot [73] may be the first robot designed for intravenous needle insertion. The system is comprised of a powered XYZ translation system with a uni-axial force sensor along the Z-axis. Firstly, the robot uses a probe with a force sensor on top to palpate the antecubital fossa at positions along its width to identify the vein's location. After a vein for insertion is located, a human operator changes the palpation probe to a needle, and rotates the robot arm to target the vein. The robot would then insert the needle along its Z-axis until it detects the venipuncture by identifying a specific characteristics of the insertion force. The evaluation experiments on this robot were conducted and demonstrated its capability to perform proof-of-concept insertions on vein phantoms.

Recently, inspired by BloodBot, several surgical robots were developed for automating the PIVC procedure. HaemoBot [5] was developed as a complicated, industrial-sized, two-arm dexterous robot with in total 19 mechanical DOFs (9 DOFs for catheter insertion, 9 DOFs for support work and 2 DOFs for controlling a stereo camera). The robot uses a Near Infra Red (NIR) vision system to find the vein and a force/torque sensor to guide the needle insertion. The system was demonstrated to successfully perform autonomous catheterization on an artificial venous bifurcation of an adult arm phantom, though no comparative results of manual operation on the same phantom was provided for comparison. In addition, the robot is also mentioned to have a potential to be applied for tele-operation but this need is not well justified.

Veebot [54, 24] is a mobile robotic platform consisting of an automatic tourniquet, a needle insertion mechanism and a vein-finding imaging system. The robotic system uses NIR imaging for the primary vein-detection and ultrasonography for confirming the selected vein's adequate blood-flow. Then the robot inserts the needle into the target vein guided by ultrasound imaging. However, although this robot has been proposed a long time ago (2010), it is only a conceptual design and no evaluation of

the robot can be found in the literature.

Compared to the three robots mentioned above, VenousPro [9, 2] may be the most successful robot design for automated intravenous intervention and blood sampling. This system employs a stereo-NIR imaging and ultrasound to build a 3D map of the detected veins in the antecubital fossa and estimate their depths. After the human operator confirms the suggested insertion site, the robot arm drives a needle/catheter to insert into the vein based on position control and real-time tracking of the needle tip using the stereo camera. This system has been demonstrated to achieve high success rates on realistic phantoms. To date, their device has also been evaluated by inserting a catheter into the tail veins of rats, showing over 80% first-stick accuracy.

Due to the task complexity, VenousPro has to equip various actuators and sensors, making the whole system relatively big and heavy. Although VenousPro is claimed to be portable, it still needs to be placed on a desk for operation. In [44], the same R&D team of VenousPro propose a conceptual design indicating a future direction to redesign the system as a small cuff-like harness that can be placed on the patient's arm for operation.

Similar to the above design, De Boer *et al.* developed a robot [14] which can be placed on top of the patient's hand for autonomous PIVC operation. The robotic device is comprised of 6 active DOFs (planar XY, Z-needle-depth-limit, pitch, yaw, and prismatic-insertion along the needle axis) for performing needle insertion and an ultrasound probe for vein detection. The ultrasound probe sweeps across the surface of the hand to detect the vein, and the needle is then aligned with the detected vein. The system detects venipuncture through finding the force drops along the insertion direction, and then halts insertion automatically. The system was characterized and evaluated based on a phantom developed in the same study with different insertion angles and speeds. These experimental results showed that the system can successfully perform automatic needle insertion on the phantom in all cases. However, no further development has been published after this initial research.

The above robots are all designed for the purpose of fully autonomous PIVC, leaving the clinician aside to perform only supplementary work. Those robots are

commonly heavy and expensive, need to be placed on a desk for operation. Compared to those grounded robots, hand-held robots have also been developed for assisting the PIVC operation. Such robots integrate sensing and on-board actuation, aiming to constitute a human-robot collaborative surgery: the clinician is responsible for localizing a proper insertion site and establishing the position and orientation of the needle for insertion, and the robotic system is responsible for the delicate insertion motion.

For instance, SAGIV [16] was developed as a hand-held robot for assisting PIVC insertion. The robot consists of a trans-illumination device plus a screen to show the location of the vein. Based on this information, the operator holds the robot, points the catheter tip to a vein site, and then presses a button to activate the catheter insertion. An integrated blood pressure sensor would then detect venous entry and stop the insertion automatically. So far this robot has only a conceptual prototype, and no detailed information related to its design and evaluation are revealed.

Other than that, some other devices are designed in an even simpler way. These type of devices aim to assist the practitioner to deal with a specific and challenging step of a PIVC procedure. Normally, they are only responsible to use some sensing technology for detection and feedback the information to the operator, not involving any decision making or insertion actuation. In fact, because these devices are cheap and can keep the operator always in control during the operation, they are very welcome by both medics and patients in the current state.

One typical example is the ultrasonography technology. Several recent studies found that longitudinal ultrasound imaging can be effective in improving the success of PIVC [67, 65]. Thanks to its capability to simultaneously display the vein and the catheterization needle, ultrasonography offers excellent guidance during the PIVC insertion procedure. However, the financial implications of using ultrasound devices for PIVC typically prevent its widespread use in clinic. Apart from having an ultrasound device available, additional training is required to operate the device and perform PIVC with it, which is not easy since it requires complicated hand-eye coordination [67]. According to the literature [48], this method is only applicable for highly-skilled

professionals.

Another technology that has been ubiquitously used in hospitals is trans-illumination. This technology addresses common difficulties associated specially to patients who are very young, dehydrated, obese, shocked or have a colored skin [23, 49], i.e., the problem of finding a good insertion site before doing the insertion. To address this problem, trans-illumination devices such as the VeinViewer (Christie Medical Holdings, Inc., TN, US), the AccuVein (AccuVein Inc., NY, US) and the VeinLite (Translite LLC, TX, US) are often used. Because NIR light is highly absorbed by hemoglobin and reflected by fat and dermis, such devices use a special camera to capture the reflected light on the insertion site area, and project the vein's location back to the area after some necessary image processing.

Another possible technology for assisting in the vein finding is through palpation. In [42], the authors developed a voice-coil-based, tactile-sensing probe that measured tissue compliance to detect vein locations. This hand-held device is mentioned to successfully identify vein location on their phantom vein. But at the end, this work does not culminate in an actual robotic prototype.

Another clinical challenge of PIVC is the venipuncture detection and the insertion depth control. The most common method for robot-assisted surgery is through sensing the insertion force on the needle/catheter. Saito *et al.* [51] recorded the needle insertion force during penetration on veins in rabbit ears as part of their development of an automated blood-sampling device. They proved that a decrease of insertion force could be detected and potentially used for halting the axial insertion motion after the needle punctures the vein automatically. However, this work did not result in the development of an actual robot.

Diversely from the above methods, VEID [60] is designed as a small electronic device that can be plugged to the end of a regular iv catheter to sense the pressure via the needle tube (Figure 2-1). Through detecting pressure change, VEID provides an audit signal to notice venipuncture to the operator. Several studies [63] have been conducted and demonstrated that this device can accurately indicate vein entry during placement of a catheter on adults.

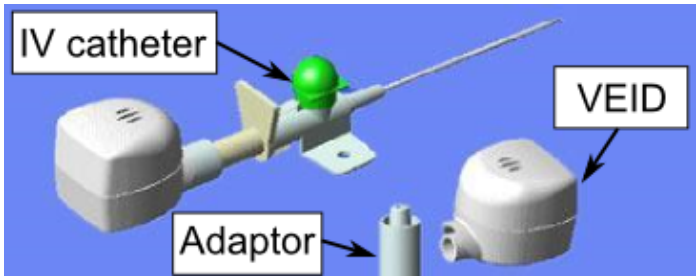

Figure 2-1: The vein entry indicator device (VEID).

We summarize the above robots and clinical devices including their features, advantages and disadvantages in Table B.1 and Table B.2.

2.3 Medical devices designed for pediatric PIVC

Among the robots and medical devices mentioned above, few of them were actually designed for pediatric PIVC or being tested with pediatric patients. VenousPro is the only autonomous robot considering pediatric patients as their target subjects. Nevertheless, its application on pediatric patients is still questionable. One big challenge is to keep the baby arm steady on the robot platform throughout the operation. Also, this robot seems only able to perform PIVC on specific insertion sites such as basilica veins on the upper limbs, thus impacting the flexibility of insertion site selection.

Instead of fully autonomous robots, medical devices that operate based on trans-illumination have already been broadly used on pediatric PIVC and proven to improve the first-attempt success rates from 25% to 58.3% [29, 8]. Nevertheless, even with trans-illumination technology, it is still very difficult to insert an IV catheter precisely into the vein due to the following 2 reasons. First, these devices are unable to indicate the venipuncture which are probably the most challenging task during the PIVC insertion. Secondly, the current devices do not provide direct assistance of PIVC insertion and the success of this process still relies very highly on the clinician's ability and experience.

By now, VEID may be the only medical device developed for guiding the catheter insertion depth on pediatric patients. In [63], a comparative experiment was con-

ducted to undergo VEID-assisted and standard PIVC on 202 healthy children. The experimental results showed that VEID-assisted PIVC achieved 89.7% success rates on difficult grade of pediatric patients compared to 23.3% in the control group who used regular iv catheters.

2.4 Discussion and thesis contributions

In spite of the fact that there were some surgical robots proposed for performing or assisting PIVC operation, very few of these designs have been developed and evaluated. In this research, rather than replacing clinicians with an autonomous grounded robot, we propose to enhance the skills of the existing staff with a hand-held collaborative robot. The hypothesis is that such device could deskill the PIVC process, leading to increased success rates for the operations. In addition, the characteristic of being hand-held could increase its acceptance by both medical staff and patients, as suggested by previous studies [52]. In order to make the device compact, cheap and light-weight for hand-held operation, the functions of the device are limited to assisting the clinician in difficult steps during PIVC. It does not address issues that can be easily overcome with mature commercial products. In addition, the device's sterilization is another concern of the design. Where possible, the device should be reusable and easily cleanable in order to reduce the treatment cost.

The research presented in this dissertation includes several contributions that advance the current state-of-the-art in robotic technologies for pediatric PIVC, including:

1. Empirical investigation of the difficulties in pediatric PIVC and current user needs. The investigation also includes a survey related to the preferred holding method of such devices.

2. Development of a novel method for detecting venipuncture through sensing and identifying the electrical impedance of tissue contacting the needle tip. This method has overwhelming advantages comparing to other existing venipuncture

detection methods.

3. Proof of the feasibility regarding the venipuncture detection system based on an animal experiment. The animal experiments were conducted to measure electrical impedance during intravenous catheterization insertions into rat's tail veins.

4. Development of a novel hand-held medical device that can detect venous entry during PIVC and give notice to the operator by lighting up an LED.

5. Development of a novel hand-held robotic device that can detect venipuncture and control the catheter insertion with an on-board motor.

6. Development of a novel hand-held robotic device that can detect venipuncture and prevent over-puncture with a disengage mechanism.

7. Development of a novel hand-held robotic device which can simplify the PIVC operation and provide safe PIVC operation including automatically inserting the catheter, detecting venipuncture, advancing the capped cannula and retracting the cored needle.

8. Definition of future directions regarding human-robot-cooperative approach for PIVC.

9. Realization of pre-clinical experiments to evaluate the developed device with potential end users (clinicians).

To conclude, this chapter presented the advantages of using robotic technology for surgical intervention and described several state-of-the-art robots and clinical devices for assisting PIVC operation. The limitations of these technologies were also described. In Chapter 3, a survey study to investigate operation details and difficulties during a conventional PIVC will be presented. The survey subjects were specialists in pediatric/neonatal PIVC, whose expertise was very helpful for defining the goals of this research.

Chapter 3

Investigation of PIVC details and specifications

This chapter lists the low-level design specifications of a robotic solution to PIVC insertion. To gain a more thorough understanding of IV insertion itself and which steps of this procedure are particularly error-prone, a survey investigation was designed and carried out to collect suggestions from specialists.

3.1 Design of survey investigation

This survey was designed to be conducted in-person with a limited number of interviewees to ensure a high practicability. Given the limited availability of surgeons, this survey was set up to gain maximal information from a limited number of interviews. A set of 8 questions about the difficulties of PIVC operation, assistive devices, and medical techniques were defined in this questionnaire. Appendix C provides a copy of questionnaire in English, and this questionnaire was then translated to Italian (Appendix D) for the survey. Because this survey was conducted in an Italian hospital, the questionnaire in Italian was believed to help the medics better understand the questions. The scope of the questionnaire was defined based on a literature study and our own experiences about the difficulties in performing PIVC.

According to different degrees of detail, each question can have multiple sub-

questions. Also, both open-ended and closed-ended question types were included in the questionnaire. For questions to collect the specialists' experiences, open-ended questions are used since the answers can exceed the investigators' expectation. Hence, the interviewees can freely write down related information or express their opinions. As for questions used to generate statistical results, a closed-ended question type is used. Suggested in [57], all the closed-ended questions in this questionnaire are designed as Likert-type scales with 7 points to represent different degrees between two opposite attitudes, such as agree and disagree, easy and difficult. The interviewee can select one level of the scale to express his/her opinion for that statement. In addition, this questionnaire contains both mandatory and voluntary questions, and red background and green background are used to distinguish them. Generally, mandatory questions are related to the main concern of this research and voluntary questions, which are optional to answer, are used to collect supplementary information. More details with regards to the objectives and the design of each question are provided below:

Q1. what is the typical number of trials before you successfully place the catheter into a neonate's peripheral vein? Why are multiple attempts required? What are the typical solutions to improve insertion accuracy? What are the typical insertion sites on young babies? What is their reaction during the operation?

Through these questions, we expect to know how often multi-attempts are required for PIVC on very young patients. Also, we would like to learn from the specialists if they have any solutions to improve the PIVC insertion. All the sub-questions in **Q1** are made open-ended types for collecting as much as possible information.

Q2. Among the insertion sites that are often selected for pediatric/ neonatal PIVC, which insertion sites are more difficult for PIVC? Why?

Based on our prior knowledge and published literature [30], some insertion sites which are often selected for PIVC operation on young babies including scalp, back of the hand, inner side of wrist, arm, and leg, are listed. For each insertion site, a 7-points Likert-type scale is provided to query the level of difficulty when PIVC is

performed on that insertion site (from 1 for 'easy' to 7 for 'difficult'). Also, under each Likert-type scale, there is a voluntary question asking about the reasons for causing this difficulty.

Q3. Please rate the difficulties and list your strategies for the following procedures of an intravenous insertion.

In this question, seven procedures during a PIVC operation, which could potentially cause difficulties, are listed: a. notice if the patient is dehydrated; b. find a good insertion site; c. perceive venipuncture; d. avoid vein sliding away during puncture; e. notice if the catheter has correctly entered the vein; f. advance cannula; and h. retreat needle.

For each procedure, a Likert-type scale is presented with 7 points to express the degree of difficulty (from 1 for 'easy' to 7 for 'difficult'). Based upon the answers to this question, we wish to know the difficult steps during a PIVC, which may be improved with robotic technology.

Also, an open-ended question is provided under every Likert-type scale to ask if the interviewee may have some strategies to address the difficulty.

Q4. Do you use any assistive device during the intravenous catheterization?

We designed an open-ended question to ask if any devices have already been used in the hospital for assisting the PIVC operation. Following the open-ended question, a Likert-type scale is given to ask whether the interviewee thinks the device is useful (from 1 for 'useless' to 7 for 'useful').

The response to this question indicates some difficult steps during a PIVC which already have technological solutions. Based on the score of the Likert-type scale, it also shows whether the interviewee is satisfied with the current technology.

Q5. How do you perceive venipuncture?

According to the authorâĂŹs knowledge, venipuncture detection is difficult to perceive, which can potentially require a robotic device for assistance. Therefore, we raise this question to ask about the sensory method for manual venipuncture detection in order to understand the reasons. Based on our prior knowledge, 3 possible

methods for detecting venipuncture are listed: sensing the change of insertion force, observing blood flashback (i.e. visually observing blood flow at the back of the needle) and observing skin deformation. The interviewee can indicate the importance of each method for perceiving venipuncture by marking the degree of the corresponding Likert-type scale. In addition, an extra open-ended question is given to collect information related to other possible methods for perceiving venipuncture. Their answers may inspire some possible detection methods that can be adopted to the robotic development.

Q6. What is your subjective experience of the operation after a difficult catheterization?

In this question, we wish the interviewees to tell us their working pressure during a PIVC operation. Especially after a difficult PIVC, do they feel nervous? stressed? or fatigued? Three Likert-type scales are given to consult the level of the above three subjective feelings. The answer to this question may show the necessity to provide a robotic solution for making the operation easier.

Q7. Could you show us your preferred way to hold this device by modelling it with plastic clay?

The importance of designing ergonomic handles in surgery and other procedures requiring high precision were highlighted in several studies [40]. As a hand-held device, the way to hold it could greatly affect the maneuverability and safety for its use [68]. Considering the lack of a holding handle design for PIVC devices, we design this question to understand the preferences between different ways to hold the device by specialists. During the investigation, they are given a piece of modelling clay and they can suggest one favorite method of holding by shaping it.

Q8. Could you please give us some comments about designing a hand-held device for intravenous catheterization?

This is an open question to obtain more suggestions from the specialists. Their concerns could help us improve the design.

3.2 Investigation procedure

In total, nine specialists from the neonatal department of San Martino Hospital (Genova, Italy) including neonatal doctors and neonatal nurses were invited to participate in this survey. All of them are very experienced with neonatal PIVC. Eight of them (average age: 53±8 years, gender: 3 males and 5 females) have more than 10 years of experience, and the other one (age range: 30-40, female) has also 4 years experience.

The survey was conducted in a meeting room of the hospital. All the subjects were organized to sit at a round table during the investigation. The investigators distributed questionnaires to each subject and explained to them the study purpose. Then, the subjects were asked to fill in the survey **Q1** to **Q6**. Theoretically, they had no time limit for completing the survey but they all finished within 1 hour. During this period, the investigators were always with the subjects to answer their queries related to the questionnaire. After that, we delivered to each subject a piece of plastic clay for modelling their favourite device's shapes (**Q7**). As mentioned above, each subject could only suggest one shape. During the whole investigation procedure, discussion was allowed so that they can remind each other any missing information.

3.3 Investigation results

3.3.1 Results from the questionnaires

According to the answers to **Q1**, 3 subjects said they needed 2 trials before successfully placing the catheter into the vein and 1 subjects said an average of 3 trials are needed. The other 5 subjects said they could not estimate the number of trials but could provide us an average success rate for each attempt: 4 subjects wrote 80% and 1 subject wrote 70%. They also listed some factors that make a PIVC operation difficult, including small vein size, fragile veins, bad visibility of the vein and find a good insertion vein site. The reactions of the baby during PIVC were mentioned to be commonly intense and intolerant. They would cry, wave limbs and be agitated, making the operation even more difficult. In addition, a typical pediatric PIVC would

need 2 clinicians, which may potentially cause difficulties due to intra-cooperation.

To improve the PIVC operation, some strategies were suggested. These strategies included holding the baby stationery, putting traction on the skin to stabilize the vein and using an elastic band to dilate the vein. Another suggestion said if the first attempt on one vein failed, it would be better to try on the other veins.

The answer to **Q1** also provided the most often selected insertion sites for pediatric PIVC including arm, head, fist and leg. These insertion sites are all listed as our pre-set options in **Q2**. Also, different levels of difficulties on different insertion sites were found according to the response to **Q2**. The veins on the arm (Ave. Score: 1.9) and head (Ave. Score: 2.8) were mentioned to be relatively easy for PIVC as they can be easily seen. The back of the hand (Ave. Score: 3.3) was also considered to be relatively easy as the veins there are easy to find but performing PIVC there could be a bit painful. Veins on the leg are normally deeper so performing PIVC on that site is particularly difficult (Ave. Score: 4.3). In addition, the inner wrist, which was not mentioned in **Q1**, was not recommended (Ave. Score: 4.5) for PIVC by the interviewees because the veins there are small and performing PIVC there could cause a lot of pain.

With regards to the difficult PIVC procedures (**Q3**), the most difficult procedures are mentioned to be avoiding the vein sliding away during insertion (Ave. Score: 3.33), finding a good insertion site (Ave. Score: 3.25), venipuncture perception (Ave. Score: 2.44) and confirming successful insertion (Ave. Score: 2.44). The other procedures were mentioned to be relatively easy.

In **Q4** when the available assistive devices for pediatric PIVC were queried, the trans-illumination device was the only mentioned device. Two participants mentioned the trans-illumination device and both of them rated it to be very helpful (Ave. Score: 7).

To perceive venipuncture (**Q5**), the most useful technique was mentioned to be through observing flashback (Ave. Score: 6.7). Using haptic sensing was said also to be an important clue (Ave. Score: 4.9). The other method 'observing skin deformation' received a relatively intermediate rate (Ave. Score: 4).

The responses to **Q6** implied potentially high working stress during PIVC on very young patients. After a difficult PIVC, the clinicians would feel nervous (Ave. Score: 4), stressful (Ave. Score: 3.9) and tired (Ave. Score: 3.9).

3.3.2 Results from the clay modelling

In total, only 7 interviewers participated in the modelling procedure. Figure 3-1(A)-(G) show these 7 modelling results. The first observation of the modelling results was that catheterization is normally performed with the clinician's hand manipulating the catheter directly above the insertion site. Their preferred ways to hold the catheter were to:

(i) grip the device using the thumb and index finger (Figure 3-1(A)-(D));

(ii) grip the device using the index finger and middle finger (Figure 3-1(E));

(iii) grip the device using the thumb and the middle finger with the index finger pressing on top (Figure 3-1(F));

(iv) grasp as shown in Figure 3-1(G).

Method (i) was broadly accepted as 4 subjects modelled the clay in a similar way, while the other 3 methods were preferred by one subject respectively.

3.4 Discussion and conclusion

There are several important messages that follow from the above investigation results.

First of all, the investigation results confirm that PIVC on very young patients is very difficult as commonly multiple attempts are needed (**Q1**), and the operators would feel frustrated after a difficult PIVC (**Q6**).

Furthermore, the survey revealed that the developed device should be able to work on flexible insertion sites as indicated by the response of **Q1** and **Q2**. Since different insertion sites such as hand, arm, leg and scalp have significantly difficult physiological structures, a robotic system aiming for autonomous PIVC is inevitable to equip

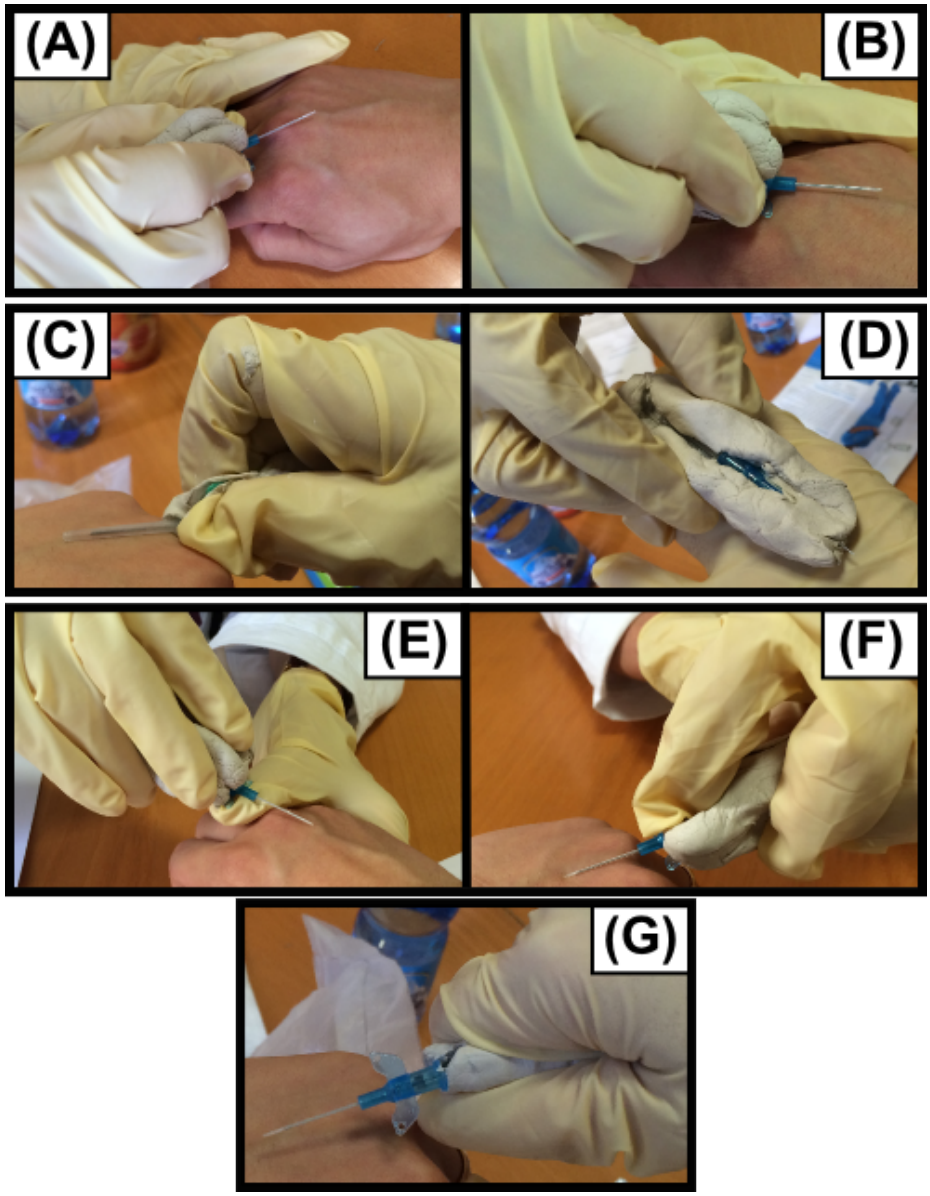

Figure 3-1: Seven suggested gestures according to the feedback of neonatalists from San Martino Hospital, Genova, Italy.

complicated actuation system in order to establish PIVC on different insertion sites. Alternatively, this clinical target can be achieved through human-robot cooperative surgery. In this perspective, the robot can be designed in a hand-held way targeting to address one or some specific clinical challenges, while a human practitioner holds this robot and targets it to a selected insertion site.

In addition, the difficult procedures resulting from **Q3** indicate several possibilities to improve the pediatric PIVC with robotic technology. The most challenging procedures of PIVC are related to the catheter insertion control such as 'avoid vein sliding away during insertion', 'perceive venipuncture' and 'notice that the catheter already correctly enters the vein'. Therefore, the specifications of the robot would be developed to assist the catheter insertion and address the difficulties of venipuncture perception. Although 'find a good insertion site' was also mentioned to be very difficult, the interviewees also reported that trans-illumination devices have already been widely used in the hospital and that this kind of device can successfully address this issue (**Q4**). Hence, the need to add the function of vein finding to the robot design specification is not considered.

Also, some good strategies to improve insertion accuracy were suggested according to the answers to **Q1** (such as holding the baby stationery, putting traction on the skin, tying an elastic band and doing PIVC on a different vein after the first attempt failed), but these strategies can all be easily achieved by human operators and thus it is not necessary to develop robotic solutions for these.

This investigation study also collected some suggestions of the ways to hold the robotic device **Q7**. In Chapter 6 during the development of hand-held robots, the handle shape is one of the main concerns. The shape of the hand-held robots would be designed based on the preferred holding way (i), allowing the user to grip it with the thumb and index finger.

The limitation of the presented activity consists of having contacted operators from a single hospital. In future work, it would be beneficial if the design specifications could be collected from a larger pool. Another possible limitation is that during the handle modelling section, the results may depends on the artistic skills of participants

and they may also be affected by the works of others.

In summary, a survey study of the traditional PIVC operation is presented in this chapter. In Chapter 4, the PIVC process will be described and the PIVC environment will be modelled. Related environmental parameters of the PIVC insertion will also be given and used for deriving the technical requirements for the robotic system design.

Chapter 4

The PIVC process and environment

4.1 The PIVC process

As outlined in [30, 11, 5], the conventional PIVC procedure can be summarized as a flowchart in Figure 4-1. The operation normally starts with some preparations such as cleaning the insertion area and tying a tourniquet on the patient's operated limb. After a suitable vein site for insertion has been found, the operator would pick up a catheter, align it with the vein, and start the insertion. The insertion should stop immediately once the operator perceives the venipuncture (through insertion force or blood flashback). Subsequently, since there is a small distance ($L_t \approx 2\,mm$) from the needle tip to the cannula tip as shown in Figure 4-3, it is very important to advance

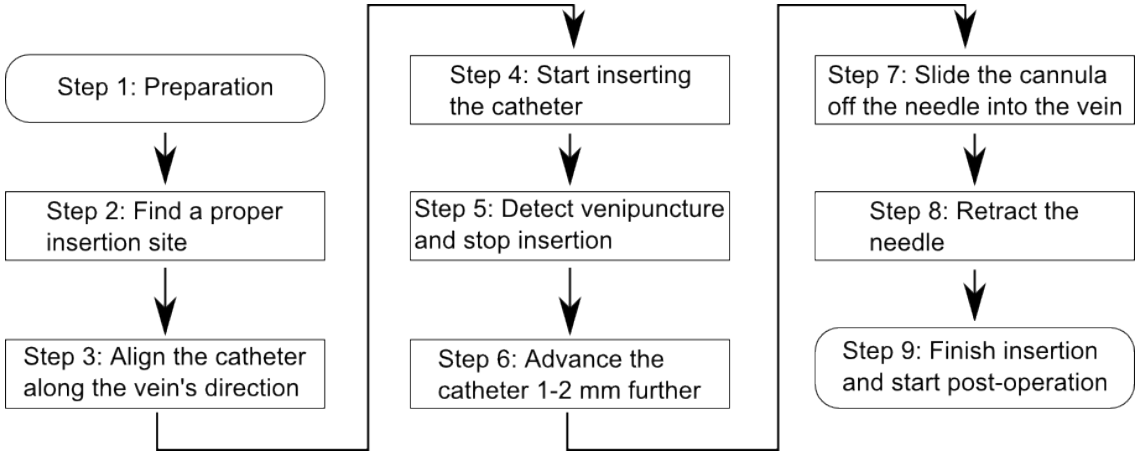

Figure 4-1: The operation procedure of PIVC.

the catheter a bit further after the first venipuncture to ensure the cannula tip also enters the vein. Then the needle is kept still while the cannula is pushed forward to slide off the needle and enter the vein. Finally, the needle is removed from the cannula, and the PIVC insertion is completed.

4.2 Environmental parameters of PIVC

Here, the anatomical environment involved in PIVC is analyzed. Figure 4-2 shows a picture of a model of such anatomy. The superficial layer of the skin is composed of a thin and stiff tissue layer called epidermis, beneath this layer one finds the dermis layer and then the fat layer. The veins of interest for PIVC are usually embedded in this fat layer [53]. During the insertion process, the needle penetrates through the epidermis, dermis, fat and the vein wall in order to enter the blood. Muscles lay beneath these layers.

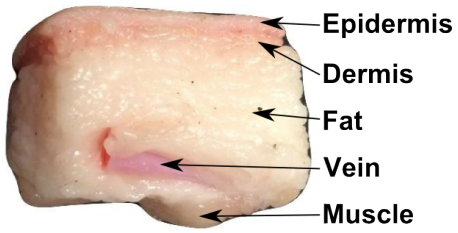

Figure 4-2: The anatomical model of the intravenous environment.

As shown in Figure 4-3, the section view of the PIVC environment is modelled to illustrate the PIVC insertion depth control which is the main focus of this research. As suggested by the specialists (Chapter 3) and Riera *et al.* [59], the robots to be designed should be able to perform PIVC on flexible insertion sites such as veins on the hand, arm and leg. Here, the peripheral veins in these possible insertion areas are considered. Specifically, in the study of Riera *et al.* [59], the inner diameter of these peripheral veins (d) and their depths in young children were measured by ultrasound. These values are listed in Table 4.1. Given the insertion angle (α) of PIVC from 15° to 25° [30], we can compute the following environmental parameters for PIVC including Insertion Length (IL), Remaining Length of Cannula (RLC) and

Safe Travel Distance (STD), which will be used to generate the design specification for the robotic system described in Chapter 5 and 6.

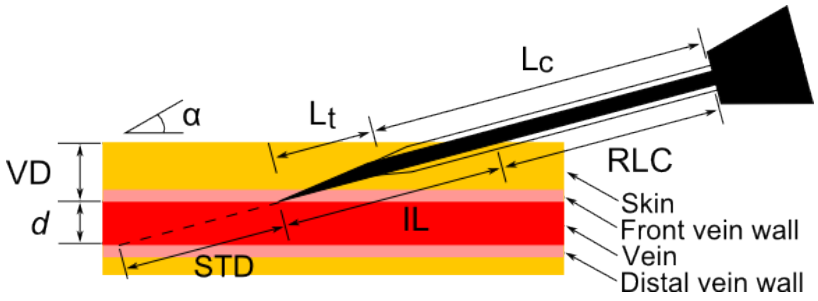

Figure 4-3: The model of PIVC environment showing a catheter inserting into a vein where α is the insertion angle, d is the vein diameter, VD is the Vein Depth, IL is the Insertion Length, RLC is the Remaining Length of Cannula, STD is the Safe Travel Distance, L_c is the cannula length and L_t is the distance between the cannula tip and the needle tip.

The Insertion Length (IL), denoting the distance along the catheter axial direction from the needle tip when it touches the skin until it punctures the front vein wall, can be calculated as

$$IL = \frac{VD}{\sin(\alpha)}. \tag{4.1}$$

After the needle tip punctures the front vein wall (its thickness $<$0.3 mm [38]), there is a Remaining Length of Cannula (RLC), which needs to be inserted into the vein after venipuncture. In this study, we consider only 26G IV catheter (SURFLO-W, Terumo Europe N.V., Belgium) which is commonly used for PIVC on newborns. Given the length of its cannula $L_c = 19$ mm, and the distance between the needle tip and the cannula tip $L_t = 2$ mm (see also Figure 1-1(A)), RLC can be calculated using:

$$RLC = L_c - (IL - L_t). \tag{4.2}$$

Another very important parameter is the Safe Travel Distance (STD), which represents the distance that the needle can insert inside the vein. This distance can be calculated from the needle tip where it starts to penetrate the front vein wall, to the

Table 4.1: Summary of the PIVC environmental parameters.

Vein location	Hand		Leg		Arm	
d (mm)	1.8		2.8		2.8	
VD (mm)	1.4		1.9		1.6	
α ($\circ$)	15	25	15	25	15	25
IL (mm)	5.4	3.3	7.3	4.5	6.2	3.8
RLC (mm)	15.6	17.7	13.7	16.5	14.8	17.2
STD (mm)	7	4.3	10.8	6.6	10.8	6.6
t_s (s)	2.3	1.4	3.6	2.2	3.6	2.2

d: vein diameter; VD: vein depth; IL: insertion length; RLC: remaining length of cannula; STD: safe travel distance; t_s: safe travel time.

place it touches the distal vein wall:

$$STD = \frac{d}{\sin(\alpha)}. \tag{4.3}$$

In addition, according to Brewer's study [5], the maximum insertion speed recorded in a manual PIVC operation was found to be about 3 mm/s (Page 150, 3.029 $\pm$ 1.099 mm/s when the cannula penetrates the vein). Here, we use the maximum insertion speed (3 mm/s) for estimating the safe travel time (t_s), which represents the time after the tip of the needle enters the vein until it touches the distal vein wall. Therefore, we can calculate the minimum of t_s, and use it for guiding the robot design in order to avoid piecing the vein. In this case, t_s can be calculated as:

$$t_s = \frac{STD}{3}. \tag{4.4}$$

4.3 Three phantoms used for this study

During this study, in total 3 realistic phantoms were used for simulating the PIVC environment. These 3 phantoms can simulate different perspectives of the PIVC environment and be used to evaluate different aspects of the developed robotic devices. The first two phantoms were designed and made based on the anatomic analysis above as part of this research work. They were made with fresh porcine tissue which

can simulate essential biological features, such as bio-impedance, of the real PIVC environment for this study. The third phantom is a commercial product that is widely used for pediatric PIVC training. This phantom possesses realistic appearance, anatomy and haptic property, which are suitable for the final robotic system evaluation utilising Bio-impedance, with human practitioners involved. More details about these three phantoms are provided below.

4.3.1 The first phantom

The first phantom was designed at the early stage of this research for validating the concept of using electrical impedance sensing for venipuncture detection. Therefore, this phantom was produced using fresh animal tissue to simulate the PIVC environment with a structure similar to that of a human being, both in terms of anatomy and bio-impedance properties. Specifically, slabs of pig belly tissue containing the epidermis, dermis and fat tissue layers were used given that their electrical impedance properties are similar to those of human's [46]. In each slab a tubular rubber balloon filled with saline solution was embedded to simulate the vein and blood.

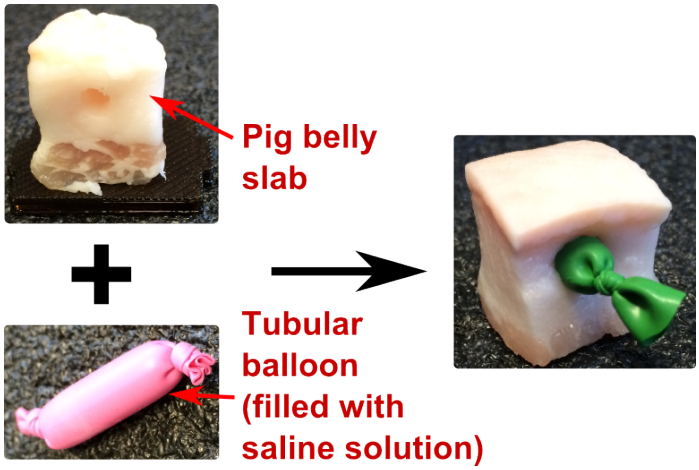

Figure 4-4: The first phantom is made by inserting a balloon (filled with saline solution) inside a pig belly slab.

The construction of the PIVC phantoms is illustrated in Figure 4-4. The pig belly slab is cut into a 15×15×20 mm rectangular block. A small ϕ 6 mm hole is drilled in the fat layer approximately 1 mm beneath the dermis layer. The tubular balloon (ϕ =

6 mm, thickness < 0.2 mm) is filled with 0.5% saline solution (which presents similar electric impedance modulus to that of real blood under 100 kHz excitation frequency) and subsequently inserted into the hole.

A limitation of such phantom design is related to the fact that the mechanical properties of the balloon may not correspond to those of a real vessel. The rubber balloons were used for convenience, both for assembling the phantom and for testing in the system evaluation experiments as described in Chapter 5. Furthermore, it is obvious that the electric impedance of rubber is different from that of a real vessel, but also this has negligible impact on the experiments since the rubber layer is very thin. When the needle tip passes through the balloon wall, the rubber material generates just a very quick electric disturbance which may not even be detected by the detection system. Another limitation of the designed phantom relates to the diameter of the balloon, which is obviously too big and not realistic. This is again for the convenience of using available material that was easy to fill with saline solution, easy to manipulate, and robust enough to be inserted into the pig belly slab.

4.3.2 The second phantom

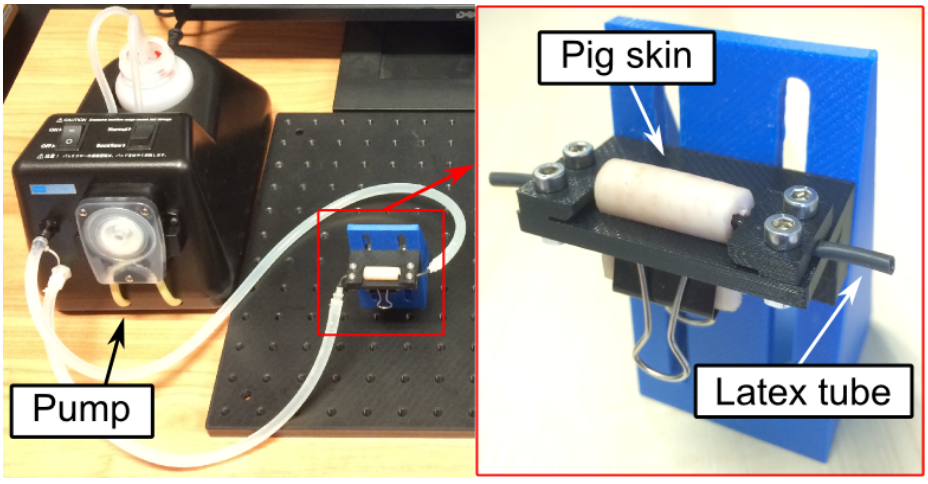

Figure 4-5: Phantom designed to simulate the PIVC environment.

Compared to the first phantom, the second phantom has a closer anatomy to simulate a typical peripheral vein environment on very young patients. As Figure 4-5

shows, the phantom was made by a small latex tube (outer diameter 2.5 mm and inner diameter 1.5 mm) which was wrapped by a layer of pig tissue including epidermis, dermis and fat layers. A circulation pump (Kyoto Kagaku Co., LTD, Japan) was connected to the tube for circulating a 0.5% saline solution through it. The size of the embedded tube is similar to the vein diameters on pediatric patients. Also, the use of latex tubes to simulate veins was investigated by Brewer [5], and it was found to produce similar haptic feedback as real veins.

One significant limitation of this phantom is due to the fact that the inner diameter of the latex tube (1.5 mm) is slightly smaller than that of a real peripheral vein ($\geq$ 1.8 mm), and its wall thickness (0.5 mm) is slightly thicker than a human's peripheral vein ($\approx$ 0.3 mm) according to [34, 38]. This may impact the realism of the second phantom. In addition, the impedance property of the tube material is different from that of a real vessel. However, this does not have a significant impact on the realism of the phantom. When probing the impedance during injection, the tube wall only causes a transient disturbance in the signal because it is very thin. Another limitation of this phantom is due to the fact that the tube can have small lateral motions during the insertion, although it was clamped within the tissue. In addition, due to the structure of the phantom, trans-illumination devices had difficulty in enhancing the vein visibility during the subsequent experiments. These limitations can potentially impact the results of catheterization based on the second phantom.

4.3.3 The third phantom

The third phantom used in this study is a commercial experimental platform from Kyoto Kagaku Co., Ltd., Japan. It includes a baby arm phantom and a circulation pump which connects to the baby arm phantom for reproducing blood circulation and blood pressure. Again, a 0.5% saline solution, whose electrical impedance property is similar to that of real blood, was colored red and used as blood substitute.

This product is a simulator specifically developed for pediatric PIVC training which can provide similar haptic feedback during the catheter insertion and flashback when the catheter is properly inserted. Nevertheless, the baby arm phantom is made

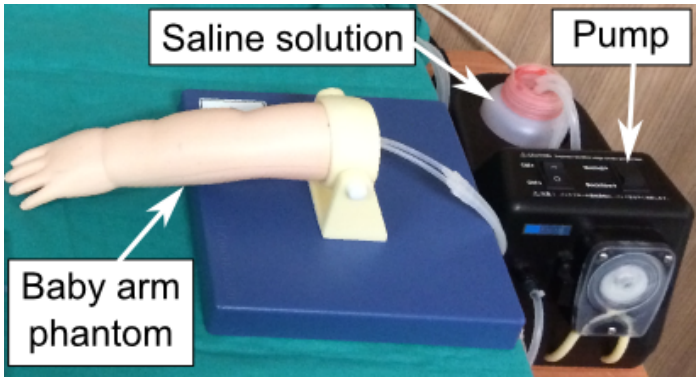

Figure 4-6: A realistic baby arm phantom that is widely used for nurse training.

of rubber which does not have similar electrical impedance properties to bio-tissues. Therefore, the third phantom is very helpful to simulate a pediatric PIVC scenario for the robots evaluation but it cannot be used for the sensing system verification.

4.4 Conclusion

In this chapter, a regular PIVC procedure is discussed and a PIVC model is provided for illustrating the PIVC environmental parameters that are used for generating the design specification later. In addition, three phantoms that are used for simulating the PIVC environment in this study are also introduced. The first two phantoms are made in the lab with fresh porcine tissue and the third phantom is a pediatric PIVC simulator purchased from the market. In the subsequent chapters, the first two phantoms are mainly used for verifying the electrical impedance based venipuncture detection system since they can simulate similar bio-impedance to that of the real PIVC environment. Because the third phantom has more realistic haptic feedback and anatomical features, it is used for the final robotic system assessment and a user-trial for comparing the robot-assisted PIVC with the unassisted PIVC.

Based on the described PIVC environment here, the following chapter, Chapter 5, discusses the development of the sensing technology for detecting venous entry and guiding the catheter insertion.

Chapter 5

Venous entry detection system for robot-assisted PIVC

As mentioned in the previous chapters, the robot must be designed to allow safe catheter insertion into a vein without puncturing through it. To achieve this goal, a sensing system that can provide fast and robust venous access detection is crucial.

In this chapter, potential sensing technologies are explored and justified to see if they can be applied to detect venous entry and guide the catheter insertion effectively. We judge a sensing system to be suitable based on the following 2 criteria:

1. The sensing system should be compatible with a 'hand-held' approach. This requires the sensing system to be compact and not influenced by small relative motion between the patient and the hand-held robot;

2. The sensing accuracy should be sufficient to allow reliable detection in difficult patients with small veins and hypotension.

5.1 Venous entry detection methods inspired by conventional PIVC

During a conventional unassisted PIVC, successful detection of venous entry relies on the clinician's capability to observe blood flashback into the needle chamber and to

sense a small change in resistance force at the moment of venipuncture. However, these two methods are found not appropriate to be used for the robot design as the reasons explained below:

5.1.1 Flashback

In addition to the survey of Chapter 3, some medical instructions [11, 49] also recommend judging venous access by visually observing blood flow at the back of the needle. However, this method cannot indicate venipuncture instantaneously. To confirm venous entry, practitioners normally need to pause the insertion and wait to see blood flashback. Especially for a small 26G pediatric catheter, this period may take about 0.38 s given the small needle hole ($\phi = 0.26\,mm$) and blood viscosity ($\eta = 2.78\,mPa.s$), according to the theoretical calculation of the time for flashback in Appendix E. Also, it may take longer until blood flashback is perceived by the practitioner. Moreover, as for premature babies, hypotension is a frequent occurrence [3]. In this case, observation of blood flashback could be even slower, and the catheter may already be inserted right through the vein before flashback can be observed.

5.1.2 Change of insertion force

Previous studies indicate that the needle insertion force can show an obvious drop at the moment it punctures through the vein wall, which is an useful information for insertion control [73]. However, most studies were based on static phantoms. In real situations, young babies undergoing operation could be waving their limbs intensely, which can introduce significant disturbance levels to the measurements leading to a detection failure. In addition, other studies were conducted to understand and model the needle insertion force. These studies found that this force could be very noisy (Page 36 of [5]) and dependent upon several factors such as insertion angle [35] and insertion speed (Appendix F). Especially for a hand-held device, the catheter insertion speed and angle can be changing during the insertion procedure, and these factors were found to be highly related to the insertion force. Also, it could be hard

and complicated to form a closed feedback loop to the hand-held device for correcting the force detection. All these factors indicate that this method is not applicable to be integrated into a hand-held device for detecting venipuncture.

5.2 Alternative sensing technologies for venous entry detection

5.2.1 Ultrasonography

As mentioned in Chapter 2, some surgical robots were developed with an on-board ultrasound probe for guiding the PIVC insertion. However, utilizing an ultrasound device can significantly increase the size and weight of the robotic setup, making it hard to adapt to the 'hand-held' approach. In addition, using ultrasound imaging to guide robotic catheterization involves a series of very computationally expensive steps such as de-blurring the image, segmenting the target vessel, and tracking the needle as it advances through the tissue. All these techniques would result in an expensive hardware setup and software development, and likely will lead to a delayed response time.

5.2.2 Blood pressure

Additional to the above technologies, another venous entry detection technology was proposed through sensing the blood pressure. This is exploited, for example, in the system called Vein Entry Indicator Device (VEID, Vascular Technologies, Israel). This device is able to detect the pressure change via the needle hole when the needle enters the vein. The effectiveness of this device and this detection method were described in Chapter 2. However, the revealed evaluation document of VEID can only prove its performance with a relatively big 22G needle [60, 63]. Whether this sensing technology can also provide accurate venipuncture detection with a small 26G needle/catheter and on hypotension children still needs to be established.

5.3 Electrical impedance sensing for venous entry detection

An alternative approach investigated in this research consists in exploiting the electrical impedance of tissues to detect venous access, since different types of tissues present different electrical impedances. This concept has been demonstrated by Kalvoy *et al.* [31]. In that study the electric impedance of different bio-materials was measured with different excitation frequencies, and with some ranges of frequencies the different bio-materials could be discriminated based on a difference in electrical bio-impedance. This has also been demonstrated by Saito's study [61], in which a closed loop circuit for the measurement of electrical impedance was formed between the needle and an electrode attached to the skin close to the insertion location. During insertion of a needle into rabbits' ear veins, both the electrical conductivity and insertion force were recorded and compared. The study found that the peak of puncture force caused by piercing the vessel wall and the electric conduction by the blood, could be simultaneously observed in some successful cases.

5.3.1 Detection system design

Although Saito's study [61] showed great potential to use electrical conductivity for venipuncture detection, their signals of electrical impedance were found unreliable as the electrical impedance was measured between the needle and the electrode attached on the skin.

Inspired by that study, we have improved the detection method and propose the use of a local electrical bio-impedance sensing system to detect venous entry. In order to do so, a standard IV needle is modified into a probe that is able to measure impedance at its tip. A 25G hypodermic medical needle ($\phi = 0.5\,\text{mm}$, MicrolanceTM 3, BD, Ireland) is used and a polyurethane-coated copper wire ($\phi = 0.2\,\text{mm}$) is placed inside the needle. This needle probe design, shown in Figure 5-1, was inspired by previous researches [4, 26] and allows the measurement of electric impedance between

the wire's exposed end and the needle tube.

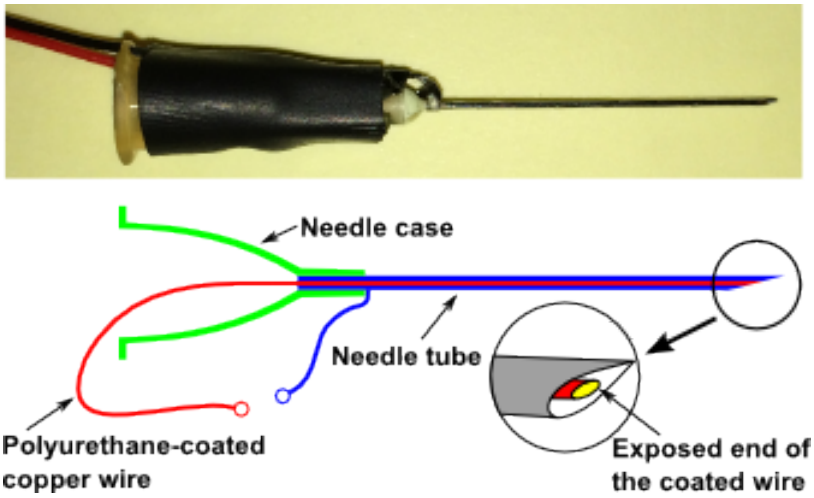

Figure 5-1: The needle probe is created from a standard hypodermic needle. The addition of an enameled copper wire to the needle tube allows the measurement of electric impedance at its tip.

During the insertion, a sinusoidal voltage is excited within the bio-material through the tip of the needle probe. Then, by measuring the current, the electrical impedance is obtained. In this study, AD5933 (Analog Devices Inc., MA, USA) is selected as the impedance converter because it can provide suitable electrical impedance measurement within the expected range for the PIVC application. Also, this chip is recommended for bioelectrical impedance analysis according to its datasheet [15]. The amplitude of the excitation voltage is set as 1 V. In the following study, the maximum current at this voltage is found not more than 1 mA which does not cause any tissue damage according to international standards IEC60601. In addition, the sampling rate of the electrical impedance measurement is optimized to 288.9 Hz (Table 5.1) to ensure fast venipuncture detection by setting the I2C communication rate to maximum, using single excitation frequency sweeping and simplifying the impedance measurement loop.

Before using this detection system in real applications, the precision of its measurements was tested. A total of 8 resistors ranging from 0.68 kΩ to 100 kΩ were used for the test. These resistance values cover the range of resistance encountered in the PIVC application. Each resistor was measured 10 times by the detection system and

Table 5.1: The sampling rate of the detection system under different excitation frequency.

Excitation frequency (kHz)	1	5	10	50	100
Sampling rate (Hz)	12.6	60.7	114.5	200	288.9

compared with the known values. The error rates were found less than 0.5% from 0.68 kΩ to 50 kΩ and less than 6% from 50 kΩ to 100 kΩ. This demonstrated that the impedance detection measurement was precise and appropriate for the application.

5.3.2 Bio-impedance measurement model

Previous studies have developed several models [46] for simulating and analysing the electrical impedance measurement of bio-tissues using a similar needle probe. Here, we adopt the model presented in [66] for analysing the bio-impedance measurement system. As shown in Figure 5-2(A), Z_{e1} and Z_{e2} represent the impedance of the electrodes (the central electrode and the needle tube respectively), and Z_n denotes the electrical impedance due to the capacitance effect between the electrodes. In this study, we denote the electrical impedance of bio-tissue as a complex value Z_t. The equivalent electric circuit model is shown in Figure 5-2(B), and Z_m is the measured electrical impedance of this equivalent circuit.

$$Z_m = \frac{(Z_n \times Z_t)}{(Z_n + Z_t)} + Z_{e1} + Z_{e2} \tag{5.1}$$

5.3.3 Preliminary validation of the venous entry detection system

Subsequently, three experiments were designed for a comprehensive evaluation of the venipuncture detection system. The first experiment measures the electrical impedance of 4 tissue types related to PIVC, namely, blood, dermis, fat and muscle. This experiment also verifies the feasibility of distinguishing blood from the other 3 bio-materials. The second experiment is designed to evaluate the system's detection

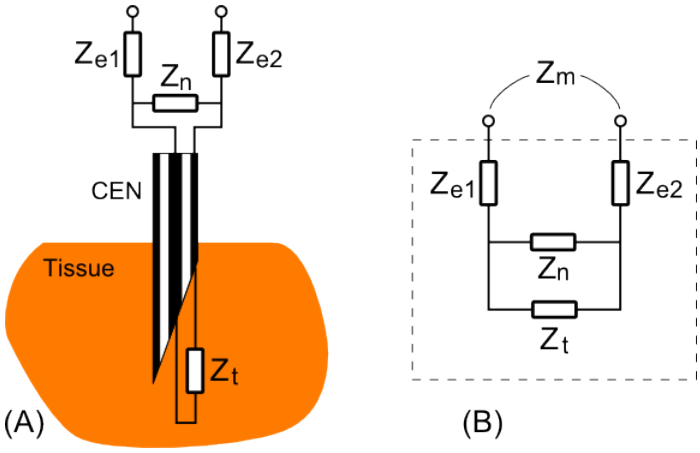

Figure 5-2: (A) Model of the bio-impedance measurement setup based on the needle probe; (B) equivalent electrical circuit.

time and distance based on real time impedance measurement. The third experiment assesses the effectiveness of the detection system to detect venous entry based on a realistic phantom.

In the second and third experiments, the detection system was integrated with a servo motion stage (MX7600R, Siskiyou Corp., USA) for controlling the needle insertion. The whole setup can be seen in Figure 5-3. During the insertion, the detection system continuously measures the electrical impedance of the reached tissue layer of the needle probe. The sensed impedance value is collected and transferred to the control computer for processing and display. The computer commands the stage motion through one serial port and receives the sensing impedance values from the DAQ through a different serial port. The computer continuously checks whether the impedance value is within the range of blood, and commands the motion stage to stop when it occurs. A block diagram illustrating this control loop is presented in Figure 5-3. In addition, the response time and response distance of the whole system was measured, which represent the time and distance from the moment when the system detects the corresponding impedance value to the moment when the motion stage is fully stopped. The mean system response time was found to be 21.6 ms and the mean response distance was 57.5 μm. These values are quite small, with the response distance being only a small fraction (1.3%) of the minimum STD value (see

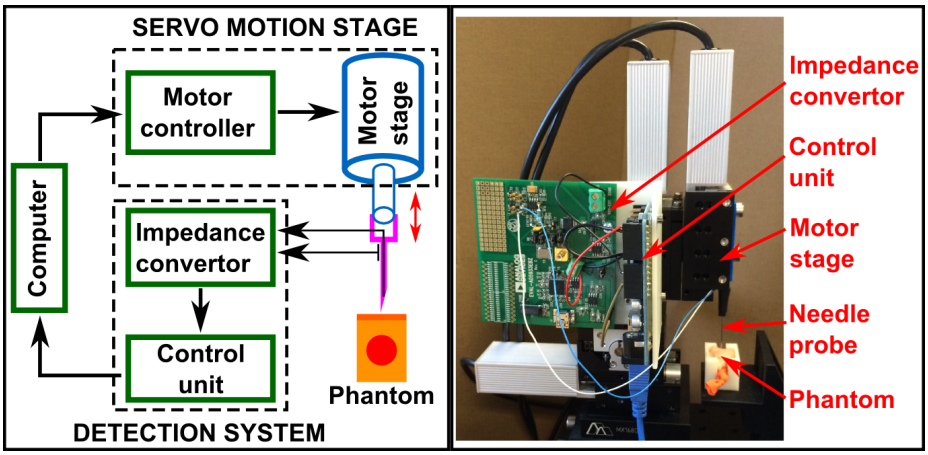

Figure 5-3: The configuration of the grounded robotic system setup used for the detection system validation.

Section 4.2).

Bio-impedance characterization of tissues

The first characterization concerned the determination of the typical electrical impedance values of different biological tissues (and blood) accessed by the needle probe during PIVC (Figure 5-4). Only the needle probe was used in this characterization. This was realized by cutting small cubes of each tissue type of interest (dermis, fat and muscle), and then inserting the needle probe into each of them with its tip totally immersed. For measuring the impedance of blood sample, fresh pig blood was collected in a small container, and then measured with the needle probe. For each tissue type, 10 samples were prepared and measured with 100 kHz excitation frequency. The excitation frequency is used because it can maximize the sampling rate [10].

The characterization results of the magnitude of the electrical impedance are shown in Figure 5-4. These results suggest that the impedance range of blood differs significantly from those of other relevant tissues, which offers an initial indication that the impedance detection system can perform robust venipuncture detection.

Characterization of the system's detection distance using a saline solution

The second characterization was realized using the experimental setup illustrated in Figure 5-5. The grounded setup is used to drive the needle probe perpendicularly

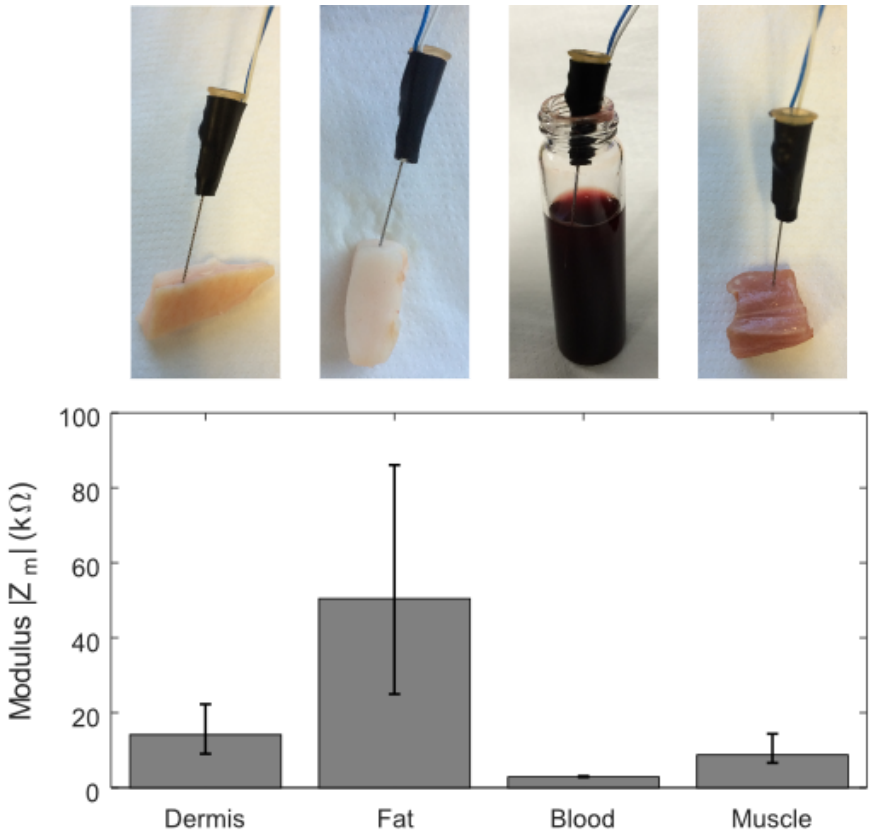

Figure 5-4: The magnitude of the electrical bio-impedance of 4 related types of tissues at 100 kHz excitation frequency: (A) Blood, (B) Dermis, (C) Fat, and (D) Muscle.

towards and into a saline solution container. A saline solution is considered to be a good substation of blood in this study as it is liquid and 0.5% saline solution is found to have similar impedance to blood [41, 1, 19]. Before the detection, the motion stage is precisely adjusted to make the needle probe just touch the liquid surface. This position is recorded as the ZERO position. Subsequently, the probe is raised up a small distance h ($h = 5\,\text{mm}$). This distance is used for the motion stage's acceleration and ensures a constant speed motion when the probe reaches the liquid surface. Then the system is commanded to run downwards in $1\,\text{mm/s}$ and it stops the motion immediately once the needle probe detects the saline solution. The final position of the needle tip, Δ, is obtained from the motion stage's built-in encoder and reflects the detection distance of the system.

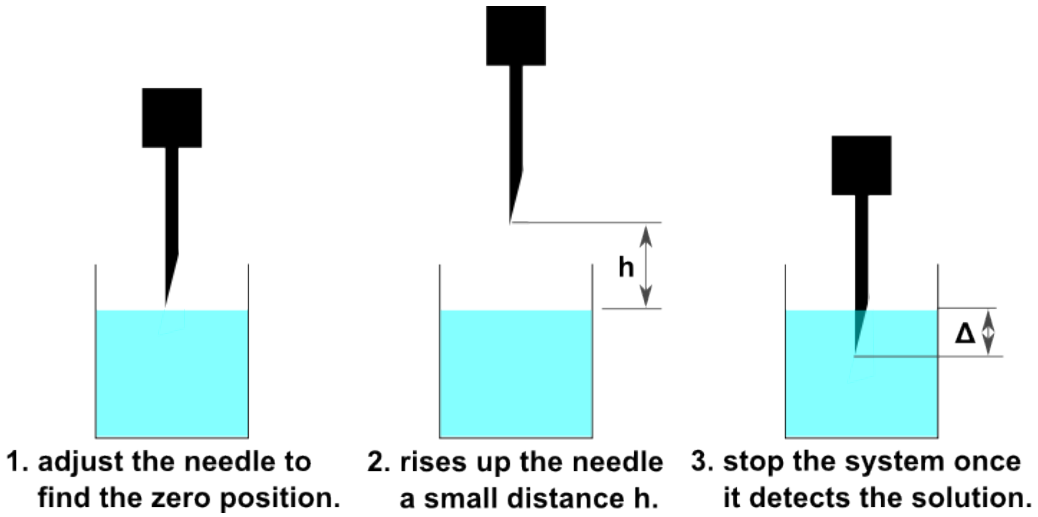

Figure 5-5: Illustration of the method used for measuring the detection distance of the detection system.

This characterization was repeated 20 times and the results revealed a mean detection distance of $817.6\,\mu\text{m}$. This fast detection is expected to be good enough for timely venipuncture detection and halting of the needle, since vessel size for catheterization is normally bigger than that.

Furthermore, a typical result of impedance magnitude $|Z_m|$ during this procedure is plotted in Figure 5-6. The result shows that after the tip of the needle probe starts entering the saline solution, the impedance value shows a gentle decrease. This can be

understood as the contacting area of the needle probe increases during this procedure. A related phenomenon was also observed in Kalvøy *et al.* study [31].

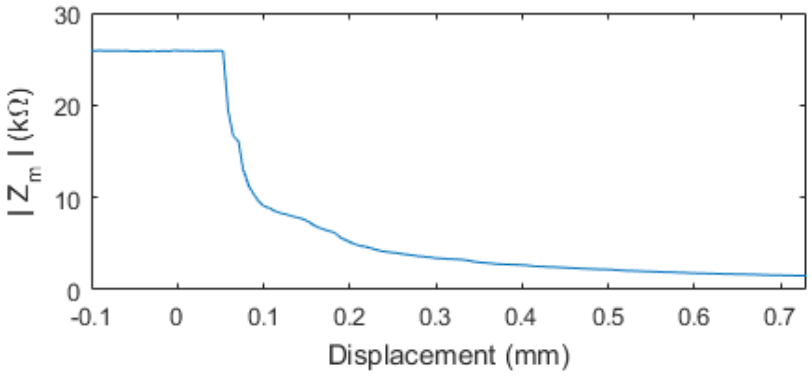

Figure 5-6: The impedance change during an insertion into saline solution.

Evaluation of the venipuncture detection system through phantom trials

A set of phantom experiments was performed to evaluate the effectiveness of the venipuncture detection system. The designed phantom (the first phantom presented in Section 4.3.1) is used for these experiments. The grounded setup is used and the motion stage is required to insert the needle probe starting from the epidermis layer. The insertion speed is set constant at 1 mm/s. The control method implemented for this application consists in continuously monitoring the electrical impedance at the needle probe tip. Once the impedance sensed ($|Z_m|$) is found to be within the range of the impedance of the saline solution ($|Z_{solution}|$), the needle insertion motion is stopped. After the insertion is finished, the balloon of the phantom is removed from the phantom for inspection. A visual check determines whether the venipuncture detection was successful.

The experiments demonstrated that the needle could successfully penetrate through the dermis and fat layer, and then stopped when the balloon wall was punctured. In this experiment, 10 phantom insertion tests were performed. Visual inspection of the balloons after each trial confirmed the presence of only one hole, demonstrating successful insertions for all 10 trials. These results indicate the feasibility and effectiveness of the venipuncture detection system proposed for robot-assisted intravenous catheterization.

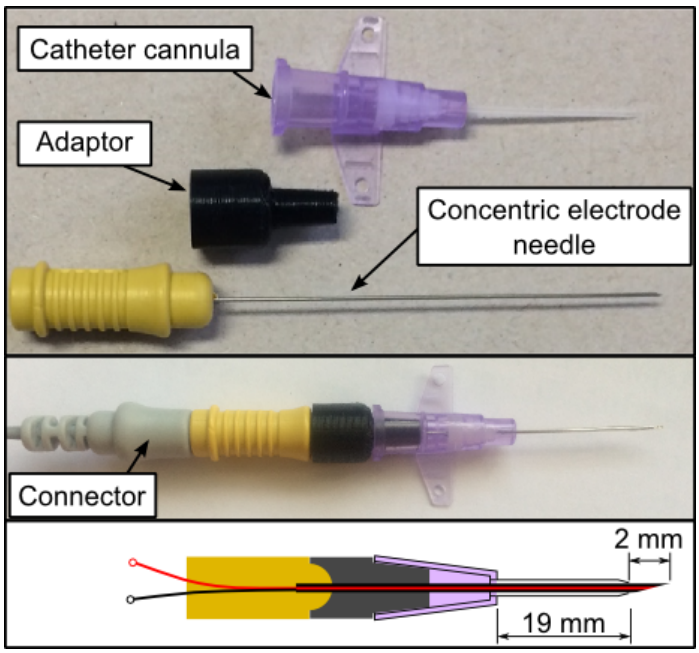

Figure 5-7: The designed CEC is made by integrating a concentric electrode needle, an adaptor and a 26G catheter cannula. The needle and the cannula of this CEC are sterile so it is safe for testing on humans and animals.

5.3.4 Design of a Concentric Electrode Catheter (CEC) for system pre-clinical evaluation

Since the needle probe presented above is difficult to sterilize before proceeding to the pre-clinical trials, we used an EMG concentric electrode needle (F8990/45, FIAB SpA, Italy) which has a similar structure to the 2 electrodes configuration for electrical impedance measurement at its tip. It is standardized and sterilized for use on human and animal. Based on that, a Concentric Electrode Catheter (CEC) was designed as shown in Figure 5-7. In order to make a IV catheter (see Figure 1-1(A)) functional for electrical impedance measurement, the needle of the catheter was replaced by a concentric electrode needle. Since the shape of the catheter cannula hub does not match the holding part of CEN, an adapter was made for connecting these two components. In this study, the adaptor was made in ABS and cleaned using medical alcohol before use. In the future, this adaptor will not be required. The shape of the holding part of the concentric needle will be redesigned so that the catheter cannula can be directly capped on it and used.

As mentioned in Section 5.3.2, the measured impedance is actually a combined value consisting of the CEC and the contacting tissue. Here, the effect of the CEC is removed in order to improve the measurement precision. According to the approach for measuring the impedance value of Z_{e1}, Z_{e2} and Z_n introduced in [66], we firstly short-circuited the CEN tip by pressing a piece of aluminium foil at the CEN tip. In this case, the measured impedance $Z_m|_{short} = Z_{e1} + Z_{e2}$. We randomly selected and measured 20 CENs, and the measured results showed that the value of $Z_{e1} + Z_{e2}$ of all the CENs are very small ($<8\,\Omega$) compared to Z_n and Z_t. Therefore, these components are removed for simplifying the model, and the resultant measured impedance Z_m equals Z_n and Z_t connected in parallel according to Equation 5.1.

$$Z_m = \frac{(Z_n \times Z_t)}{(Z_n + Z_t)} \tag{5.2}$$

With regards to the impedance value of Z_n, it can be measured with the tip of CEN 'open' (no load at the needle tip). In this case, the measured impedance $Z_m|_{open} = Z_n$.

5.3.5 *In vivo* electrical impedance measurement during PIVC on a human adult

To further validate the proposed venous entry detection method, an *in vivo* measurement of electrical impedance during PIVC was performed. This was done on an adult volunteer using a clinical concentric electrode needle (F8990/45, FIAB SpA, Italy), which is sterile and certified for human use. A medical doctor performed the needle insertion into the Basilic vein in the forearm of the volunteer using a standard manual procedure. Such a vein was chosen for having a typical diameter over 6 mm, which allows easy insertion and confirmation of venous entry by the doctor. In addition, the medical doctor who performed the insertion had more than 10 years of PIVC experience, so was very practical and confident with the operation.

A total of two vein insertions were performed and the obtained results were consistent. The magnitude of the measured bio-impedance $|Z_n|$ of both trials are plotted

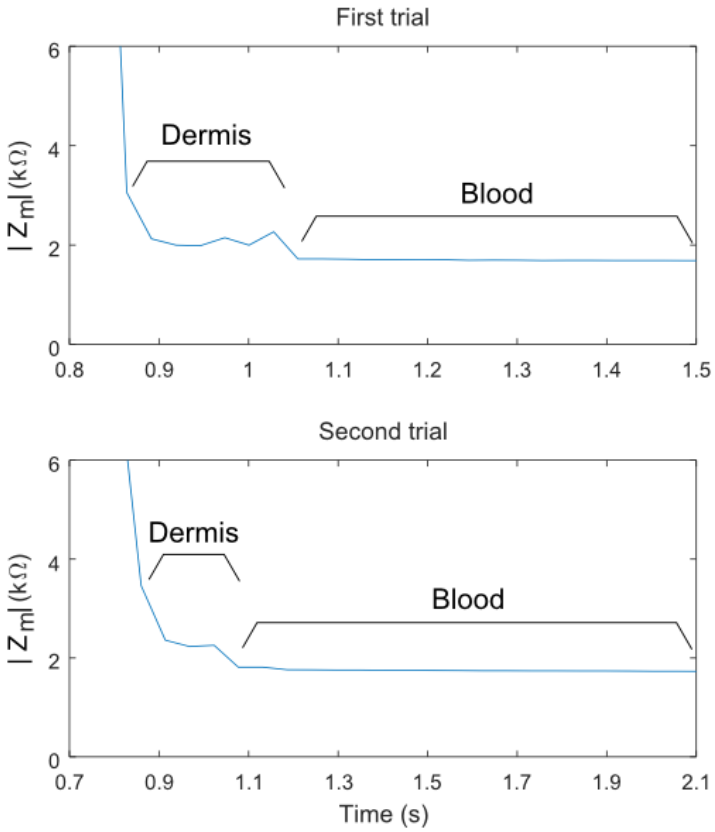

Figure 5-8: The electrical impedance measurements (magnitude) from 2 *in vivo* needle insertions into a Basilic vein of an adult volunteer.

in Figure 5-8. The plot shows that the impedance of dermis and blood can be easily identified. However, impedance values similar to those expected for fat were not found during these injections. This is possibly due to the fact that the Basilic vein was very superficial at the point of injection, where the fat layer was very thin. In any case, these results indicate that using electrical impedance to automatically detect the venipuncture is feasible.

5.3.6 Animal study for evaluation and optimization of the venipuncture detection system

Subsequently, an *in vivo* animal study was conducted to verify the venous entry detection method by checking whether the venous access can be identified from the

electrical impedance measurement during intravenous insertion to the lateral vein on a big rat's tail. The in vivo experiments have been done in accordance with animal ethical standards approved by the Ministero della Salute, Italy (authorization number: 263/2017-PR).

The experimental scenario is shown in Figure 5-9(A). We chose the lateral vein on a big rat's tail because this vein is peripheral, easily available and commonly used for blood collection. The CEC designed in Section 5.3.4 was used. During the PIVC insertion, the CEC needs to pass through a layer of skin and then the vessel is reached (Figure 5-9(B)). This anatomic structure is similar to a human's peripheral vein [69]. Different excitation frequencies (10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 kHz) were tested in this experiment. During each insertion, a fixed excitation frequency was applied. For each frequency, 4 successful catheterizations were recorded for subsequent data analysis. In total, 15 rats were used in this study and each rat was not punctured more than 3 times. In order to have randomized samples of data, each measurement was collected with a different CEC, rat and excitation frequency.

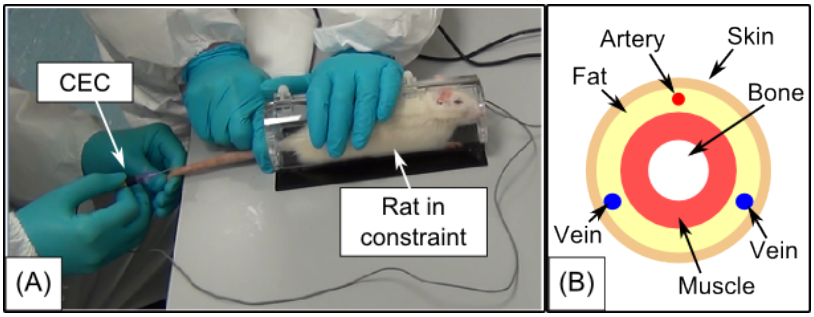

Figure 5-9: (A) Experimental setup to measure electrical impedance from *in vivo* CEC insertion into a rat's tail vein; (B) a sketch showing the cross section of a rat's tail.

At the beginning of each catheterization, the CEN intra-electrode impedance Z_n was measured and recorded by exposing the CEN tip to air. Then, an experienced technician from the animal facility of IIT (Istituto Italiano di Tecnologia, Genova, Italy) performed the insertion. The technician could approximately estimate the catheter entering the vein when she could 'slide the catheter smoothly'. Once inside the vein, the technician waited for about 2 second before taking out the CEN. This

facilitated the identification of venous entry time and provided a wealth of data related to intravenous blood impedance. Once the CEN was retracted, a small volume of blood was collected through the cannula. This confirmed the venous entry and also allowed further measurements of the electrical impedance of fresh blood.

In this study, the electrical impedance values in Equation 5.2 are interpreted in a format of a real part R (resistance) and an imaginery part X (reactance). Instead of using only the magnitude of the bio-impedance for blood identification, the new representation include 2 channels data, which may lead to a more reliable detection.

- The measured impedance: $Z_m = R_m + jX_m$;
- The CEN intra-electrode impedance: $Z_n = R_n + jX_n$;
- The tissue impedance: $Z_t = R_t + jX_t$.

Therefore, Z_t can be computed by deducing Z_n from the measured value Z_m:

$$\begin{cases} R_t = \frac{R_m(R_n^2+X_n^2)-R_n(R_m^2+X_m^2)}{(R_n-R_m)^2+(X_n-X_m)^2} \\ X_t = \frac{X_m(R_n^2+X_n^2)-X_n(R_m^2+X_m^2)}{(R_n-R_m)^2+(X_n-X_m)^2} \end{cases} \tag{5.3}$$

Figure 5-10 shows a typical bio-impedance measurement ($R_t + X_t$) during a PIVC insertion into a rat's tail vein. According to the reference value measured from the blood samples, the period when the CEN enters the vein and contacts blood can be easily identified. The bio-impedance measurement during the period of venous entry is consistent, and a step change of value can be observed just before the venous entry. This step change is estimated to happen at the moment of venipuncture when the contacting tissue type changes from skin to blood. Thus, the data before the step change are also collected and considered as the bio-impedance of skin.

For each excitation frequency (f = 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 kHz), the collected bio-impedance values of skin and blood were collected respectively and plotted as shown in Figure A-1 (Appendix A). The bio-impedance values of blood are plotted in red stars and the skin values are plotted as blue dots.

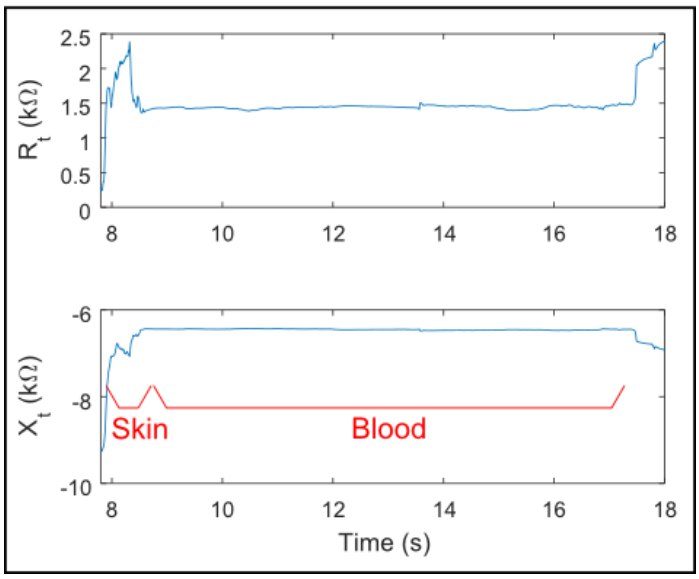

Figure 5-10: A typical results of bio-impedance R_t and X_t during insertion of CEN into a rat's tail vein.

Subsequently, the Matlab Classification Learner app (MathWorks, Inc., Massachusetts, US) was used for classifying the bio-impedance values of blood and skin. Three Classification methods including simple decision tree, linear discriminant, and SVM with Coarse Gaussian Kernel, were tested on the data. These three classifiers were chosen because: 1) they can effectively prevent data over-fitting; 2) they can be implemented on small embedded system; 3) they have fast prediction speed and use small amounts of memory.

The cross-validation accuracy provided by the Matlab Classification Learner app with different excitation frequencies from 10 kHz to 100 kHz are listed in Table 5.2. The experimental results of all three classifiers indicate that 100 kHz is the best excitation frequency for blood identification based on the rat's tail PIVC model. With this excitation frequency, the error rate of misclassifying the bio-impedance between blood and skin are nearly 0 in all three classification methods. We selected the decision tree classifier for implementation in the detection system because of its simplicity. Based on the experimental data, the threshold for blood identification was set to R_t<1.507 kΩ and X_t>-1.497 kΩ.

Table 5.2: The cross-validation accuracies to classify the bio-impedance values of blood and skin in different classification methods and with different excitation frequencies.

f (kHz)	10	20	30	40	50	60	70	80	90	100
DT	87.5%	98.3%	92.8%	95.1%	95.1%	100%	89.4%	97.7%	99.4%	100%
LD	74.5%	88.3%	83.8%	88.7%	88.5%	95.9%	78.7%	84.9%	98.2%	99.3%
SVM	74.7%	95.5%	88.2%	89.3%	89.6%	98.2%	82.8%	92.1%	98.6%	100%

DT: Decision tree; LD: Linear discriminant; SVM: Support Vector Machine.

5.4 Discussion and conclusion

In this chapter, a novel detection system for robot-assisted PIVC was presented. The system is able to discriminate vascular entry during the needle insertion process by measuring the electric impedance of tissues at the needle tip. This sensing method was found to be robust and highly promising given the fact that the impedance value of blood is significantly different from that of surrounding tissues, such as fat and dermis. Hence, this fact was used to determine when the needle tip penetrates the vein wall and contacts the blood.

Subsequently, several experiments were conducted for evaluation. The detection system was firstly integrated into the robotic system as part of the needle insertion control loop and tested with a realistic porcine phantom. The results revealed that the robotic system could effectively detect the impedance change and stop the needle insertion as soon as venipuncture occurred, guaranteeing successful insertions. Subsequently, a preliminary *in vivo* human experiment was conducted. The experimental results again demonstrated the concept of using electrical impedance sensing for venipuncture detection. During the needle insertion into a peripheral vein, the moment of venous entry can be clearly identified. Moreover, this detection system was optimized through a series of *in vivo* animal experiments. 100 kHz was found to be the best excitation frequency for classifying blood from the skin tissue.

All the results demonstrated that the electrical-impedance-sensing based venipuncture detection system is suitable for the design target. Apart from being compact, cheap, and accurate, the developed sensing system can achieve fast and robust venipuncture detection as deemed appropriate for PIVC on small veins. In addition,

as observed during the *in vivo* animal experiment, the bio-impedance measurement was not affected by the small changes in the insertion speed and angle, indicating that the proposed detection system can well satisfy the hand-held application. In addition, after the *in vivo* animal experiments were finished, all the rats were kept for 2 months, and none of them died during this period. This also indicates that the proposed detection method based on bio-impedance is safe.

We acknowledge this study has some limitations. First of all, only a 26G CEN was investigated, while 24G and 22G IV catheters are also commonly used for operating PIVC on pediatric patients and for different treatment purposes. The electrical bio-impedance measured with a different gauge of CEN can be different, which may require more experiments for characterization in the future. Secondly, the maximum excitation frequency explored in this study is 100 kHz, which is the limit of the electrical impedance converter used. Although venous entry can be effectively detected by applying 100 kHz excitation frequency, future developments could also explore and evaluate the efficacy of blood identification in PIVC with a higher excitation frequency.

The next chapter, Chapter 6, introduces the concept of smart hand-held devices for catheter insertion control and over puncture prevention during pediatric PIVC.

Chapter 6

Development of smart hand-held robotic devices

6.1 The hand-held robotic devices development

In Chapter 5, a novel venipuncture detection system based on electrical impedance sensing at the needle tip is developed and evaluated. This venipuncture detection method offers a cheap, simple and reliable solution compared to the other existing methods including force sensing, computer vision techniques, pressure sensing and ultrasound. In this chapter, based on this detection system, different hand-held robotic systems are designed to control the catheter insertion and complete the catheterization.

Study [52] reviews the current development of medical robots and points out that 'the role of the current generation of surgical robots is to assist rather than replace the operating surgeon'. In this perspective, the preferable way for improving the medical treatment quality is through combining the respective advantages of the robot and its operator. Therefore, in this research we aim to develop hand-held collaborative robots which can enhance the skills of the existing staff, leading to increased success rates for the operations. Also, as mentioned in Section 3.4, hand-held robotic device can facilitate the design for flexible insertion sites. In addition, the characteristic of being hand-held could increase its acceptance by both medical staff and patients, as

they have a physically smaller footprint and can make use of much of the surgeon's existing dexterity, provide enhanced surgical precision and high usability [72].

In total, 4 hand-held robotic devices were developed as shown in Figure 6-1. In each device, different mechanism is integrated to offer a different level of task assistance during a PIVC.

- Device 1 is called the SVEI, short for 'Smart Venous Entry Indicator'. This is the simplest device without any actuation. The user performs the entire PIVC him/herself. The device simply informs the operator when the needle tip enters the vein by lighting up an LED that is integrated in the SVEI's casing.

- Device 2 is called the Smart hand-held Device for Over puncture Prevention (SDOP). This device integrates a latch-based disengage mechanism to prevent piercing the vein during PIVC. The user still needs to perform the PIVC insertion manually. At the moment of venipuncture, the device automatically activates the disengage mechanism to stop further advancement of the catheter, thus minimizing the possibility of penetration of the distal vein wall. The subsequent procedures (Step 6 - 9 described in Chapter 4) still need to be done by the operator.

- Device 3 is called the SAID ('Semi-Autonomous Intravenous access Device'). It integrates a motor to control the catheter insertion. The user is only required to target the device to a vein site, then hold the device still, and activate it. The device automatically inserts the catheter and stops the insertion when venipuncture is detected. After that, the user needs to advance the cannula and retract the needle manually.

- Device 4 is called the CathBot representing 'a hand-held roBot for peripheral intravenous Catheterization'. The device uses a crank-slider mechanism and a solenoid actuator to convert the complicated intravenous catheterization motion to a simple linear forward motion. The user just needs to push the device's handle forwards and the device would automatically complete the PIVC insertion procedures from Step 5 to Step 8 as interpreted in Section 4.1.

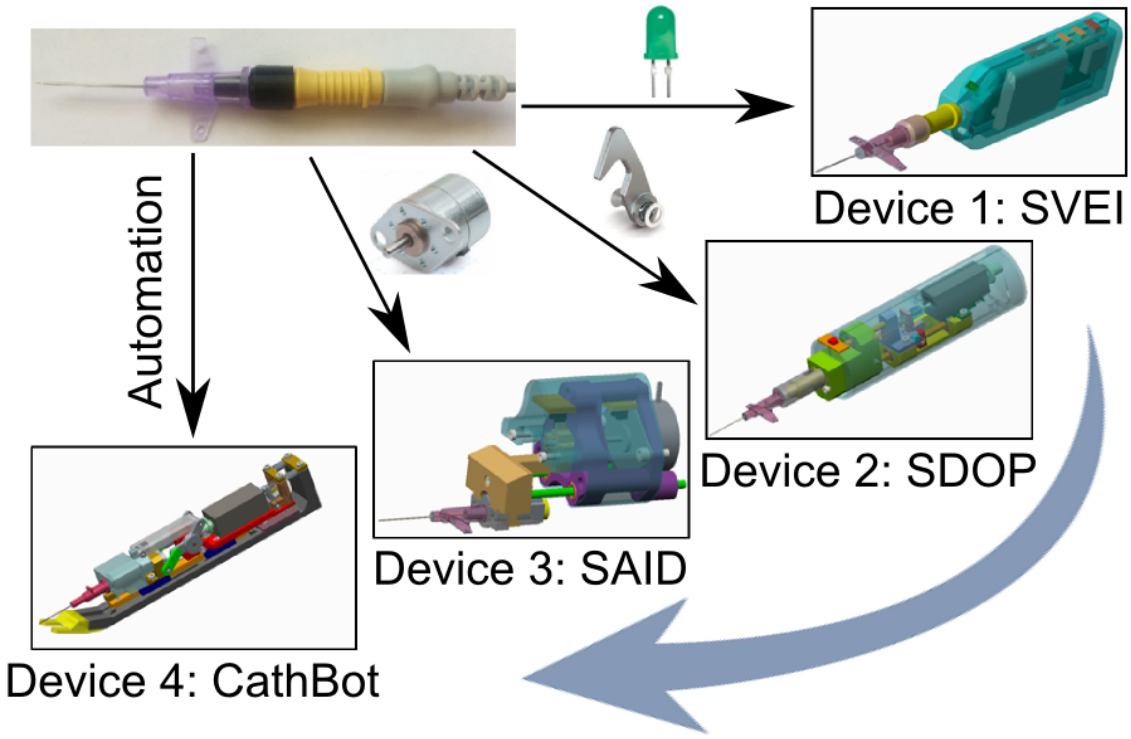

Figure 6-1: The development of 4 hand-held robotic devices.

The sections below present the design of the 4 devices respectively.

6.2 SVEI: Smart Venous Entry Indicator

6.2.1 Design Specifications

The design of SVEI is specified to only provide a notice to the operator at the moment of venous entry during a PIVC operation. Thus, the design requirements of such a device are simple. The most important requirement for SVEI is to provide fast and accurate venous entry detection. Also, as a hand-held device, it should be compact, lightweight and simple to use. A CEC (introduced in Section 5.3.3) can be directly plugged into it and used for PIVC operation.

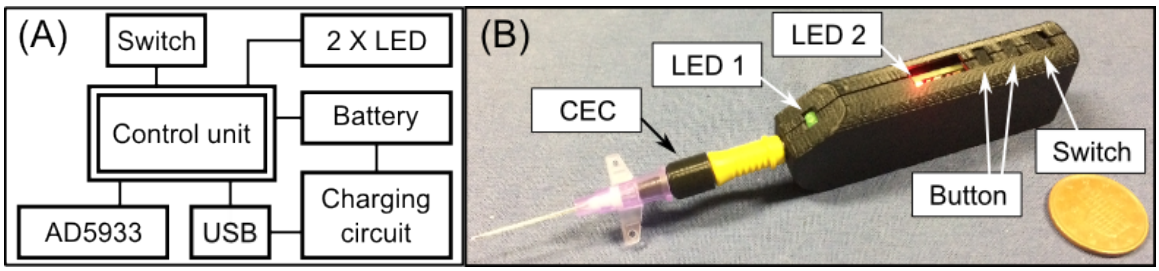

Figure 6-2: (A) The system configuration of SVEI; (B) a prototype of SVEI.

6.2.2 Device design

Figure 6-2(A) shows the configuration of SVEI. It includes a control unit (Atmega328P, Atmel Co., USA) which reads the electrical impedance measurements from the AD5933 through I2C. A switch controls the power of SVEI for the user to turn it on/off. Two LEDs connect to two digital pins of the control unit for output. When the device is on, LED 2 (red LED) is lit for indication. Meanwhile, the control unit starts reading data from AD5933 and processing the data continuously. When the measured value is found within the range of blood, LED 1 (green LED) is lit to indicate the venous entry. A battery is integrated into SVEI for power supply allowing the device to be cordless. The battery can be recharged through a charging circuit when SVEI is connected to a USB power source. Also, via the same USB port the control unit can connect to a PC for uploading the electrical impedance measurements in real time. In addition, the current version of SVEI has two push buttons, both of which are used for debugging purpose. They will be removed in a future design.

6.2.3 Device characterization

After a prototype was realized as shown in Figure 6-2(B), SVEI was characterized to ensure it can fulfil the design requirements. Firstly, the electrical impedance measurement capability of SVEI was tested using known resistors from 1 kΩ to 50 kΩ. Less than 2% error rate was found in that range. Also, the sampling rate of SVEI is found to be about 300 Hz which is fast enough to indicate venous entry given the minimal safe travel time of 1.4 s (see Section 4.2). In addition, the SVEI is only 18 g and its shape is based on the survey result described in Chapter 3 allowing user to

grip it comfortably. After a full charge, the SVEI can continue working for more than 6 hours, allowing it to work in some emergency situations where a power supply may not be available.

6.3 SDOP: Smart hand-held Device for Over puncture Prevention

The SDOP is developed to address not just the difficulty of venipuncture detection, but also the difficulty found in being able to stop pushing the catheter forwards right after the venipuncture. Due to physiological limitations and motion inertia, the second phase is actually hard to achieve for clinicians. Consequently, over-puncture is a common reason for failure in pediatric PIVC.

6.3.1 Design Specifications

Figure 6-3(A) shows a simplified model of the second device inserting an IV catheter into a peripheral vein. The configuration of the proposed robotic device consists of a venipuncture detection system and a latch-based disengage mechanism. If the venipuncture detection system finds that the measured value is within the range of blood, it immediately activates the disengage mechanism and lights up a LED to indicate blood detection. Once the disengage mechanism is activated, it prevents further insertion of the catheter by decoupling the device's casing motion from the catheter. Even though the operator continues pushing the device, the catheter would remain at the same insertion depth due to friction with the tissue.

After the tip of the needle enters the vein, the device should respond fast enough to stop the catheter advancement. This requires the device to detect the venipuncture and rapidly disengage the catheter from the casing advancing movement. According to the analysis of the PIVC environment described in Chapter 4, the response time for SDOP should be less than 1.4 s.

After the disengage mechanism is activated, there are 2 axial forces acting on

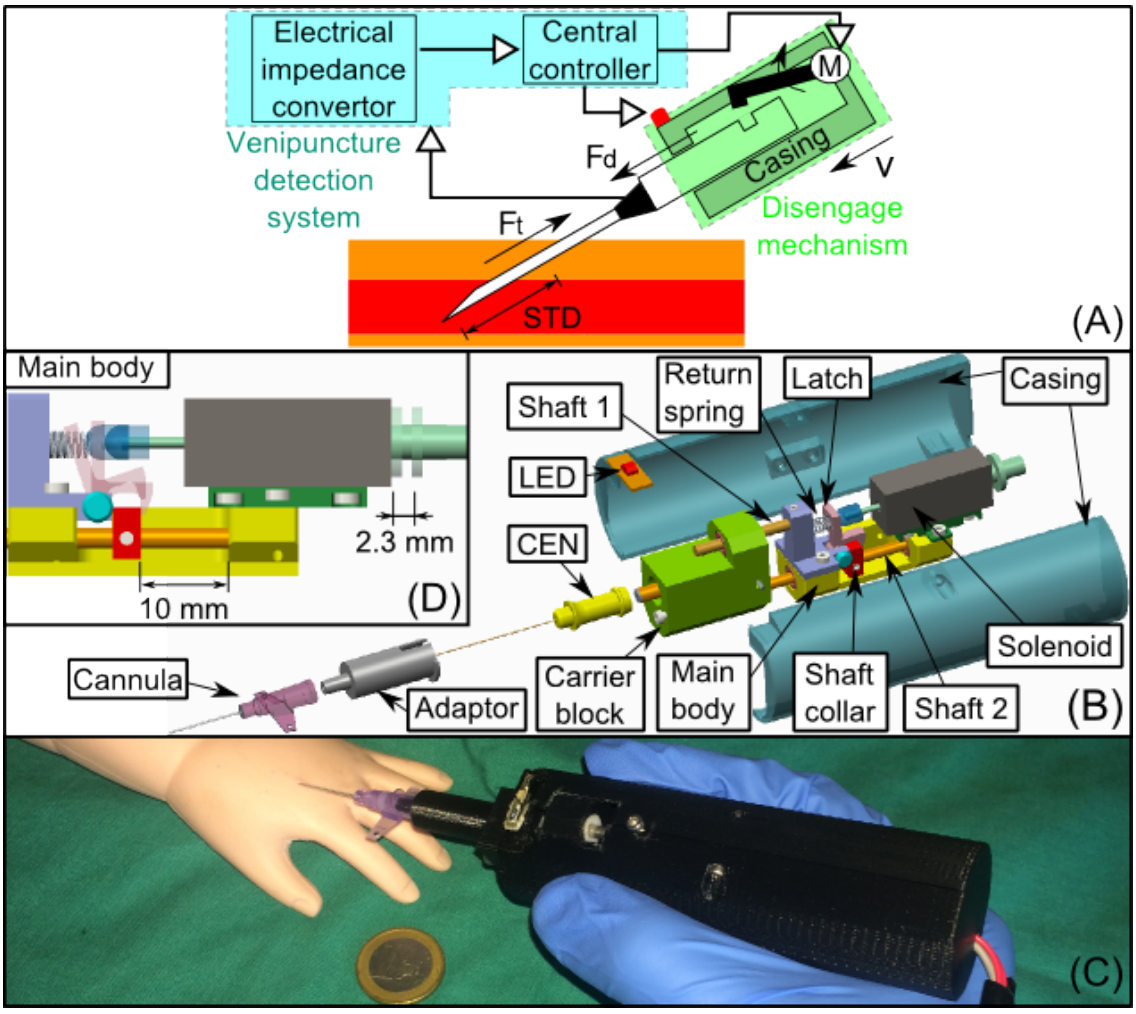

Figure 6-3: (A) system configuration of SDOP; (B) 3D modeling of SDOP; (C) a prototype of SDOP; and (D) a zoom view of the disengage mechanism.

Table 6.1: Summary of the system design specifications of SDOP.

Design specifications	Parameter
`Safe travel time`	<1.4 s
`Friction` (F_d)	<1 N
`Weight`	<0.4 kg
`Other requirements`	Ergonomic shape Easily cleanable

the shaft that carries the catheter if the casing is still moved forwards. One is the tissue-catheter friction F_t. The other is the friction between the casing and the shaft F_d. A study by Zivanovic and Davies [73] recorded the insertion force during a needle inserted into a phantom arm at a constant insertion speed, indicating the minimum of F_t is about 1 N. To ensure the catheter is not moved by the casing, the device should be designed with F_d smaller than F_t (1 N).

For a hand-held device, ergonomics is another importance issue which requires the design to be light-weight ($<$ 400 g) and easy to grasp [13]. TABLE 6.1 summarizes the technical requirements.

6.3.2 Device design

As shown in Figure 6-3(B), the device is comprised of a carrier block, a main body and a pair of casings. The casings are attached to the main body for easy grasping by a user. Two parallel shafts are used to connect the carrier block to the main body, and allow it to slide only along the insertion direction. When the latch is closed, it locks the shaft collar on Shaft 2 so that the carrier block is fixed to the main body (Figure 6-3(D)). The carrier block can slide backwards when the latch is open. After the disengage mechanism is activated, the user can still push the device forwards a small distance 10 mm with the catheter fixed in placed. In order to have fast actuation and simple control, a solenoid (8M100262, Mecalectro) is selected as the actuator which can satisfy the design requirement of the disengage mechanism to open the latch. Please refer to Appendix G for more details with regards to the disengage mechanical design.

In addition, a new adaptor is designed for connecting the cannula and the con-

centric electrode needle, and for locking them to the carrier block. The casings form a cylinder of 30 mm diameter with the LED placed on top. The casings are made in ABS. A prototype was made as shown in Figure 6-3(C). In addition, a sterile drape can be used to cover the device and the holding part of the CEC for clinical use. This drape can have rubber bands to seal its ends.

6.3.3 Device characterization

Response time: Activation of the disengage mechanism should be fast after the catheter enters the vein. Here, the response time of the mechanism was measured. The device was fixed on a platform and a laser range sensor was used to measure the displacement of the solenoid plunger. Then the solenoid was activated and the displacement of the plunger was recorded. The measurement was repeated 5 times and the time from the solenoid open status to the close status, representing the mechanical response time of the latch, was extracted. An average of 69.6 ms was found. Considering an extra 21.6 ms for the electrical impedance detection, the total response time for the whole system is 91.2 ms, which is comparatively small given the required response time 1.4 s.

Sliding friction: The friction F_d between the main body and the shaft within the reserved distance was measured. For this, an ATI Nano17 force sensor was connected between the device's casing and a linear motion stage. The device's latch was open and the carrier block was fixed to a stationary platform, allowing the casing to move axially when driven by the motion stage. Various tilt angles (15°, 30°, 45°, 60°, 75° and 90°) were tested to evaluate potential effects of gravity and lateral forces on the CEC. The motion stage drove the casing to move 10 mm along the axial direction in a constant speed of 1 mm/s. The friction F_d was found to be 0.19 N on average with SD=0.05 N among different insertion angles. This value is much smaller than F_t (1 N) and thus satisfies the design requirements.

6.4 SAID: Semi-Autonomous Intravenous access Device

SAID aims to constitute a collaborative robot-assisted surgery, one in which the clinician is responsible for establishing the position and orientation of the catheter for insertion, and the device takes care of the delicate forward insertion. Compared to SDOP, SAID also involves the insertion control in order to provide a constant insertion speed. During the insertion procedure, the user is required to adjust the insertion direction to target the vein, hold the device still and activate it. By measuring the electrical impedance at the needle tip, SAID identifies the type of tissue contacting the needle tip and stops the insertion when it enters the vein.

6.4.1 Design Specifications

Stringent specifications are listed in Table 6.2 to ensure SAID can provide effective assistance during such a delicate task of pediatric PIVC. The device is designed with only one DOF for the insertion depth control.

The design of SAID requires it to be able to insert the catheter into the vein but not puncture through it. Hence, the two most important design parameters are the safe travel distance (STD) and insertion length (IL). Here, the minimum value of STD and the maximum value of IL from Section 4.1 are used to define the design specifications of SAID, such as to guarantee that the device can be used in all the described conditions.

Apart from the above, the insertion speed is also an important design parameter. As presented in Brewer's study [5], the axial speed during manual PIVC operations is typically around $2 \pm 1\,\mathrm{mm/s}$. That same study also indicates that a robotic mechanism for needle insertion on humans should be able to generate more than $2.5\,\mathrm{N}$ for successful operation. However, after the design of SAID, the second phantom which is fabricated with a layer of *ex vivo* pig skin (see Section 4.3 'The second phantom') was used for the device evaluation. The insertion force on such phantoms was mea-

Table 6.2: Summary of the system design specifications of SAID.

Design specifications	parameter
Insertion force	>5 N
Safe Travel Distance (STD)	<4.3 mm
Insertion length (IL)	>7.3 mm
Insertion speed	1 - 3 mm/s
Weight	<0.4 kg
Other requirements	Ergonomic shape Easy sterilization

sured to reach a maximum of 5 N with a 26 G catheter. Therefore, 5 N was set as the minimum required injection force to be provided by the device.

Also, as a medical device, it should be easily sterilized to fulfil the safety concerns. Finally, the ergonomic perspective must also be addressed to make the device easy and comfortable to use. Therefore, the design requirements include aspects such as maximum weight, size and shape. Again as in Table 6.1, the maximum acceptable device weight was estimated as 0.4 kg considering it is a hand-held device used for precision tasks. Its size and shape, on the other hand, were loosely defined to be as small as possible, with the constraint of being comfortably grasped by an adult user.

6.4.2 Device design

The system configuration of SAID is shown in Figure 6-4(A). A central controller reads the electrical impedance measurement from an impedance converter and controls a stepper motor for inserting the catheter. The Nanotec LSP2575 stepper motor is selected because it can provide enough insertion force (10 N) and displacement (30 mm) for this application. The designed CEC (as presented in Section 5.3.3) can be easily mounted to the carrier of SAID for operation and removed after use. In addition, two IR position sensors are included as limit sensors to aid in device positioning. A footswitch is used for the insertion control. The motor inserts the catheter when the footswitch is activated, and stops the insertion when it is released. During the insertion, if the acquired impedance value corresponds to that of blood, the insertion is stopped immediately regardless of the footswitch status.

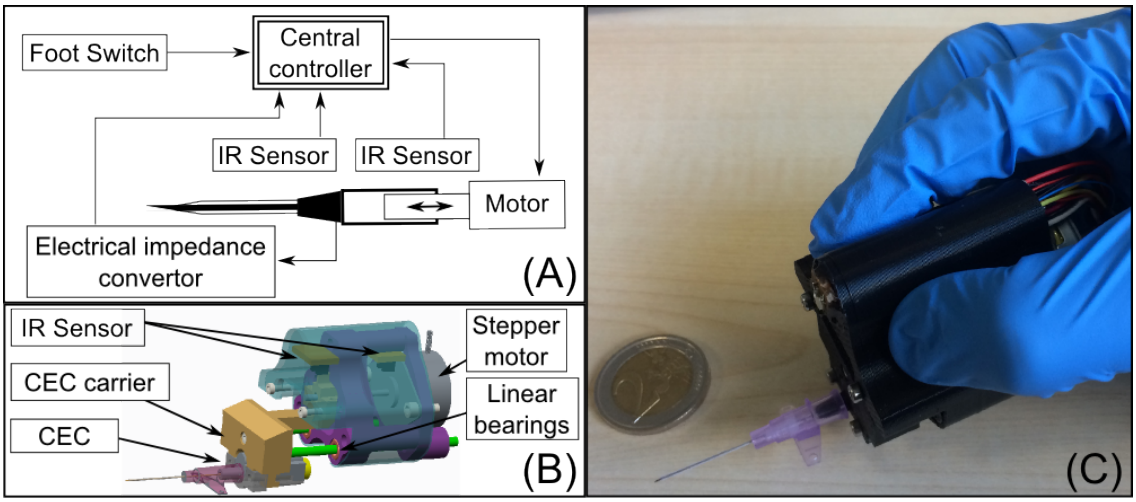

Figure 6-4: (A) The system configuration of SAID; (B) 3D modelling of SAID; (C) a prototype of SAID.

6.4.3 Device characterization

The robotic system's response

Firstly, SAID was evaluated to ensure it provides a fast response for venous entry detection by measuring the overshoot distance. As shown in Figure 6-5(A), SAID was firstly clamped to a 4-axes motion stage for characterization. The orientation of the position stage was adjusted to make SAID point downwards to the surface of a saline solution. The height of the catheter was finely monitored until its tip just touched the liquid surface. This position was set as the origin. Then SAID was retracted by 2 mm, and subsequently activated to insert the catheter downwards. It was automatically stopped when the saline solution was detected. The number of executed motor steps relative to the origin, corresponding to the overshoot distance, was collected. This test was repeated 5 times. The response time was found to be 21.6 ms and the average overshoot distance was found to be 0.67 mm, which is smaller than the safe travel distance for pediatric PIVC (see Section 4.2).

Evaluation of the actuation and sensing system on a grounded setup

Secondly, the effectiveness of venipuncture detection of SAID was validated. This test was performed with the second phantom (see Section 4.3). Again, SAID was clamped to a 4-axes motion stage as a grounded setup as shown in Figure 6-5(B).

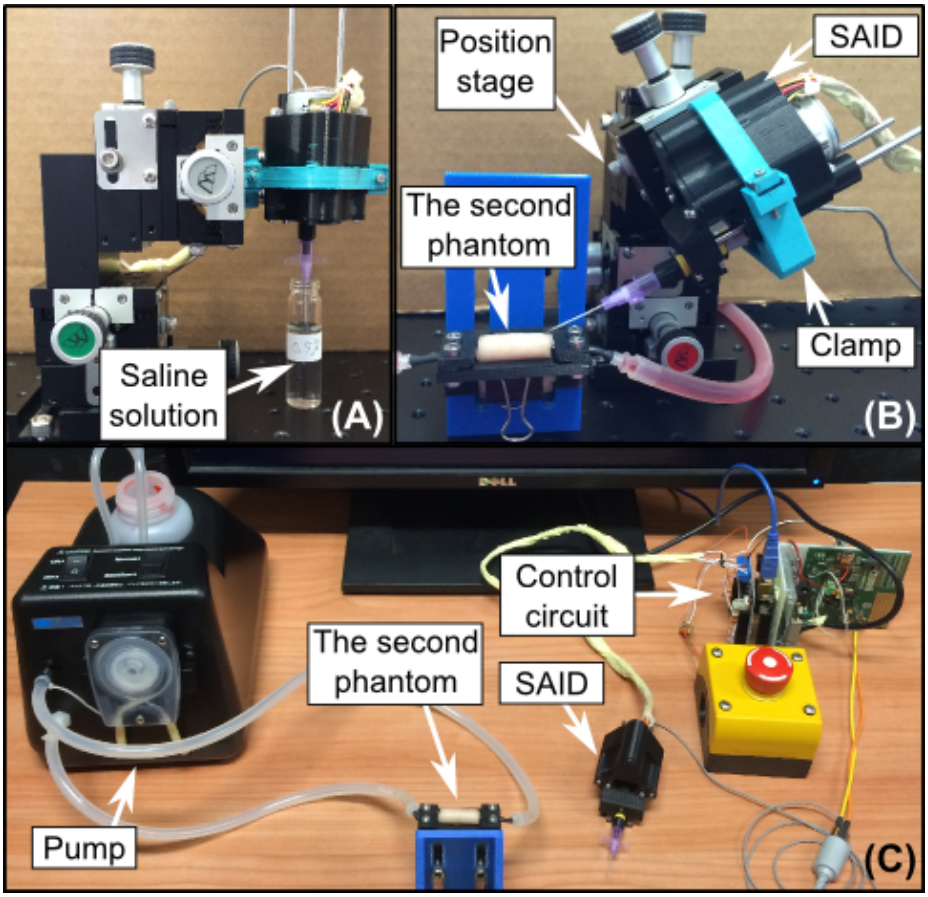

Figure 6-5: (A) The experimental setup to characterize the robotic system's response of SAID; (B) The experimental setup to evaluate SAID as a grounded setup with the second phantom; (C) The experimental setup with human subjects involved to evaluate SAID's performance.

Therefore, potential disturbances related to an user's performance could be removed. During the tests, SAID was carefully positioned to target the phantom vein, perform the insertion and stop automatically when blood was detected. The insertion tests were repeated 10 times and 5 trials failed. All the failed cases were found to be because the insertion completely missed the vein and passed alongside it.

PIVC performance assessment experiments

The third experiments were again conducted on the second PIVC phantom as in the previous experiment (Figure 6-5(C)). In these experiments, 10 naïve subjects (8 males and 2 females, average age 29 years old) were involved in the experiment. None of them had previous experience with PIVC. The subjects were divided in two groups:

5 in the Experimental group and 5 in the Control group. During the experiments, the subjects were required to select an insertion site on the second PIVC phantom, align the catheter along the latex tube of the phantom, and try their best to insert the catheter into it (the tube's location can be estimated by its extended ends clamped on the frame). For subjects in the Experimental group, the insertion was done by stepping on the foot switch after the catheter was targeted and aligned along the latex tube. They were instructed to hold the device steadily during the insertion and adjust the catheter orientation whilst targeting the tube. SAID detected the venous entry and stopped the insertion automatically. Subjects in the Control group were required to perform the catheterization by hand with an ordinary 26G IV catheter, and judge the venipuncture moment through perceiving a small change of the insertion force and stop the insertion at this point.

For each subject, the number of successful operations over all 5 experimental trials was counted. For those failed attempts, the possible reasons were noted down and categorized qualitatively in terms of: Miss-target (catheter passed by alongside the vein), Prior-to-puncture (catheter did not enter the vein) and Puncture-through (catheter punctured completely through the vein).

The experimental results demonstrate a significant difference ($p < 0.01$) in scores between the 2 groups. Subjects who used SAID had a much higher success rate (88%) than those who didn't (12%). In addition, the reasons for failure between the Experimental group and the Control group were compared. From the results of the Control group, the common reasons were: stopping the insertion either too early before reaching the tube (48%), or too late after puncturing the distal wall (18%). In addition, 1 'miss-target' failure (4%) was found in the Control group and 2 cases (8%) were found in the Experimental group. This may be due to the fact that trans-illumination devices were not provided to highlight the latex tube's location in this assessment so that it could be hard for the subjects to target the catheter to the latex tube precisely. In addition, one case of 'puncture-through' was noted in the Experimental group. The reason was found that the catheter penetrated a point very close to the vein edge, and caused the vein to be compressed during the insertion.

Vessel deformation during the insertion was considered in the study but found not to be significant in practice.

Comparing the results between the second experiment (50% success rates) and the third experiment (88% success rates), it demonstrates that online correction of the needle insertion direction was necessary and this reinforces the idea of human-robot cooperation and points to a clear benefit of the proposed hand-held robotic device configuration.

Furthermore, a questionnaire was submitted to the subjects for acquiring feedbacks on the usability of SAID. According to the results of the questionnaire, SAID was highly appreciated by the subjects on all points gauging the device's usability.

6.5 CathBot: a handheld robot for autonomous PIVC

Both SAID and SDOP are developed to address the difficult procedure of venipuncture detection and insertion control (Step 5 in Section 4.1). However, the subsequent steps (Step 6: advancing the catheter 1 mm further; Step 7: sliding the cannula into the vein; and Step 8: retracting the needle) were also found to be critical for the success of catheterization. Therefore, we proposed a new design called CathBot, which aims on the one hand to automate the PIVC insertion with improved precision in venous access control; and on the other hand, to allow intra-operative control to the operating clinician over the whole operation.

6.5.1 Design Specifications

The catheterization motion during the PIVC operation from Step 5 to Step 8 can be reconsidered as a combination motion that 1) the cannula is always pushed toward the vein and 2) the needle does a return motion: it is advanced towards the vein before Step 6, and retracted after that.

The CathBot is designed to achieve the above procedure, including both motions of cannula and needle. In order to successful complete the required motions, some technical requirements for CathBot are defined. Specifically, after venipuncture (Step

5), the needle is to advance a small displacement d_{n1} in Step 6, which is strictly controlled to be 1 mm in order not to exceed the STD. Afterwards, CathBot pushes the cannula forwards with a displacement d_c, ensuring the remaining length of cannula (RLC, see Section 4.2) can be inserted into the vein (Step 7). Meanwhile, the needle is retracted (Step 8). The retraction distance of needle d_{n2} is set to be more than the maximum IL provided in Section 4.2 so that the needle can be eventually retracted outside the skin. These design specifications are listed in Table 6.3.

In addition to the above technical requirements, the design of CathBot is also required to consider the ergonomic factor and sterilization, which are similar to those of the previous 3 devices.

6.5.2 Device design

CathBot uses a crank-slider mechanism to convert the complicated and dexterous catheterization procedure to a simple forward motion. The 3D modeling and a prototype of CathBot can be seen in Figure 6-6. With CathBot, the operator needs only to push its handle forwards along the insertion direction during the PIVC insertion, and the device can automatically complete the PIVC by inserting the cannula into the vein accurately and then retracting the cored needle. More details regarding of the device design will be provided below.

Figure 6-7 shows the 3D modeling and the exploded view of CathBot. The device is designed with a symmetric structure. A linear guide (3) is used and fixed on the base (2) for guiding the insertion direction. On this linear guide, the main body (1) and the connector (16) are fixed on 2 sliders respectively. Before every use, a new Concentric Electrode Needle, CEN (10) is plugged into the connecter (16). The original shape of the CEN (10) and the adaptor (11) (please refer to Section 5.3.3) are slightly modified, aiming to generate a sliding pair between them as required in Step 7. For this, a casing is made to cover the needle and to reshape it as a cylinder. Also, the adaptor is reshaped to make it into a handle (11) to aid in user grip and manipulation. On the handle (11), a small shaped recess is designed to allow the linkage (18) to be easily fastened and disconnected.

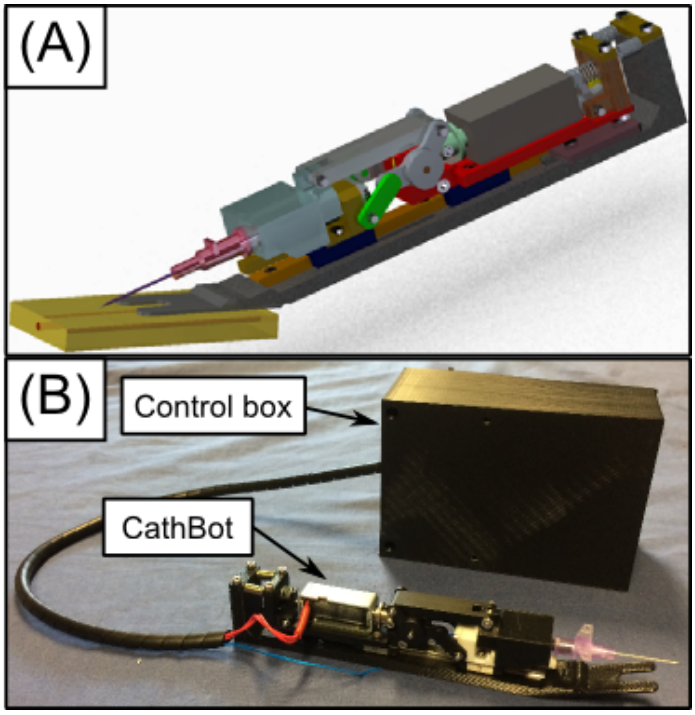

Figure 6-6: (A) The 3D modelling of CathBot and (B) A prototype of CathBot.

A solenoid actuator (8M100262, Mecalectro)(4) is fixed on the main body (1) to control both the ratchet (6) and the brake assembly (8). The ratchet (6) and two Cranks (5) are fixed on the same shaft (15) by set screws, which is assembled onto the main body (1) with a pair of bearings (7). The brake assembly (8) is fixed on the main body (1), and a pair of return springs (9) connects its top surface to the base (2) for initializing the position of the device. In addition, a shoe (13) is designed to buckle onto the base (2) to assist the operator to control the insertion angle to 20°.

The workflow of the proposed mechanism to simultaneously advance the cannula and realise a return motion of the needle is shown in Figure 6-8(c). Initially (see Step 4, Figure 6-8(c)), the solenoid (4) is deactivated and the spring of the brake assembly (8) pushes the solenoid plunger 2 mm away from the solenoid body. In this case, the brake (8) unlocks the main body (1) from the base (2) and allows the main body (1) to slide along the linear guide (3). Meanwhile, a small latch mounted onto the head of the solenoid plunger locks the ratchet (6). Since the crank (5) and the ratchet (6) are fixed on the same shaft (15), pushing of handle (11) does not rotate the

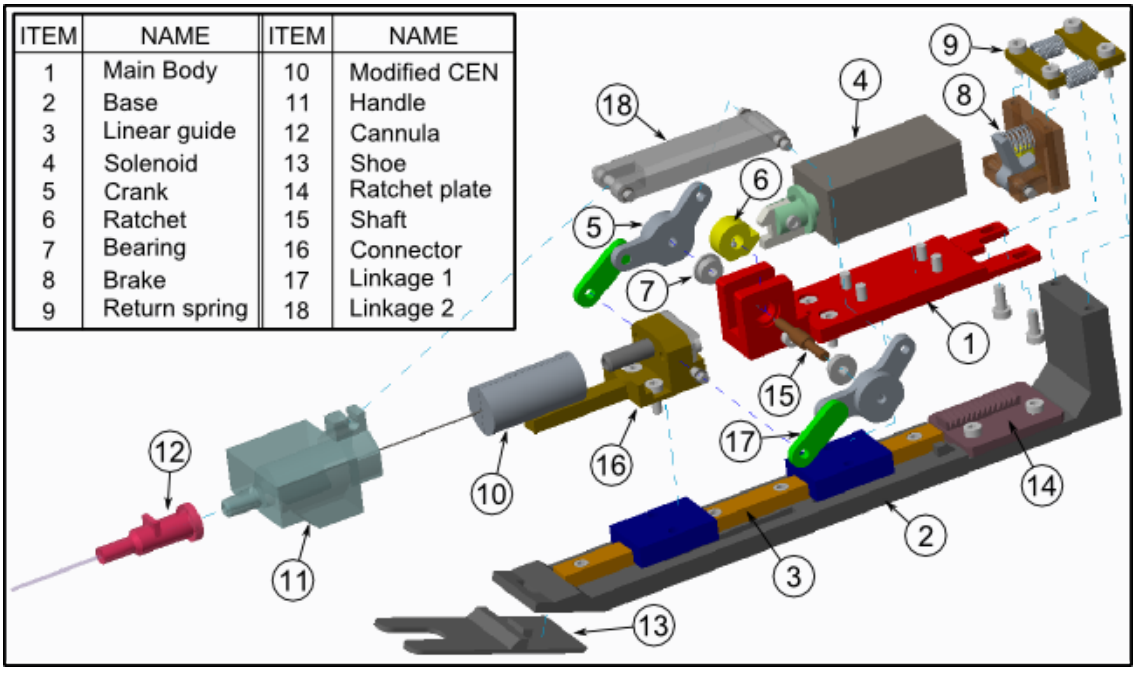

Figure 6-7: The exploded view of CathBot

shaft (15), but moves the cannula (12) and the needle (10) forwards together. During this procedure, the detection system continues sensing the electrical impedance at the CEN tip and checking the measurements. Once the measured value is found to be within the range of blood, it is considered as venipuncture (see Step 5, Figure 6-8(c)), and the solenoid (4) would immediately be activated to pull back the plunger. Therefore, the ratchet (6) is released, and the brake assembly (8) is activated to lock the main body (1) to the base (2). Afterwards, continuously pushing the handle (11) manually would start to rotate the crank (5). Through the crank-slider mechanism, the needle (10) would firstly advance 1 mm further (see Step 6, Figure 6-8(c)) and then be retracted out of the skin (see Step 8, Figure 6-8(c)), whilst the cannula (12) would always be advanced into the vein during these procedures.

Figure 6-8(a) shows a schematic diagram of the crank-slider mechanism. Point O, P, Q denote the rotation center of shaft (15), the slider connecting to CEN (10), and the pivot point connecting to linkage 2 (18) respectively. Figure 6-8(d) shows the schematic diagrams of the crank-slider mechanism in Step 4-5, the end of Step 6, and the end of Step 8 respectively. Here, we use P_i to represent Point P in different

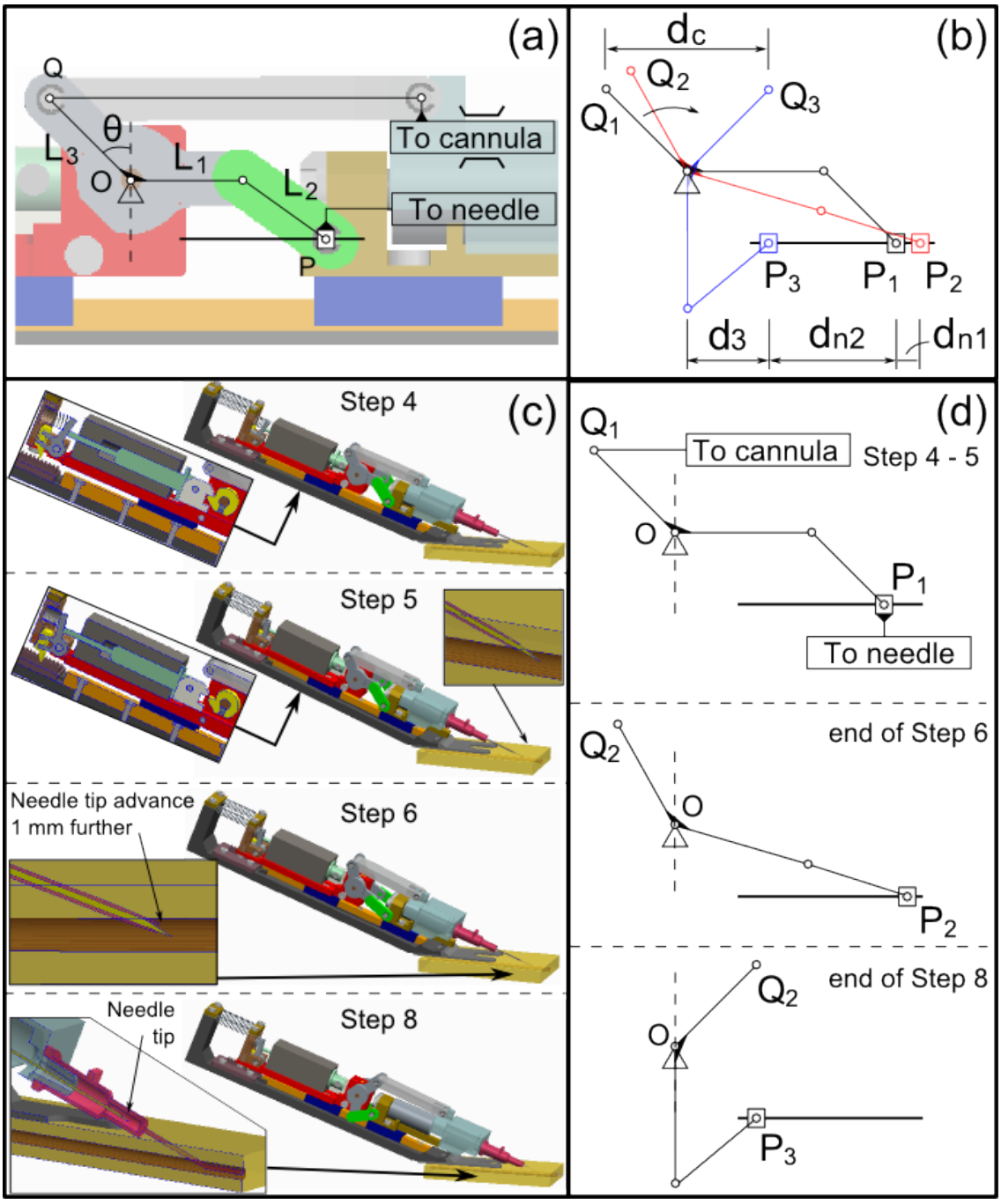

Figure 6-8: (a) the schematic diagram of crank-slider mechanism; (b) different colors are used to show the crank-slider mechanism in different steps during a PIVC; (c) CathBot in different steps during a PIVC insertion with detailed section views; (d) the corresponding schematic diagrams of the crank-slider mechanism in different steps.

Table 6.3: Summary of the system design specifications of CathBot.

Parameters	Required	Achieved
d_3	>5.5 mm	8 mm
d_{n2}	>7.3 mm	10 mm
d_{n1}	1 mm	1 mm
d_c	$\geq$ 17.7 mm	17.7 mm

steps: P_1 is the position at the moment of venipuncture (Step 5), P_2 represents the position of the slider at the end of Step 6, and P_3 is the end position after the needle is retracted (end of Step 8). During the rotation of the crank (5), point Q passes Q_1, Q_2, and Q_3.

The schematic diagrams of the crank-slider mechanism shown in Figure 6-8(d) are summarized in Figure 6-8(b) for a parametric analysis. Different colors (black, red and blue) are used to show the crank-slider mechanism at different stages of the procedure. The needle displacement d_{n1} and d_{n2}, described in Section 6.5.1, can be derived from position P_2 and P_3 to the initial position P_1. In addition, d_c representing the displacement of cannula (12) advancement, is the distance between Q_1 and Q_3. For easy structural arrangement, the horizontal distance d_3 between P_3 and Point O is set to be larger than 5.5 mm. We further constrain the range of the swing angle θ of the crank (5) to be from -45° to 45° in order to avoid a sharp return angle. Also, we limit the size of each component in order to make the device as compact as possible. Then we calculate the parameters of the crank-slider mechanism (L_1, L_2 and L_3) and have: L_1=10.4 mm, L_2 = 9.4 mm and L_3 = 12.5 mm. This design allows CathBot to achieve specifications as listed in Table 6.3, satisfying all the design requirements.

In addition, CathBot only weighs 85 g and can be gripped comfortably during the operation. With respect to the device sterilization, components that contact the patient, including the shoe (13), the cannula (12), CEN (10) and handle (11), are required to be disposed of after use. These components are cheap and designed to be easily dismounted from the device. In addition to that, the device can be covered by a drape as commonly applied on other mechanized medical devices.

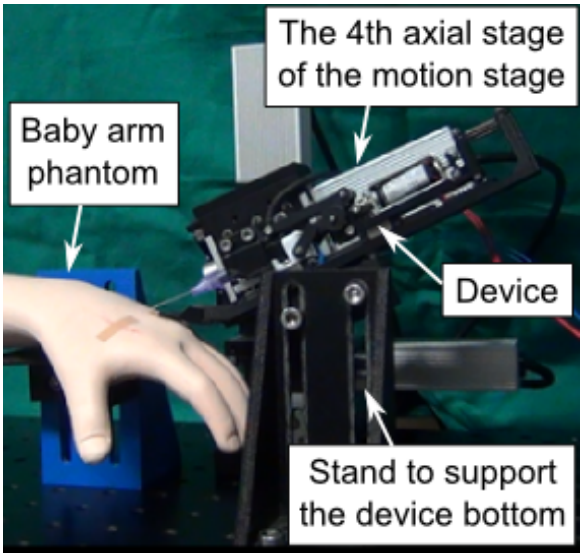

Figure 6-9: The device is mounted on a motion stage for characterization.

6.5.3 Device characterization

As part of the system evaluation, CathBot was firstly tested by mounting it on a motion stage (Siskiyou Corp., USA) as a grounded robot with all potential influences of a human operator removed. The setup for this evaluation is shown in Figure 6-9. The third phantom described in Section 4.3.3 was used, and the realistic baby arm phantom was firmly locked on a stand. A saline solution with similar electrical impedance properties to blood, was used as a blood substitute and was circulated inside the baby arm phantom by the pump from the same company. Then the shoe of the device was laid onto the baby arm, and another stand was used to support the device at its bottom. The handle of the CathBot was mounted on the 4th axial stage of the motion stage (see Figure 6-9). The 4th axial motion stage was used to simulate the user's hand motion that pushed the handle of the CathBot to advance with 1 mm/s insertion speed. The advanced displacement was set to be 18 mm. This distance was set after some pre-tests and it is sufficient for inserting the cannula into the vein. After the device finished the stroke, CathBot was removed with the cannula still in place. If blood was seen to flow out through the cannula, this trial was marked as a successful trial.

In total, we conducted 5 trials and all the trials were successful as blood flowed

out through the cannula in all 5 cases. During the PIVC procedure, the device could detect venipuncture, activate the solenoid, subsequently advance the cannula and retract the needle. This demonstrates that CathBot is capable of successfully performing catheter insertion using the realistic pediatric phantom. This reassures us so that we can now involve human subjects for a complete usability evaluation.

6.6 Discussion and Conclusion

In this chapter, 4 hand-held robotic devices are developed based on the venipuncture detection system presented in Chapter 5. All the devices are characterized and verified to fulfil the design requirements. Table B.3 in Appendix B summarizes the add-in mechanisms, advantages and disadvantages of the 4 developed devices. With different add-in mechanisms, different devices can provide different levels of task assistance during a PIVC operation.

Different devices constitute different Human-Robot-Interaction scenarios as the devices provide different levels of assistance and intervention during the PIVC procedure. From Device 1 (SVEI) to Device 2 (SDOP) to Device 3 (SAID) to Device 4 (CathBot), the process control of a PIVC operation and the responsibility taken by the robot device, gradually increases. The result is that the procedure becomes simpler for the operator. However, to achieve a higher level of task autonomy, a more complicated mechanical design is normally required to be added into the device and this could increases the cost and complexity of the device significantly. Therefore, this motivates us to proceed to the next step of device evaluation and comparison (as shown in Chapter 7) with human subjects involved to test the designed devices in a realistic pediatric PIVC scenario.

Chapter 7

Preliminary PIVC performance assessment experiments

A series of experiments were designed and conducted to assess and compare the performance of 4 designed hand-held robotic devices. This study also included a control group performing the PIVC test in a conventional way for comparison. This experiment is different to the characterization tests of SAID presented in Section 6.4.3. In the characterization tests of SAID, we used the second phantom (Section 4.3.2) which was designed for evaluating the bio-impedance sensing. In this chapter, the third phantom (Section 4.3.3) was used. The third phantom has a more realistic haptic and anatomic property, which is more suitable for evaluating the overall robotic performance during a PIVC operation. Below we present the experimental setup, experimental design, evaluation metrics and results.

7.1 Experimental design

In total, 25 naïve subjects (20 males, 5 females, average age: 29 years) were recruited and equally divided into 5 groups: one *Control* group, one *SVEI* group, one *SDOP* group, one *SAID* group and one *CathBot* group. The *Control* group was asked to complete the PIVC insertion task using an ordinary 26G medical IV catheter (0.64 mm diameter and 13° bevel tip, SURFLO-W, Terumo Europe N.V., Belgium), while the

other groups used one of the robotic devices for the same task. The device they used was indicated in the group name. The subjects recruited for the experiments included only people with engineering background: PhD students, postdocs and technicians. None of them had a medical background or previous experience in needle injection or catheterization.

All subjects received verbal and written information describing the experiments and its goals, and then provided written informed consent in accordance with recommendations from the Istituto Italiano di Tecnologia and the Declaration of Helsinki.

The experiment started with an instruction session including a 5-minute tutorial video providing fundamental knowledge about PIVC [30] and an instruction document [62]. The subjects were asked to first watch the video and then read the instruction document, which showed details of the PIVC insertion procedure to be performed. Except for the subjects belonging to the *Control* group, the other subjects received also a document with instructions for the use of the assigned device which they would use later for performing the PIVC.

After the instruction session, the subjects proceeded with the hands-on session of the experiment. This consisted of 10 attempts to catheterize a baby arm phantom. The subject was required to follow the PIVC instructions provided earlier. The procedure included: 1) picking up the assigned device (a robotic device or an ordinary catheter); 2) locating a proper insertion site; 3) aligning the catheterization needle to the target vein; 4) inserting the catheter; 5) stopping insertion (through manual perception or automatically); and 6) removing the needle (and the device) leaving the cannula in the site for inspection. For each trial, the following data was collected for offline analysis:

- Video overview of the operation;
- Trial result: Successful or failed PIVC attempt;
- Experimenter annotations related to the cause of failure.

At the end of the hands-on experiments, a questionnaire was submitted to obtain feedback from the subjects. The questionnaire consisted out of two parts: One generic

to obtain feedback about user satisfaction; the other specific to the groups using a robotic device to obtain feedback on the device usability.

For the experiment of SAID, the hand motion was also recorded. This is because the usage of SAID is different to the conventional way of manipulation. During the operation, the user is required to hold the device still, and the hand motion that moves the device forward or backward could impact the success of the trail. Hence, a 3D motion tracking system is used to record the operator's hand motion for analysis.

7.2 Experimental setup

Figure 7-1 shows the experimental setup prepared for PIVC performance assessment. The trials were performed on a desk, and near it a video camera was installed to record an overview of all trials performed during the experiment. The experimental platform included a baby arm phantom (the third phantom as described in Section 4.3), which is a simulator specifically developed for pediatric PIVC training. A circulation pump was connected to the baby arm phantom for reproducing blood circulation, which also enables the observation of 'blood' flowing out through the cannula when it is properly inserted. A 0.5% saline solution, whose electrical impedance property is similar to that of real blood, was colored red and used as blood substitute. In addition, a Vein Finder (BVF-260, Shenzhen Bestman Instrument Co., Ltd., China) was used to provide trans-illumination and increase the contrast of the vein with its surrounding material.

During the experiments of the *SAID* group, an Optitrack system with four Flex-13 cameras (NaturalPoint, Inc., USA) was also installed around the desk to track the subject's hand motion. This system was carefully calibrated and presented a mere 0.09 mm re-projection error. Two markers were tracked during the experiments: one on the baby arm and the other on the index finger of the subject's operating hand.

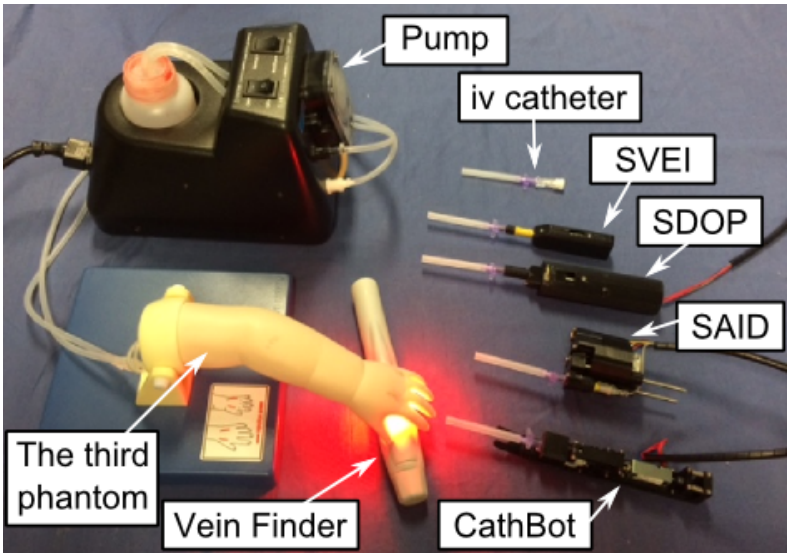

Figure 7-1: Experimental setup for PIVC performance assessment.

7.3 Experimental metrics

The average success rate, the first-stick accuracy, and the mean number of attempts until the first successful catheterization were the main metrics used to assess PIVC performance. These were all based on the success/failure classification of each PIVC attempt. Multiple attempts of insertion in a single trial were forbidden and would be considered as a failed trial. For example, retracting the catheter back to the vein after an over shoot would still be considered as a failed insertion. Other than that, after the insertion was completed and the needle was retracted from the cannula, if 'blood' was observed flowing out through the cannula, the PIVC was considered to be successful. If blood did not flow out, the trial was considered a failed attempt.

Also, the reasons for failure were analyzed as part of the overall PIVC performance analysis. The failures were categorized as: *Miss-Target*, *Overshoot*, *Undershoot* and *Unknown*. *Miss-Target* (MT) included all cases in which the needle missed the target vein, passing alongside it. The other conditions were confirmed at a post-trial phase, during which the experimenter pulled out the cannula slowly. If at some point during this process blood flowed out through the cannula, this was considered as a clear indication that the catheter had punctured completely through the vein. Therefore, the failure was due to an injection too deep and the error was classified as an *Overshoot*

(*OS*). Otherwise, if no blood was seen, the length of cannula inserted into the phantom was evaluated. If it was found too short (based on the experience and judgement of the experimenter), the failure was considered to be due to an insertion too short, and the error was classified as an *Undershoot* (*US*). For other failures without a clear cause, the classification *Unknown* was used.

Another important metric extracted from the collected experimental data was trial time. This was defined as the time period between the moment the subject decided on the insertion site and the moment the needle was extracted from the cannula. Trial time for each PIVC attempt was extracted through an offline analysis of the experimental videos. Then, data for each subject was processed to calculate the average operation time.

Finally, the questionnaires submitted to the subjects also provided assessment metrics. These consisted in a list of statements (see Appendix H) to which the subject was asked to state his/her level of agreement. Feedback was provided based on Likert-type scales with 10 points (with 1 indicating 'strong disagreement' and 10 indicating 'strong agreement'). The answers from all subjects in each experimental group were analyzed together in terms of Mean (M) and Standard Deviation (SD) to extract overall feedback for each aspect covered by the questionnaires. In addition, a global usability score of the second part of the questionnaire was computed based on the following equation:

$$SUS_{score} = (\sum_{i=7,8,11} q_i + \sum_{i=6,9,10} (10 - q_i)) \times 1.67. \tag{7.1}$$

where q_i represents each statement. For some questions which had a negative meaning, the score of that question was deducted by 10 to report a positive score. Then, the statement's scores were added together and multiplied by 1.67 to convert the original scores of 0-60 to 0-100.

Hand motion data related to the insertion phase of the PIVC process was a metric extracted from the experimental data of the *SAID* group. The overall hand motion trajectory for each trial was analyzed and divided in three phases: preparation, in-

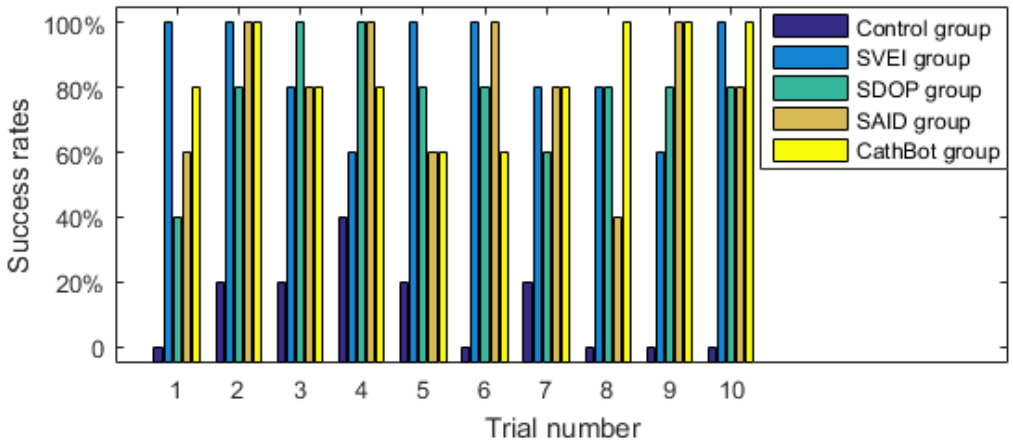

Figure 7-2: PIVC success rate as a function of the attempt number for each experimental group.

sertion and post-insertion. In the preparation phase the subject picked up the device and positioned the tip of the needle at the selected insertion site. The insertion phase covered the whole procedure of needle insertion until venipuncture. This was followed by the post-insertion phase, which included pushing the catheter into the vein and removing the device. Because our concern was to check whether the operator can hold SAID steadily during the insertion phase, the hand motion analysis was performed whilst considering only this process.

7.4 Experimental results

7.4.1 Success rates

In total, 50 trials were collected for each group. The success rates achieved as a function of the number of attempts are presented in Figure 7-2. The *SVEI* group and the *CathBot* group achieved the highest average success rate of 86% (±15%) and 84% (±8%) respectively, followed by the *SAID* group of 80% (±16.7%) and the *SDOP* group of 78% (±14.7%). All of them are much higher than the success rate of the *Control* group which reached only 12% (±16%). The Welch Two Sample t-test method was used to analyse the differences among the groups statistically. Firstly, we

combined the results of the robot-assisted PIVC groups including the *SVEI* group, the *SDOP* group, the *SAID* group, and the *CathBot* group. This result is compared with the result of the *Control* group, and it was found that the difference between them was statistically significant (t = -8.09, p-value = 0.0003), proving an obvious improvement of success rate for pediatric PIVC by using a robotic device. Secondly, the same analysis method was applied to every two groups within the robot-assisted PIVC groups. The analysis results showed that the differences between any two groups were not statistically significant since all the p-values are more than 0.47.

The first-stick accuracy achieved by each group can also be seen from Figure 7-2. All the subjects in the *SVEI* group achieved the first stick accuracy, and 4 out of 5 subjects in the *CathBot* group also succeeded in their first trials. As for the *SAID* group, the first stick accuracy was found to be 60% (3 out of 5), and also 2 out of 5 subjects using SDOP for the experiments achieved successful PIVC insertions in their first attempt. In contrast, the first-stick accuracy of the *Control* group was zero, i.e., none of the subjects were successful at the first attempt.

The experimental results also revealed the mean number of attempts until the first successful catheterization. As mentioned above, all the subjects using SVEI succeeded in their first attempt. With the help of CathBot, subjects could also achieve their first successful attempt with an average of 1.2 trials. In addition, the experimental results registered 1.4 and 1.8 as the mean number of attempts for the *SAID* group and the *SDOP* group respectively. Also, the experimental data show that all subjects performing robot-assisted PIVC were able to successfully catheterize the baby arm phantom within three attempts. In contrast, this value could not be computed for the *Control* group as not all subjects achieved a successful PIVC within the 10 attempts performed.

The above results are summarized and presented in Table 7.1.

7.4.2 Failure analysis

Failure reasons are summarized and reported in Table 7.2. Among the failed trials of the *SVEI* group, six were found to be *OS* and one was found to be *MT*. As for

Table 7.1: Summary of experimental outcome of PIVC for the 5 user groups.

Group	Ave. success rate	First stick accuracy	Mean no. to first success	Ave. operation time (s)	SUS
SVEI	86%±15%	5 out of 5	1	23.9	77.8
SDOP	78%±14.7%	2 out of 5	1.8	18.8	81.5
SAID	80%±17%	3 out of 5	1.4	19	75.8
CathBot	84%±8%	4 out of 5	1.2	16.9	72.8
Control	12%±16%	0 out of 5	-	36.2	NA

Table 7.2: The failure reasons for each group.

Group	Failures			
	OS	*US*	*MT*	Unknown
SVEI	6	0	1	0
SDOP	3	8	0	0
SAID	0	6	2	2
CathBot	2	1	3	2
Control	18	14	3	9

the failures of the *SDOP* group, three cases were found to be *OS*, and the other eight cases were *US*. On the *SAID* group, six failures were due to *US* and two failures were *MT*. The other two cases were hard to classify and thus set to 'Unknown'. The failed cases for the *CathBot* group and the *Control* group were more diverse. The failures of the *CathBot* group had two cases of *OS*, one case of *US*, three cases of *MT* and two cases *Unknown*. And for the *Control* group, most cases consisted in *OS* (18 cases) or *US* (14 cases). *MT* accounted for 3 cases of the failures, while for the other 9 cases the reason for failure could not be determined.

7.4.3 Trial times

Table 7.1 also summarizes the trial times measured for subjects in each group with the failed attempts removed. This was done because failed catheterizations resulted in extremely long or short trials not representative of the time needed to perform PIVC. The processing of the acquired data resulted in an average operation time of 23.9 s, 18.8 s, 19 s, and 16.9 s for the *SVEI* group, the *SDOP* group, the *SAID* group and the *CathBot* group respectively. This result shows that using SVEI to complete

Table 7.3: The results of the questionnaire to investigate the subjects' opinions on the User satisfaction (Part 1) and the device's usability (Part 2).

	Question	SVEI	SDOP	SAID	CathBot	Control
Part 1: user satisfaction.	Q1	8.8±1.2	8.6±0.8	8.8±0.4	8.4±0.8	3.8±1.9
	Q2	3.8±3.3	1.8±1.2	3±1.3	2.6±1.4	8.2±2.1
	Q3	1.6±0.8	1.6±0.5	2.4±1	2.8±2.6	6.6±2.6
	Q4	10±0	9.2±0.7	7.2±1.2	9.2±0.7	7±1.1
	Q5	1±1.4	1.8±0.7	1.6±0.5	1.6±0.8	3.2±2.7
Part 2: assessment of the device's usability.	Q6	0.2±0.8	2.6±1.4	2.4±1.5	3.4±3	-
	Q7	8.6±0.5	9±1.1	7.4±0.8	7.4±1.9	-
	Q8	8.6±1.4	8±1.7	7±1	8.4±1	-
	Q9	1±1.1	1.8±1.2	2.4±2.3	4.2±2.7	-
	Q10	1±0.9	2.4±0.5	2.4±2.3	3.6±2.7	-
	Q11	8.8±0.8	8.6±0.8	8.2±0.4	9±1.1	-

the task would require a longer time than using one of the other devices. This can be easily understood as the subject using SVEI to do the PIVC operation needs to complete the whole procedure manually and carefully. In contrast, a subject who uses the CathBot just needs to push the handle of the device continuously and the robotic device would complete the whole procedure. Thus, the shortest time on average is needed for the operation. For the *Control* group, the mean time concluded from the 6 successful attempts was found to be 36.2 ± 18.3 s. However, since the success rates were very low, the analysis of the trial time may not be representative enough. In the future, additional experimentation would be required to draw significant conclusions.

7.4.4 Questionnaire

Feedback data received through the questionnaires is summarized in Table 7.3, and the Pearson product-moment correlation method was used for the data analysis. The data show that all the robot-assisted PIVC group subjects felt overall satisfied with their performance in the pediatric PIVC task (*SVEI* group: M = 8.8, SD = 1.2; *SDOP* group: M = 8.6, SD = 0.8; *SAID* group: M = 8.8, SD = 0.4; and *CathBot* group: M = 8.4, SD = 0.8), while the *Control* group subjects were mostly unsatisfied (M = 3.8, SD = 1.9). In addition, at the individual level, the user satisfaction was found highly correlated with their success rates (r = 0.903, p = 6.7×10^{-10}).

The data also shows that subjects who achieved higher success rates tended to think that the task was not difficult (r = -0.612, p = 0.0011), and that they could easily complete it with the given device (r = -0.482, p = 0.015). Subjects assisted by a hand-held robot considered the PIVC task not difficult (*SVEI* group: M = 3.8, SD = 3.3; *SDOP* group: M = 1.8, SD = 1.2; *SAID* group: M = 3, SD = 1.3; and *CathBot* group: M = 2.6, SD = 1.4), while subjects in the *Control* group rated it as difficult (M = 8.2, SD = 2.1). Subjects in the groups using hand-held robots to complete the task also thought it was easy to achieve success (*SVEI* group: M = 1.6, SD = 0.8; *SDOP* group: M = 1.6, SD = 0.5; *SAID* group: M = 2.4, SD = 1; and *CathBot* group: M = 2.8, SD = 2.6), while subjects in the *Control* group thought it was not easy to perform PIVC with an ordinary catheter (M = 6.6, SD = 2.6). Also, subjects in the *SVEI* group, the *SDOP* group and the *CathBot* group believed that they needed a short period of practice to achieve high success rates (*SVEI* group: M = 10, SD = 0; *SDOP* group: M = 9.2, SD = 0.7; and *CathBot* group: M = 9.2, SD = 0.7). In comparison, the *Control* group and the *SAID* group thought that they might need a longer time of practice to achieve a good PIVC performance (*SAID* group: M = 7.2, SD = 1.2; and *Control* group: M = 7, SD = 1.1). Finally, subjects from the *Control* group felt more tired (M = 3.2, SD = 2.7) than those from the other groups (*SVEI* group: M = 1, SD = 1.4; *SDOP* group: M = 1.8, SD = 0.7; *SAID* group: M = 1.6, SD = 0.5; and *CathBot* group: M = 1.6, SD = 0.8) after the trials.

Feedback regarding the second part of the questionnaire shows that all of the robotic devices were appreciated by the subjects under all considered dimensions of usability. The results were highly polarized around the extreme points of the scales, demonstrating their coherence and significance. Very high global usability scores were received as 77.8 for the *SVEI* group, 81.5 for the *SDOP* group, 75.8 for the *SAID* group and 72.8 for the *CathBot* group.

7.4.5 Hand motion

The hand motion during the insertion phase of the PIVC process was recorded during the user-trials of the *SAID* group. The acquired hand motion data for each insertion

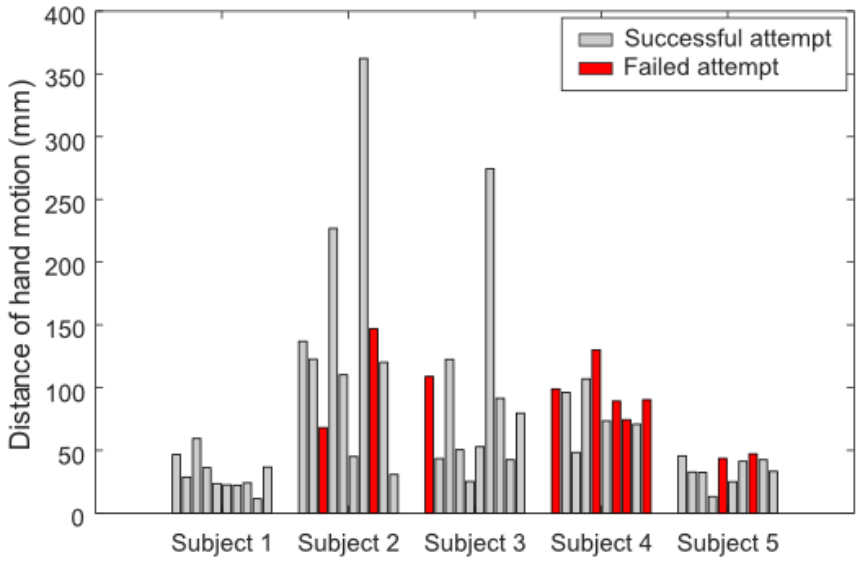

Figure 7-3: Distance of hand motions recorded for the catheterization needle insertion phase for the *SAID* group.

normally shows a trajectory winding within a small range. In order to quantize the user's hand motion, the length of each trajectory was computed and presented in Figure 7-3. We use red bars to represent the failed attempts and gray bars the successful ones. The results show that although we instructed the subjects in the *SAID* group to hold the device still during the insertion, the average hand motion distance was still found to be 75.63 mm.

7.5 Discussion

The experimental results presented above clearly demonstrate that the use of any one of the designed robotic devices for pediatric PIVC has the potential to significantly decrease the need for practitioner's experience. This is observed from the big difference in success rate achieved by the groups using a robotic device (86% of the *SVEI* group, 78% of the *SDOP* group, 80% of the *SAID* group, 84% of the *CathBot* group) and the *Control* group (12%). Only two of the subjects from the *Control* group succeeded in the task within 10 trials, and none of them succeeded in their first trial. As observed from the results, even these two subjects were not able to

consistently repeat such success in subsequent trials. This highlights the fact that, although it is obvious that people do learn to perform successful pediatric PIVC with traditional catheterization systems, this clearly takes much more than 10 attempts. On the other hand, the success rates of this study can only indicate the results of naïve subjects, and the outcomes could be different for medical staff or people who underwent a PIVC training program.

In accordance with comments from the literature, this study also shows that the majority of failures with the traditional catheterization system are caused by a miss detection of venipuncture, leading to a too deep or too shallow needle insertion. This confirms one of the results from the survey investigation (see Chapter 3) that the conventional way of venipuncture detection based on haptics and observing flashback is very difficult for beginners.

In contrast, high success rates were obtained in the other groups with robot-assisted technology. The experimental data clearly demonstrated that SVEI helps naïve users to master pediatric PIVC faster compared to the traditional method. Thanks to the electrical-impedance-based venipuncture detection technology, the failed insertions due to *OS* and *US* were significantly reduced. Nevertheless, the insertion control is still relying on the user capability. Especially during Step 6 (see Section 4.1), a OS or US failure could often happen if the subject advanced the catheter too short or too deep.

SDOP was found to greatly improve the pediatric PIVC performance for naïve users. This can be seen from the fact that the average success rates were much higher (78%) compared to the *Control* group (12%). However, there were still 11 failed insertions: 3 cases of *OS*, and 8 cases of *US*. We estimate all the *OS* and *US* errors were caused by Step 6 (see Section 4.1 and Section 6.3) because: First, the device could successfully detect venipuncture and activate the disengage mechanism for all the trials. Second, the subjects also mentioned it was difficult for them to control the 'advance' distance due to their lack of experience.

The experimental results also proved SAID can significantly improve naïve subjects' performance of pediatric PIVC, allowing 100% success within two attempts.

Nevertheless, six failures were observed in the *SAID* group due to *US*. This could be explained by the fact that when SAID's actuator drives the catheter insertion, the hand operating the device is pushed backwards by the reaction force. Therefore, if the user cannot hold his/her hand still, the actuator may reach its stroke limit before the needle reaches the vein. This reason was also demonstrated by the hand motion recording. Considering the mean vein depth mentioned in Section 4.2, the catheter needs to travel less than 5.4 mm from the top of skin to the hand vein. However, the hand motions recorded during the trials were found to be 75.63 mm. Apart from adjusting the needle insertion orientation, the hand trajectories also show the operating hand being pushed backwards during the insertion process. This indicates a potential benefit could be given by adding a support mechanism to this device for preventing the user's hand being pushed backward.

Among all the groups, the *CathBot* group were found to assist naïve users to achieve the best performance in pediatric PIVC irrespective of the *MT* failures. Only 3 cases of *OS* and *US* were found in total. The reason for *US* was found due to the catheter bending during the insertion. Hence, after the insertion stroke finished, the catheter had not yet entered the vein. In addition, the suspected reasons of the *OS* cases are: 1. the insertion angle was too steep, or 2. the user pushed the device too hard and it may compress the insertion site making the vein close. The other three known failures were found to be *MT*, even though a trans-illumination device was used. This on the one hand proves the difficulty of controlling the insertion direction along the central line of the vein, and on the other, shows a future optimization direction to address this challenge.

Another benefit by using the hand-held robotic device for pediatric PIVC includes the required task time during the PIVC insertion is considerably shortened. The results reveal that the average time for PIVC with a robotic device is much faster than that of a conventional unassisted PIVC. Specifically, the *CathBot* group (16.9 s) allows the fastest operation among all the groups. This is mainly because CathBot improves the procedure as the user just needs to push its handle forwards and the device completes those complicated and delicate PIVC procedures.

The questionnaire results showed very high satisfaction rates in four robot-assisted PIVC groups compared to the *Control* group. This was expected from the performance data as satisfaction is clearly correlated to success rate. Among these four robot-assisted PIVC groups, SDOP received the highest satisfaction rates. This could be due to the fact that the way SDOP is operated is closer to that of the conventional procedure. This feature may also shorten the learning curve as indicated in Q4 of the SUS questionnaire. On the other hand, CathBot was rated low in terms of SUS (see Table 7.1). Although the subjects in that group were confident with their performance in pediatric PIVC with CathBot (M = 8.4, SD = 0.8), they stated that this device was overall complicated (M = 3.4, SD = 3) and not very easy to use (M = 7.4, SD = 1.9). They may need the support of a technical person (M = 4.2, SD = 2.7) and need to learn many things about the device before they get going with it (M = 3.6, SD = 2.7).

One deficiency of this study is that we did not record the electrical impedance change during the PIVC procedure. In the future, more user-trials studies will be conducted for device evaluation and this data type will be definitely collected and analysed.

7.6 Conclusion

In this chapter, the validation and performance assessment of the developed hand-held robotic devices are presented through a comparative experiment involving a realistic pediatric PIVC phantom and naïve subjects. The performance of naïve subjects using 4 different hand-held robotic devices and an ordinary IV catheter were analyzed, demonstrating that all the developed robotic devices can provide significant improvements for pediatric PIVC. Benefits highlighted by the experiment include greatly shortened operation time, higher average success rates, higher first-stick accuracy, easier operation and better user satisfaction. As clearly shown in the experimental results, the use of any one of the developed robotic devices by naïve subjects could result in an average PIVC success rate of more than 78%, an incredible first-stick

accuracy of more than 40% and an average of less than 1.8 attempts until the first successful catheterization. All of these metrics compare extremely positively, even with performance data for expert practitioners from the literature, supporting the need for continued investment in the technology to bring it to clinical tests as soon as possible. Therefore, in the next chapter, Chapter 8, a pre-clinical study is presented. In that study, medical personnel are invited to evaluate the developed robotic device on the baby arm phantom and provide us some feedback to improve the design.

Chapter 8

Pre-clinical experiments with medical personnel

This chapter describes a comparative experiment involving medical personnel that was realized to evaluate the SVEI hand-held device on a baby arm phantom. The goal was to obtain quantitative and qualitative feedback from professionals and potential users. SVEI was chosen for this study due to the following considerations:

1. In Chapter 7, SVEI was demonstrated to help naïve subjects achieve very good PIVC performance in terms of average success rates and first-stick accuracy.

2. Compared to the conventional PIVC operation, SVEI only provides a venipuncture detection function while keeping the rest of the catheterization operation as the conventional method. This allows studying the impact of the core technology proposed in this thesis, namely the electrical impedance sensing system to detect venipuncture during intravenous catheterization.

8.1 Experimental design

The experiments were conducted at the San Martino hospital, Genova, Italy. All of the subjects invited to this study had medical background. However, due to different job duties, some participants never performed PIVC in practice before. Based on their PIVC experience, we divided the subjects into 2 groups: Those who had performed

PIVC operation before were grouped in the Expert group and the others were grouped in the Non-Expert group. This allowed us to compare the performance between two groups, and evaluate the effectiveness of SVEI for assisting different potential user groups during a PIVC operation.

Before the experiment, all subjects received verbal and written information describing the experiments and its goal. They were also asked to provide written informed consent in accordance with recommendations from the Istituto Italiano di Tecnologia and the Declaration of Helsinki.

Then a 5 min tutorial video about the PIVC process [30] was provided. However, watching this tutorial video was not mandatory since experts were obviously very familiar with the process. Subsequently, the experimenters presented SVEI to the subjects and introduced its working principle with both verbal and video instructions.

Finally, each subject was required to perform a total of 6 PIVC trials on the baby arm phantom. In each group, half of the participants were asked to perform 3 trials with an ordinary iv catheter first and then 3 more trials with SVEI. The other half of the participants were asked to use SVEI in the first 3 trials and then use an iv catheter in the other 3 trials.

The experimental setup for this experiment was similar to the one used in the preliminary PIVC performance assessment experiments (presented in Chapter 7) including a baby arm phantom (see Section 4.3.3 'The third phantom'), a pump for circulating a 0.5% saline solution inside the baby arm phantom, a SVEI, a regular 26G IV catheter (SURFLO-W, Terumo Europe N.V., Belgium), a Vein Finder (BVF-260, Shenzhen Bestman Instrument Co., Ltd., China), and a video camera for recording an overview of all trials performed during the experiment.

At the end of the experiment, a questionnaire was delivered to the subject to collect information about their experience and satisfaction with the device. In this study, a new questionnaire based on the System Usability Scale (SUS) [6] was designed. It consisted of 14 statements based on 5-points Likert-type scales with each point of the scale representing a different level of agreement with the statement, i.e., from "strongly disagree" for point 1 to "strongly agree" for point 5. Upon receiving the

Table 8.1: The SUS questionnaire results show the Mean value and Standard Deviation of user evaluation of the robotic device after the experiment (from 1 for "strong disagreement" to 5 for "strong agreement"). E represents the responses from Experts and NE represents the responses from Non-Expert.

Questions	E	N-E
1.I am very satisfied to my performance with a regular iv catheter.	3.3±0.8	3.8±1.3
2.I am very satisfied to my performance with SVEI.	4.1±0.8	3.9±1.3
3.I feel very easy to complete the task with a regular iv catheter.	3.5±0.9	3.7±1.4
4.I feel very easy to complete the task with SVEI.	3.9±1.3	4.1±1.1
5.I think that I would like to use this system frequently.	4±1.2	3.8±1.1
6.I found the system unnecessarily complex.	2.5±1.5	2.1±1.4
7.I thought the system was easy to use.	3.3±1.7	4.3±0.6
8.I think that I would need the support of a technical person to be able to use this system.	2±1.4	1.9±1.1
9.I found the various functions in this system were well integrated.	4.3±0.9	4.7±0.5
10.I though there was too much inconsistency in this system.	1.4±0.5	1.2±0.4
11.I found the system very cumbersome to use.	2±1.1	3±1.3
12.I felt very confident using the system.	3.9±1.3	3.7±1
13.I needed to learn a lot of things before I could get going with this system.	1.8±1.1	1.6±0.6
14.I would imagine that most people would learn to use this system very quickly.	4.6±0.7	4.8±0.4

questionnaire, every subject was requested to read each statement and indicate how much s/he agrees with it by marking the correspondent point on the scale. The first four questions regarded satisfaction with the achieved performances, and the other 10 questions were adopted directly from the SUS questions (see Table 8.1). This questionnaire was then translated to Italian for actual use (see Appendix I).

8.2 Experimental metrics

In this study, the most important metrics to evaluate a PIVC performance included the overall success rate and first stick accuracy. The mean number of attempts before a successful insertion, which was used in the preliminary evaluation, was not included in this study. This was because every subject only had 3 trials of SVEI-assisted and 3 trials of unassisted PIVC. Furthermore, some subjects were not able to perform a successful insertion within 3 trials.

Here, the same standards used in Chapter 7 to judge a successful PIVC insertion and estimate failure reasons were utilized. Failure reasons were classified in 4 categories: Miss-Target (MT), Overshoot (OS), Undershoot (US) and *Unknown*.

Another important metric was the time period used for the catheter insertion procedure. This metric was extracted from the video recordings as the time between the moment the subject decided on the insertion site until the moment the needle was extracted from the cannula.

In addition, the marks from the questionnaire were used as another metric for evaluating SVEI. The answers from all subjects were analyzed together in terms of mean and standard deviation to come to an overall evaluation of the SVEI's usability.

8.3 Experimental results

In total, this study included eight subjects in the Expert group and twelve subjects in the Non-Expert group. The Expert group consisted of medical doctors and nurses, all having >5 years of experience in PIVC operation. Subjects in the Non-Expert group included medical students, medical assistants and medical doctors, who claimed no prior experience in PIVC. In both groups, the numbers of female subjects and male subjects were equal.

Table 8.2: The average success rates achieved by different subject groups in different PIVC methods.

	Unassisted PIVC	SVEI-assisted PIVC
Expert	33.3%	75%
Non-Expert	58.3%	69.4%

8.3.1 Success rates

The experimental results demonstrated that the overall success rate of PIVC for all the subjects increased from 48.3% with the conventional method to 71.7% when SVEI was used. The difference between the two methods was statistically significant (Welch Two Sample t-test, t = -2.17, p-value = 0.036). Both experts and non-experts could greatly benefit from this new medical device. As the results presented in Table 8.2, when SVEI was used, experts achieved 75% success rates, much higher than their performance with the conventional method (33.3%). As for non-experts, a considerably high success rate of 69.4% was achieved with SVEI compared to the success rate of 58.3% with the conventional method.

Moreover, the improvement of PIVC performance by using SVEI could also be observed by comparing the individual success rates of SVEI-assisted PIVC and unassisted PIVC. Specifically, for each subject, the numbers of successful insertions in 3 unassisted attempts and 3 SVEI-assisted attempts are shown in Figure 8-1. The results reveal that all experts achieved better or equal results with SVEI than the traditional method, and in the Non-Expert group, the performance of 9 out of 12 subjects achieved better or equal success rates when SVEI was used compared to a traditional method.

Regarding the first-stick accuracy as shown in Table 8.3, the improvement seen in the Expert group when SVEI is used is obvious: 5 out of 8 subjects (62.5%) succeeded in the first attempt, and the other 3 subjects successfully inserted the catheter at their second attempt. However, when they performed the PIVC insertion in the conventional way, only 2 experts (25%) could successfully insert the catheter at their first attempt, and only these two subjects could also successfully insert the catheter at the second attempt. On the other hand, among 12 non-expert subjects,

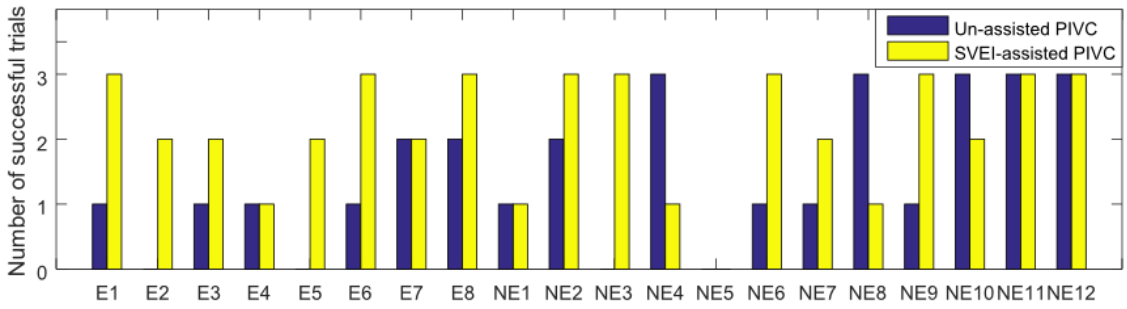

Figure 8-1: The number of successful trials in unassisted PIVC and SVEI-assisted PIVC for each subject. E: Expert; NE: Non-expert.

Table 8.3: The success rates of PIVC at the first attempt and within two attempts.

	Unassisted PIVC		SVEI-assisted PIVC	
	First attempt	Within 2 attempts	First attempt	Within 2 attempts
E	25%	25%	62.5%	100%
NE	58.3%	66.7%	66.7%	83.3%

E: Experts. NE: Non-Expert.

8 subjects (66.7%) succeeded at the first attempt with the assistance of SVEI and 10 subjects (83.3%) could successful perform the PIVC insertion within 2 attempts. When considering the conventional method, 7 subjects (58.3%) succeed at their first attempt, but only 1 more subject (83.3%) was successful with two attempts.

8.3.2 Failure analysis

The reasons of failed insertions in both Expert group and Non-Expert group were collected and summarized in Table 8.4. This results again show that SVEI could effectively help both experts and non-experts to avoid catheter overshoot (*OS*) and undershoot (*US*) during the PIVC insertion. In the Expert group, the occurrence of

Table 8.4: Analysis of the failed insertions.

	Expert		Non-Expert	
	iv catheter	SVEI	iv catheter	SVEI
OS	8	2	7	3
US	5	3	7	5
MT	0	0	0	2
Unknown	3	1	1	1

OS and *US* was 8 cases and 5 cases during the unassisted PIVC trials. This number decreased to 2 cases and 3 cases when SVEI was used. Similar phenomena was also observed in the Non-Expert group as the failed insertions due to *OS* reduced from 7 cases to 3 cases, failures due to *US* reduced from 7 cases to 5 cases. In addition, 2 failed SVEI-assisted PIVC insertions were found due to *MT* by non-experts.

8.3.3 Trial times

This study also recorded the operation time for both SVEI-assisted PIVC and unassisted PIVC. The time of failed trials were not considered because failed operations normally resulted in much longer or shorter time which could not represent the time needed for PIVC. The experimental results revealed that the operation time for inserting catheter with the assistance of SVEI could be slightly faster than the conventional way. For experts, it averagely took them 14.2 s (SD=3.1 s) to insert a regular catheter without SVEI, and 11.6 s (SD=3.6 s) to do the same task with SVEI. Also, in the Non-Expert group, the operation time was found to be 14.4 s (SD=5.2 s) in a conventional way and 10.6 s (2.9 s) for a SVEI-assisted PIVC. The differences of operation time between the Expert group and the Non-Expert group were very small and non-significant.

8.3.4 Questionnaire

The results of the SUS questionnaires are shown in Table 8.1. The feedback acquired from the first four questions shows that Experts were more satisfied with their performance with SVEI (4.1±0.8) compared to their performance in the conventional PIVC way (3.3±0.8). They felt that the task became easier with SVEI (3.9±1.3) than with only a regular catheter (3.5±0.9). As for the Non-Expert group, the subjects were overall satisfied with their performances in both SVEI-assisted PIVC (3.9±1.3) and unassisted PIVC (3.8±1.3). Nevertheless, they also agreed that SVEI could make the task easier for them (4.1±1.1) compared to the conventional method (3.7±1.4). The satisfaction of the performance was found highly correlated to the success rates

(r=0.319, p=0.045).

In addition, according to the feedback from the other 10 questions, SVEI was appreciated by both experts and non-experts under all dimensions of usability expressed by the SUS scales. The subjects were very confident to use SVEI for the task (3.9±1.3 and 3.7±1), and they felt like using SVEI in the future (4±1.2 and 3.8±1.1). They mentioned that they could quickly learn how to use SVEI (1.8±1.1 and 1.6±0.6), and they also believed that most people could learn to use SVEI very fast (4.6±0.7 and 4.8±0.4) as well. In addition, SVEI received a positive assessment from both experts and non-experts. It was mentioned to be well integrated (4.3±0.9 and 4.7±0.5) and consistent (1.4±0.5 and 1.2±0.4). However, with regards to the system complexity, some subjects said the SVEI was a bit complex (2.5±1.5 and 2.1±1.4) and cumbersome (2±1.1 and 3±1.3). When asked to evaluate the ease of use of SVEI for PIVC, non-experts said that it was easy for them (4.3±0.6) while experts perceived it as a little bit difficult (3.3±1.7).

8.4 Discussion

The experimental results clearly show that SVEI can greatly improve the performance of pediatric PIVC for both experts and non-experts as reflected in the improved average success rates from 48.3% to 71.7%. Especially for experts, their average success rate in unassisted PIVC was only 33.3%, but with the assistance of SVEI, their success rates were improved significantly to 75%. Also for the Non-Expert group, success rates improved from 58.3% to 69.4% with the help of SVEI. This again confirms that the PIVC operation is very difficult even for experienced medical staffs. With the help of SVEI, the challenging venipuncture detection procedure can be addressed more easily, and thus PIVC performance of both experts and non-expert were found to be greatly improved.

From the above results, it is a bit strange to see that the success rate of the unassisted PIVC trials achieved by the experts was lower than non-experts. One of the possible reasons could be because the experts did not take the conventional trials

serious enough. This could be observed because when they did the PIVC trials with the new device, they seemed to be more concentrated and thus all of them could succeed at least once within 2 attempts. In addition to that possible reason, we also noticed that the success rate of those non-experts is relatively high according to literature. This could be because on the one hand, the non-experts might pay more attention to the unassisted PIVC trials as that was new to them; on the other hand, all of them had medical background and they might have been doing some medical operations which possibly enhanced their skills on the PIVC operation. Additionally, the stress-levels were low as the operation was carried out on a phantom instead of a real patient.

Although SVEI was demonstrated to significantly reduce the occurrence of *OS* and *US* by enhancing the venous entry detection, the subjects still required to operate the catheter insertion manually. Controlling the catheter insertion was found not easy even for experts. As observed during the experiments, failed insertions due to *US* were commonly happened when the insertion angle was too flat during the insertion. Also, some non-experts did not dare to insert the catheter deep enough and they stopped the insertion since they guessed the catheter already passed through the vein. In addition, *OS* failures commonly happened when the subjects inserted the catheter too fast and penetrated also the distal vein wall. This reinforced our idea of the development of SDOP, SAID and CathBot to provide insertion control in addition to venipuncture detection.

Furthermore, the experimental results show that the operation time could be slightly shortened in the SVEI-assisted PIVC. For a successful unassisted PIVC insertion, it could cost about 14 s to complete the PIVC procedure. In SVEI-assisted PIVC, the required time period for the same procedure was found to be about 11 s for both experts and non-experts. This result indicated that a more effective approach to speed up the PIVC procedure is through improving the success rates and reducing the number of attempts. Also, compared to the operation time by naïve subjects in the preliminary study in Chapter 7 (23.9 s), the subjects in this study performed the PIVC operation much faster. This, as mentioned above, could potentially increase

the possibility to puncture through the vein.

According to the feedback regarding Question 5 in the SUS questionnaire, SVEI was mentioned to be a bit complex (2.5±1.5 rated by experts and 2.1±1.4 rated by non-experts) and cumbersome (2±1.1 rated by experts and 3±1.3 rated by non-experts). This feedback is intriguing since SVEI has a simple structure and does not change the way of PIVC manipulation. On one hand, this information motivates us to further optimize the design of the robotic devices to make them more compact and user friendly. On the other hand, another extended set of trials for device evaluation and user investigation with medical personnel will be necessary to better understand this perspective.

With regards to the feedback from the SUS questionnaire, most responses were consistent between experts and non-experts. These results were highly polarized towards the extreme points of the scales, which demonstrate their coherence and significance. However, different opinions were given by experts and non-experts related to the SVEI's easiness of use (Question 7). Most Non-Experts agreed that SVEI was very easy to use (4.3±0.6) while experts said it was not very easy (3.3±1.7). This difference might be caused by the fact that experts were more used to the conventional way of PIVC manipulation and thus they may need some practice to adapt to a new way for venipuncture detection.

8.5 Conclusion

This chapter presents a pre-clinical study to evaluate SVEI in terms of performance and usability. This study was conducted on the same experimental platform as the one used in Chapter 7. Medical personnel including both PIVC experts and non-experts were invited to perform 6 PIVC trials on the realistic baby arm phantom: 3 trials with SVEI and the other 3 trials with only a regular iv catheter. The obtained results are highly motivating and demonstrate that SVEI can indeed improve PIVC for both experts and non-experts. The success rate of expert subjects was found to increase from 33.3% to 75%, and for non-experts subjects, the average success rate

increased from 58.3% to 69.4%. This indicates that on one hand even for clinicians with many years PIVC experiences they may still need such device's assistance to have guaranteed first-stick accuracy; on the other hand, SVEI could be very beneficial to beginners as it can help them achieve considerably high success rates within short time of training. The appreciation of SVEI was also corroborated by the results of the system usability analysis, which depicted SVEI as well designed and easy to learn.

In short, this study shows that even a simple hand-held device like SVEI can have a large impact on the success rate of pediatric PIVC, potentially bringing significant benefits to patients and practioners alike.

Future work will invite more subjects (both Experts and Non-Experts) to the user-trails study. Also, we will ask the participants to be more patient and careful in order to collect more valid data for comparison.

Chapter 9

General conclusions and recommendations for future work

This chapter presents conclusions regarding to the work described in this doctoral dissertation. The main contributions are summarized, followed by some suggestions regarding future directions of research related to this work.

9.1 Conclusions

This dissertation reports on the development and evaluation of dedicated robotic technology aimed at assisting clinicians in performing PIVC on pediatric patients in a safe and successful manner. The key findings and novel contributions of this dissertation are listed below.

- This research work is targeted to design a hand-held robot for addressing the challenge of inserting the catheter precisely into the vein without puncturing through it. Venous entry detection is a very critical but challenging process during a PIVC operation. Firstly, this was mentioned as one of the biggest difficulties in the PIVC operation according to the survey study (Chapter 3). Secondly, through comparing the experimental results between robot-assisted PIVC and unassisted PIVC in Chapter 7 and 8, it clearly shows that when

the venous entry was indicated during the PIVC operation, the success rates of PIVC were significantly improved.

- At the beginning of this research work, a survey was conducted with specialists in the hospital to obtain perspectives related to the difficulties faced during pediatric PIVC and user requirements for an assisted device. Based on the received feedbacks from this survey, the design objective of providing robotic assistance of venous entry detection during PIVC operation was confirmed. In addition, this survey also resulted in suggestions for a preferred shape of device holder.

- Prior developments on venipuncture detection methods have been thoroughly investigated. It was found that these methods are not suitable for being integrated into a hand-held robot or adapted to pediatric PIVC. Therefore, in this research work, a novel venipuncture detection system was proposed based on sensing the electrical impedance at the needle tip. Subsequently, this system was characterized to ensure it could provide accurate and fast sensing. Furthermore, a preliminary human test and animal experiments were conducted to verify this detection system. The promising results that were obtained demonstrated that this system can effectively identify blood from the other surrounding tissue during a PIVC insertion so it was deemed appropriate for the PIVC application. In addition, the electrical-impedance-sensing based venipuncture detection system was found to be compact, cheap and can be easily compatible with the hand-held approach.

- Based on this venipuncture detection system, 4 hand-held robotic devices were developed aiming to enhance and deskill the PIVC procedure. The hand-held approach was selected for the robot design because it facilitates the design for allowing PIVC on flexible insertion sites, has a physically smaller footprint, and allows the clinician to be involved throughout the operation.

- The first developed device is called the SVEI. It integrates an LED to indicate

venous entry. After a prototype was made, SVEI was validated. It was proved to possess fast and accurate electrical impedance sensing. The design is light weight, cordless and can be easily gripped for operation.

- The second device is called the SDOP. It can detect venipuncture and prevent over-puncture with a disengage mechanism. The characterization of SDOP shows that the device has a fast response and low internal friction, allowing to effectively disconnect the handle and the catheter for avoiding overshoot.

- The third device is called the SAID. It integrates a stepper motor for providing enhanced insertion control. SAID was characterized and proved to have fast response with 21.6 ms response time and 0.67 mm overshoot distance. Then, a series of user trial experiments were conducted involving human subjects (Section 6.4.3). During the experiments, the subjects were asked to perform PIVC trials on a realistic phantom with SAID or with a regular iv catheter. The results of the comparison showed that SAID can help naïve subjects achieve a considerably high success rate (88%) compared to those who did not use the device (12%).

- The final hand-held robotic device designed during this research explores the automatic approach for catheterization. CathBot was developed to convert the complicated catheterization motion to a simple pushing-forward motion. After the development, it was mounted on a motion stage for validation. The motion stage was used to simulate the user's hand motion to push the handle of CathBot forward. This test was repeated 5 times and the results were highly convincing as in all trials CathBot was able to successfully insert a cannula into a realistic baby arm phantom and retract the needle.

- This dissertation also describes preliminary experiments conducted to evaluate all the developed hand-held robotic devices (SVEI, SDOP, SAID and CathBot) with naïve subjects and a realistic baby arm phantom (Chapter 7). A control group using a regular iv catheter to do the same task was also part of the ex-

periment. The experimental results showed that all the developed devices could significantly improve the PIVC performance in terms of average success rate, first-stick accuracy and mean number of trial before the first attempt. Among these four robotic devices, subjects assisted by SVEI achieved the highest average success rates. Also, CathBot was found to be highly effective for assisting the insertion depth control as the failure rates related to (OS and US) were the lowest.

- Finally, a pre-clinical study to evaluate SVEI was conducted. Medical personnel including PIVC experts and non-experts were invited to perform PIVC on a baby arm phantom with SVEI and a regular iv catheter. The comparison of the experimental results of SVEI-assisted PIVC and unassisted PIVC clearly showed that SVEI can greatly improve the PIVC performance for both experts and non-experts. Thanks to the enhanced venipuncture detection provided by SVEI, the average success rate increased from 48.3% to 71.7%, and less overshoot and undershoot failures occur. Feedback received from questionnaire investigation also revealed highly positive assessment of SVEI under various aspects of usability.

9.2 Recommendations for future work

The contributions in this dissertation can lead to new lines of research in the areas of robot-assisted surgery applied on needle-based diagnosis and treatment procedures. Below several potential directions to improve this study are listed:

9.2.1 Further optimization of the robotic devices

Hand-held devices require the robotic technology to be of low complexity and compact. It should also exploit cooperation between the clinician and robot for the benefit of the operation as illustrated in Section 6.1 and Section 6.4.3. Hence, further optimization of the robotic devices are required in order to make the devices more

compelling for clinical use. An iterative design procedure could be done involving potential users in the design cycle for suggesting more ergonomic and user-friendly features. Some possible development directions for each device are listed as below.

- One very important perspective of the future design is related to the device fabrication. The fabrication of the devices should follow relevant regulation for medical equipments including material selection, manufacturing process and sterilization requirements. In addition, some components of the designed robotic devices should be further optimized in order to facilitate mass production.

- The holding part of the concentric electrode needle used in this study does not match the hub of the cannula (Figure 5-7), and thus an adapter is needed. In the future, the CEC will be customized to avoid the need for such an adaptor.

- SVEI is the device which is closest to be commercialized. The further development of SVEI could focus on making the device smaller, cheaper and more user-friendly.

- The next step for SDOP will focus on miniaturizing the device. Also, the sterilization of the current design could be a bit tricky (see Section 6.3.2). Except that the CEC is disposed after use, it requires a special drape with rubber bands to cover the device. A further structural optimization is required so that the device can be easily sterilized. Another future direction is to apply the concept of a disengage mechanism to the other related robot-assisted needle insertions, in which overshoot is strictly forbidden.

- The future development of SAID would be focused on reducing the effect from the user hand motion. As suggested in Section 7.5, a support mechanism will be added, whilst still maintaining the hand-held nature of the device.

- CathBot can be another potential clinical device which can greatly facilitate the PIVC procedure for non-experts. However, a casing is needed in order to cover the device for sterilization purpose.

9.2.2 Clinical translation

In the previous chapters, several realistic phantoms were used during the development and validation of the developed technologies. Also, animal experiments and a preliminary human test were conducted to validate the core sensing technology for venipuncture detection, i.e., the electrical impedance sensing system. However, translating the presented technology to the final clinic utility still requires further validations in both technical and clinical perspectives. Since the developed devices belong to the III class medical device according to the European Council Directive 93/42/EEC (MDD), strict technical qualification tests will be conducted in order to fulfil the international standards such as IEC 60601-1, ISO 13485, and ISO 14971 before obtaining the CE premarket approval. Furthermore, more systematic tests on peripheral veins of humans are essential for demonstrating the effectiveness of the developed technologies.

Appendix A

Figures

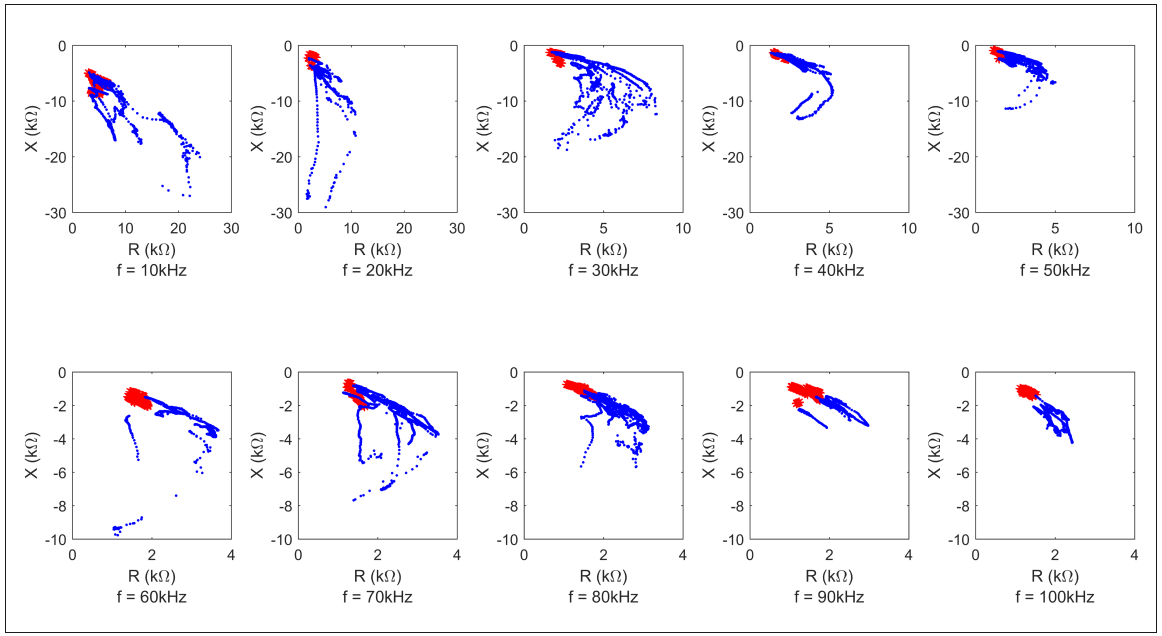

Figure A-1: The measured bio-impedances (R_t and X_t) whilst a CEN was inserted into a rat's tail vein with different excitation frequency (f = 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 kHz) are plotted. The blue dots are the measured bio-impedance of skin and the red stars are the measured bio-impedance of blood. (There are 4375 blood sample points + 2576 skin sample points in f=10 kHz, 4832 blood samples points + 1482 skin sample points in f=20 kHz, 3311 blood samples points + 1650 skin sample points in f=30 kHz, 3804 blood samples points + 2736 skin sample points in f=40 kHz, 3313 blood samples points + 3776 skin sample points in f=50 kHz, 5622 blood samples points + 1018 skin sample points in f=60 kHz, 2764 blood samples points + 2607 skin sample points in f=70 kHz, 3883 blood samples points + 3420 skin sample points in f=80 kHz, 4049 blood samples points + 1129 skin sample points in f=90 kHz, 4832 blood samples points + 1189 skin sample points in f=100 kHz.)

Appendix B

Tables

Table B.1: Comparing different state-of-the-art robots for PIVC operation.

Automation level	Robotic system	Vein localization method	Venous entry detection method	Pros	Cons
Fully autonomous PIVC robots	BloodBot [73]	palpation	insertion force	It operates PIVC automatically.	It requires the body part to remain stable during the whole procedure.
	HaemoBot [5]	Near-Infrared	insertion force	It operates PIVC automatically.	It is very heavy and expensive. It requires the body part to remain stable during the whole procedure.
	Veebot [54, 24]	Infrared	ultrasound	It is a mobile platform and perform autonomous PIVC.	PIVC insertion guided by ultrasound requires complicated algorithm.
	VenousPro [9, 2]	3D Infrared	3D Infrared & Ultrasound	It is a portable robot that performs autonomous PIVC.	It needs to be placed on a table for operation. It requires expensive software and hardware.
	Maguire & Chen [44]	3D Infrared	3D Infrared	It is relatively small and perform nearly autonomous PIVC.	It could be hard for sterilization.
	De Boer *et al.* [14]	ultrasound	insertion force	It is relatively small and perform nearly autonomous PIVC.	The venipuncture detection based on insertion force could be unreliable.
Hand-held robot	SAGIV [16]	Near-Infrared	blood pressure	It is relatively cheap and has small size.	It requires the user to hold the robot, target a vein and control the robot.

Table B.2: Comparing different state-of-the-art clinical devices for PIVC operation.

Automation level	Robotic system	Vein localization method	Venous entry detection method	Pros	Cons
Clinical device	Ultrasound probe [65]	ultrasound	ultrasound	Ultrasound probe can displace the location of the vein and the IV catheter in real time.	It is expensive, and requires the user to pass specific trainings.
	VeinViewer [8] & VeinLite [32]	Infrared	Not applicable	It is cheap and can highlight the vein's location.	It can not provide the depth information of the vein and the IV catheter.
	Love *et al.* [42]	Voice coil	insertion force	It demonstrates the possibility to use palpation for locating a vein and to use the insertion force for venous entry detection.	It did not result to a real integrated device.
	Okuno *et al.* [51]	Not mentioned	insertion force	It shows a possibility for detecting venipuncture through sensing a change on the insertion force.	Not all the results were consistent.
	VEID [60]	Not applicable	blood pressure	It is cheap and simple. It is demonstrated to detect venous entry effectively.	It may not be suitable for patient with low blood pressure. The sensor may contact blood during its use.

Table B.3: Comparing the 4 hand-held robotic devices developed in this study.

Device	**Integrated mechanism**	**Advantages**	**Disadvantages**
SVEI	An LED	Simple and cheap	The user needs to operate the whole PIVC procedure
SDOP	A latch mechanism	The operation of SDOP is intuitive, and it can prevent overshoot.	The user needs to operate the whole PIVC procedure
SAID	A linear motor	The PIVC operation with SAID is simple and SAID can automatically stop catheter insertion after venipuncture.	The SAID-assisted PIVC operation requires the user to keep the operating hand not moving during the insertion.
CathBot	A crank-slider mechanism	The PIVC operation using CathBot is simple and safe.	The device is complicated and relatively expensive

Appendix C

Questionnaire for survey investigation (English)

Questionnaire about the Procedure of Catheterization

Personal Information

Index		Job title
Age	Gender	

How many years have you worked on catheterization?	
How many patients have you operated intravenous catheterization per day?	
How many hours per day you need to operate the catheterization?	

We will ask you to answer some questions regarding the requirements for the use of devices designed to assist intravenous catheterization. For each question you can provide more than one answer.

The areas highlighted in red will be the maditory questions, while the green areas will be the voluntory questions.

1. Which kinds of patients are difficult for catheterization?

Category of patient : _____Neonate_____

Typical number of trials before a successful insertion	
Number of operators that required	

- Reason:

  _____

- Typical solution to increase insertion accuracy:

  _____

- Typical insertion sites:

  _____

- Reaction of the patients:

  _____

Category of patient : _____

Typical number of trials before a successful insertion	
Number of operators that required	

- Reason:

  _____

- Typical solution to increase insertion accuracy:

  _____

- Typical insertion sites:

  _____

- Reaction of the patients:

  _____

2. For doing operation on the following groups of patients, which insertion site is more difficult for the operation? Why?

Neonates and babies less than 2 years old

Please mark the table below, from “easy” on the left to “difficult” on the right.

Insertion site	Easy						Difficult
Scalp							

Why?

_____

Insertion site	Easy						Difficult
Back of the hand							

Why ?

_____

Insertion site	Easy						Difficult
Inner side of the wrist							

Why?

_____

Insertion site	Easy						Difficult
Arm							

Why?

_____

Insertion site	Easy						Difficult
Leg							

Why?

_____

Are there any other difficult insertion sites for this group of patients? why?

_____

3. Please rate the difficulties and list your strategies for the following procedures of the intravenous insertion..

Please mark the table below, from “easy” on the left to “difficult” on the right.

Procedure	Easy						Difficult
Find a good insertion site							

Do you have some strategies to address that if it is difficult?

_____

Procedure	Easy						Difficult
Perceive venipuncture							

Do you have some strategies to address that if it is difficult?

_____

Procedure	Easy						Difficult
Avoid the vein sliding away during insertion							

Do you have some strategies to address that if it is difficult?

_____

Procedure	Easy						Difficult
Notice if the catheter correctly enters the vein							

Do you have some strategies to address that if it is difficult?

_____

Procedure	Easy						Difficult
Advance the cannula into the vein							

Do you have some strategies to address that if it is difficult?

_____

Procedure	Easy						Difficult
Retreat the needle							

Do you have some strategies to address that if it is difficult?

_____

Procedure	Easy						Difficult
Find the patient dehydrate							

Do you have some strategies to address that if it is difficult?

_____

Please tell us other possible procedures that have difficulty in intravenous catheterization?

_____

4. Do you use any assistive device during the intravenous catheterization?

Device	Function

Could you please tell us whether you think that device is useful? Please mark the table below, from "extremely useless" on the left to "extremely useful" on the right.

Extremely useless						Extremely useful

Device	Function

Could you please tell us whether you think that device is useful? Please mark the table below, from "extremely useless" on the left to "extremely useful" on the right.

Extremely useless						Extremely useful

5. Could you please tell us how do you perceive the venipuncture:

Please mark the tables below to show the importance of the detection methods, from "Not Importance" on the left to "Very Important" on the right.

	Not importance				Very importance		
Haptic sensing on the needle							

	Not importance				Very importance		
Observing blood flashback to the needle hub							

	Not importance				Very importance		
Observing the deformation of skin							

Are there any other methods for you to perceive the venipuncture?

_____

6. What is your subjective experience of the operation after a difficult catheterization?

Please mark the table below, from “definitely no” on the left to “definitely yes” on the right..

Subjective experience	Definitely no						Definitely yes
Nervous							

Subjective experience	Definitely no						Definitely yes
Stressful							

Subjective experience	Definitely no						Definitely yes
Tired							

Can you write down if you have any other feelings after a difficult catheterization?

7. If there is a device to assist the intravenous catheterization, how do you prefer to hold it? The clay will be provided for you to model your favorite shape of the handle for that device.

8. Could you please give us some comments about designing a hand-held tool for intravenous catheterization?

Appendix D

Questionnaire for survey investigation (Italian)

Questionario su Procedure di Cateterizzazione

Informazioni personali

Numero Partecipante		Professione
Età	Genere	

Da quanti anni impieghi procedure di cateterizzazione?	
Quanti pazienti sottoponi a cateterizzazione intravenosa al giorno?	
Per quante ore al giorno effettui questo tipo di intervento?	

Ti chiederemo di rispondere ad alcune domande riguardanti i requisiti per l'uso di dispositivi progettati per assistere la cateterizzazione intravenosa. Per ciascuna domanda potrai fornire più di una risposta.

Le aree evidenziate in rosso costituiranno lo spazio in cui potrai scrivere la tua risposta, mentre le aree in verde ti permetteranno di fornirci ulteriori informazioni in risposta ai quesiti.

1. Che tipo di pazienti presentano difficoltà nella cateterizzazione?

Categoria di pazienti: _____Neonato_____

Numero tipico di tentativi andati a buon fine	
Numero di operatori necessario	

- Motivazione:

  _____

- Soluzioni Tipiche:

  _____

- Sito di inserimento dell'ago:

  _____

- Reazioni del Paziente:

  _____

Categoria di pazienti: _____

Numero tipico di tentativi andati a buon fine	
Numero di operatori necessario	

- Motivazione:

  _____

- Soluzioni Tipiche:

  _____

- Sito di inserimento dell'ago:

  _____

- Reazioni del Paziente:

  _____

2. Per effettuare operazioni sui seguenti gruppi di pazienti, quale punto di inserzione è più difficoltoso per l'operazione? Perchè?

Neonati e bambini sotto i 2 anni

Segna quale casella corrisponde alla tua valutazione, da "Facile" per la casella più a sinistra a "Difficile" per la casella più a destra.

Sito di inserzione	Facile						Difficile
Testa							

Motivi?

_____

Sito di inserzione	Facile						Difficile
Dorso della mano							

Motivi?

_____

Sito di inserzione	Facile						Difficile
Lato interno del polso							

Motivi?

_____

Sito di inserzione	Facile						Difficile
Braccio							

Motivi?

_____

Sito di inserzione	Facile						Difficile
Gamba							

Motivi?

_____

Esistono altre difficoltà per questo gruppo di pazienti? Perché?

_____

3. Per favore valuta i seguenti punti critici nelle procedure di cateterizzazione in termini di difficoltà, ed elenca le tue strategie per risolverli.

Segna quale casella corrisponde alla tua valutazione, da "Facile" per la casella più a sinistra a "Difficile" per la casella più a destra.

Procedura	Facile						Difficile
Trovare un buon punto di inserzione							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Procedura	Facile						Difficile
Percepire l'avvenuta puntura							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Procedura	Facile						Difficile
Evitare che la vena scivoli durante la puntura							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Procedura	Facile						Difficile
Notare l'avvenuta puntura lungo la vena corretta							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Procedura	Facile						Difficile
Percepire l'avanzare del tubetto per la cateterizzazione nella vena							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Procedura	Facile						Difficile
Ritirare l'ago							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Procedura	Facile						Difficile
Percepisci se il paziente è disidratato							

Hai strategie per superare questa criticità in caso presenti eccessiva difficoltà?

_____

Potresti per favore indicarci altre possibili procedure che presentano difficoltà nella cateterizzazione intravenosa?

_____

4. Usi dispositivi che assistano la cateterizzazione intravenosa?

Dispositivo	Funzione	Gruppi di pazienti per i quali è utilizzabile

Quanto ritieni che questo dispositivo sia utile? Segna quale casella corrisponde alla tua valutazione, da "Decisamente Inutile" per la casella più a sinistra a "Decisamente Utile" per la casella più a destra.

Decisamente Inutile						Decisamente Utile

Dispositivo	Funzione	Gruppi di pazienti per i quali è utilizzabile

Quanto ritieni che questo dispositivo sia utile? Segna quale casella corrisponde alla tua valutazione, da "Decisamente Inutile" per la casella più a sinistra a "Decisamente Utile" per la casella più a destra.

Decisamente Inutile						Decisamente Utile

5. Valuta per favore l'importanza del tuo modo di percepire (visivamente o tattilmente) la venipuntura:

Segna quale casella corrisponde alla tua valutazione, da “Poco importante” per la casella più a sinistra a “Molto importante” per la casella più a destra.

	Poco importante						Molto importante
Sensazione tattile di aver bucato la cute							

	Poco importante						Molto importante
Osservazione del sangue nella camera di visualizzazione							

	Poco importante						Molto importante
Osservazione della deformazione della pelle durante l’inserzione							

Esistono altri metodi che useresti per percepire la venipuntura?

6. Qual è la tua esperienza soggettiva dopo una difficile cateterizzazione?

Segna quale casella corrisponde alla tua valutazione, da “Decisamente no” per la casella più a sinistra a “Decisamente sì” per la casella più a destra.

Esperienza soggettiva	Decisamente no						Decisamente sì
Nervosismo							

Esperienza soggettiva	Decisamente no						Decisamente sì
Preoccupazione							

Esperienza soggettiva	Decisamente no						Decisamente sì
Stanchezza							

Potresti indicare eventuali altri stati d’animo vissuti solitamente dopo una difficile cateterizzazione?

7. Se esistesse un dispositivo per assistere la cateterizzazione intravenosa, come preferiresti impugnarlo? Ti verrà fornito ora del materiale plastico da modellare per mostrarci la forma ideale dell’impugnatura per tale ipotetico strumento.

8. Potresti per favore fornirci alcuni suggerimenti per progettare un dispositivo che possa realmente agevolare la procedura di cateterizzazione intravenosa?

Appendix E

Blood flashback time for a 26G needle

The Poiseuille's Law (E.1) is applied to calculate the blood flow rate.

$$Q = \frac{\pi p r^4}{8\eta L} \ . \tag{E.1}$$

where p is the pressure difference, r is the inner radius of the needle tube, η is the viscosity of blood, and L is the length of the needle tube. In addition, the volume of the needle tube is

$$V = \pi r^2 L \ . \tag{E.2}$$

Hence, the time for blood to flow through a 26G needle tube can be calculated as:

$$t = \frac{V}{Q} = \frac{8\eta L^2}{p r^2} \ . \tag{E.3}$$

Given $p = 50\ mmHg = 6666.12\ N/m^2$ [3], $r = 0.13\ mm$, $\eta = 2.78\ mPa/s$ and $L = 44\ mm$, the flow time results in $t = 0.38\ s$.

Appendix F

Modelling needle insertion force during insertion into soft tissue

Modelling needle forces during insertion into soft tissue

Zhuoqi Cheng*, Manish Chauhan, Brian L. Davies, Darwin G. Caldwell and Leonardo S. Mattos

***Abstract*— Robot-assisted needle-based surgeries are sought to improve many operations, from brain surgery to spine and urological procedures. Force feedback from a needle can provide important guidance during needle insertion. This paper presents a new modelling method of needle force during insertion into soft tissue based on finite element simulation. This is achieved by analysing the results of a series of needle inserting experiments with different insertion velocities. The forces acting on the needle are then modelled based on the experimental results. A simulation is implemented to verify the designed model.**

I. Introduction

Surgical robots are now commonly used in hospitals for providing better surgical performance. Many studies illustrate that robot-assisted surgery can result in better outcomes compared to manual surgery [1]. One example is medical needle intervention, a common but high challenging technique used for accessing tissue structures. Robot-assisted needle-based surgery has been developed and applied in many operations such as fetal hypoplastic left heart syndrome [2] and brachytherapy seeds implanted inside the prostate [3]. Another example is intravenous operation: patients may be stabbed several times before the needle is successfully inserted and there is often great variation in needle insertion skills among medical personal. To reduce the dependence on skilled technicians, decrease procedure time, and reduce errors during intravenous needle and cannula insertion procedures, Harris *et al*. developed an autonomous intravenous robot called Veebot which is able to insert a hypodermic needle into a pre-selected vein. [4]

For effective performance, an automatic intravenous robot requires feedback for vein targeting, needle localization and needle steering. Needle insertion force is a significant variable since it can imply information about insertion depth and trajectory. It can also help to identify and model different tissue types and provide feedback for precise control during robotic needle insertion by enabling reduced tissue deformation and needle deflection [5]. Previous studies [6] also indicate that needle insertion force shows an obvious drop at the moment when it punctures through the vein wall, which is an useful information for automatic control.

Since information about the forces acting on the needle can play an important role in precise needle insertion control, it is necessary to have an accurate model of such forces to be able to properly design a detection and identification system. In addition, it is desirable to model the magnitude of the insertion force such that it can accurately match the actual measurements [7], especially for applications based on predictive force control. For example, haptic feedback can greatly improve needle-based procedures and in such systems reliable models can be valuable to minimize problems related to inaccurate force measurements or latencies. [8]

In order to understand the force changes on the needle during insertion into homogeneous soft tissue, this paper presents a method for modelling and simulating such forces. A series of needle insertion experiments on bio-mimetic phantoms are conducted. Based on the experimental data, the force acting on the needle is analysed and modelled using a finite element method. This paper is arranged as follows. A needle insertion force model with theoretical analysis is introduced in Section II. In Section III, an experiment is designed and conducted to measure the needle insertion force. The measured force information is then used for the model design in Section IV. In addition, a finite element method is also utilized for the modelling simulation. Discussion and conclusions are provided in Section V.

II. Characterization of Needle Insertion Force

Techniques to model needle insertion force have been explored in previous studies. Brett *et al*. [9] tested the needle insertion force on three material samples, namely, skin layer, fatty/loose muscle tissue and ligamentum flavum. These three components were then combined to obtain the force during the whole insertion procedure. Fukushima and Naemura developed a visualization system to represent the needle tip force using a recursive least squares method and a disturbance observer [10].

Okamura *et al*. [11] used experiments to populate theoretical models of force involving stiffness, friction, and cutting. Their study indicates that the total force acting on the needle f_{needle} can be divided into three variables: cutting force, stiffness force and friction.

$$f_{\text{needle}}(z) = f_{\text{cutting}}(z) + f_{\text{stiffness}}(z) + f_{\text{friction}}(z) \qquad (1)$$

where z is the displacement of the needle tip. Specifically, the cutting force f_{cutting} denotes the force that sustains the tissue fracture during needle insertion while the stiffness

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force $f_{\text{stiffness}}$ is the force caused by the tissue's deformation. Friction f_{friction} exists between the needle and tissue due to the tissue's clamping effect. Furthermore, according to their analysis, after puncture of the capsule, the stiffness force becomes zero. Thus, a modified Karnopp friction model is used to describe the friction where the cutting force is described as a constant. The values of cutting force and friction are affected by the needle insertion velocity, but if the velocity is constant during the insertion, these two forces remain constant.

The study of Okamura *et al*. [11] provides a very good framework for understanding the needle insertion forces. However, there are several shortcomings in their model. First of all, the tissue's viscous effect, which is very important during needle insertion, is not emphasized. Secondly, the three force component models are fitted to the experimental results without considering their scientific understanding.

In this paper, previous models are reconsidered and a simulation based on the finite element method is proposed in order to have a better understanding of the forces acting on the needle during insertion. Experiments are first performed to obtain force information on the needle. Subsequently, different force components are analysed and corresponding models are built. The tissue's viscous effect during needle insertion is emphasized. Simulation is then performed to verify the proposed model. Primarily, three assumptions are made for this study:

- Single material and homogeneous phantoms are used to simulate muscle tissue;
- The needle is perpendicular to the tissue surface and moves along its axis;
- Only needle axial force is considered.

III. Needle Insertion Force Measurements

A series of experiments were designed and performed to measure the needle insertion force. Results were used to provide evidence for the modelling in Section IV.

A. Experiment Design

The experiments measured the total force on the needle with respect to the absolute needle displacement. There are two main considerations in this experiment.

The first consideration is that the needle insertion forces are measured with respect to the needle absolute displacement (z in Eq. 1) rather than relative insertion depth, although the relative insertion depth of needle has more physical meaning. However, due to the deformation of the tissue during needle insertion, the relative insertion depth could be not only very difficult to obtain, but also difficult to use. In contrast, the needle's absolute displacement is more straightforward. Hence, the total force f_{needle} on the needle is recorded with the absolute needle displacement z as illustrated in Fig. 1. Here, the experiment is designed with a 15 mm stroke.

Secondly, for each insertion, the velocity is set as a constant in order to maintain a constant fracture force [12]. In addition, the experiment was first tested at very low velocity

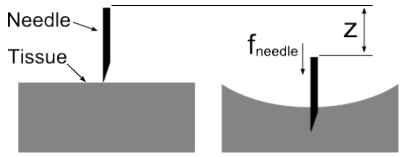

Fig. 1. The experiment is designed to measure the needle insertion force with respect to the absolute needle displacement.

(0.03 mm/s). This was done to minimize the effect of velocity on the insertion force. Subsequently, it was repeated with various insertion velocities (0.3 mm/s, 0.9 mm/s, 1.5 mm/s and 2.1 mm/s) for a better understanding of the influence of velocity on the needle insertion force.

B. Experimental Setup

The experimental setup can be seen in Fig. 2. A servo linear stage (7600-XYZR, Siskiyou Corp., USA) was used to insert the needle into the tissue. A normal hypodermic medical needle (bevel tip, $\phi = 0.9$ mm) was used and attached to an uniaxial force sensor (FSG005WNPB, Honeywell, USA). This force sensor was used to measure the force along the insertion direction which was equivalent to the effective force on the needle. The phantom samples were 30 mm in diameter and 20 mm high. A silicone-based material was used to build a phantom whose mechanical properties are similar to porcine soft tissue (muscle) according to previous studies [13].

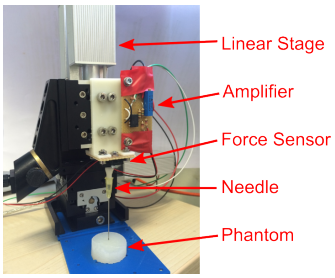

Fig. 2. Experimental set-up for measuring needle insertion force.

C. Experimental Result and Discussion

The experimental results are shown in Fig. 3. The graph shows the total needle insertion force during the whole insertion procedure which starts from the needle tip touching the phantom surface and ends after an absolute displacement downwards of 15 mm. The yellow circle represents the needle insertion force with respect to its displacement in almost static motion (v = 0.03 mm/s), while the red dot, green cross, blue plus and black star represent respectively the results associated to the different insertion velocities of 0.3 mm/s, 0.9 mm/s, 1.5 mm/s and 2.1 mm/s.

According to the results, two conclusions can be drawn. Firstly, the cutting force is shown to be small compared to friction and stiffness force because the needle insertion force does not have an obvious jump when tissue is fractured. This conclusion can be physically understood because the

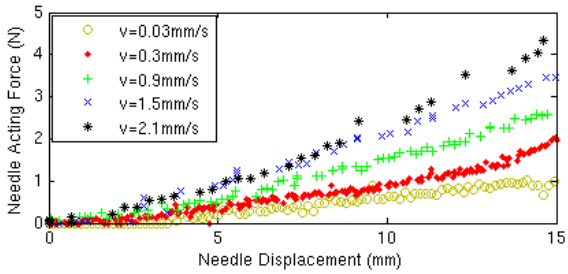

Fig. 3. Experimental results of the needle insertion force

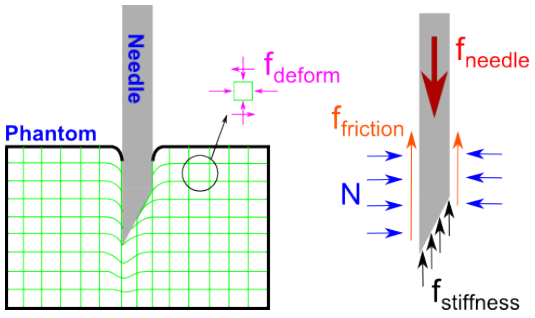

Fig. 4. For the finite element model, f_{deform} represents the stresses on the phantom element during the needle insertion. f_{needle} is considered as the sum of $f_{\text{stiffness}}$ and f_{friction}. $f_{\text{stiffness}}$ is the force acting vertically on the bevel tip due to phantom deformation. Besides, since the phantom is firmly clamping on the needle (N represents the normal force acting on the needle surface), the friction f_{friction} is generated.

diameter of needle is tiny and its bevel is designed to be very sharp so that it ensures effortless tissue cutting. Secondly, besides the fracture force, the needle insertion velocity shows an obvious influence on the friction: the difference between curves under different velocities increases with the insertion depth. This phenomenon can be understood as a viscous friction effect.

IV. MODELLING NEEDLE INSERTION FORCE USING FINITE ELEMENT METHOD

Based on the experimental results above, a new method to understand and simulate the needle insertion force using finite element method is proposed.

A. Modelling of Forces Acting on the Needle

As discussed above, the forces on the needle depend on the insertion velocity into the bio-mimetic phantom. According to the study [11], the needle insertion force f_{needle} can be understood as a combination of force for cutting the phantom f_{cutting}, force for overcoming tissue stiffness $f_{\text{stiffness}}$ and force for resisting the friction f_{friction}. However, since the cutting force barely has a magnitude associated with it, it is neglected in the following simulation and the model becomes:

$$f_{\text{needle}} = f_{\text{stiffness}} + f_{\text{friction}} \tag{2}$$

Here, $f_{\text{stiffness}}$ is defined as the force that results from the reaction force acting on the bevel tip of the needle due to the phantom deformation. The bio-mimetic phantom is a rubber-like hyper-elastic material with similar nonlinear deformation behaviour as human muscle tissues [13]. This is due to the elastic properties of the tissue structure and also to collision with and puncture of the inner structures. As can be seen in Fig. 4, $f_{\text{stiffness}}$ is the force needed to overcome the reaction force on the needle's tip by the deformed phantom.

A finite element mesh is applied to the phantom, and $\{f_{\text{deform}}\}$ is the stress matrix applied to the phantom elements. During needle insertion, the phantom is squeezed by the needle, and the finite element model can be expressed as:

$$[K]\{U\} = \{f_{\text{deform}}\} \tag{3}$$

where $\{U\}$ is the strain matrix of the elements; and $[K]$ is the stress-strain matrix of the phantom. In this paper, the Mooney-Rivlin model is applied [14] for modelling the bio-mimetic phantom. In continuum mechanics, the MooneyRivlin model is commonly used to describe a hyper-elastic material whose strain energy density function is a linear combination of two invariants of the left Cauchy-Green deformation tensor. Based on this model, $f_{\text{stiffness}}$ can be calculated through finite element simulation while the tissue deformation is highly complicated during needle insertion.

f_{friction} is estimated from an understanding of the viscous and damping friction. Since the damping viscous force is a function of the velocity of needle insertion, the two components (static friction and kinetic friction) affect its magnitude. As the needle tries to enter the tissue and penetrate the surface, the stiffness of the tissue surface opposes the needle motion. This opposition force is modelled in the static friction component $f_{\text{s}}(z)$. Meanwhile, as can be observed from the experimental results, the friction force increases with the needle insertion velocity. Hence, there should be another kinetic friction component $f_{\text{k}}(v, z)$ that contributes to the energy dissipation.

$$f_{\text{friction}}(v, z) = f_{\text{s}}(z) + f_{\text{k}}(v, z) = \mu_s N + \mu_k N \tag{4}$$

where μ_s and μ_k are the friction coefficient of the static friction and kinetic friction respectively. In addition, N represents the normal force acting on the needle surface from the phantom surface which can be seen in Fig. 4. This force is perpendicular to the direction of motion of the needle.

Furthermore, to include the sliding velocity between mating surfaces in the kinetic friction, the kinetic friction coefficient can be written as

$$\mu_k = \eta v \tag{5}$$

where the proportionality factor η is known as the damping constant. Thus, Eq. 4 can be written as

$$f_{\text{friction}}(v, z) = (\mu_s + \eta v)N \tag{6}$$

B. Model Construction and Simulation

As specified in the model proposed above, during the needle insertion, the phantom deformation and the normal force N are changing in a complicated way. The finite element method is considered to be a very powerful tool to simulate the proposed needle insertion model. Because

the amount of the cutting force is small, it is ignored in this model. Without the cutting force, the needle penetration can be considered as frictional sliding with the crack propagation neglected. Ansys software is then chosen to construct the model and simulate the combined force of the friction and stiffness force on the needle during insertion.

Fig. 5 shows the 3D modelling of needle and phantom. The 3D model is designed and built as a half portion such that it is possible to implement interference contact between needle and tissue. The phantom model is built as a block with 20 mm long, 10 mm wide and 20 mm height while the needle is modelled as a half section of normal hypodermic needle (diameter: 0.9 mm, bevel tip angle: 20°, length: 20 mm).

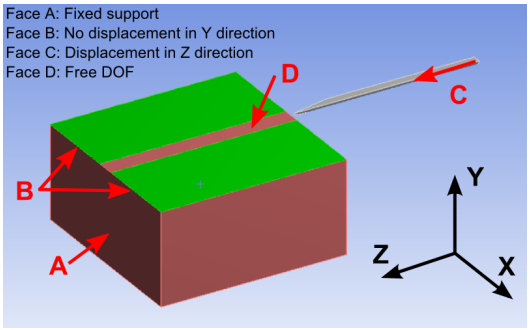

Fig. 5. Finite element model of needle inserting into phantom. The brown block represents the phantom while the silver half cylinder represents the needle. In the Ansys DOF restriction, Face A is set with fixed support. The top surface of the phantom model is splitted into three areas with two green facets (Face B) setting no displacement in Y direction and the middle area (Face D) free of DOF. The rightist section face of the needle model is set with a $15mm$ displacement in Z direction.

As indicated in Fig. 5, the left face of the phantom (A) is a fixed support while the needle (C) can only move along the Z axis and insert into the phantom for 15 mm. The top face of the phantom model is separated into 3 areas. Two areas shown in green (B) are restricted without displacement in Y axis while the remaining middle area (D) is free. The purpose of this design is to make the simulation closer to the real situation. During the simulation of insertion, the needle is immersed into the phantom and the deformed phantom should firmly clamp on the needle. The width of the middle area D is set to be 2 mm in order to ensure result convergence.

As stated above, the phantom model is defined with hyper-elastic material where the Mooney-Rivlin model is applied. Material constant $C10$ and $C01$ is set as 0.8 MPa and 0.16 MPa (silicon soft rubber). Besides, the needle is modelled using structural steel, whose Young's Modulus is 2e5 MPa and Poisson's Ratio is 0.3.

C. Simulation Result

According to the modelling analysis above, the static friction coefficient μ_s is found to be 0.05. In addition, the friction coefficients are changed for the kinetic part with η = 0.08. The red, green, blue and black curves shown in Fig. 6 represent the simulation results of the needle insertion force with different insertion velocities: 0.3 mm/s, 0.9 mm/s, 1.5 mm/s and 2.1 mm/s respectively. Compared to the experimental results in Section III, the simulation of the model confirms that the experimental results are dependent upon the needle insertion velocity.

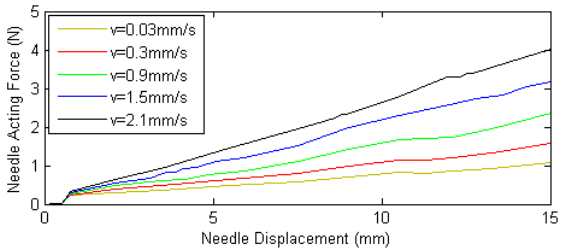

Fig. 6. Simulation results of needle insertion force at different insertion velocities.

V. Discussion and Conclusions

This paper has presented a model design and simulation for understanding the forces acting on the needle during its insertion into homogeneous soft tissue. Finite element simulation and viscous effects are used to model the needle insertion force. A series of experiments were conducted at various insertion velocities. Subsequently, the experimental results are analysed and used for model construction. Then a finite element simulation is presented based on this designed model. The simulation is implemented and demonstrates the validity of this designed model. The conclusion from this modelling and simulation is that by observing the insertion velocity and needle insertion force, the insertion depth of needle can be estimated, which can be highly beneficial in the control of robot-assisted needle insertion surgery. Also the simulation is novel compared to other previous work in that it includes the effects of velocity, giving a closer approximation to measured tissue forces.

Although the simulation matches the experimental results, there are still many aspects of this work that can be improved. Currently, only homogenous bio-mimetic phantoms have been used in the experiment. Animal tissue will be tested in the next step to provide a closer relationship to reality. In addition, some simulation coefficients were designed by trial and error, and in future these will be measured more scientifically. Also, the lateral force on the needle due to its bevel tip effect will be studied in order to improve the design model.

Acknowledgment

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References

[1] G. Barresi, N. Deshpande, L. S. Mattos, A. Brogni, L. Guastini, G. Peretti, and D. G. Caldwell, "Comparative usability and performance evaluation of surgeon interfaces in laser phonomicrosurgery," in *Intelligent Robots and Systems (IROS), 2013 IEEE/RSJ International Conference on*. IEEE, 2013, pp. 3610–3615.

[2] M. Heverly, P. Dupont, and J. Triedman, "Trajectory optimization for dynamic needle insertion," in *Robotics and Automation, 2005. ICRA 2005. Proceedings of the 2005 IEEE International Conference on*. IEEE, 2005, pp. 1646–1651.

[3] N. J. Cowan, K. Goldberg, G. S. Chirikjian, G. Fichtinger, R. Alterovitz, K. B. Reed, V. Kallem, W. Park, S. Misra, and A. M. Okamura, "Robotic needle steering: Design, modeling, planning, and image guidance," in *Surgical Robotics*. Springer, 2011, pp. 557–582.

[4] R. J. Harris, J. B. Mygatt, and S. I. Harris, "Systems and methods for autonomous intravenous needle insertion," Patent, Dec. 22, 2011, uS Patent App. 13/335,700.

[5] N. Abolhassani, R. V. Patel, and F. Ayazi, "Minimization of needle deflection in robot-assisted percutaneous therapy," *The international journal of medical Robotics and computer assisted surgery*, vol. 3, no. 2, pp. 140–148, 2007.

[6] A. Zivanovic and B. L. Davies, "A robotic system for blood sampling," *Information Technology in Biomedicine, IEEE Transactions on*, vol. 4, no. 1, pp. 8–14, 2000.

[7] M. H. Saito and T. Togawa, "Detection of needle puncture to blood vessel using puncture force measurement," *Medical and Biological Engineering and Computing*, vol. 43, no. 2, pp. 240–244, 2005.

[8] D. De Lorenzo, Y. Koseki, E. De Momi, K. Chinzei, and A. M. Okamura, "Experimental evaluation of a coaxial needle insertion assistant with enhanced force feedback," in *Engineering in Medicine and Biology Society, EMBC, 2011 Annual International Conference of the IEEE*. IEEE, 2011, pp. 3447–3450.

[9] P. N. Brett, T. Parker, A. J. Harrison, T. A. Thomas, and A. Carr, "Simulation of resistance forces acting on surgical needles," *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, vol. 211, no. 4, pp. 335–347, 1997.

[10] Y. Fukushima and K. Naemura, "Estimation of the friction force during the needle insertion using the disturbance observer and the recursive least square," *ROBOMECH Journal*, vol. 1, no. 1, pp. 1–8, 2014.

[11] A. M. Okamura, C. Simone, and M. D. O'Leary, "Force modeling for needle insertion into soft tissue," *Biomedical Engineering, IEEE Transactions on*, vol. 51, no. 10, pp. 1707–1716, 2004.

[12] M. Mahvash and P. E. Dupont, "Mechanics of dynamic needle insertion into a biological material," *Biomedical Engineering, IEEE Transactions on*, vol. 57, no. 4, pp. 934–943, 2010.

[13] Y. Wang, B. L. Tai, H. Yu, and A. J. Shih, "Silicone-based tissue-mimicking phantom for needle insertion simulation," *Journal of Medical Devices*, vol. 8, no. 2, p. 021001, 2014.

[14] I.-S. Liu, "A note on the mooney–rivlin material model," *Continuum Mechanics and Thermodynamics*, vol. 24, no. 4-6, pp. 583–590, 2012.

Appendix G

The latch design of SDOP

Figure G-1 shows the latch design. Point O denotes the pivot of the latch, and Point N is the contact point between the shaft collar and the latch's claw. We set line ON parallel to the axial direction such that the acting force on the latch by the shaft collar F_c cannot push the latch to open. In addition, the opening of the latch does not push the shaft collar forwards. The length of ON is 6 mm. Point P represents the point where the solenoid plunger pushes the latch to open, and the length OP is set to be 9 mm for easy hardware arrangement. In addition, the end point of the latch jaw is denoted as M, and M' represents the same point when the latch is open. To lock the shaft collar, MN is made vertical and 1 mm in length. When the latch is open, distance y denotes the vertical distance from M' to line ON. We set y to be 0.5 mm, and thus the displacement of the solenoid, x, can be calculated as:

$$x = OP \times \tan(\theta) = OP \times (\tan(\sin^{-1}(y/OM') + \tan^{-1}(MN/ON))) = 2.3mm. \quad \text{(G.1)}$$

where θ is the rotation angle of the latch. Also, the solenoid should generate enough force to open the latch during the PIVC insertion. The latch and the shaft collar are made from aluminum, and the friction coefficient is $\mu = 1.05$. In addition, F_c is found to reach a maximum of 2.5 N [5]. Therefore, to open the latch, the solenoid acting force is $F_s = OB \times \mu \times F_c/OC = 1.75\,N$. Although the actual F_s could be slightly bigger than 1.75 N due to the return spring, it is still able to be achieved by

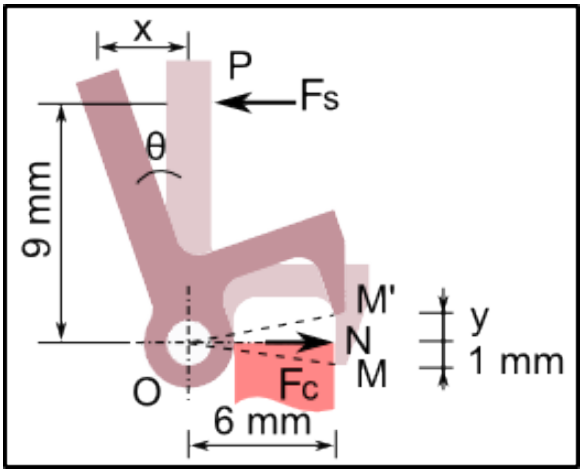
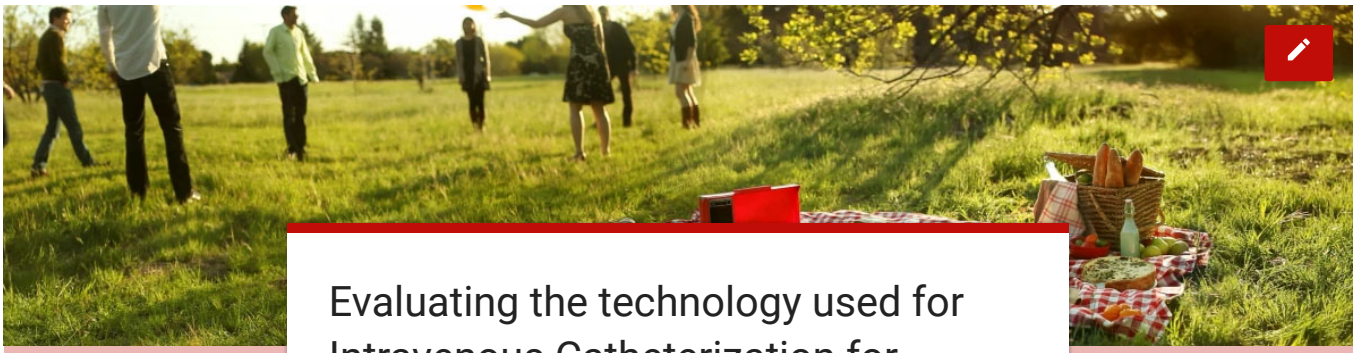


Figure G-1: The latch design of SDOP.

the selected solenoid.

Appendix H

The questionnaire for the preliminary evaluation of the designed robotic devices.



Evaluating the technology used for Intravenous Catheterization for Pediatric Care

Thank you for participating in our experiment. We hope you had fun attending and learnt something.

We want to hear your feedback about this experiment. Please mark the tables below and let us know your thoughts.

Q1. I was very satisfied to my performance

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q2. This task was overall very difficult.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q3. It was very difficult to use the current technology to complete the task.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

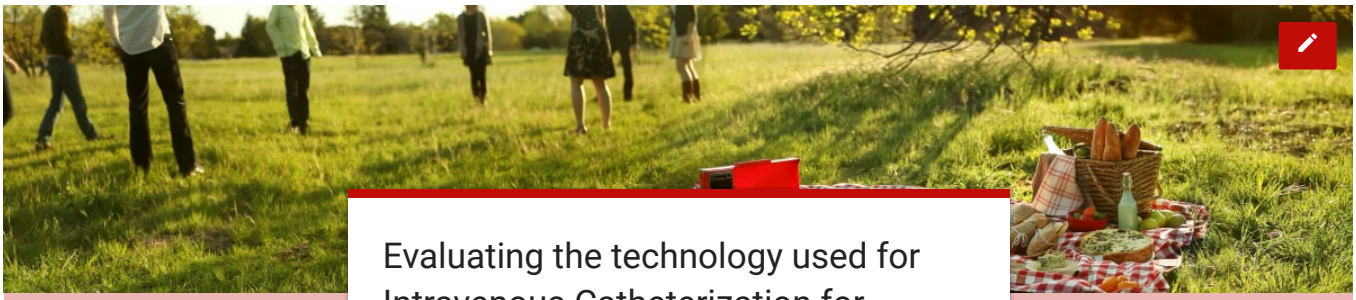
Q4. I would need a short period of practice to reach a high success rate with the current technology.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q5. I feel exhausted after all the trials.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

NEXT



Evaluating the technology used for Intravenous Catheterization for Pediatric Care

Access the device

Q6. I agreed that this device was unnecessarily complex.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly disagree

Q7. I agreed this device was very easy to use.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q8. I thought that this device integrated various functions very well.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q9. I would need the support of a technical person to be able to use the device.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q10. I needed to learn many things of the device before I could get going with it.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

Q11. I believed that most people could learn to use this device very quickly.

	1	2	3	4	5	6	7	8	9	10	
Strongly disagree	○	○	○	○	○	○	○	○	○	○	Strongly agree

ID

Your answer

BACK SUBMIT

Never submit passwords through Google Forms.

Appendix I

Questionnaire for pre-clinical evaluation of SVEI (Italian)

Scopo

Lo scopo di questo esperimento è quello di valutare l'usabilità di 2 modelli di dispositivi palmari intelligenti per la Cateterizzazione Intravenosa Periferica (PIVC) in pazienti pediatrici.

Descrizione dell'esperimento

Questo esperimento è composto da due diverse parti. Dapprima vi verrà richiesto di leggere il documento fornitovi precedentemente, riguardante la PIVC in pazienti pediatrici e le istruzioni per l'utente di entrambi i dispositivi. Successivamente, vi verrà richiesto di effettuare, per un totale di 6 volte, una PIVC sul fantoccio di braccio di bambino. Di queste 6 prove dovrete eseguirne 3 con un catetere regolare 26G IV, e 3 con SVEI. La sequenza con cui verranno utilizzati i due diversi dispositivi verrà decisa dallo sperimentatore.

Regular IV catheter

SVEI

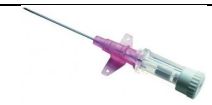
Ogni prova inizia prendendo il dispositivo assegnato (SVEI o un catetere IV) e termina con la rimozione dell'ago dalla cannula, dopo che quest'ultima è stata inserita nella vena. Nel caso in cui vi rendiate conto che potreste aver già inserito il catetere troppo in profondità ed aver forato la vena dal lato opposto, siete pregati di estrarre il catetere ed informare lo sperimentatore. **NOTA IMPORTANTE: Siete pregati di non effettuare inserimenti multipli & retrazioni durante una singola prova!**

Soggetto No.			Professione	
Sesso		Età	( ) < 30; ( ) 30 – 40; ( ) 40 - 50; ( ) 50 – 60; ( ) 60 – 70; ( ) > 70.	
Hai esperienza con l'inserimento di aghi o PIVC?				Sì / NO
Se sì, indica quanti anni di esperienza hai:				

Dispositivo	Prova	Successo/fallimento	Motivo
	1		
	2		
	3		
	1		
	2		
	3		

Completa le tabelle di seguito per farci sapere il tuo livello di accordo con le affermazioni.

- **Sono molto soddisfatto della mia prestazione con…**
  (I am very satisfied to my performance with …)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5
	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

- **Ho trovato molto semplice completare il task con…**
  (I feel very easy to complete the task with ...)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5
	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

- **Penso che vorrei utilizzare questo sistema frequentemente.**
  (I think that I would like to use this system frequently.)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

- **Ho trovato il sistema inutilmente complesso.**
  (I found the system unnecessarily complex.)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

- **Ho pensato che il sistema fosse semplice da usare.**
  (I thought the system was easy to use.)

Fortemente d'accordo				Fortemente in disaccordo
1	2	3	4	5

- **Penso che avrei bisogno di supporto o di personale tecnico per essere in grado di usare il sistema.**
  (I think that I would need the support of a technical person to be able to use this system.)

Fortemente d'accordo				Fortemente in disaccordo
1	2	3	4	5

- **Ho trovato che le varie funzioni in questo sistema fossero ben integrate.**
  (I found the various functions in this system were well integrated.)

Fortemente d'accordo				Fortemente in disaccordo
1	2	3	4	5

- **Ho pensato che ci fosse troppa incoerenza in questo sistema.**
  (I thought there was too much inconsistency in this system.)

Fortemente d'accordo				Fortemente in disaccordo
1	2	3	4	5

- **Ho trovato il sistema molto ingombrante da usare.**
  (I found the system very cumbersome to use.)

Fortemente d'accordo				Fortemente in disaccordo
1	2	3	4	5

- **Mi sono sentito molto sicuro utilizzando il sistema.**
  (I felt very confident using the system.)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

- **Ho dovuto imparare molte cose prima di poter utilizzare questo sistema.**
  (I needed to learn a lot of things before I could get going with this system.)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

- **Immagino che la maggior parte delle persone imparerebbe a utilizzare questo sistema molto rapidamente.**
  (I would imagine that most people would learn to use this system very quickly.)

	Fortemente d'accordo 1	2	3	4	Fortemente in disaccordo 5

Hai qualche suggerimento per il progetto SVEI?

Bibliography

[1] D Andreuccetti, R Fossi, and C Petrucci. An internet resource for the calculation of the dielectric properties of body tissues in the frequency range 10 hz-100 ghz. *Internet document*, 1997.

[2] Max L Balter, Alvin I Chen, Timothy J Maguire, and Martin L Yarmush. The system design and evaluation of a 7-dof image-guided venipuncture robot. *IEEE Transactions on Robotics*, 31(4):1044–1053, 2015.

[3] K Bauer, O Linderkamp, and HT Versmold. Systolic blood pressure and blood volume in preterm infants. *Archives of disease in childhood*, 69(5 Spec No):521–522, 1993.

[4] Ciaran Bolger, Michael O Kelleher, Linda McEvoy, M Brayda-Bruno, André Kaelin, J-Y Lazennec, J-C Le Huec, C Logroscino, P Mata, P Moreta, et al. Electrical conductivity measurement: a new technique to detect iatrogenic initial pedicle perforation. *European Spine Journal*, 16(11):1919–1924, 2007.

[5] R Brewer. Improving peripheral iv catheterization through robotics: From simple assistive devices to a fully-autonomous system. *Doctor of Philosophy, Stanford University*, 2015.

[6] John Brooke. Sus-a quick and dirty usability scale. *Usability evaluation in industry*, 189(194):4–7, 1996.

[7] Penny Brown. An iv specialty team can mean savings for hospital and patient. *Journal of Infusion Nursing*, 7(5):387–392, 1984.

[8] Laura L Chapman, Brenna Sullivan, Amanda L Pacheco, Charlene P Draleau, and Bruce M Becker. Veinviewer-assisted intravenous catheter placement in a pediatric emergency department. *Academic Emergency Medicine*, 18(9):966–971, 2011.

[9] Alvin Chen, Kevin Nikitczuk, Jason Nikitczuk, Tim Maguire, and Martin Yarmush. Portable robot for autonomous venipuncture using 3d near infrared image guidance. *Technology*, 1(01):72–87, 2013.

[10] Zhuoqi Cheng, Brian L Davies, Darwin G Caldwell, and Leonardo S Mattos. A venipuncture detection system for robot-assisted intravenous catheterization.

In *Biomedical Robotics and Biomechatronics (BioRob), 2016 6th IEEE International Conference on*, pages 80–86. IEEE, 2016.

[11] Elaine Cole. Cannulation and venepuncture. *Blood*, 16(10.8):9–4, 2016.

[12] Melanie Crowley, Carla Brim, Jean Proehl, Susan Barnason, Sherry Leviner, Cathleen Lindauer, Mary Naccarato, Andrew Storer, Jennifer Williams, Ann-Marie Papa, et al. Emergency nursing resource: difficult intravenous access. *Journal of Emergency Nursing*, 38(4):335–343, 2012.

[13] William H Cushman and Daniel J Rosenberg. Human factors in product design. *Advances in human factors/ergonomics*, 14, 1991.

[14] T De Boer, M Steinbuch, S Neerken, and A Kharin. Laboratory study on needle–tissue interaction: Towards the development of an instrument for automatic venipuncture. *Journal of Mechanics in Medicine and Biology*, 7(03):325–335, 2007.

[15] Analog Devices. Ad5933 datasheet, 2007.

[16] Lev Lavy et al. Less pain for kids, with robotic iv insertion device.

[17] Dana Etzel-Hardman. Teaching iv therapy to pediatric nurses. specialized training programs alleviate pain for both patients and practitioners. *RN*, 71(11):24, 2008.

[18] Anne Marie Frey. Success rates for peripheral iv insertion in a children's hospital. *Journal of Infusion Nursing*, 21(3):160–165, 1998.

[19] S Gabriel, RW Lau, and Camelia Gabriel. The dielectric properties of biological tissues: Ii. measurements in the frequency range 10 hz to 20 ghz. *Physics in medicine and biology*, 41(11):2251, 1996.

[20] David A Goff, Pamela Larsen, Jason Brinkley, David Eldridge, Dale Newton, Timothy Hartzog, and J Routt Reigart. Resource utilization and cost of inserting peripheral intravenous catheters in hospitalized children. *Hospital pediatrics*, 3(3):185–191, 2013.

[21] PN Gopalakrishnan, N Goel, and Sujoy Banerjee. Saline irrigation for the management of skin extravasation injury in neonates. *status and date: New, published in*, (3), 2010.

[22] Lisa A Gorski. Infusion nursing standards of practice. *Journal of infusion nursing*, 30(3):151–152, 2007.

[23] Nikolaus A Haas. Clinical review: vascular access for fluid infusion in children. *Critical care*, 8(6):1, 2004.

[24] Richard Harris and Joe Mygatt. Veebot. http://www.veebot.com/about.html.

[25] SJ Harris, F Arambula-Cosio, Q Mei, RD Hibberd, BL Davies, JEA Wickham, MS Nathan, and B Kundu. The probot an active robot for prostate resection. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, 211(4):317–325, 1997.

[26] David J Hernandez, Vladimir A Sinkov, William W Roberts, Mohamad E Allaf, Alexandru Patriciu, Thomas W Jarrett, Louis R Kavoussi, and Dan Stoianovici. Measurement of bio-impedance with a smart needle to confirm percutaneous kidney access. *The Journal of urology*, 166(4):1520–1523, 2001.

[27] Ann F Jacobson and Elizabeth H Winslow. Variables influencing intravenous catheter insertion difficulty and failure: an analysis of 339 intravenous catheter insertions. *Heart & Lung: The Journal of Acute and Critical Care*, 34(5):345–359, 2005.

[28] Matjaz Jakopec, F Rodriguez y Baena, Simon J Harris, Paula Gomes, Justin Cobb, and Brian L Davies. The hands-on orthopaedic robot" acrobot": Early clinical trials of total knee replacement surgery. *IEEE Transactions on Robotics and Automation*, 19(5):902–911, 2003.

[29] Roland N Kaddoum, Doralina L Anghelescu, Mary E Parish, Becky B Wright, Luis Trujillo, Jianrong Wu, Yanan Wu, and Laura L Burgoyne. A randomized controlled trial comparing the accuvein av300 device to standard insertion technique for intravenous cannulation of anesthetized children. *Pediatric Anesthesia*, 22(9):884–889, 2012.

[30] Aman Kalra. Iv insertion technique in infants and small children. https://www.youtube.com/watch?v=bu5zgfZFViY.

[31] Håvard Kalvøy, Lars Frich, Sverre Grimnes, Ørjan G Martinsen, Per Kristian Hol, and Audun Stubhaug. Impedance-based tissue discrimination for needle guidance. *Physiological measurement*, 30(2):129, 2009.

[32] Yiannis L Katsogridakis, Roopa Seshadri, Christine Sullivan, and Mark L Waltzman. Veinlite transillumination in the pediatric emergency department: a therapeutic interventional trial. *Pediatric emergency care*, 24(2):83–88, 2008.

[33] Min Joung Kim, Joon Min Park, Nuga Rhee, Sang Mo Je, Seong Hee Hong, Young Mock Lee, Sung Phil Chung, and Seung Ho Kim. Efficacy of veinviewer in pediatric peripheral intravenous access: a randomized controlled trial. *European journal of pediatrics*, 171(7):1121–1125, 2012.

[34] Bradley G Klein. *Cunningham's Textbook of Veterinary Physiology-E-Book*. Elsevier Health Sciences, 2013.

[35] Yo Kobayashi, Jaesung Hong, Ryutaro Hamano, Kaoru Okada, Masakatsu G Fujie, and Makoto Hashizume. Development of a needle insertion manipulator for central venous catheterization. *The International Journal of Medical Robotics and Computer Assisted Surgery*, 8(1):34–44, 2012.

[36] Laura L Kuensting, Scott DeBoer, Reneé Holleran, Barbara L Shultz, Rebecca A Steinmann, and Jeanne Venella. Difficult venous access in children: taking control. *Journal of Emergency Nursing*, 35(5):419–424, 2009.

[37] Yik San Kwoh, Joahin Hou, Edmond A Jonckheere, and Samad Hayati. A robot with improved absolute positioning accuracy for ct guided stereotactic brain surgery. *IEEE Transactions on Biomedical Engineering*, 35(2):153–160, 1988.

[38] Nicos Labropoulos, Kelli Leilani Summers, Ignacio Escotto Sanchez, and Joseph Raffetto. Saphenous vein wall thickness in age and venous reflux-associated remodeling in adults. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*, 5(2):216–223, 2017.

[39] Pamela Larsen, David Eldridge, Jason Brinkley, Dale Newton, David Goff, Timothy Hartzog, Nancy Darden Saad, and Ron Perkin. Pediatric peripheral intravenous access: does nursing experience and competence really make a difference? *Journal of Infusion Nursing*, 33(4):226–235, 2010.

[40] Zheng Li, Guohui Wang, Juan Tan, Xulong Sun, Hao Lin, and Shaihong Zhu. Building a framework for ergonomic research on laparoscopic instrument handles. *International Journal of Surgery*, 30:74–82, 2016.

[41] David R. Lide. Crc handbook of chemistry and physics - 80th edition 1999-2000. *Crc Press*, 15(7):504, 1999.

[42] Lonnie J Love, John F Jansen, and Peter D Lloyd. Force-based needle insertion for medical applications. In *Intelligent Robots and Systems, 2009. IROS 2009. IEEE/RSJ International Conference on*, pages 2592–2597. IEEE, 2009.

[43] Frederike Lund, Jobst-Hendrik Schultz, Imad Maatouk, Markus Krautter, Andreas Möltner, Anne Werner, Peter Weyrich, Jana Jünger, and Christoph Nikendei. Effectiveness of iv cannulation skills laboratory training and its transfer into clinical practice: a randomized, controlled trial. *PloS one*, 7(3):e32831, 2012.

[44] Tim Maguire and Alvin Chen. Fully automated vascular imaging and access system, August 29 2013. US Patent App. 14/013,181.

[45] Ernst Martin, Daniel Jeanmonod, Anne Morel, Eyal Zadicario, and Beat Werner. High-intensity focused ultrasound for noninvasive functional neurosurgery. *Annals of neurology*, 66(6):858–861, 2009.

[46] Orjan G Martinsen and Sverre Grimnes. *Bioimpedance and bioelectricity basics*. Academic press, 2011.

[47] Arthur G Money, Julie Barnett, Jasna Kuljis, Michael P Craven, Jennifer L Martin, and Terry Young. The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC medical informatics and decision making*, 11(1):15, 2011.

[48] Chris Moore. Ultrasound-guided procedures in emergency medicine. *Ultrasound Clinics*, 6(2):277–289, 2011.

[49] Olubukola O Nafiu, Constance Burke, Andy Cowan, Narko Tutuo, Sarah Maclean, and Kevin K Tremper. Comparing peripheral venous access between obese and normal weight children. *Pediatric Anesthesia*, 20(2):172–176, 2010.

[50] Helen Ogden-Grable and Gary W Gill. Phlebotomy puncture juncture: preventing phlebotomy errorsâĂŤpotential for harming your patients. *Laboratory Medicine*, 36(7):430–433, 2005.

[51] Daisaku Okuno, Tatsuo Togawa, Hirokazu Saito, and Kiichi Tsuchiya. Development of an automatic blood sampling system: control of the puncturing needle by measuring forces. In *Engineering in Medicine and Biology Society, 1998. Proceedings of the 20th Annual International Conference of the IEEE*, volume 4, pages 1811–1812. IEEE, 1998.

[52] Christopher J Payne and Guang-Zhong Yang. Hand-held medical robots. *Annals of biomedical engineering*, 42(8):1594–1605, 2014.

[53] Ian Peate. *Medical-surgical Nursing at a Glance*. John Wiley & Sons, 2015.

[54] Tekla S Perry. Profile: veebot [resources_start-ups]. *IEEE Spectrum*, 50(8):23–23, 2013.

[55] Soo Jay Phee, Soon Chiang Low, VA Huynh, Andy Prima Kencana, ZL Sun, and K Yang. Master and slave transluminal endoscopic robot (master) for natural orifice transluminal endoscopic surgery. In *Engineering in Medicine and Biology Society, 2009. EMBC 2009. Annual International Conference of the IEEE*, pages 1192–1195. IEEE, 2009.

[56] Tarun K Podder, Ivan Buzurovic, Ke Huang, Timothy Showalter, Adam P Dicker, and Yan Yu. Reliability of euclidian: An autonomous robotic system for image-guided prostate brachytherapy. *Medical physics*, 38(1):96–106, 2011.

[57] Carolyn C Preston and Andrew M Colman. Optimal number of response categories in rating scales: reliability, validity, discriminating power, and respondent preferences. *Acta psychologica*, 104(1):1–15, 2000.

[58] B Reynolds. Neonatal extravasation injury: case report. *Infant*, 3(6):230–232, 2007.

[59] Antonio Riera, Melissa Langhan, Veronika Northrup, Karen Santucci, and Lei Chen. Remember the saphenous: ultrasound evaluation and intravenous site selection of peripheral veins in young children. *Pediatric emergency care*, 27(12):1121–1125, 2011.

[60] M Rotstein, D Geva, A Ben-Or, and N Lieberman. Vein entry indicator device-veid®-efficacy and safety evaluation. *European Journal of Anaesthesiology (EJA)*, 17:35, 2000.

[61] Hirokazu Saito, Kohji Mitsubayashi, and Tatsuo Togawa. Detection of needle puncture to blood vessel by using electric conductivity of blood for automatic blood sampling. *Sensors and Actuators A: Physical*, 125(2):446–450, 2006.

[62] Gil Z Shlamovitz. Pediatric intravenous cannulation. 2015. `http://emedicine.medscape.com/article/2008690-overview#showall`.

[63] Eliahu Simhi, Ludmyla Kachko, Elhanan Bruckheimer, and Jacob Katz. A vein entry indicator device for facilitating peripheral intravenous cannulation in children: a prospective, randomized, controlled trial. *Anesthesia & Analgesia*, 107(5):1531–1535, 2008.

[64] Massimiliano Simi, Pietro Valdastri, Claudio Quaglia, Arianna Menciassi, and Paolo Dario. Design, fabrication, and testing of a capsule with hybrid locomotion for gastrointestinal tract exploration. *IEEE/ASME Transactions on Mechatronics*, 15(2):170–180, 2010.

[65] Coben Thorn and L Connor Nickels. Ultrasound-guided peripheral intravenous access. In *Atlas of Emergency Medicine Procedures*, pages 13–15. Springer, 2016.

[66] Dennis Trebbels, Felix Fellhauer, Michael Jugl, Gerd Haimerl, Mart Min, and Roland Zengerle. Online tissue discrimination for transcutaneous needle guidance applications using broadband impedance spectroscopy. *IEEE Transactions on Biomedical Engineering*, 59(2):494–503, 2012.

[67] Christopher A Troianos, Gregg S Hartman, Kathryn E Glas, Nikolaos J Skubas, Robert T Eberhardt, Jennifer D Walker, Scott T Reeves, et al. Guidelines for performing ultrasound guided vascular cannulation: recommendations of the american society of echocardiography and the society of cardiovascular anesthesiologists. *Anesthesia & Analgesia*, 114(1):46–72, 2012.

[68] Kryztopher D Tung, Rami M Shorti, Earl C Downey, Donald S Bloswick, and Andrew S Merryweather. The effect of ergonomic laparoscopic tool handle design on performance and efficiency. *Surgical endoscopy*, 29(9):2500–2505, 2015.

[69] G Vanhoutte, M Verhoye, E Raman, M Roberts, and A Linden. In-vivo non-invasive study of the thermoregulatory function of the blood vessels in the rat tail using magnetic resonance angiography. *NMR in Biomedicine*, 15(4):263–269, 2002.

[70] Fred H Warkentine, Mary Clyde Pierce, Doug Lorenz, and In K Kim. The anatomic relationship of femoral vein to femoral artery in euvolemic pediatric patients by ultrasonography: implications for pediatric femoral central venous access. *Academic emergency medicine*, 15(5):426–430, 2008.

[71] CE Wilkins and AJB Emmerson. Extravasation injuries on regional neonatal units. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, 89(3):F274–F275, 2004.

[72] Ferdinando Rodriguez y Baena and Brian Davies. Robotic surgery: from autonomous systems to intelligent tools. *Robotica*, 28(2):163–170, 2010.

[73] Aleksandar Zivanovic and Brian L Davies. A robotic system for blood sampling. *IEEE Transactions on Information Technology in Biomedicine*, 4(1):8–14, 2000.