REAL-TIME VISUALISATION AND ANALYSIS OF TACTILE INFORMATION USING FORCE SENSORS DURING ARTERIAL THREADING

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ABSTRACT

Despite the investment in procedure-based simulators in endovascular training programmes, there is a growing concern over the lack of effective haptic feedback, which means that trainees must rely on live practice to develop skills and knowledge of the tactile aspect of Mechanical Thrombectomy. The live procedure carries a significant risk to patients, and the opportunity to carry it out is often limited, which can delay the trainee's development. This research presents a novel tactile controller designed to simulate the physical characteristics of arterial threading for mechanical thrombectomy to assess the efficacy of haptic feedback information generated using force-sensing resistors and game-engine technology for simulating and recording arterial threading. The experimental work was performed in a Virtual Learning Environment to evaluate the effectiveness of the force-sensing box trainer in simulating the physical resistance of an artery in mechanical thrombectomy. The generated force data is presented to a user in a real-time virtual operation theatre indicating the level of applied force. This work demonstrated the successful integration of force-sensor data into a Virtual Learning Environment inside the Unreal Engine. The data can be exported for further analysis by the end-users after completing the simulation to investigate the user's performance. Analysis of the obtained experimental data from the real-time simulation study demonstrated the ability of the system to identify changes to applied force and impacts generated by a user in a real-time simulation using force-sensitive data for simulated arterial threading, indicating the level of applied force exhibited by the user. Supervising practitioners can use the experimental data to determine the number of impacts and force applied during a simulation.

GLOSSARY

Angiography: A type of X-ray used by interventional neuroradiologists to diagnose patients. It involves injecting contrast fluid into the blood flow to help visualise the blood vessels so doctors can identify any problematic anomalies.

Arterial Threading: This is where a surgeon navigates an arterial catheter up a patient's artery over a guidewire to help navigate effectively.

Building-Information-Model (BIM): A three-dimensional data set containing geometric and physical characteristics of an environment for spatial development, construction, and engineering often used in large construction projects.

Catheterisation: This is where a surgeon inserts a medical device (catheter) into the patient's body via a surgical incision into the patient's artery.

Computer-Aided-Design (CAD): Technology used to generate and reconstruct 3D artefacts and environments, such as terrestrial laser scanning and point cloud.

DICOM: "Digital Imaging and Communications in Medicine" is the standard file type commonly associated with, and used in, medical imaging and managing the relevant data.

Endovascular: Endovascular surgery is a minimally invasive practice commonly used to treat medical conditions affecting blood vessels, such as aneurysms, blood clots, and stroke.

Endovascular Thrombectomy: An Endovascular Thrombectomy is a minimally invasive procedure used by interventional neuroradiologists to remove blood clots from a patient using image guidance techniques (also referred to as a Mechanical Thrombectomy).

Fused Deposition Modelling: an extrusion-based 3D printing methodology using thermoplastic filament to print 3D geometry designed in CAD software.

Ischaemic Stroke: A type of stroke. Ischaemic Stroke occurs when a blood clot blocks the blood flow to the brain, depriving it of blood and oxygen.

Neuroradiology: A sub-specialist branch of Radiology that provides diagnostic and therapeutic procedures relating to abnormalities in the spine, head, and neck.

Photogrammetry: Photogrammetry is a 3D modelling method of extracting 3D data from photographs.

Radiology: Radiologists are specialist medical practitioners that diagnose and treat disease and injuries using medical imaging techniques such as X-rays, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI).

Virtual Reality: Virtual reality involves creating a virtual 3D representation of an artefact or environment in which a user is immersed using head-mounted displays and interact with virtual artefacts using gesture controllers.

PUBLICATIONS

Journal Papers (Under Review)

i. Latham, K., Kot, P., Al-Jumeily, D., Waraich, A., Muradov, M., Kolivand, H., Puthuran, M., Chandran, A. Force-Sensor Visualisation and Game-Engine VLE for Haptic Simulation of Arterial Threading in Mechanical Thrombectomy. *Multimodal Technologies and Interaction*, 2022, Under Review. (IF. 4.5)

Conference Papers

ii. Latham K, Kot P, Waraich A, Al-Jumeily D, Puthuran M, Chandran A. A review on the development of a virtual reality learning environment for medical simulation and training. In: 2019 International Conference on Applications and Systems of Visual Paradigms. Rome, IARIA, 2019, 1–6.

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CHAPTER 1 INTRODUCTION

In the UK, people who suffer an Acute Ischaemic Stroke (AIS) can have a highly trained surgeon perform a Mechanical Thrombectomy (MT) to remove the blood clot from the artery and restore blood flow to the brain, reducing the risk of long-term disability and potentially death for the patient (Stroke Association, 2019). MT is a new procedure with limited coverage in the UK. Still, it has been cited for having better functional outcomes in patients as compared to "clot-busting" thrombolysis medication, which can cause bleeding in the brain and cause potential complications (Stroke Association, 2019).

The challenge for MT services in the UK is the lack of trained practitioners to provide adequate coverage for stroke patients. The Royal College of Radiologists' census indicates that there are currently only 82 Neuro Interventional Consultants in the UK, with 47% of UK trusts and health boards demonstrating inadequate 24/7 provision for Interventional Neuroradiology services, with a growth of only 7% over the last five years, despite high vacancy rates (Royal College of Radiologists, 2021).

Given the complexity of the procedure and inherent risks posed to a patient when guiding a catheter through an artery, trainee Interventional Radiologists (INRs) traditionally rely on simulation technology to teach them how to perform a Mechanical Thrombectomy to supplement their training. A trainee will not be able to practise on a live patient due to a reduction in working hours and the urgency in which a patient needs treatment, which necessitates that an expert practitioner will complete the procedure. As trainees improve their skills and knowledge, they can gain practical experience with a patient.

However, the crucial problem that simulation training faces is the lack of haptics that conventional simulation trainers provide, focusing instead on task-based competency, despite there being evidence to suggest that the addition of haptic cues in simulation has the positive effect of improving the surgical experience and cognitive load when performing complex tasks (Rangarajan *et al*., 2020)

As technology has advanced over the last few decades, simulation technology has begun to make use of more immersive technologies such as Virtual Reality (VR), Augmented Reality (AR), and Mixed Reality (MR), with technological advancements in real-time technology and pioneering research on the benefits of immersive technology. Immersive applications have been found to enhance the quality of medical training of a practitioner in multiple ways. Research has shown that simulation training can support objective assessment by tracking quantitative and qualitative metrics used to assess performance (Van Herzeele *et al*., 2007).

An intrinsic strength of immersive simulation training using AR/VR/MR is the ability to provide content-rich simulations that are more immersive and of higher quality than their screen-space rendered predecessors, which enhances engagement and the quality of training (Byl *et al*., 2018), (Gunn *et al*., 2017). Simulation training also benefits the practitioner by allowing the opportunity to repeatedly practise procedures and tasks in a safe environment with a reduction in resource expenditure, which helps to improve the transference of skills acquired in virtual reality to real-world scenarios (Hamilton *et al*., 2020). Additionally, a risk-free environment allows the user to take time to understand the nature of the procedure and risks involved and develop a greater knowledge of how to avoid them, or how best to approach more complex steps in an operation which is safer than allowing them to operate on live patients (Li *et al*., 2017).

1.1 Acute Ischaemic Stroke

An Acute Ischaemic Stroke occurs when a blood clot forms in one of the arteries leading to the brain, cutting off the blood supply. The arterial supply consists of two paired arteries that lead up the neck and into the cranium, the **vertebral arteries** and **internal carotid arteries;** these arteries create an anastomotic circle called **The Circle of Willis** (Oliver, 2021)**.** The internal carotid arteries consist of the following four arteries:

- **Ophthalmic artery** –supplies the structures of the orbit.
- **Posterior Communicating Artery** – which acts as an anastomotic 'connecting vessel' in the circle of Willis.
- **Anterior Choroidal Artery** –supplies structures in the brain essential for motor control and vision.
- **Anterior Cerebral Artery** – which supplies part of the cerebrum.

Along with the internal carotid arteries, the Circle of Willis contains three pairs of arteries:

- **Anterior Cerebral Arteries** – terminal branches of the internal carotid arteries
- **Internal Carotid Arteries** – located near the origin of the Middle Cerebral Arteries. (Also described on the previous page).
- **Posterior Cerebral Arteries** – terminal branches of Basilar Artery.

The Circle of Willis is completed by two "connecting vessels," the **Anterior Communicating Artery**, which connects the two anterior cerebral arteries, and the **Posterior Communicating Artery,** the branch of the internal carotid artery that connects the internal carotid arteries to the posterior cerebral artery.

From this, the blood supply is diverted to three distinct regions of the brain:

- The anterior cerebral arteries supply blood to the **anteromedial** section of the cerebrum.
- The middle cerebral arteries, situated laterally, provide blood to the **lateral** part of the brain.

- The posterior cerebral arteries direct blood to the medial and lateral sections of the **posterior cerebrum.**

Should a stroke occur, the longer it goes untreated, the more brain tissue is lost in the form of neurons, synapses, and myelinated fibres. Research estimates that for each hour a stroke goes untreated, the loss of tissue ages the brain by 3.6 years (Saver, 2006). This means that over ten hours the brain will age by 36 years.

1.2 Intravenous Thrombolysis

Before Mechanical Thrombectomy became a popular form of treatment for AIS, patients who suffered a stroke often received Intravenous Thrombolysis (IVT) treatment (Routledge, 2020). When Mechanical Thrombectomy is not suited for a case, IVT treatment will be performed. Thrombolysis involves using “clot-busting” medication, such as Alteplase and Tenecteplase, to dissolve the blood clot, restore blood flow to the brain, and improve recovery (Stroke association, 2018).

The standard approach for treating patients with large vessel occlusion (LVO) resulting from an AIS is administering IVT treatment, provided it is within four and a half hours of the stroke onset (Berge et al., 2021).

1.2.1 Efficacy of performing IVT prior to MT versus direct-MT

Lin *et al*. 2022 investigated IVT administration before MT to identify differences in the functional outcome of patients receiving MT compared to IVT+MT. The author identified potential advantages to performing IVT before an MT, i.e., IVT can reduce brain ischaemia when reperfusion occurs, dissolve distal thrombi that arise from clot fragmentation during stent retrieval and be used in place of MT when a clot is inaccessible due to patient safety. Furthermore, Lin *et al* also identifies potential disadvantages to performing an IVT before MT, which include a delay in starting MT if an IVT must be completed, which prolongs effective treatment, the risk of partially segmenting the thrombus and causing it to travel further through the artery, causing complications as it may go out of reach during an MT. In addition, IVT can increase the chance of haemorrhaging (Lin *et al*., 2022). A meta-analysis of studies comparing direct MT with IVT before MT, was conducted to identify which provided the best functional outcome for patients after 90 days, using the Modified Rankin Scale (Bruno *et al*., 2010), which ranks a patient's condition on a scale of 0-6.

Table 1: Modified Rankin Scale Assessment Measuring Patient Outcomes.

0	**The patient exhibited no indication of symptoms.**
1	The patient demonstrated no clinically significant disabilities.
2	Minor disability – The patient can live without assistance but face difficulty conducting all past activities.
3	Moderate disability – The patient requires support for completing specific tasks (shopping, cleaning, etc.) but can walk unassisted.
4	Moderately severe disability – Unable to address bodily needs without assistance and cannot walk without aid.
5	Severe disability – Requires constant medical care and support.
6	Death.

The review identified that regarding functional independence in patients (mRS 0-2), direct MT yielded marginally better results than performing an IVT before MT, with direct MT scoring 46% compared to IVT+MT scoring 45.5%; regarding freedom from disability (mRS 0-1), direct MT scored 25.6% compared to 24.2% when conducting an IVT before MT. Furthermore, successful reperfusion in patients at the end of a procedure was higher when practitioners performed an IVT before MT (IVT+MT: 81%/MT: 76.5). However, intracranial haemorrhaging was 9% higher in patients when a patient received IVT treatment before an MT (36.3%) compared to direct MT (27.8%). Lastly, relating to all-cause mortality after 90-days, the direct MT produced a mortality rate of 17.4%, compared IVT+MT mortality rate of 16.4%, indicating marginally better outcomes for IVT+MT. However, given the marginal differences, the period in which practitioners must treat a stroke and the associated costs, skipping IVT and proceeding directly to MT is a viable strategy. The health risks associated with performing IVT also back this up, with the chances of intracranial haemorrhaging being higher than direct MT and the risk of the thrombus fragmenting and travelling further up the artery, causing further complications, thus prolonging effective treatment and functional outcomes.

1.2.2 Tenecteplase thrombolysis for acute ischaemic stroke

Warach *et al.* 2020, conducted a meta-analysis of published clinical trials in Tenecteplase, investigating the different doses of Tenecteplase used in IVT and the impact on patients through eight critical studies. The aim was to identify the effects of different dosages on the functional outcome of recanalisation, reperfusion, and neurological improvement, including Symptomatic Intracranial Haemorrhage (sICH) and 3-month disability on a modified Rankin scale. The study identified that Tenecteplase improved recanalisation in LVO and had better outcomes for disability-free living without increasing the sICH than Alteplase. However, despite these findings, the author discusses the issues with dosage in Tenecteplase and the side effects; a study by Haley *et al.,* 2005 was terminated earlier due to the occurrence of sICH in 15.4% of patients when a dose of 0.5mg/kg was used in patients. Another study compared 0.25mg/kg to 0.4mg/kg and identified that the frequency of sICH was significantly higher when the higher dose was used. Different dosages of Tenecteplase do not produce any significant advantage over one another (Warach *et al*., 2020).

In a pilot study by Haley *et al*. 2005, Tenecteplase was investigated to identify whether it could improve functional outcomes in patients and reduce the risk of sICH in stroke patients. The author immediately identified that despite Alteplase being an approved treatment for patients with AIS within 3-hours of onset, this treatment is limited due to practitioners' concerns regarding the haemorrhagic complications. More importantly, it was estimated that up to 40% of patients who receive this treatment promptly might remain severely disabled or die due to the treatment (Haley *et al*., 2005). The study involved treating patients who demonstrated stroke symptoms with severe measurable deficits according to the NIH stroke scale (NINDS, 2012) and could be treated within a 3-hour window from the onset of the stroke. The number of patients was expected to be per dosage level, beginning at 0.1mg/kg and was planned to go up to 0.6mg/kg. The study consisted of four groups: 0.1 mg/kg, 0.2 mg/kg, 0.4 mg/kg, and 0.5 mg/kg; with the 0.5 mg/kg group only consisting of thirteen participants. "Excessive bleeding in patients with myocardial infarction" is the reason for limiting the maximum dosage to this amount.

Following the treatment, doctors closely monitored patients in an ICU or acute stroke centre, where the necessary blood pressure and neurological checks could be performed. The author distinguished minor bleeding events (gum bleeding, shaving cuts, etc.) that only required a simple compression from major bleeding events (hypotension resulting in further surgery or blood transfusion). Furthermore, intracranial bleeding was categorised as either symptomatic or asymptomatic based on the worsening neurological condition caused by the haemorrhage. Patients demonstrating intracranial bleeding underwent emergency CT scans and an additional NIH stroke scale assessment. Furthermore, all patients underwent follow-up CT scans approximately 48 hours following treatment to detect any asymptomatic bleeding or complications.

The author noted that enrolment into the study ceased due to safety concerns following the death of 2 out of 13 (15%) patients in the 0.5mg/kg group caused by sICH, which was combined with the growing concern of the trend associated in the risk of ICH with increased dosage, while not demonstrating any significant benefit to the patient, which was measured both by 24-hour neurological improvement and 3-month outcome (90-day functional outcome). This is also reflected by the "major neurological improvement at 24 hours", which found the smallest dosage had the best outcome for 36% of patients, and higher dosages of 0.2mg/kg and 0.4mg/kg only demonstrated 24% and 16%, respectively; 0.5mg/kg showed an increased improvement at 23%. However, the sample size was 50% smaller than other groups, and would not have been as high if twenty-five patients were trialled, as noted by the author.

Campbell *et al*. 2020, investigated the effect of IVT Tenecteplase on cerebral reperfusion before MT for patients with LVO AIS to determine if it improved patients' functional outcomes, comparing dosages of 0.25mg/kg to 0.4mg/kg (Campbell *et al*., 2020). Campbell *et al*. 2015, hypothesised that a dosage of 0.4mg/kg could be beneficial in establishing full reperfusion in patients when administered prior to an MT procedure within a 4.5-hour window from symptom onset. Patients who could receive treatment within the timeframe provided and demonstrated cerebral vascular occlusion of the ICA via CT scans were eligible for this study. Patients demonstrating "premorbid disability" defined on the mRS as three or greater were excluded from this study.

Three hundred patients were selected with a 50/50 split of those receiving a 0.25mg/kg dosage and 0.4mg/kg dosage. The dosage was delivered as an intravenous injection, with a follow-up clinical assessment after 3 days and a phone call at 90 days to assess the patient's mRS score. The successful reperfusion was defined as the restoration of blood flow to a level of 50% or greater or the lack of retrievable thrombus located in the ICA. This was assessed independently by two interventional neuroradiologists using intracranial angiography prior to thrombectomy.

Secondary outcomes were assessed in a similar manner to other literature reviewed, and the patient's level of disability at the 90 days mark was assessed using the mRS score (Quinn *et al*., 2009), as well as assessing the NIHSS score to identify improvement to the neurological deficit, on a scale of 0-42 with the higher score indicating worse neurological deficit (NINDS, 2012).

Of the three hundred patients, thrombolysis was successful in accomplishing full reperfusion in 86% of patients from both groups, with the remaining 14% requiring an MT procedure to deal with residual thrombus fragments. Both control groups saw instances of sICH, with 4.7% of patients in the 0.4mg/kg group and 1.3% of patients in the 0.25mg/kg group. Additionally, out the three hundred patients, 17% of the 0.4mg/kg group died following the treatment, while 15% of the 0.25mg/kg group died following the treatment. While reperfusion was successful prior to MT in patients with MCA occlusions, sixty-six patients with ICA occlusions failed to achieve reperfusion prior to MT. During the study, it was identified that the higher dosage of Tenecteplase led to an increase in death at 90 days. Lastly, the author indicates that there is no evidence of improved efficacy in higher dosages and that the lower dosages tend to be more appropriate and potentially less harmful when used to treat AIS.

The work reviewed in the sections above aimed to identify the optimal dosage for Alteplase and Tenecteplase used frequently in IVT treatment and whether they provide any significant clinical advantage for patients when conducted prior to an MT procedure. While there was indication that substantial reperfusion was achieved in many cases, there was a visible trend of concern over asymptomatic/symptomatic intracranial haemorrhaging that had a negative impact on the patient's 90-day outcomes and NIHSS score, either culminating in the death of the patient or the patient surviving, but with moderate to severe disability. Even with thrombolysis, numerous cases still required an MT procedure to be completed, with the observation that in most cases the thrombolysis can be omitted for fear it would just make the patient's situation worse. This is an interesting observation in that of the studies reviewed in this section, the effective window for conducting IVT treatment on a stroke patient appeared to range from 3 hours to 4.5 hours, citing the efficacy of the treatment within this window, though some studies went beyond this. Interestingly, the SSNAP annual thrombectomy reports dashboard shows that the median time for onset to thrombolysis in the UK is 2 hours and 17 minutes, with the shortest median time being 1 hour and 51 minutes and longest median time being 3 hours and 50 minutes (SSNAP, 2022). In terms of LIQR, the shortest time from onset to thrombolysis ranged from 1 hour and 27 minutes to 2 hours and 53 minutes.

Additionally, with the performing of a Mechanical Thrombectomy, the national median time goes up to 6 hours and 14 minutes, with the shortest onset to completion median being 4 hours and 53 minutes, and the longest median being 9 hours and 48 minutes; the shortest report times range from 3 hours and 17 minutes to 6 hours and 33 minutes

1.3 Mechanical Thrombectomy

A Mechanical Thrombectomy is a minimally invasive endovascular procedure performed on patients who have suffered an Acute Ischaemic Stroke in the ICA or MCA. A trained interventional neuroradiologist will insert a catheter into a patient's artery via the femoral artery and guide a catheter up to the site of the blood clot using image guidance and tactile feedback from the catheter as they slide it along the patients artery. To assist surgeons, supporting Radiologists perform an angiography, which involves medical contrast dye (fluoroscopy) being injected into the artery, causing artery systems to show up on scans, allowing them to identify where a blood clot has formed. The surgeon then deploys a stent device into the clot, which meshes with the clot and allows the surgeon to retrieve the clot via the catheter, thus restoring the blood flow to the brain.

Compared to existing treatments for AIS, including Alteplase/Tenecteplase IVT therapy, the rate of achieving good functional outcomes in patients is 20% higher than traditional medical therapies; good functional outcomes can occur in over 60% of patients if successful recanalisation occurs within 4.5 hours of onset, however unlike IVT, with effective selection and planning, MT can still be highly effective and safe to perform up to anywhere between 6 hours and 24 hours from onset (Ford *et al*., 2019).

While a relatively new procedure, with randomised control trials that began in January 2015, Mechanical Thrombectomy has quickly developed a track record for improving the functional outcomes of patients who undergo this procedure after 90 days when compared to standard medicinal and therapeutic approaches such as Thrombolysis. These outcomes relate not only to the successful recanalisation of occluded arteries in the ICA or MCA, but also relate to significantly improving the rate of disability-free survival and quality of life in patients (mRS 0-2), as identified by additional studies (Weiss *et al*., 2019), (Ford *et al*., 2019), (NICE, 2016), (Campbell *et al*., 2015), (Di Giuliano *et al*., 2019). As such, radiologists training to specialise in interventional neuroradiology must now demonstrate competency in this procedure in addition to other standardised procedures. The problem faced by interventional neuroradiology is the understaffing of stroke centres and shortage of interventional neuroradiologists (Royal College of Radiologists, 2021). In addition to this, the complexity, rarity and inherent safety risks of mechanical thrombectomy treatment means that training practitioners need constant supervision, even in the later stages of their education, compared to other procedures, and might not have the opportunity to develop competency in practice during their three years sub-specialist training, which is further worsened by chronically understaffed interventional radiology departments (RCR, 2021).

According to the SSNAP annual thrombectomy reports (SSNAP, 2022), with the performing of a Mechanical Thrombectomy, the national median time goes up to 6 hours and 14 minutes, with the shortest onset to completion median being 4 hours and 53 minutes, and the longest median being 9 hours and 48 minutes; the shortest report times range from 3 hours and 17 minutes to 6 hours and 33 minutes.

Due to the successful validation of Mechanical thrombectomy as a procedure for treating stroke patients with much better outcomes for patient safety and 90 days functional outcomes, it is quickly becoming a key procedure for interventional neuroradiologists to be competent in when training. The use of mechanical thrombectomy has demonstrated a major improvement in mortality and patient safety when compared to the use of thrombolysis and become a crucial aspect of neuroradiologist training programmes.

The problem is that it takes 6 years to become qualified as an interventional neuroradiologist (3 years standard radiology training, 3 years sub-specialist training). Radiologists' training to specialise in interventional neuroradiology will have little opportunity to perform mechanical thrombectomies outside of simulation training due to patient safety concerns. Combined with the limited number of qualified practitioners who need to supervise training practitioners, this means that training practitioners will qualify with limited knowledge and experience of mechanical thrombectomy. This implies that while there will be a contribution to the workforce, the impact will not be so substantial due to the required additional supervision for newly qualified practitioners that have not gained enough confidence in the procedure to perform it unsupervised in an already understaffed workforce, which demonstrates the need for more suitable alternatives to supervised learning.

1.1. Research Challenge

1.3.1 Number of Registered Practitioners compared to Number of Cases

Interventional Neuroradiologists are highly trained radiologists qualified to perform complex, minimally invasive surgical procedures such as Mechanical Thrombectomy on patients who have suffered an ischaemic stroke resulting from a blood clot forming in the cerebral or carotid artery cutting off the blood flow to the brain (NHS, 2019). The Sentinel Stroke National Audit Programme showed that over 89,000 patients were admitted to hospital following a stroke, with only 1.8% of eligible patients receiving MT treatment (Sentinel, 2020). The report also suggests a worsening timeframe of stroke onset to hospital arrival, with the average onset to arrival time being 3 hours 15 minutes. The timeframe between the onset of a stroke and arrival time at a hospital for assessment and intervention is critical in limiting the damage caused by a stroke. While the UK averages 100,000 strokes per year, approximately 36,000 of these result in death, classifying stroke as a leading cause of disability and death in the UK and worldwide (British Heart Foundation, 2020), (World Stroke Organisation, 2019), (Stroke association, 2018).

A workforce report by the Royal College of Radiologists highlights a critical shortage of practitioners qualified to perform radiology procedures (Royal College of Radiologists, 2021). The deficit includes specialist roles such as interventional radiology and interventional neuroradiologists trained to perform complex, minimally invasive procedures such as MT, Stent Retrieval, and Aneurysm Coiling on patients following Acute Ischaemic Stroke (AIS) (Stroke Association, 2019).

The current workforce figures for Interventional Neuroradiology show that UK trusts employ only 82 Whole Time Equivalent (WTE) interventional neuroradiologists. While there are 127 stroke centres in England, there are only twenty-four neuroscience centres available across England capable of providing MT services to patients, requiring hospitals and stroke centres to transport patients to one of the twenty-four centres for treatment (Sentinel, 2020), (Ford *et al*., 2019).

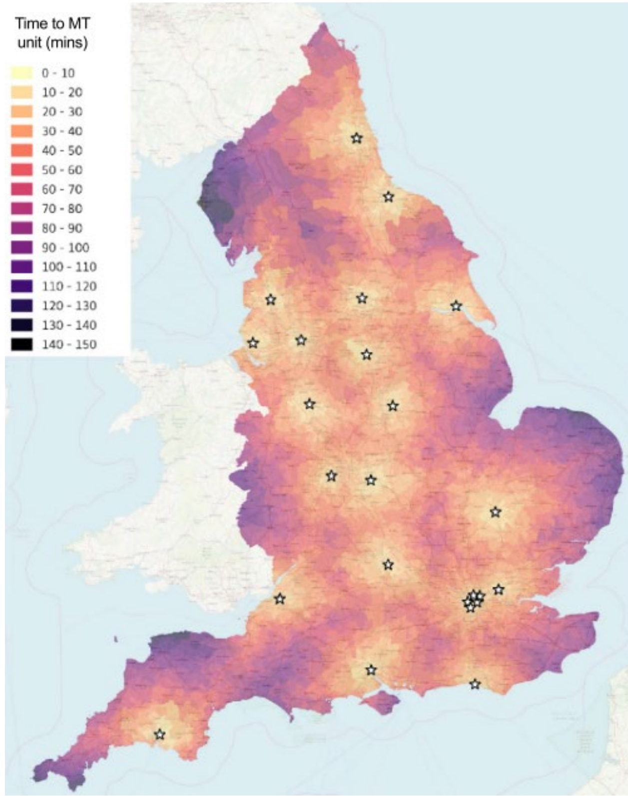


Figure 1.1: Available Neuroscience centres in England with travel time.

Due to the rising demand for radiology imaging and interventional radiology services within the UK, it has become crucial for hospitals to have access to 24/7 neuroradiology cover for acute medical and surgical procedures and provide adequate provisions and staffing to support stroke patients (RCR, 2017), (British Society of Interventional Radiology and The Royal College of Radiologists, 2019). To be achieved, the recommendation is that centres offering MT have a minimum of six interventional neuroradiologists available.

Sixty-two additional interventional neuroradiologists would be needed to provide adequate 24/7 provisions for MT and stroke support across the twenty-four centres. For interventional radiology, research estimates that an additional 379 interventional radiologists would be required to provide the staffing needed (British Society of Interventional Radiology and The Royal College of Radiologists, 2019), (Intercollegiate Stroke Working Party, 2016), (Reidy, 2020), and (Frank, 2017).

1.3.2 Cost and Threat of Prolonged Training Time

Figures provided by the Royal College of Radiologists (Royal College of Radiologists, 2021) break down the radiology expenditure regarding workforce, focusing on outsourcing (hiring radiologists from abroad), insourcing (hiring radiologists from within the UK), and ad-hoc locums (those taking on additional responsibilities to their own) show that between 2015 and 2020, overall radiology expenditure has risen by £118M from £88M in 2015 to £206M as of 2020 (Royal College of Radiologists, 2021). Since 2018, the report indicates that expenditure related to ad-hoc locum practice has stayed between £27M and £29M, while the price for insourcing has routinely shrunk from £57M to £51M, a 10.5% decrease from 2018 while outsourcing expenditure rose from £81M in 2018 to £128M in 2020, indicating a 58% increase. Despite the high expenses, the total workforce is only expected to grow by 3% over the next five years, which has fallen from the 4% average growth seen in previous years, attributed to the recruitment of only four whole-time-equivalent interventional radiologists, equivalent to 1% growth (Board of the Faculty of Clinical Radiology, 2020).

The standard training protocol for interventional neuroradiologists is to complete three years of Specialty Training (ST) in clinical radiology training; ST1-3 is a module and system-based practice in the clinical radiology curriculum, with ST4 being the stage where trainees begin specialist study in interventional radiology, going up to ST6, with trainees choosing to enrol in a subspecialty (such as interventional neuroradiology or interventional oncology) around ST5 or their fifth year (RCR, 2021). The overall duration for interventional neuroradiology training is 72 months (6 years): 36 months are spent on core radiology training and standardised practices, 12 months spent studying advanced neuroimaging and neurosciences, and 24 months spent focusing on sub-speciality training, such as interventional neuroradiology (Lenthall *et al*., 2017).

By the end of their training, the interventional neuroradiologist will be able to comfortably perform complex endovascular procedures on patients with no supervision and be expected to manage the various aspects of the procedure such as imaging and selection, planning, and procedure execution, reporting, and any post-operative tasks.

Given the shortages involved in interventional neuroradiology and the costs involved, it has led to a shortage of mechanical thrombectomy services in most regions, which has the adverse effect of reducing the chances of a trainee getting to perform this procedure on a patient and gaining valuable real-world experience due to the risks associated with this complex procedure (Crossley *et al*., 2019).

1.4 Aim and Objectives

This project aims to develop a novel tactile controller designed to simulate the physical characteristics of arterial threading for mechanical thrombectomy to assess the efficacy of haptic feedback (the physical resistance or feedback felt by the user during a simulation indicate collision or interaction) and relevant data using force-sensing and game-engine technology for simulating and recording arterial threading.

Research Objectives:

- Investigate current trends in medical simulation training platforms, training in interventional neuroradiology and mechanical thrombectomy, and serious gaming and gamification.
- Develop a sensor-based "box trainer" for simulating an arterial bend, generating real-time force-sensor data, and evaluating data generation's efficiency for detecting applied force.
- Create a 3D virtual operating theatre for real-time simulation and visualisation of sensor data.
- Develop a system for interfacing and extracting sensor data in a serious game application for data analysis.
- Analyse and evaluate generated data to determine the effectiveness of the designed system and application for detecting applied force and impact in simulated arterial threading.

1.5 Contribution to Knowledge

This thesis demonstrates the development of a novel tactile controller designed to simulate the physical characteristics of arterial threading in mechanical thrombectomy using force-sensing technology. The novel platform provides physical resistance and calculates the relevant haptic information to the user, visualising the changes in applied force in real-time and analysing the output for performance assessment, and providing a quantifiable and objective metric from the applied force data for neuroradiologist training. The data is analysed to provide indication of the practitioner's level of force and number of impacts performed during a simulated procedure to determine the progress of a trainee clinician and how well they respond to physical resistance when threading a simulated artery.

1.6 Thesis Structure

The research in this thesis is laid out in multiple chapters, and a brief description of each chapter is provided below:

Chapter 2 – Literature Review: This chapter will investigate what Interventional Neuroradiology is, how a Mechanical Thrombectomy is performed, and the current medical training and interventional neuroradiology situation in the UK. This chapter will highlight the critical need for more trained interventional neuroradiologists and critically evaluate the existing state-of-the-art research and commercially available technologies for simulation training outlining the gaps and limitations of existing studies.

Chapter 3 – Introduction to Simulation Platform and Design Considerations: This chapter will introduce the technical specification and requirements of the project. The discussion will also look at the relevant technologies that were identified and investigated, and the ones chosen for this project.

Chapter 4 – Methodology: This chapter will describe methods used to develop the key components and necessary functionality to build a working prototype for virtual arterial threading simulation with physical resistance and force detection.

Chapter 5 – Results: This chapter presents the results of the research, the subsequent data analysis and ensuing impact classification. The chapter will demonstrate how the results and data analysis evolved over the project.

Chapter 6 – Discussion: This chapter will provide a discussion of the project and justification for the results generated. It will detail the way the data was generated and analysed.

Chapter 7 – Conclusion and Future Developments: The closing chapter of the thesis will conclude this research by describing the work packages accomplished in the project. A discussion on how the work can be expanded upon or improved for future investigation is also provided.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter will provide insight into the state of interventional neuroradiology in the UK, looking at the current curriculum for the training and development of interventional neuroradiologists, investigate the use of haptic feedback in simulation training as well as identify cases studies where haptic feedback has been used to improve the simulation training, both in medical training and other industries, and the outcomes and limitations of these examples. Furthermore, the chapter will investigate current standards in mechanical thrombectomy training and evaluate examples of simulation training and haptic systems to explore currently used technologies. The chapter concludes by exploring the immersion and engagement of VR medical simulation training and its benefits.

As technology is advancing, there is a growing interest among the medical community in using simulation technology to enhance the development of complex skills and procedures in novice practitioners. In Interventional Neuroradiology, practitioners must have the ability to safely thread a catheter through a patient's artery during a Mechanical Thrombectomy (MT) to prevent injury and safely complete the procedure. The Sentinel Stroke National Audit Programme showed that over 89,000 patients were admitted to hospital following a stroke, with only 1.8% of eligible patients receiving MT treatment (Sentinel, 2020). The report also suggests a worsening timeframe of stroke onset to hospital arrival, with the average onset to arrival time being 3 hours 15 minutes. The timeframe between the onset of a stroke and arrival time at a hospital for assessment and intervention is critical in limiting the damage caused by a stroke. This has the negative effect of hindering the development of a resident surgeon’s skills and confidence in their specialisation.

2.2 Interventional Neuroradiology

2.2.1 Training and Development

Mechanical thrombectomy is a specialised procedure in interventional neuroradiology, a subspeciality of radiology. Current training programmes in interventional neuroradiology require six years of training to complete; the first stage includes three years of training in core radiology skills, the fourth year focuses on advanced competencies in diagnostic radiology, such as imaging techniques and the fifth and sixth years focus on developing specialised interventional neuroradiology training and skill development (Lenthall *et al*., 2017).

Trainees are required to have completed the initial three years (Level 1) of clinical radiology training, also referred to as ST1, ST2, and ST3, with interventional radiology training building upon the existing curriculum with three additional stages, ST4, ST5, and ST6, to become a qualified interventional neuroradiologist (RCR, 2021).

Progression in sub-speciality training is mapped to capabilities in practice that distinguish how competent the trainee is across the stages of their interventional radiology training programme:

1. Level 2: During ST4, the trainee can only act with direct supervision. Training at this level means that a supervising doctor is present for all interventional procedures and patient care.
2. Level 3: By ST5, the trainee can act with minimal or indirect supervision. At this stage, the trainee can work unsupervised to a degree and communicate indirectly with supervision to obtain advice and direction. However, a supervisor must be on hand for procedures.
3. Level 4: By ST6, the trainee can act independently. The trainee will be working on the same level as a consultant and not need supervision regarding patient care or procedure.

By the end of their three-year sub-specialist training, the INR will be able to comfortably perform endovascular procedures on patients with little to no supervision and be expected to handle various aspects of the procedure, including patient selection, planning, executing the procedure and any reports and post-operative tasks following the procedure.

The *Interventional Radiology Specialty Training* Curriculum (RCR, 2021) dictates that as a part of the sub-specialist training curriculum, resident neuroradiologists are expected to be able to perform a variety of complex tasks and procedures to treat stroke patients and are expected to improve their level of ability, progressing each year from the beginning of their sub-specialist training to the point they obtain their Certificate of Completion of Training (CCT), as shown in table 2.

Table 2: Progression and milestones for general interventional radiology training with expected progression.

Milestones and procedures			ST4	ST5	ST6	CCT
All	Treatment of haemorrhage	**Critical Progression Point**	2	3	4	**Critical Progression Point**
	Treatment of ischaemia		2	3	4	
	Management of sepsis		2	3	4	
	Management of luminal stenosis/obstruction		2	3	4	
	Management of thrombo-embolic disease		2	3	4	
Vascular Intervention	Abdominal endovascular aortic aneurysm repair (EVAR)		2	3	4	
	Thoracic endovascular aortic aneurysm repair (TEVAR)		2	3	4	
	Complex EVAR e.g., fenestrated techniques.		2	2	3	
Interventional Oncology	Tumour ablation		2	3	4	
	Tumour embolotherapy		2	3	4	

While the practitioner is expected to be competent in all areas of neuroradiology, it is unlikely that they will reach a level of competency in which they can act unsupervised in more of the complex aspects of their field due to inherent safety risks. It is rare to be unsupervised, even at the later stage of training as some conditions are rare, hence, the practitioner will need to spend time following the completion of their training building up their experience. Due to this, most practitioners are expected to reach level 3 at ST6, as shown in table 3.

Table 3: Progression and Milestones for Procedures in Interventional Neuroradiology Training with Expected Progression.

Milestones and procedures		ST4	ST5	ST6	CCT
US guided arterial puncture (including carotid artery puncture)	**Critical Progression Point**	2	3	4	**Critical Progression Point**
Cerebral and spinal angiography including use of microcatheters, triaxial systems and occlusion testing		2	3	3	
All endovascular forms of treatment of intra/extra cranial aneurysm and treatment of cerebral vasospasm		2	2	3	
Embolization for haemorrhage e.g., epistaxis and vessel trauma		2	2	3	
Endovascular procedures for device migration, malfunction, or vessel perforation		2	2	3	
Cervical vessel angioplasty and stenting including carotid blow out		2	2	3	
Endovascular treatment of stroke due to large vessel occlusion (mechanical thrombectomy)		2	3	3	
Thrombolysis (arterial and venous sinus)		2	3	4	
Embolization of Dural, brain, craniofacial or spinal tumour		2	2	3	
Embolization of cerebral, Dural and spinal AVM or AVF		2	2	3	

The crux of the issue is that due to the shortage of INRs (Interventional Neuroradiologists), access to MT services is limited in regions, which has the knock-on effect of reducing the opportunities a trainee must have to practise this complex procedure. On occasion when an MT is being performed, they may not get the chance due to the risks associated with the image-guided procedure (Crossley *et al*., 2019).

Due to the nature of MT as a minimally invasive surgical procedure and the limited opportunities for trainees to practise, simulation training is used to support training and help improve their procedural knowledge and technical skills. Traditional approaches of gaining skills through experience usually work; in the case of MT, it does not guarantee the practitioner will perform the procedure independently within the timeframe outlined by existing curricula (Liebig *et al*., 2018).

Simulation training has seen growing popularity in various specialised surgical programs, with mentoring practitioners supplementing traditional training practices with simulation in a trainee's programme (Miller *et al*., 2019). Simulation training can remove the level of capabilities and patient safety from the equation when a trainee is performing a virtual procedure, which can reduce the stress levels of the trainee. Simulators also allow the supervising practitioner to provide feedback and guidance without concerning themselves with patient safety, improving the quality of assessment and helping the trainee develop more quickly.

2.2.2 Mechanical Thrombectomy Simulation Training

A Mechanical Thrombectomy is a minimally invasive endovascular procedure conducted by Interventional Neuroradiologists on a patient who suffered a stroke. The procedure involves guiding a catheter up to the blood clot site that is cutting off the blood supply to the brain, in the cerebral or carotid arteries. A stent device retrieves the blood clot and removes it from the artery to restore blood flow to the brain.

Due to the apprenticeship model used in training Interventional Neuroradiologists (INR), most trainees learn through imitation and repetition and training under an expert practitioner throughout their education (Miller *et al*., 2019). The training period for trainees in this field is three years of core radiology training and an additional three years of sub-specialist training in interventional neuroradiology.

Combined with the European Working Time Directive (EWTD), this has reduced trainees' training time and operative experience, leading to an investment in simulation trainers to provide more opportunities for trainees to develop their skills (Humm *et al*., 2020). Simulation trainers give the practitioner a detailed and approachable breakdown of procedures and tools to improve the knowledge and understanding of the procedure and what it involves, allowing users to learn and retain information in a stress-free environment.

An essential feature in simulation platforms and training is the accurate replication of physical characteristics related to the anatomy and tooling to improve technical motor skills to help improve the practitioner's performance capabilities. Despite the importance of haptic feedback and physical representation in INR simulation training, most state-of-the-art simulation trainers lack effective haptic feedback and information regarding the application of force from a practitioner. Hence, surgeons cite the lack thereof as the most significant weakness of simulation training (Overtoom *et al*., 2019).

The reason for designing this system is to provide a smaller, adaptable solution that allows trainees to practise arterial threading in MT anywhere, whereas industry-standard platforms such as Mentice VIST (Mentice, 2021a) and 3D Systems ANGIO Mentor (3D Systems, 2021) often require plenty of space and, at times, a dedicated training environment that not all centres can provide.

Additionally, a fundamental limitation of desktop VR simulators, which rely on just screen-based simulation, is the lack of immersion and feel of "being there," which is down to a screen not being able to provide the fidelity or content required to create an immersive simulation experience. The use of high-fidelity VR technology such as head-mounted displays and 6-dof (degree-of-freedom) has been found to improve the immersion of a given simulation and increase user-presence and engagement as opposed to traditional monitor-based solutions commonly used (Buttussi and Chittaro, 2018). High-fidelity VR offers a higher sense of presence and spatial awareness and can provide in-depth interactions and visualisations that can support simulation training.

The work detailed in this study seeks to demonstrate the platform's ability to integrate sensor data into a virtual reality environment that can help inform practitioners of the amount of force they are using when threading an artery. To tackle this issue, the approach taken involves creating a box trainer that allows for the secure placement of tubing to simulate a patient's artery with an array of Force-Sensing Resistors (FSR) attached at the midpoint of the tube to measure the applied force from the tubing, with any changes or impacts identified in the system. An Arduino Nano is used to read the sensors' data before sending the data to Unreal Engine to present feedback to the user in real-time.

2.2.3 State-of-the-art Simulation Training Platforms

The most recent state-of-the-art simulation training platform for MT simulation training is the Mentice VIST (Vascular Intervention Simulation Trainer) which allows for the practice of stent retrieval in mechanical thrombectomy, aneurysm coiling, and attainment of the steps involved in the procedures (Mentice, 2019). The VIST G7 is a small-scale platform that can be situated in a variety of settings to allow learning anywhere (See Figure 2.1).

A step-up from the Mentice VIST G7 platform is the Mentice VIST Lab, a large-scale simulation platform that provides realistic workflow and multi-user collaboration. The key difference between the G7 and VIST Lab is that the G7 is a portable platform that can be moved, stored, and interacted with in various spatial settings.

The VIST Lab, however, is a stationary solution that requires a large space in which to operate, as it provides high-fidelity interaction through a life-size mannequin with pre-determined insertion points and internal artery system and is designed for compatibility with industry-standard c-arm systems to allow for team-building exercises by allowing INRs to work alongside radiography technicians (See Figure 2.2).

Research conducted by Crossley *et al* 2019 sought to conduct validation studies on the performance metrics used in simulation training for mechanical thrombectomy using Mentice VIST G5 Vascular Intervention System Trainer (Crossley *et al*., 2019). The study describes the need for effective simulation training provisions for the following reasons: (a) limited access to mechanical thrombectomy services in certain regions linked with the shortage of interventional neuroradiologists trained to perform mechanical thrombectomy to a competent level; and (b) potential risk that a patient is exposed to during image-guided surgical procedures that make it dangerous for trainee neuroradiologists to practise (on patients).

It was established that effective simulation training would require a comprehensive characterisation of the procedure being simulated, with a clear definition of the different steps and phases and be used to identify sub-optimal performance and errors. These characterisations could serve as the foundation in which to provide trainees with formative feedback on their performance in simulation training and help demonstrate their progression.

The study aimed to characterise and validate in detail a reference approach to mechanical thrombectomy that identified (a) the number of phases, (b) the number of steps, and (c) the number of errors that could be used to distinguish the performance of a novice INR from an experienced INR and integrated into a simulation trainer. The characterisation of the mechanical thrombectomy procedure took seven months to produce and involved working with the simulator development facility to optimise the fidelity of the technical aspects of the simulation. The result is a ten-phase procedure consisting of forty-six steps and fifty-seven potential errors that could occur in practice, both critical and non-critical. The characterisation adhered to specific tenets of angiography that define good practice: (a) releasing pressure from catheter or guide wire when resistance is felt to avoid perforating the vessel wall and (b) catheter manipulation should only ever be backwards in the absence of a guidewire to avoid vessel scraping. Deviation from these standardised practices, will constitute an error.

The characterised reference approach to mechanical thrombectomy was presented and agreed upon with twenty-one expert INRs who agreed with the defined characteristics such as procedure phase, step count, and error count. The metrics and characterised definitions are used in the simulation to support assessment. The core parameters used to assess performance in the simulation training were (1) duration of the procedure in minutes, from initial catheter insertion to successful recanalization of the occluded vessel, (2) number of phases completed, (3) number of steps completed, (4) the number of handling errors made, (5) the amount of contrast agent used in millilitres, and (6) total amount of fluoroscopy used during the procedure in millilitres.

The reference approach to mechanical thrombectomy produced, supports the training of the novice INR by providing objective assessment of their performance and allows expert INRs to observe their performance over time to ensure they can consistently perform the procedure at a competent level before allowing them to perform the procedure on live patients.

Additionally, the Simbionix AngioMentor is commonly used for training and provides users with multiple tools to support teaching and learning that can guide the trainee through the procedure safely in diverse ways, such as anatomical views, warning prompts and it documents extensive parameters about performance (3D Systems, 2021); the Simbionix AngioMENTOR is comparable to the VIST G7 in size and likewise, can be transported and assembled quickly in a variety of clinical and educational settings (See Figure 2.3).

Simbionix also offer the AngioMENTOR Suite II, a “true-to-life” platform for high-fidelity simulation and multi-user collaboration between INRs and Imaging Technicians, designed specifically to be used in a clinical environment.

Akin to the Mentice VIST Lab, Simbionix solution offers practitioners a life-size patient with several integrated access sites to perform various endovascular approaches from various start points, compatibility with c-arm systems, and real-time image interpretation and manoeuvring for team-building exercise (See Figure 2.4). The Suite set-up provides practitioners with a more in-depth and realistic workflow for learning endovascular procedures such as endovascular thrombectomy, however, similar to the VIST Lab, is specific to clinical settings and requires the use of a large space or medical theatre.

The platforms described above provide robust functionality and accurately recreate endovascular procedures relevant to interventional neuroradiology training. A vital part of these systems is their ability to provide assessment criteria to supervising practitioners to assess the practitioner’s progress effectively. However, they focus on procedural knowledge and task-based competency and provide little or no support for tactile feedback that can enhance the practitioner’s abilities by providing some form of physical resistance to corroborate what they see on the screen during practice.

Additional research supports the idea that interaction and engagement in a high-fidelity VRLE can improve a participant’s performance and skills when physical engagement or practice is impractical or otherwise unavailable. Compared to training with physical apparatus, users training with virtual components made more promising progress than users trained with just physical equipment (Murcia-López and Steed, 2018).

Table 4: Summary table demonstrating current platforms for MT simulation training.

Platform	Advantages	Disadvantages	Haptic	Dimensions
Mentice VIST G5	Supports real world clinical devices up to 24F. Small footprint – Laptop-based. High-fidelity procedural simulation. Portable platform via wheeled pelican case/briefcase.	Inefficient haptic feedback. Solo-user experience. Expensive operating costs. Approx: £95,046. Does not involve catheterisation or stent removal and closing of entry point. Requires moderate amount of space, such as an office desk.	No	G5 Device (115cm x 40cm x 15cm). Laptop, Monitor, VIST Control Box (63cm x 50cm x D30cm).
Simbionix Angio Mentor Flex II	Quick plug-and-play system. Supports fluoroscopy and simulates real-world table controls Small footprint – Laptop-based. Portable platform via wheeled pelican case/briefcase.	Inefficient haptic feedback. Solo-user experience. Expensive operating costs. Does not involve catheterisation or stent removal and closing of entry point. Requires moderate amount of space, such as an office desk.	No	Mentor Flex II Platform (115cm x 40cm x 15cm). Laptop, Monitor, Flex Device (63cm x 50cm x D30cm).

Mentice VIST Lab	True-to-life interventional suite. Supports fluoroscopy and real-world devices. Haptic feedback enabled via life-size mannequin. Multi-user environment.	Large footprint requiring a lot of space to fit, such as an existing angio-theatre. Longer set-up time. Does not simulate catheterisation or removal of stent device and closure of wound.	Yes	Mentice VIST Lab (2m x 1m x 2.5m) (approximated)
Angio Mentor Suite II	True-to-life interventional suite. Compatible with actual C-Arm allowing collaboration with x-ray technicians. Haptic feedback enabled via life-size mannequin with predefined entry points. Multi-user environment.	Requires an angio-theatre to be available due to size and compatibility with real-world medical machinery. Longer set-up time. Does not simulate catheterisation or removal of stent device and closure of wound.	Yes	Angio Mentor Suite II (2m x 1m x 2.5m) (approximated)

2.2.4 Recent Advancements in Mechanical Thrombectomy Training

Matthias Bechstein *et al* 2021 investigated the benefits to training and supervision in mechanical thrombectomy using remote live streaming support from an expert Interventional Neuroradiologist (Bechstein *et al*., 2021). The study investigated whether remote live streaming could be used to supervise and train Radiologists in performing endovascular thrombectomies in remote regions that lack access to expert interventional Neuroradiologists. Six Radiologists, each with no experience in Mechanical Thrombectomy, conducted an anatomically distinct Mechanical Thrombectomy procedure using the Mentice VIST with an expert Neuroradiologist with over 15 years of experience in Neuroradiology. The proposed system allows the supervising Neuroradiologist to log into a live stream using a 360° camera, microphone and speaker and standalone server that could connect online and transmit the livestream data. The criterion used to assess the Radiologist's level of ability consisted of several measures of success including (a) time to recanalisation of occluded vessel, (b) percentage of thrombus removed by stent retrieval, (c) and the speed of stent retrieval. Inversely, the failure conditions for the simulation were failing to recanalise the occluded vessel five consecutive times. The results of this study showed that remote supervision was just as effective as on-site supervision with marginal differences between stent retrieval time and successful recanalisation of the occluded vessel. Additionally, practitioners felt it was less intimidating being observed remotely as opposed to having a supervisor present with them. However, a clear problem with the proposed solution was the detachment between supervisor and scenario, which meant it was impossible for the supervisor to intervene and interact with the catheter manually to advise the Radiologist how best to proceed regarding the physical resistance and force. This indicates that a critical part of the procedure is developing an understanding of the applied forces and physical resistances present in the artery during catheterisation.

Research conducted in robot-assisted surgery (RAS) shows similar research being conducted to determine the level of force applied to an artery to help train neuroradiologists in catheterisation and arterial threading. Researchers investigated using a Phantom Omni haptic device, traditionally used for 3D sculpting, combined with a unity environment with a 3D representation of a blood vessel to provide haptic feedback to users (Jin *et al*., 2021), (Guo *et al*., 2017). The proposed system involved manipulating a virtual catheter through a virtual artery in a 3D environment, based on a "glass model" that provides practitioners with several representations of common arterial navigation scenarios. The displacement of the catheter is driven by the haptic device, which calculates the movement and distance from the virtual artery, with resulting collision with the virtual artery signalling to the haptic device to adjust the amount of resistance it provides the user. The results of the study indicate that while the proposed system could provide force-feedback, there was an error rate of 10% in force evaluation and catheter navigation, this is due to discrepancies in the accuracy of displacement between the haptic device and the Unity 3D environment.

A further study investigated the use of the above system with patient specific DICOM data to understand how the haptic device worked in a more dynamic environment (Yu *et al*., 2019). By using the displacement to identify where the virtual catheter was located relative to the virtual arterial vessel, the system could provide visual prompts to indicate how the practitioner was performing, with different warnings for different proximities to the virtual arterial wall. To test this system, the researcher had two teams perform a catheterisation: team one completed the task with no visual or haptic feedback, only the virtual catheter and artery for reference, while team two had the virtual catheter and virtual artery as well as visual and force-feedback to help them complete the task. The results from this study demonstrated major differences on the trajectory of the catheter in virtual reality, with team one demonstrating only 36% safe trajectory in virtual arterial threading, and team two showing 52% safe trajectory.

Yeshwanth Pulijala *et al* 2018 conducted a randomized control trial on the effectiveness of immersive virtual reality in surgical training to support the growth in the self-confidence and knowledge of practitioners (Pulijala et al., 2018). The study sought to examine the effect that self-confidence had on the performance of resident surgeons during their training and the impact that VR surgery has on a resident's self-confidence and procedural knowledge. The author noted that despite training methods evolving, many novice practitioners feel overwhelmed during their training, with the potential for "unintended mishaps" to occur from the errors caused by a lack of confidence. Similar to other studies, it is implied that a reduction in working hours due to the EWTD and insufficient opportunities to be involved in the operating of a live patient is a major catalyst for errors during operating. It is stated that there is a growing need for training tools that support the development of a resident's confidence and also the ability to develop skills and knowledge to complement their fundamental skills.

The study involved the development of a VR surgery tool that used an Oculus Rift DK2 and Leap Motion Controller to demonstrate Le Fort I Maxillary Osteotomy and allow practitioners to complete a VR Jaw Reconstruction, a complex procedure with limited training tools available to residents. The application provided users with a 360° experience of an operating room, stereoscopic visualisation of surgery tasks, and interaction to provide users with an immersive learning experience. Users were able to interact with the 3D environment, patient anatomy, and instrumentation. CBCT scans were used to supplement the 3D data and a quiz was created to provide real-time feedback to users during interaction.

The author tested for the efficacy of VR surgery training for novice residents throughout multiple centres using a single-blind randomised control trial. The null hypothesis for this study was that there would be no changes in a resident's perceived self-confidence after VR training in the control group and study group, with the alternative outcome of self-confidence levels of the study differing from those of the control group following the study. The important metric in this study is the comparative evaluation scores of perceived self-confidence levels in residents before and after the training, which is measured by a 5-point Likert scale, with the secondary outcome being the change in the resident's knowledge level and impact on perceived self-confidence levels. For recruitment, 95 full-time residents from across seven dental schools, with limited exposure to Le Fort I Osteotomy took part in the study. Following recruitment, users were assigned to the control (n = 44) and study (n = 51) groups using parallel randomisation.

The study design involved three questionnaires, a pre-intervention questionnaire and demographic questionnaire providing the initial baseline data for perceived self-confidence and knowledge, with a post-intervention questionnaire looking at the impact of the VR training. The questionnaires looked at the proficiency in the various aspects of the procedure, such as patient anatomy, instrumentation, and the order of procedural steps, as well as questions testing for knowledge to correlate with their perceived self-confidence. Qualitative feedback was also provided by residents regarding the best and worst aspects of the application.

The results of the study showed that pre-intervention levels of confidence and knowledge were comparable between both groups with no significant discrepancies. Post-intervention results showed that residents in both groups showed an increase in self-confidence levels, however, based on the pre-intervention results, the control showed a small increase of 0.234 in self-confidence, while the study group demonstrated a significant increase of 0.642 in self-confidence. The study group also outperformed the control group regarding knowledge-based questions.

Through this study, it was identified that VR was paramount among residents for the boost in confidence and knowledge, with an immersive and content-rich virtual environment supporting development. Additionally, it was found that VR training has a significantly larger impact on less experienced practitioners in comparison to more experienced residents, which is vital to help build a strong foundation on which they can develop professionally.

Matthias Süncksen *et al* 2018 conducted research on whether a VRLE focused on recreating radiographic procedures could be employed in medical training to improve the attainment of skills in radiography technicians. The author noted that intra-operative imaging carries a significant risk of radiation exposure to the patient and operating team with a growing need for more adequate training in this regard. The proposed solution is a VR serious game developed for HTC Vive using Unity that simulates the task of c-arm navigation and intraoperative radiography that offers a more immersive experience compared to desktop solutions. The development of this application involved integrating a 3D scene of an operating theatre, with functioning c-arm and medical screens. The user is tasked with reproducing a given radiographic image by manipulating the c-arm. The radiographic images were supplemented by the incorporation of DCMTK, a toolkit that allows the integration of DICOM image sets, which are visualised using average intensity projection volume rendering, and provided a realistic simulation of real-world medical imaging techniques.

To make the software more effective, the c-arm is fully functioning and can be moved and rotated along its different axes with virtual radiographs doable in single-shot, pulsed, or fluoroscopic mode, allowing the operator to analyse the patient. The task of completing the radiography can be completed either in a simple non-medical context or a medical context, with users being given an image of a medical scan and having to recreate it. The performance of the trainee was evaluated on three criteria: accuracy of radiographic image (section and orientation), time needed to achieve the image recreation, and accumulative patient dosage. The application also allowed expert users to create tasks that could be provided to trainees to practise on. The application uses gamification elements to provide users with an immersive and challenging experience, with different levels of difficulty and points rewarded for accuracy, time, and overall exposure.

The evaluation of the platform was completed in two distinct contexts: nine layman users assessing overall usability, and 68 healthcare professionals assessing the overall utility. Both groups were introduced to the application, which consisted of an overview of the application and the tasks they can complete. The layman group were given a User Experience Questionnaire to complete as part of the experience, with additional questioning on how they rated the desktop and VR applications. The healthcare professionals were given the same user experience questionnaire and were asked whether they believe the VR application to be beneficial for medical training. The results of the study indicated that a majority of users found the application useful for medical simulation training and identified aspects beneficial to the application, such as the realism and task recreation, with users feeling stimulated by the realistic simulation of a real-world scenario, which was noted by users with substantial experience in an operating room.

Cecilie Våpenstad *et al* 2017 investigated the transference of technical skills following training in a virtual reality platform with haptic feedback for laparoscopy (Våpenstad et al., 2017). The author identified that VR simulators can provide consistent proficiency-based training with objective assessment tools and can replicate complex set-ups without the need for preparation, therefore providing each candidate with a fair and identical test. It is also identified that while many research projects identify the transference of skills from a virtual setting to a clinical setting, the effectiveness that transference has is still debated and the author adds that it is crucial that VR simulation reproduces the technical challenges a surgeon will encounter, such as physical resistance via haptic feedback. A criterion-based program was designed to be used with the LapSim VR Simulator to investigate its predictive validity; by using validity over time-based training, all trainees can be expected to attain the same competency level within the simulator. The study involved two groups who were evaluated using an organ model in a box trainer simulating a cholecystectomy; the groups consisted of a control group (n = 14) where users did not receive practical training with the simulator, and the study group (n = 16), who did receive practical training with the simulator.

To supplement the training and ensure all users had a baseline experience to start, all users received a one-hour lecture on the procedure being performed, observed a surgeon performing the procedure using the simulator, and spend ten minutes familiarising themselves with the instruments involved with the procedure. The procedures performed were recorded and assessed by two independent expert surgeons who rated the video using criteria determined by the Global Operative Assessment of Laparoscopic Skills (GOALS) tool such as depth perception, bimanual dexterity, efficiency, and tissue handling, with each category scored on a scale of one to five (C-SATS, 2022).

The criterion-based challenges involved five tasks relating to procedure competency: coordination, clip applying, lifting and grasping, fine dissection, and pattern cutting, each with predetermined configurations and assessment criteria for completing the scenario. The assessment criteria included near misses, keeping instruments in view at all times, correct placement of clips, and no damage to tissue. The results of the study found that the control group scored significantly better video ratings than the users in the study group, with improved depth perception, bimanual dexterity, and efficiency. For the criterion-based training, the study group demonstrated higher video-ratings and a decrease in the number of trials needed to pass the VR training, with the added observation that users who frequently played video games that require bimanual dexterity and depth perception, such as the Xbox Kinect, and Nintendo Wii, performed significantly better in those aspects. A correlation with this study and others is the observation that the operating room is not an ideal place for novice residents to develop technical skills owing to the ethical concerns, working time directives, and nature of minimally invasive surgery, and that while the author finds there are thirty-three simulators on the market, only eight of them had been part of a validation study, which leads to difficulty for trainers to develop an effective curriculum based on these platforms. The discussion focused on how haptic feedback is important for a lot of technical tasks in laparoscopy and other surgical fields. The author noted that while this is a crucial aspect of VR training, it is often difficult to produce high-fidelity haptic feedback that accurately simulates real -world physical resistance and issues such as frequency response, force production and resolution can be inefficient. The author describes how the study did not show any benefit to VR training regarding the transfer of skills to a clinical setting and that VR is limited in terms of the construct validity of developed simulators and the lack of realistic haptic feedback.

The limitation with these studies is the method in which the haptic feedback is reproduced. The haptic feedback of the aforementioned studies is either mechanically driven or digitally derived, which can detract from the immersion of the simulator and also provide inaccurate feedback to novice practitioners. Low-fidelity haptic feedback undermines a resident's training as they will become used to the haptic response of the simulated procedure and not be familiar with the haptic response found in the real-world equivalent. For MT, this is even more critical as, of the two stimuli required to perform the procedure, the sense of touch is paramount with users required to understand how the artery is responding to the catheter that the practitioner is inserting. The studies identified that minimally invasive surgery such as MT requires a high degree of accuracy and realism regarding physical resistance and tactile feedback. The omni phantom haptic device used only offered translational displacement on the X, Y, and Z axis, with no rotation mentioned, which implies the virtual catheter was controlled from the tip end and not the sheath end. In reality, surgeons would have to manipulate the catheter by rotation, which is not mentioned in these studies, but is a crucial part of catheter manipulation in arterial threading for vascular intervention. Additionally, the state-of-the-art systems only provided haptic feedback in the larger, lab suite set-ups, with the smaller systems omitting this feature, making it difficult for practitioners to develop this competency, as most medical facilities do not have the space available to host the larger systems and would have to close off an existing theatre. For the immersion aspect of medical training, VR simulators, and by association, frequent experience with motion-based gaming systems, was implied to be beneficial to the development of the practitioner, with a consistent scenario that could be repeated with minimal set-up, and a 3D immersive experience in which to interact with anatomy, instrumentation and equipment, helping to provide a more significant learning experience to the user, increasing the attainment of skills and knowledge.

Table 5: Summary Table for Literature Review on Research in Mechanical Thrombectomy.

Author	Year	Study	Equipment	Results
Bechstein	2021	Remote Live Streaming Support as opposed to local supervision	Angiography Suite. Mentice VIST G5 Simulator. Axis P5515 360° rotating camera. Small form factor server. On-camera microphone and loudspeaker.	This study demonstrated that novice practitioners could conduct and complete an MT under remote supervision with comparable results to those supervised locally.
Jin	2021	Total Force Analysis and Safety Enhancing for Operating both Guidewire and Catheter in Endovascular Surgery	Catheter manipulation unit. Guidewire manipulation unit. Laser sensor. Calibration Unit. Catheter control unit. Magnetic field generator. Guidewire control unit.	This study identified that force-sensing technology could be utilised in robot-assisted surgery to identify collisions between guidewire/catheter and arterial wall, improving patient safety during MT.
Crossley	2019	Validation studies of virtual reality simulation performance metrics for	Mentice VIST Lab.	The study found that VR simulation designed with performance metrics objectively distinguished novice

		mechanical thrombectomy in ischaemic stroke		and expert practitioners based on time to recanalisation, fluoroscopy usage, steps completed. They also noted that novice users had more variability in their results than expert users.
Yu	2019	The Characteristics Evaluation of a VR Simulator-based Catheter Training System	Catheter manipulation unit. Guidewire manipulation unit. Laser sensor. Calibration Unit. Catheter control unit. Magnetic field generator. Guidewire control unit.	The study found that the use of a haptic tool when conducting VR simulation training improved the practitioner's hand-eye coordination during surgery and helped develop better control of the instrumentation and improve patient safety.
Pulijala	2018	Effectiveness of Immersive Virtual Reality in	Oculus Rift DK2. Leap motion hand tracker.	Results showed that VR simulation improved the users' self-confidence and

		Surgical Training - A Randomized Control Trial		procedural performance. With VR, environments and tool interaction provided deeper insight for early-stage practitioners.
Süncksen	2018	Gamification and virtual reality for teaching mobile x-ray imaging	HTC Vive.	The results showed that most users found the gamification and virtualisation of medical procedures to be an attractive, stimulating, and novel experience. Ninety-eight percent of users agreed VR simulation was beneficial to medical education.
Guo	2017	The Virtual Reality Simulator-based Catheter Training System with	Catheter manipulation unit. Guidewire manipulation unit. Laser sensor. Calibration Unit. Catheter control unit. Magnetic field generator.	Haptic tools can be applied to VR simulation training and provide force-feedback based on interaction with a virtual artery, improving patient

		Haptic Feedback	Guidewire control unit.	safety, with a 10% margin of error.
Våpenstad	2017	Lack of transfer of skills after virtual reality simulator training with haptic feedback	LapSim VR Simulator.	The results showed that simulation training laparoscopy did not improve a practitioner’s skills or demonstrate transference to a live setting. The author cites the poor mechanical performance of haptic feedback, which led to the development of bad habits during training.

2.2.5 Haptic Feedback in Surgical Training

Research into simulation training highlights the significance of haptic feedback in a practitioner's training. It is imperative that a simulation platform with haptic feedback can accurately recreate the physical resistance and sensation the practitioner is exposed to during live practice. By doing so, the practitioner can better develop their fine-motor skills and understanding of the different sensations present during an MT procedure (Latham *et al*., 2019b), (Kaluschke *et al*., 2020). There is additional research investigating tactile sensitivity and how different users experience tactile feedback and how it affects their perception of a virtual environment, which notes that effective tactile feedback can improve the immersion of the simulation and relax the practitioner, reducing their stress levels and other physiological parameters (Zhao *et al*., 2021).

Medical practitioners have invested much work into haptic feedback, with practitioners aiming to simulate physical characteristics to help develop muscle memory, motor skills, and hand-eye coordination. Research into haptic feedback and its effect on the attainment of surgical skills in trainees is still debated among medical experts, arguing that effective haptic feedback requires accurate representation and response time from the simulator to provide realistic haptic feedback. Some researchers say that effective feedback is better suited for more complex procedures and advanced practitioners (Overtoom *et al*., 2019), (Våpenstad *et al*., 2017), (Alaraj *et al*., 2015).

2.2.6 Haptic Feedback in Other Sectors

2.2.6.1 Case Study 1: Tactile Feedback in Wearable Gloves in a Simulated Wheel Change

While the development of haptic feedback has seen prominence in numerous areas of medical research there exist multiple examples of haptic simulation outside the medical community that demonstrate both the advantages and disadvantages of haptic cues in simulation training when combined with audio-visual cues.

A study conducted by Cooper *et al* 2018 investigated the effects of multisensory feedback on task performance and sense of presence within a VRLE where users are tasked with changing the wheels on a racing car (Cooper *et al*., 2018). The researchers describe how despite the improvements in simulation fidelity when multiple sensory modalities are stimulated, there are still many obstacles that constrain how many sensory modalities can be stimulated within a simulation environment. The author goes onto explain the limited opportunities for tactile feedback in virtual interactions, noting the commonly used force-feedback technology that generates force based on the users input and provides force to specific points on the body, such as finger-tip (Touch Haptic Devices (3D Systems, 2021)). The article describes the use of vibrotactile feedback which is commonly seen in wearable haptic devices, such as bHaptics Tactosy (bHaptics, 2022) and Manus Prime X (Manus Machinae BV, 2021) and gesture controllers, such as Meta Quest and Vive Focus, that provides a more efficient form of feedback to users, helping distinguish between textures and shapes more effectively and improving spatial guidance in the learning of new activities and providing warning or information cues in complex tasks (such as driving a vehicle or completing a mechanical task).

Following on from this, the authors look at whether substitute sensory cues will be beneficial to task performance and user experience, which forms of sensory cues are most effective for performance metrics, and the modes of feedback, such as multisensory, bimodal, and unimodal.

The task involves users interacting with the virtual environment and completing a wheel change on a virtual racing car using a pneumatic tool whilst substitute cues such as audio, visual, and haptic, provide task-related information. The user’s head and hands, and pneumatic tool were tracked in the real-world using VICON tracking systems that translated their real-world locations into the virtual environment projected in stereoscopic view onto a Powerwall.

The user experienced tactile feedback through vibration motors attached to the VICON tracking gloves, which provided varying ranges of vibration cues to the user, ranging from 15Hz (when participants are holding a wheel bolt), to 250Hz when the bolt was securely fastened. The vibration cues simulated the intensity of the pneumatic tool as the user secured the bolt to the wheel, with a moderate level of force when screwing a bolt in and out of place (85Hz). Tactile cues were present during any interaction with the pneumatic tool or wheel, such as carrying to and from the vehicle.

The task involved completing a wheel change in the quickest possible time and began when the user picked up the pneumatic tool, where they then had to unscrew all the bolts from the wheel, remove it and place it on a nearby stand, before retrieving a replacement wheel and attaching it to the racing car and screw the bolts back in, with the scenario ending when the user placed the tool back down.

The study was repeated with several designs to user sensory feedback, audio, visual, tactile, audio-visual, audio-tactile, tactile-visual, and audio-visual-tactile, to compare the difference in completion times and sense of presence within the virtual environment. Results of the study demonstrated that of the control groups, audio-visual-haptic had the best time to completion and sense of presence, with the results demonstrating that across each stimulus, the inclusion of tactile feedback significantly improved response time and sense of presence, when compared to a bimodal or unimodal form of sensory stimulus.

The study identified that multimodal sensory cues providing task-relevant information and feedback significantly reduced completion time in the given task and improved users' perception and involvement in the VRLE. This is despite the audio-visual-haptic cues not necessarily being natural cues but more abstract in nature, and thus having a negative impact on the immersion of the scenario and sense of presence. This indicated that in a simulated learning environment, informational fidelity outweighs visual fidelity and is more beneficial to the simulated experience with the tactile feedback providing additional context and clues to the user as how to complete the task being simulated when combined with audio-visual clues. These findings are backed up in a follow-up study that looks at the effects that multisensory cues have on the transference of training and task perception in real-world practice (Cooper *et al*., 2021).

2.2.6.2 Case Study 2: Haptic Feedback in Gesture Controllers in Virtual Pump Maintenance

Winther *et al* led a study into the development and evaluation of a VR simulation for training engineers in performing pump maintenance to compare against supervised training and video training (Winther *et al*., 2020). The challenge faced by simulation training is that to effectively recreate a physical experience, multisensory stimuli require careful programming and implementing to accurately reflect real-world practice; if a stimulus is programmed incorrectly, it will detract from the experience. The author identified two core aspects of simulation training that determined the practitioner's level of ability. The first is skill acquisition, which is an aspect of training that can be divided into three sections: *cognitive* (user develops knowledge of the task), *associative* (the user can associate various parts of the task with its environment to make better decisions), and *autonomous* (the task can be completed with less cognitive load and attention). The purpose of skill acquisition is to ensure that new employees have a higher transference of learning. The second is transfer of practice, which involves *learning* and *recalling*. The idea of this is to train the user's memory of a task, which can be affected by whether the task is practised in the same environmental context or not, the latter of which can detract from the user's experience, known as *contextual dependent memory*, a highly relevant factor for virtual environments.

To compare the different forms of learning (supervised, video, VR), several evaluation metrics were identified, with the common parameters including:

- **Completion Time:** An objective and common parameter in user evaluation that is used in experiences that have a defined start and end, such as assembly tasks or manufacturing. It is often combined with other metrics such as error count, which can help identify level of performance.

- **Number of errors:** the second common metric used to evaluate performance is the number of errors a user makes during training such as picking up the wrong instrument, failing to follow procedure, applying incorrect interactions, etc.
- **Knowledge Retention:** knowledge retention is used to measure how much a user remembers of a task between attempts and can be measured using parameters such as completion time and error count across multiple tests, which can help identify the loss of trained knowledge between each test.
- **Confidence in Actions:** A subjective parameter used to evaluate how confident a user is in their actions during practice.

The simulation involved having users complete a virtual simulation on an application developed in Unity 3D with a Vive headset and controllers using a windows PC with GeForce GTX1070 Graphics Processing Unit. The simulation was based on existing training simulations used in pump maintenance with the task being split up into steps accompanied by contextual audio-visual cues to inform the user via narration and object highlights.

The user interacts with the virtual environment using virtual hands that track the controller movement and adapt to the user’s input (i.e., the hand closing when the user presses the trigger of the respective controller). The use of gestures in the virtual hand provides context clues to how the user can interact with the environment, such as the hand closing suggesting they can pick items up. In terms of haptic feedback, the application employs haptic feedback as an indicator that a task has been completed or is being completed, such as screwing a screw with a torque screwdriver, which provides haptic feedback to simulate the clicking and fastening of the screw.

The combination of haptic feedback and gesture controllers provided users with clear indication of progress and allowed them to develop more natural hand movements, and that with further development, the feedback could be enhanced to support additional development.

The results of this study demonstrated that in the context of pump maintenance, virtual reality was not adequate in its simulation of the task, with users struggling to understand the controls, memorise task steps, and more concerningly, since the simulation only required users to place an object near the required location before snapping its location and rotation, users were not aware of how to position the object correctly.

Lastly, users felt unsure of what could or could not be assembled. The author indicates that the richness provided by the hands-on experience in pairwise and video training methods, while difficult to simulate could present a great benefit to learning.

The author identifies that the virtual reality could be improved using hand tracking to allow users to perform more natural hand gestures and interact with the environment in an intuitive manner. Additionally, a crucial mistake they identified was "railroading" users into performing the task in the correct way and not allowing the user to explore and learn through trial and error, which inherently removed the need for the user to contemplate their actions.

2.2.7 Limitations

The case studies described in this section highlight two distinct forms of haptic feedback in virtual reality: vibrotactile feedback using wearable technology, and haptic feedback through gesture controllers.

Haptic feedback is used as an indicator in conjunction with audio-visual cues to guide the user input as opposed to providing indication of resistance to the user, except for applying force feedback to indicate no more force can be applied. In the first study, the haptics are driven by a virtual tool tracked by a proxy-pattern controller that sends haptic cues to the user when a screw is correctly fitted. However, like most examples of haptic feedback, this is computed by the application and does not consider the physical properties of the material being interacted with, which can provide a less realistic haptic cue and misinform the user and distract from the experience. In the scope of this doctoral research project, the tactile resistance of arterial threading must be realistic to correctly inform the user of their applied force with digitally produced feedback potentially undermining the training potential of the platform.

In the second study, users make use of gesture controllers in VR to complete a task; a limitation of controllers is the approximate simulation of the gestures the hand is making with the hands on the controller not accurately reflecting how the user is gripping the tool and with certain complex tools or interactions could confuse the user and create doubt in their actions, as identified in the study. Additionally, in mechanical thrombectomy, gesture controllers would not be a viable option as the user requires dexterity and hand movements that the controllers would not allow.

What the case studies do identify, however, is that in more “hands-on” tasks such as the pipe maintenance, a physical real-world model that they can interact with can be the optimal approach with users being able to interact more intuitively with it, learn through trial and error, and gain an understanding of the physical characteristics of the components involved. In addition to this, the first study highlights the possibility of haptic feedback distracting the user and decreasing the accuracy and quality of performance; problematic in complex scenarios such as MT. Since MT uses sight and touch to correctly perform the procedure, it can be assumed that the data pertaining to the tactile feedback needs to be as realistic as possible and allow the user to make use of their own hands.

It is possible that the best path to take towards creating a virtual arterial threading simulator is to create a "glass model", a physical recreation of an artery system (Reddy *et al*., 2021). Doing so would allow the user to interact with the device with their own hands allowing them to interact more intuitively and develop better gesticulation and motor control in the procedure and could also be used to provide physical resistance and tactile feedback directly to the user from the physical properties of the material and not rely on computing the feedback and providing it via wearable technology or controllers.

2.3 Immersion and engagement

Regarding immersion and user engagement, users benefit from a higher level of immersion that enhances the quality of learning more than contemporary training methods. Since virtual reality simulation training provides more content-rich scenarios that can be interacted with, users can engage more freely with the resources and receive better training. With the addition of audio-visual-haptic multisensory cues to provide contextual cues that can inform the user's performance and indicate progress, practitioners gain an additional boost to performance and user experience even at the cost of surface fidelity and can improve transfer of training from virtual reality to reality (Cooper *et al*., 2021).

Research conducted by Süncksen *et al* shows that virtual reality provides more user-friendly training environments and learning tools compared to traditional approaches when investigating virtual reality for c-arm navigation and x-ray imaging (Süncksen *et al*., 2018).

The study that was conducted involved users operating a c-arm and contrast dye to recreate a radiographic image with constraints such as operating time and patient dosage. As efficiency in fluoroscopic imaging is a core skill for x-ray imaging, virtual reality offered a reliable way of measuring the amount of contrast dye a practitioner used during a test, which helped them identify how they could improve their efficiency, as well as improve their handling of the c-arm. The results of user experience questionnaires (UEQ) demonstrated that users found the application to be attractive and stimulating, with users finding it easy to engage with the tools and systems provided to complete the task.

In a study conducted by Pulijala *et al*, the effect of immersive virtual reality on a user's level of confidence was explored (Pulijala *et al*., 2018). The article described how, despite technological advancements in training, 28-40% of novice residents lack the confidence to safely perform major maxillofacial surgical procedures. The study had novice surgical residents split into two groups: a study group that used Oculus Rift with Leap Motion, and a control group that were provided with PowerPoint slides of comparative quality. The study group had access to stereoscopic 3D videos, tools, anatomy, and patient data through the oculus rift to actively engage with. The control group were provided with 2D images and videos of patient anatomy.

Prior to the test, all users were questioned on their perceived self-confidence and procedural knowledge, which acts as a baseline for post-test questioning. While all participants indicated they improved in confidence and knowledge, the study group consistently outscored the control group in most areas. Feedback indicated that the virtual reality surgery experience provided a more in-depth learning experience than conventional approaches and offered better transfer of knowledge that helped significantly boost the resident’s confidence.

2.4 Summary

The studies and technologies described in this chapter highlight several crucial aspects of MT training that demonstrate the need for effective haptic feedback in simulation training. Firstly, the case study on the Mentice VIST G5 indicates that the system detects when the user interacts with the artery incorrectly and triggers an error, such as perforating the arterial wall or not removing pressure when in proximity to the wall, indicating that the ability for the user to feel when this is about to occur is imperative. The case study on remote supervision (Bechstein *et al*., 2021) demonstrates that while the practitioners feel less intimidated in practice when the supervisor is not present in the room, the inability for the supervisor to intervene and demonstrate correct form and explain what the user is feeling during the interaction detracts from the quality of the training/operating and hinders the user's ability to develop an understanding of the interaction and application of force. The third case study makes use of digitally calculating the instrument's location through the displacement of a tooltip and then calculating the proximity to the arterial wall and applying force-feedback to demonstrate that resistance to the user. The limitation here is that the digital deriving of location and haptics is artificial, with location being approximated due to the discrepancy in world scale between reality and virtual reality, and with artificial haptics not being as accurate as its real-world counterpart.

To summarise, there is a lot of research being conducted into characterising and simulating complex medical procedures and utilising real-time and immersive technology to enhance the quality of training that a practitioner receives and supplement existing training frameworks. The work detailed in this chapter has demonstrated the beneficial impact that technology has had on medical training regarding the ability to virtually perform a procedure or remotely supervise a trainee and quantify their performance. Successfully replicating the procedure-steps and tasks, equipment, and instruments used in a procedure offers the trainee a chance to explore the medical scenario and gain a better understanding of the instrumentation and tasks involved; it can also provide a better insight into where the trainee is performing better or worse and help supervisors gauge their development.

Furthermore, as opposed to live practice which provides inherent risks to the patient and added levels of stress to the trainee, simulation training removes the pressure of failure from the equation and allows them to develop their skills at a more comfortable pace and familiarise themselves with obstacles or risks within the procedure.

CHAPTER 3 INTRODUCTION TO SIMULATION PLATFORM AND DESIGN CONSIDERATION

3.1 Introduction

This chapter will demonstrate the relevant theories and principles behind the different workflows and systems explored in this research project. The chapter will describe the design considerations specific to this project such as what data is being collected for analysis and why. The chapter will then discuss the different resistors and sensors that were considered for data collection and the microcontrollers used to read and communicate the acquired data, and then describe the different workflows for creating the VRLE and physical box trainer.

3.2 Design Considerations of the System

Due to how the chosen sensors work (Force-Sensitive Resistors) when responding to pressure, the variable used to determine the output parameter is the incoming voltage resistance, which is determined by the level of resistance felt by the sensor during catheterisation. This is because in the real-world, the practitioner will navigate a catheter up an artery and respond to the change in physical resistance. This variable will be read by firmware loaded onto a microcontroller in real-time and calculated to provide a parameter relating to the amount of force a user is applying, which will infer the level of force applied and if an impact has occurred. This can be expanded upon when more sensors are introduced and involve calculating the average of all the incoming sensor variables to provide the overall output parameter. The output of this firmware will need to be communicated directly into a virtual environment inside Unreal Engine 4, which means accounting for baud-rate and event time inside the game engine. To ensure the analysis is robust and able to withstand human error or misinterpretation, the data generated regarding the applied force and impacts will be analysed using a time-series anomaly detection algorithm using a moving average to determine the level of force applied, and any impacts.

3.3 Haptic System

This section will discuss the different technologies available for the generation of haptic feedback and numerical data regarding feedback and describe the principle behind their usage, the advantages, and limitation of existing technologies.

3.3.1 Force Sensing Resistors

A Force Sensitive Resistor (FSR) is a small piezoresistive sensor that allows a user to detect a variety of applied forces including physical pressure, squeezing, and weight. FSRs return a single analogue reading, which relates to the amount of resistance being providing by incoming force. FSRs measure the level of compression and operate with a maximum current of 1 mA and provide a resistance of 1MΩ.

As Figure 3.1 shows, the FSR works by sandwiching an adhesive spacer with a wide opening between a layer of flexible substrate with a printed semiconductor and a layer of flexible substrate with printed interdigitating electrodes. As pressure is applied to the surface, the two layers will connect and make the resistance fall.

For the development of a box trainer in mechanical thrombectomy, a Force-Sensitive Resistor is advantageous due to the method in which it works, the idea for this trainer is as a catheter moves through a simulated artery, the FSR will react to any changes in the pressure as it passes over the sensor's surface. Additionally, the simplicity in its implementation makes it an ideal choice as you just connect it to an analogue pin and can readily read out the data as a single variable, meaning that you can connect several onto a single microcontroller and parse the incoming data in a quick manner. Furthermore, the size of the FSR compared to other sensors is smaller, as it consists of a thin piece of polymer and film, and are only a few millimetres wide, making it excellent for low-profile development.

The disadvantage of FSR is that the response time and accuracy of the sensor readings can vary from sensor to sensor, with some showing better linearity and response time than other sensors (Hollinger and Wanderley, 2006). Additionally, researchers have identified that the modern design of FSRs using polymers means that the repeatability is hindered due to the creep phenomenon in the form of the sensor result drifting throughout an experiment or showing hysteresis (Paredes-Madrid *et al*., 2017), however, the author theorised that creep and sensitivity degradation could be managed by providing sufficient source voltage. It was shown that over the course of an hour, a higher source voltage (0.03v, 0.22v, 0.4v, and 2V) led to a reduction in drift occurring within the current, and that a higher load (50 KPa, 100KPa, 150KPa, and 200KPa) contributed to increased amount of drift over the hour. By ensuring an optimal source voltage is provided, sensor drift can be significantly reduced when under increased load from dynamic and static forces.

3.3.2 Optical Sensor

Haptic feedback through optical sensors relies on light intensity and optical reflection between surfaces with varying indices of refraction. The optical sensor is commonly made up of a light source, a transduction surface, and a photo detector that tests for the reflection (See Figure 3.2).

The optical sensor looks for changes in the reflection of the light source on a given surface, which can be correlated to incoming impact. Optical sensors have been investigated previously for minimally invasive surgery and looked at correlating the estimated force with the relative change in light intensity (Bandari et al., 2020). Using image-based intensity estimation to capture images at a resolution of 640x480 pixels with an 8-bit RGB colour range, which was converted to greyscale, the platform is capable of reading in the light intensity from a range of 0 (off) to 255 (full intensity). This allows the platform to analyse incoming images and create thresholds for the various levels of force (See Figure 3.3).

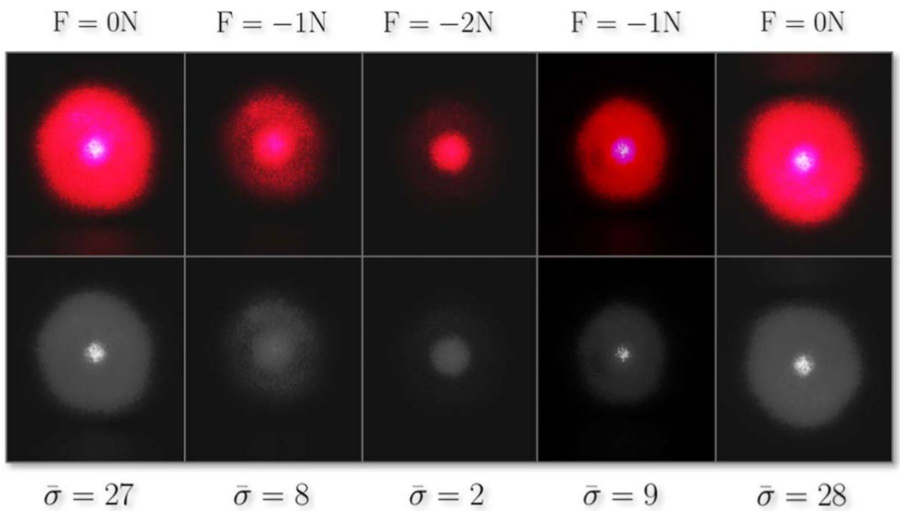


Figure 3.1: Light source grayscale intensity and estimated force values.

The study found that using an optical sensor for haptic feedback via light intensity modulation demonstrated a minimum force detection of 0.2N, error margin of <0.1N, and a resolution of 0.05N, which would be adequate for the context of this project as the system would require a high accuracy reading, and the resistance to electromagnetic noise would improve the reliability of readings. However, the crucial limitation for this technology is the resolution of the image is quite small, and while it can be increased, this would increase the computational time. Additionally, the method in which this sensor operates would not be viable for the current system as it would need to be connected to the microcontroller while being inserted into the catheter, which means a small and flexible device would be required so as to not adjust the artery or catheter and produce artificial readings. Furthermore, the system is required to operate in real time, therefore the calculation and transmission speed of data needs to be as quick as possible. Additionally, the shape and rigidity of the devices need to allow for a flexibility and movement that the optical sensors do not provide.

3.3.3 Actuator Technology

Another common technology for haptic feedback in medical simulation is actuators that provide resistance to the user in response to a change in a scenario's variables.

In the case of vascular intervention, the more displacement a catheter gets, the more resistance is produced by the haptic device (Guo *et al*., 2017).

Various medical training systems utilising actuators often involve an “off-the-shelf” haptic device commonly used in 3D modelling, such as the Geomagic Touch (3D Systems, 2021), and are mostly used to provide physical resistance similar to that of the real-world scenario they simulate.

A study in the application of VR technology in medical simulation training found the Geomagic Touch X and similar devices were used in clinical simulations, primarily laparoscopy, arthroscopy and orthopaedics (Li *et al.*, 2017). The author identifies the need for effective simulation training in laparoscopic training as a response to the EWTD and to improve patient safety by reducing the need to operate on patients and expose them to danger. The examples of haptic feedback and devices include an orthopaedic simulation on a femur, where the user drills and reams cortical and cancellous bone with the haptic device providing various resistances and physical sensations when encountering tissue and bone, notably, the different tactile resistance between cortical and cancellous bone. However, the author identifies that the response rate and intensity of feedback in commercial haptic devices is too weak to emulate certain tactile characteristics, this is especially true when combined with the need to demonstrate physical characteristics such as density.

An additional study was identified that investigated the development of a virtual reality catheter training tool by using a phantom omni haptic device (similar to the Geomagic Touch X) (Guo *et al*., 2017). This simulation involved communicating the displacement of the tool to a digital twin of the medical catheter and artery, calculating the offset and collisions in the virtual setting before calculating the necessary resistance and providing feedback to the haptic device.

The author identified two limitations to the use of a haptic device for catheter training. Firstly, the speed reported by the system is different to that of the real-world speed and this error grows as the displacement grows, caused by the latency within the system, in which the system is not communicating the signal to the computer quick enough and then not receiving it back in time. This can lead to incorrect readings as the offset can differ from the user's real input and provide false results to the haptic device. Secondly, the sensitivity of the haptic device means it detects even the most minute vibrations of the hand and can amplify the displacement, causing the platform to produce erroneous distances.

Commercially available haptic devices such as Geomagic Touch and Omni Phantom can provide users with physical resistance to tactile surfaces through actuator motors. In the context of MT and this thesis, actuator technology used in industry standard haptic devices would not be suitable as the latency caused by the "back-and-forth" communication would hinder the reliability of sensor readings. Additionally, the response to user input would need to be quick enough to provide accurate information regarding user input. A crucial limitation in the applications described above, is that the haptic device only functions as a tool for physical resistance when an accurate reconstruction of the anatomy is provided for the haptic device's collision detection. To develop something similar would involve additional complex systems that would be able to track changes in the model and adjust the tubing to fit it so that the physical resistance was accurate when the physical box trainer was used.

Table 6: Table summarising various technologies for calculating and communicating haptic information.

Transduction method	Parameter	Advantages	Disadvantages
Piezoresistive (FSR)	Resistance	High frequency response and refresh rate; easy to use; single variable output allows for faster transfer speed.	Reproducibility issues; hysteresis.
Optical	Light Intensity	High resolution; sensitivity; resistant to electromagnetic noise.	Rigidity; complex set-up; slow transfer speed due to computationally expensive processes required to convert and estimate force; noisy results and slow refresh rate.

Actuator	Resistance	6-degree-of-freedom force feedback (x, y, z); designed for hand movement including wrist pivoting; high resolution.	Bulky in size; expensive to purchase, requires additional programming to read out data; numerous variable outputs and calculations hinder transfer speed; latency can have significant impact on accuracy and transfer speed of displacement.

3.4 Microcontrollers

A core component of the system proposed by this thesis is the microcontroller that will be used to communicate sensor data produced by the sensors to the game engine. A crucial factor for the microcontroller was its size factor, since the platform is small, the microcontroller would need to be small as well so as to not obstruct any wiring or tubing used to build the system up. Additionally, the microcontroller would need to accommodate FSRs which make use of analogue pins.

Factoring in that this thesis is a proof-of-concept, and that most of the legwork would be done within the game engine, it was decided to start with a simple board, the Arduino Nano was chosen for the initial prototype. The Arduino Nano is based on the ATMega328 chip with an operating voltage of five volts and is powered by a USB-B Mini port, which also provides serial communication. The board provides up to 32kb of memory (2kb of which is used by bootloader) used to store the firmware running on the board and provides eight analogue pins, which are compatible with the FSRs used in this study. Finally, the board is one of the smallest microcontrollers by Arduino at only 18x45mm.

Throughout this study, the Arduino Nano demonstrated effectiveness in its simplicity by allowing an array of sensors to be connected and running to generate several variables that are calculated and stored on the board for communication to a third-party application via configurable baud rate, beginning at 9,600 bits-per-second and going up to 115,200 bits per second. The reliability of the Nano board led to its extended use throughout the project.

Additional boards were considered and explored during this study for different purposes, such as Arduino Due, Mega, and Nano 33 BLE.

The Arduino Due is a 32-bit board based on the Atmel SAM3X8E ARM Cortex-M3 CPU and provides twelve analogue pins as opposed to the Nano’s 8, and can also be powered by a DC jack, reducing load on the USB connection. However, the issue with the Due is that it is a larger size board at 101.52x53.3mm and has an operating voltage of only 3.3v compared to the Nano’s 5 volt.

The Mega 2560 is an ATMega2560 board with DC power supply and sixteen analogue inputs, double that of the Nano. It is a comparable size to the Due making it a larger board increasing the likelihood of obstruction.

The Arduino Nano BLE was investigated in the later stages of the project as a consideration since the proposed platform did not need so many inputs but might benefit from enhanced connectivity for communication and the portability of the platform. This is because the controller requires a USB connection to the host PC to run, which meant it had to be positioned correctly and removing the need for the USB could potentially improve reliability if the USB were tampered with.

To this end, we considered the Arduino Nano 33 BLE for its Bluetooth Low Energy, which would allow the device to communicate sensor data wirelessly as opposed to via USB cable, freeing up the USB port for a power supply, such as a battery or AC adapter. The Nano 33 BLE is based on the nRF52840 microcontroller and runs a 32-bit ARM Cortex-M4 CPU with 1mb of memory, and compared to the Nano, has 4 ADC (Analogue-Digital-Converter) pins extending the number of sensors attached to the device. The limitation here was that the BLE version of the Nano runs at 3.3 compared to the Nano's 5 volt.

Overall, the technical specs of the BLE are much better than its predecessor, the Arduino Nano. Bluetooth connectivity was tested using "nRF Connect," an Android application that can read incoming data advertised by Bluetooth devices and was able to read the incoming data. However due to project scope and time constraints, the wireless connectivity was not explored further as it would not provide any significant contribution to the deliverables of this project.

Beyond Arduino, the project also investigated the Raspberry Pi platform, which provides several versions of the Pi microcontroller, comparable to the Arduino boards, the Raspberry Pi Zero and Raspberry Pico. The Raspberry Pi Zero 2 W is a quad-core 64-bit 1GHz ARM Cortex-A53 based board that comes in at 65 x 30 mm and has 512MB of memory (Raspberry Pi, 2022c). The Zero 2 W board also comes with a range of connectivity such as 2.4GHz Wireless Lan, Bluetooth 4.2, BLE, USB 2.0 OTG, microSD slot, and a Mini HDMI. The Raspberry Pico is a dual core 133MHz Arm Cortex M0+

board with 264kb of SRAM and 2MB of flash memory and comes with a micro-usb port and 3 ADC pins, while the rest are digital or PWM (Raspberry Pi, 2022b). Additional Pico boards include the Pico H and the Pico W, the Pico H is identical to the standard Pico except it comes with pre-soldered headers and is the most comparable to the Arduino Nano. The Pico W is identical to the Pico, except that it also comes with 2.4GHz Wireless Lan, supporting up to four client connections (Raspberry Pi, 2022a).

The limitation with Raspberry Pi is that the design of these microcontrollers differs from Arduino in that an ADC (analogue-to-digital converter) device is required to convert the sensor reading from an analogue input to digital so that the Raspberry Pi can read it. While the Pico and Zero boards come with some ADC pins (Pico has 3), the Arduino boards can support analogue natively with a higher number of available pins, which means an added cost for the platform if the Raspberry Pi boards were chosen. Furthermore, Raspberry Pi requires certain boards to be running PiOS, such as the Pi Zero series, where firmware is loaded onto, and in general is run like a miniature PC, with a display connected via HDMI and USB connected mouse and keyboard. Since the scope of the project requires just a single variable in the form of an analogue float value, the additional I/O connections of the Raspberry Pi are unnecessary and just take up room that could be better utilised with a smaller board. The benefit of the Arduino Nano board is that it supports a decent number of analogue ports natively, takes up the least space within the platform, and does not require any additional software or firmware to be running, and as an advantage over Raspberry Pi boards, has an established plug-in for Unreal Engine allowing direct communication between Arduino boards and Unreal Engine (Villani, 2021).

3.5 Proxy Pattern Controller

Originally, the platform was going to be completely virtual, with the user interacting with a virtual catheter and artery system using gesture controllers, however, the scope of the platform required that the platform provided haptic force of some kind, and while haptic gloves had been investigated (Cooper et al., 2018, 2021), it appeared that haptic gloves would interfere with holding the gesture controllers or prohibit optical hand tracking via HMD outside tracking (where available); the other issue identified was that it would not provide any resistance to the user, just a tactile rumble, such as Manus Prime (Manus Machinae BV, 2021). To this end, a mixed reality approach was considered, where a proxy pattern controller would be designed, and 3D printed to mimic the real-world scenario in a physical manner. This approach involves using physical tubing to simulate the characteristics of the artery and allow the user to insert a medical catheter into it. FSRs would be placed along the tube at a point which will detect the catheter as it is passed through the artery. The proxy pattern controller will be designed with a modular approach in mind that allows the practitioner to adjust the start and end location of the tubing to produce different angles and bends to provide varying levels of challenge and resistance, see Figure 3.5. This plans to build on the way in which current MT simulation trainers work that allow users to insert physical medical devices by allowing them to have modular access to the platform so that physical resistance can be provided to the user and modified to increase the challenge, which would provide a high-fidelity response to the physical resistance compared to haptic gloves or gesture controllers.

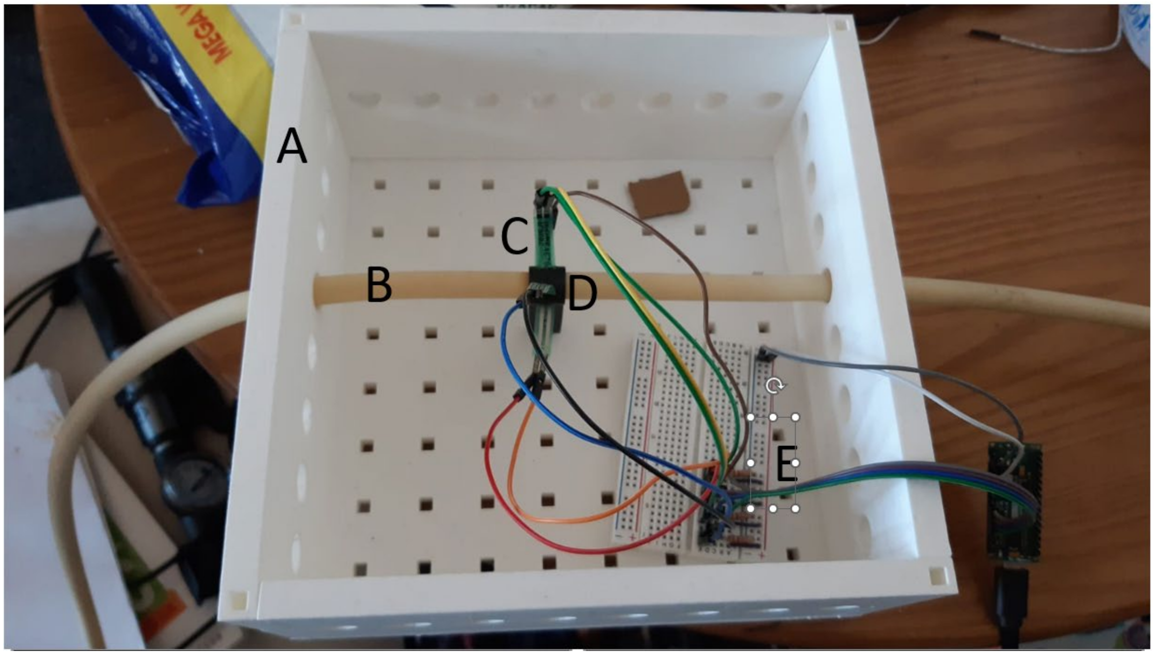


Figure 3.2: Overview of arterial threading controller. (a) FDM 3D printed box with tube holes to insert tube and peg holes to insert sensor pins; (b) neoprene tubing used to simulate artery for catheterisation; (c) force-sensitive resistor that is clamped to the arterial tube to read sensor data; (d) FDM 3D printed pin that the tube is threaded through allowing sensors to read changes in the applied force; (e) breadboard and arduino circuit used to record and analyse the incoming sensor data to communicate to third party applications.

3.6 Development of Virtual Medical Theatre

For the virtual medical theatre that provides an immersive learning environment for the practitioner, several methods are considered for development: photogrammetry, CAD/TLS, and conventional modelling.

3.6.1 Photogrammetry

Photogrammetry is an accessible form of 3D reconstruction, allowing a developer to convert photographed environments into three-dimensional models that capture complex details and information regarding the artefact (Morandi *et al*., 2017). The process for collecting photographic data and extracting 3D information is efficient due to the ability to navigate an environment or artefact and capture large number of images to improve the resolution of the final result (Fassi *et al*., 2016). Using tie-points, third-party software, such as Agisoft or Pix4d, can align photographs where it identifies visual artefacts in the images and generates vertices, which are stitched together to generate a 3D mesh. The idea behind using photogrammetry is to capture a three-dimensional "snapshot" of a working environment that the practitioners will feel familiar with, or develop a familiarity with, to improve on-boarding and help them develop an understanding of the layout, organisation, and develop a sense of confidence by having a better understanding of the working environment.

The advantage of Photogrammetry is the efficient automation that allows a developer to simply collect and provide the 2D images for the software to process with minimal input, meaning the developer can launch the process and focus on other tasks. The disadvantages of this methodology, however, can include processing time, file size and resolution, requiring, in some cases, substantial optimisations to be compatible with real-time rendering engines such as unity or Unreal Engine.

3.6.2 Building Information Modelling

The investigation into the use of BIM data for the visualisation of the operating theatre was based on work that showcased the use of these complex data sets in immersive applications for case studies such as on-boarding staff in fast-pace and high-risk environments (Hurst *et al*., 2018), developing and improving health and safety processes (Chen *et al*., 2021), assessing and recording structural health in infrastructures, including bridges and tunnels (Insa-Iglesias *et al*., 2021). Traditionally, large, and expensive construction projects will make use of BIM data that contains CAD data relevant to the environment to ensure consistency across the various aspects of construction and development, ensuring bespoke equipment can correctly fit, that electrical systems or water piping will not be prohibited and remain accessible, and that any design considerations or obstacles can be detected at an earlier stage of the design review. In the case of endovascular treatment, CAD data existed of a stock angioplasty theatre used by Siemens to visualise CAD models of their expensive medical systems, such as the bi-plane, medical bed, and the floor and ceiling mounted c-arms used for medical imaging. The development of CAD data can involve pre-existing structures as well as laser-scanned 3D geometry (either through handheld scanners or mounted stations) that is processed and filtered based on the different elements. TLS-to-CAD/BIM methods can be advantageous for similar reasons to photogrammetry in the efficiency of data collection, however TLS capturing has the added benefit of improved structural accuracy in the geometry for further 3D modelling (Antova and Tanev, 2020). In the case of this thesis, CAD data was provided by Siemens Healthcare to provide an accurate model of a currently used medical system for angioplasty theatres and endovascular treatment.

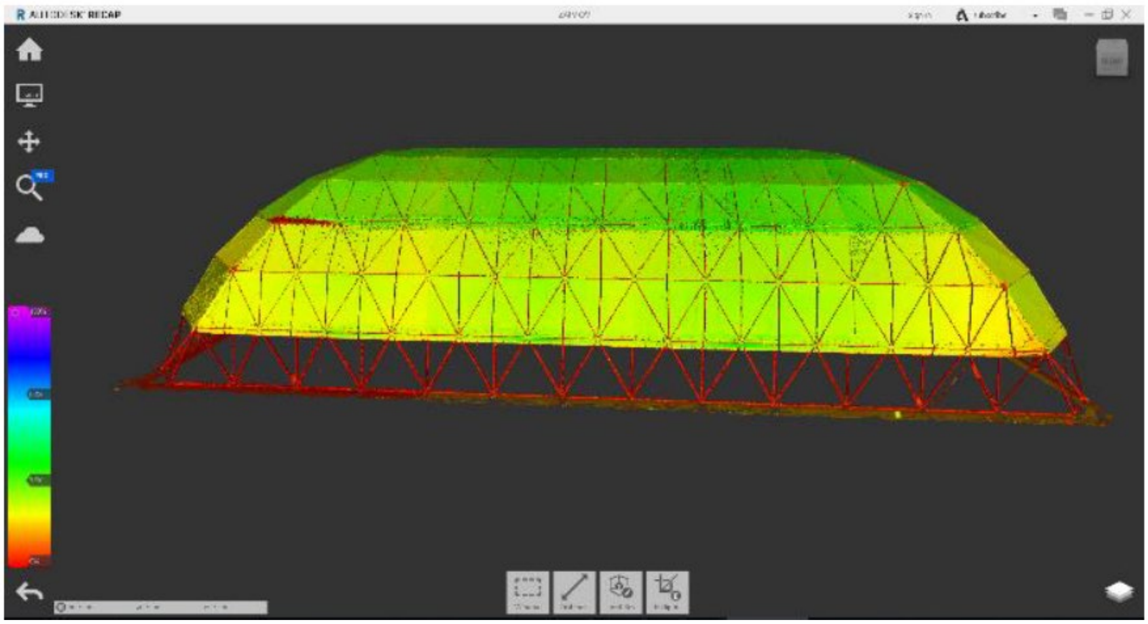


Figure 3.3: Example of point cloud generated from Leica Nova MS60 Scanning station (Antova and Tanev, 2020).

3.6.3 3D Modelling and Design

The final method involves using traditional 3D modelling software to construct 3D geometry and information regarding the virtual environment and equipment. The approach consists of manually constructing geometry based on real-world reference or concept art, to produce a virtual environment or artefact (Latham *et al*., 2017). This involves beginning with either 2D splines or 3D geometry to start developing the geometry and building up the model through additional modifiers and geometry elements with a target polycount and end use specified (low-poly for VR compared to high-poly cinematic quality). The advantages of this approach involve full creative control over the design process and ability to modify the environment or artefacts to better suit the project's need and it is much more controllable in terms of quality and file size than the previous two methods. The disadvantage lies in that, with full creative control comes the time resources and workflow knowledge required to produce an accurate reconstruction.

3.7 Summary

To summarise, the FSRs are considered the effective and straightforward way to collect sensor data regarding a user's applied force compared to actuator and optical-based haptic devices. This is due to the FSR only requiring a single application of force to a filament grid, whereas the haptic devices described, required additional displacement data or mathematical programming and collision geometry to imply the resistance to the user, which opens potential problems if the displacement does not line up with what occurs in virtual reality, and vice-versa.

The use of Arduino Nano helps with the platform's need to be compact and portable, with the board only requiring a usb connection and holding room for eight analogue FSRs, with USB-B-Mini allowing for constant communication of serialised data into the real-time engine. The small form factor microcontroller will also be fully functional inside the 3D printed box trainer, where it can be connected to the tubing as it is adjusted, to provide consistent readings.

For the development of the virtual theatre, a hybrid approach combining CAD data of the medical equipment and systems with hand-modelled environment will be explored as this provides equipment that, with simple optimisation, can be performant for real-time engines, while providing full control over the appearance of the environment around it.

Utilising the incoming voltage of the FSR and converting it to a simple analogue signal allows for the collection of a single metric that can be increased with each sensor equipped to the system and calculated into average force if needs be and can be communicated efficiently using serial communication over USB. Additionally, given that the data is collected in real time over a timeframe, the time-series data can be analysed using a rolling average algorithm to detect levels of force and impacts with a low CPU-overhead and memory impact.

CHAPTER 4 METHODOLOGY

4.1 Introduction

This study developed a tactile controller and virtual learning environment that enables trainees to practise their arterial threading. The proposed system aimed to mimic an arterial bend's physical resistance and communicate the measurable applied force to the user to help provide a realistic experience and help them understand how the artery felt in different scenarios. The aim of this research was to design a small-scale and intuitive method for providing physical resistance and detecting applied force in arterial threading for mechanical thrombectomy. This chapter highlights the design process of the research project and demonstrate the design choices, experimental set-up, and data collection and analysis. Section 4.2 will introduce the project framework, a flowchart outlining the research methodology. Section 4.3 will discuss the development of the box trainer used to provide physical resistance and generate data relevant to applied force. Section 4.4 will demonstrate the software created to generate the sensor data and communicate it from an Arduino device to a Python environment for recording and analysis. Section 4.5 will document the processes of developing the virtual reality learning environment that the sensor system will be integrated into. Section 4.6 will look at the method used to conduct serial communication Unreal Engine 4 to record and export sensor data. Section 4.7 will demonstrate the software designed to conduct an analysis of the generated data to detect applied force and impacts. Lastly, section 4.8 will look at the end-user experience testing and analyse the platform's usability characteristics.

4.2 Design Process

A framework was designed to provide a structured approach to the research methodology and details various stages and deliverables of the project (See Figure 4.1).

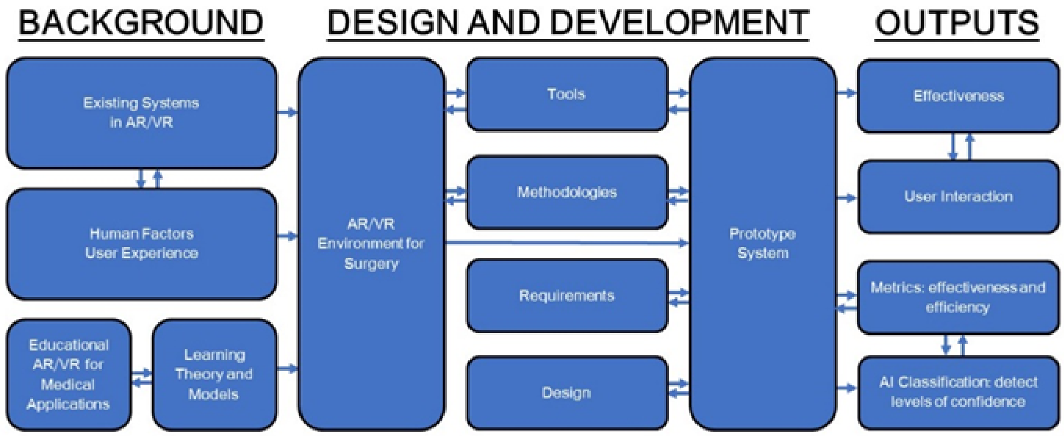


Figure 4.1: PhD framework of methodology.

The first stage of this research project was to review existing literature to identify existing technologies and methods used to conduct medical simulation training and the user experience/human factors that influence their efficacy as training tools. Based on the literature review, it was evident that commercially available medical simulation technology in neuroradiology lacked effective haptic feedback or resistance models relevant to the development of fine motor skills and required a large space to operate effectively, which in live practice is difficult due to the number of cases a centre might receive throughout the year. Platforms identified through research seeking to enhance training through the inclusion of haptics in procedural based simulators demonstrated a common limitation: the scale of the equipment required to perform the required interactions and interface with a simulation trainer required a large amount of space, such as a theatre-sized room, meaning practitioners need to either limit the available resources to patients or go without training in this manner. Additionally, the use of deferred tele haptics that are inferred based on calculations within a real-time engine has been cited previously as being ineffective due to approximation and inability to effectively mimic physical characteristics of human tissue, which can hinder a trainee's progress. While actuator technology has been explored in-depth for these types of systems, the quality of response has been brought into question. Therefore, force-sensing technology was explored to ascertain whether a platform could be created that provides "forward resistance" in the form of physical resistance that registers the user's applied force and calculates the force after detection, as opposed to before. This detection could then be analysed to identify the various stages of applied force and impacts and be used as a metric to classify the level of performance.

For this study, a proxy controller was built to simulate arterial threading, with a Virtual Reality Learning Environment (VRLE) created to act as a digital twin of a live operating theatre for the trainee to practice the MT treatment method. The collected data was analysed in Python to detect the number of impacts and degree of applied force. The purpose of this was to help practitioners and assessors see the amount of applied force and impacts that occurred during arterial threading. Evidence of applied force going too high can be an indication of excessive force, where the user has pushed too hard on the catheter and collided with the arterial wall, an act that in live practice could lead to an arterial puncture or arterial wall shearing which can cause damage to the arteries and cause severe medical complications.

To develop the box trainer, an FSR was connected to an Arduino Nano to record applied force from different tube materials to find the best material to use for the catheterisation and detection of applied force using FSRs. The initial configuration used a force-sensing resistor applied to a medical catheter that would be navigated using a smaller catheter to detect the force applied by the user (See Figure 4.2).

The Arduino Nano was chosen for the initial proof-of-concept build due to its small form factor (18 x 45mm / 7g) making it extremely lightweight and low profile for the box trainer. The Nano is equipped with eight analogue pins allowing up to eight FSRs to be connected to the device. The Nano also allows for serial communication at varying levels of speeds (baud rate) from 300 up to 115,200. There was possibility of upgrading to a larger board such as Arduino Mega, which provides support for up to sixteen sensors or Arduino Due which provides support for twelve. Additionally, networked Arduino boards such as the Nano 33 BLE were also investigated for networking purposes, but the implementation was not explored in this project.

Experimental results in Section 4.3.1 showed an inability to correctly detect applied force and pressure due to the rigidity of the catheter material, the configuration was updated to use polyurethane tubing instead as it was more malleable than the catheter tubing and could detect limited applied force from the catheter. (See Figure 4.3).

The results of the polyurethane tubing showed while it could detect applied force a little better than the catheter tubing, the density of the material made it difficult for the FSR to pick up any applied force or pressure. At the same time, it was noted that the single FSR could only detect applied force or pressure from the point it was applied to and that if the platform was to be able to effectively detect applied force, then it would need to use multiple FSRs around a point in the bend to detect applied force from all angles.

To this end, the Arduino system was refactored to convert the sensor reading to an array that would be looped through with each FSR being stored as an individual index to store a reading to read applied force from different angles. Furthermore, the material used for the tubing was changed to neoprene to improve the readability of pressure being applied through the tubing, which provided a more malleable response to bending and the softness allowed the pressure to be detected more consistently and clearly during experiments (See Figure 4.4).

Based on the design considerations in Section 4.3.2 and outcomes in Section 5.2, a box trainer was designed, and 3D printed that accommodates a neoprene tube to simulate the artery and force-sensing resistors (FSR) that collected force-sensor data. An Arduino Nano then received the sensor data as an input and calculate the average force applied by the user as an output.

A Virtual Learning Environment (VLE) was created in Houdini Engine and imported into Unreal Engine 4 to receive and present the output from the sensor system to the user in an immersive virtual environment. This involved developing a procedural network that allowed for the creation of a room layout and automatic geometry placement and programming an actor to read the incoming sensor data, store it in an array to save for analysis, and present it to the user via the user interface.

Using Python, the data produced in Unreal Engine was imported, converted to a "Data Frame," and analysed to determine the standard deviation of a given window of data to detect areas where impacts or applied force have been detected and quantify this data and present it to the user to support the training and assessment. This chapter provides detailed methodologies for each of the various aspects of the project.

4.3 Development of Proxy Pattern Controller

The design and development of a force-sensor based box trainer that simulates arterial threading in Mechanical Thrombectomy differs from existing state-of-the-art training simulators. By using force sensitive resistance of a physical component as opposed to actuator technology, the physical resistance experienced by the user was physically accurate as opposed to the artificial resistance produced by a collision in 3D space (Guo *et al*., 2017), (Yu *et al*., 2019).

The approach described in this research used an array of force-sensing resistors to calculate the average applied force detected at a specified "midpoint" of the simulated artery that determines how much force was being applied by the user (Latham *et al*., 2019a). The data generated by this system was collected over a period to identify where impacts or applied force were detected and at what level.

The FSR consists of two layers encapsulating a circuit path where a current travels through when the circuit is live. By pressing against the FSR, the gap between the outer layers is reduced and applies resistance to the FSR by reducing the voltage.

4.3.1 Initial Design

The initial study of the sensor system platform comprises using a single FSR that would be manually held against the catheter in a way that doctors would hold the catheter when navigating an artery, which was connected to an Arduino Nano to read the incoming sensor data (See Figure 4.2).

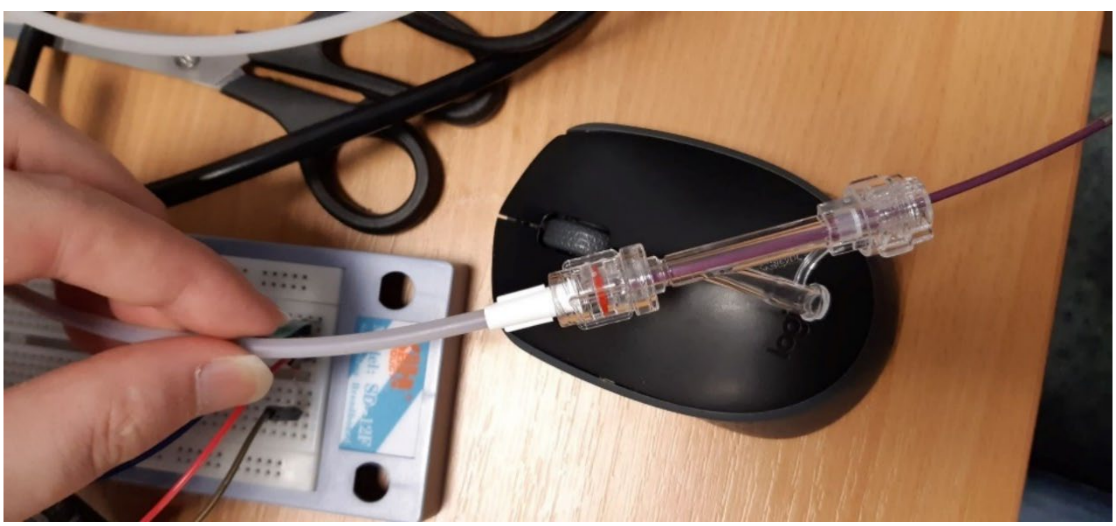


Figure 4.2: Initial set-up of sensor system with medical catheter and FSR.

The tubing used for the initial system was a standard medical catheter and two microcatheters. Several issues arose from this method, that severely impacted the quality of the data received. The physical contact with the hand meant an inconsistent external pressure applied, which influenced the data obtained by the sensor, producing noisy data that made it hard to distinguish what data was from the catheter movement. While flexible, the density of the catheter made it difficult to effectively detect movement from inside, resulting in not being able to detect applied force correctly. The Arduino Nano was chosen initially due to its small size and minimalistic set-up, as the system does not require any complex functionality, and a smaller device would be optimal for the box trainer's portable size.

4.3.2 Updated Design I: Polyurethane Tubing and Single-Sensor Adhesion

To prevent jeopardising the integrity of the sensor data through physical contact, the design was changed to simulate the artery being pressed against the attached sensor to the tube using adhesive tape. A polyurethane tube was used to simulate the artery wall with the catheter being used to detect the pressure as it passed through the simulated artery (See Figure 4.3).

Figure 4.3: Updated design with polyurethane tubing and medical catheter.

The problem with the polyurethane tubing was that while the sensor did manage to detect some applied pressure from the catheter inside the tube, it was a very weak signal. Manual application was applied to the sensor to determine the sweet spot on the tube, to allow for better positioning along the apex point of the bend in the tube. Due to the small size of the sensor when compared to the surface area of the tubing, a manual calibration was performed to identify where along the tube was the best place to position the sensor that allowed it to detect the impact from the catheter on the internal side of the tube wall. The adjustment of the sensor allowed for data to be collected with marginally more success. Additionally, the polyurethane tubing proved to be too rigid and dense to produce the bends needed and provide efficient data capture. For this issue, the polyurethane tubing was swapped with 2cm neoprene tubing, which provided more flexibility for bending, and a lighter material that enhanced the readability of the sensor data. The results from the tube selection experiment are available in sections 5.3 and 5.4

Furthermore, it was observed that if the catheter was not angled in the precise manner, then the readings would not be picked up correctly, and therefore provide inaccurate data results. To resolve this, the sensor system was adapted to incorporate an array of sensors attached to the tubing, to allow the system to detect impact from four directions. The implementation of additional sensors improved the quality of the results, allowing for all four sensors to be read and average force be measured. The results from the improved set-up can be seen in sections 5.3 and above.

4.3.3 Updated Design II: Neoprene Tubing and Multi-Sensor Adhesion

To improve upon the existing platform, two changes were made to improve the robustness of the platform. Polyurethane tubing was replaced with Neoprene tubing to simulate the artery, due to it being more flexible, lightweight, and providing a softer surface area, which allows for easier manipulation and contorting (Realmuto and Sanger, 2019). Additionally, the change led to an improvement in response time in which the sensors picked up a disturbance in the tubing due to a change in physical pressure proximal to the sensor and even along the tubing, meaning more pressure data could be transmitted (Jones and Jordan, 1962). Secondly, the FSR configuration was updated from a single sensor to an array of four sensors to collect data from multiple angles that cover the entire point of a bend, improving the reliability of the sensor reading system (See Figure 4.4).

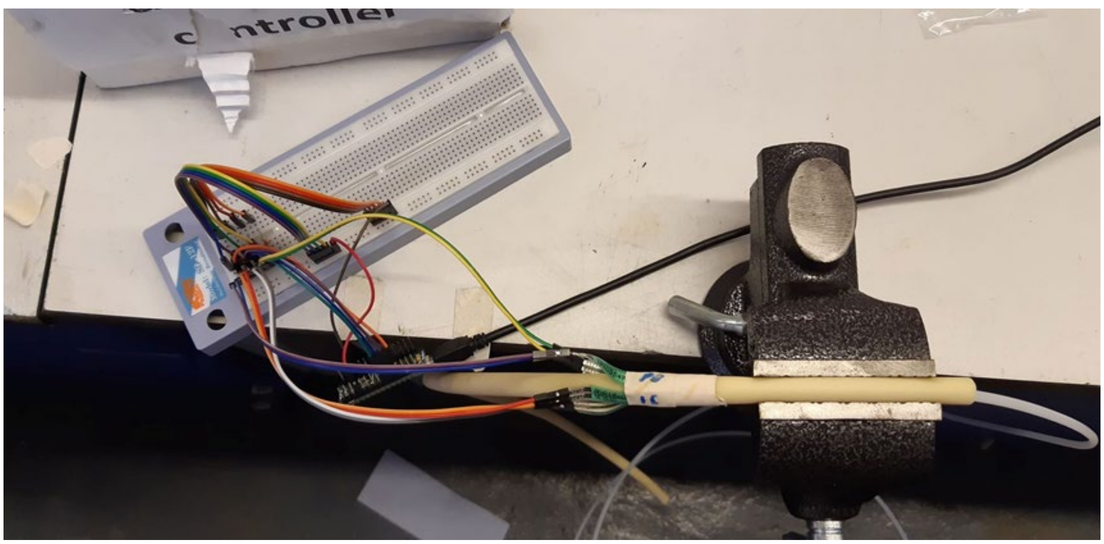


Figure 4.4: Updated system with sensor array attached to neoprene tubing.

The system works by sliding a catheter into a neoprene tube, which was held in place using a table clamp, securing the bend, the four FSRs are currently taped to the tube and connected to a breadboard, which consists of an array of 22kΩ resistors, which then connects to the Arduino Nano (See Figure 4.5).

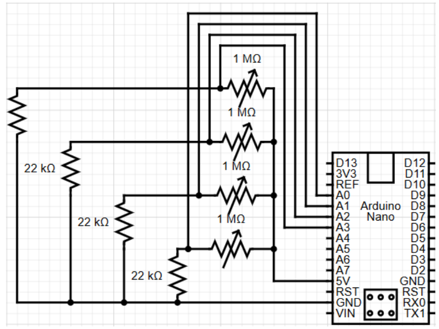


Figure 4.5: Schematic for the sensor system.

4.3.4 Initial Fused Deposition Modelling 3D Printing and Sensor Clamping

The sensor frame used in the project was designed in Autodesk 3DS Max 2019 (Autodesk, 2012) as a modular kit, allowing the frame to be redesigned and to optimise the 3D printing process (See Figure 4.6).

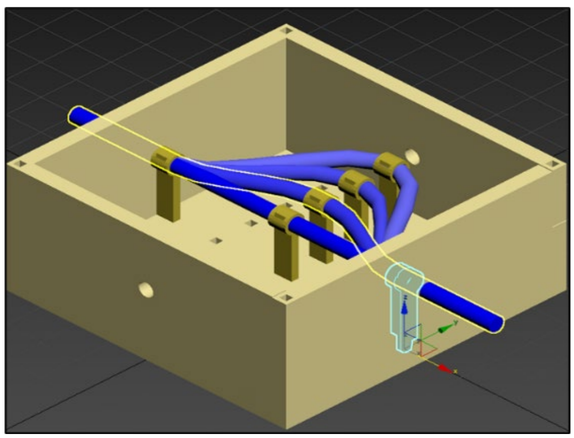


Figure 4.6: 3D model of system frame for simulating arterial threading.

The frame involves (a) a base panel with an array of socket holes for sensor pins and wall mounts; (b) four wall pieces with a hole for tubing to be inserted; and (c) sensor pins modelled to secure four force-sensing resistors to the tube as it passes through the ring, secured in place by the sockets in the base panel. This was accomplished using Boolean modelling techniques that allow geometry to be created that subtracts from the main frame meshes, such as the cylindrical holes and square peg holes.

The 3D model was exported as an STL stereolithography filetype to be 3D printed using Fused Deposition Modelling (FDM) so that it could be assembled to house the Arduino Nano, sensor system and neoprene tubing that acted as the controller for virtual arterial threading simulation (See Figure 4.7).

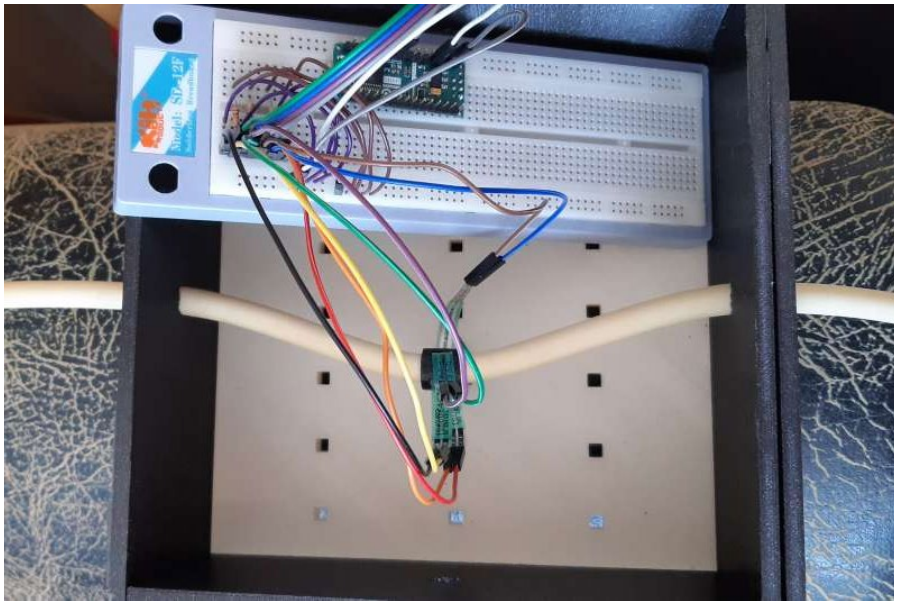


Figure 4.7: Printed box trainer housing Arduino Nano, sensor system, and tubing.

The development of the box trainer for arterial threading simulation allowed the focus of data collection to shift from determining whether FSRs can detect applied force in arterial simulation, to determining whether the data collected from simulation was reliable enough to use as an indicator of applied force or impact.

Through repeated testing, it was identified that the generated data was being adversely affected by the frame’s design and that the tube holes were gripping the tube too tightly. The results from this experiment can be found in section 5.2. Whenever the bend was modified by the user, the tube would try to adjust to the change and the resulting change in grip would cause sensor drift and hysteresis at times as the tube tried to return to a natural position. This meant that while in an idle state, the system would produce noise that could be misidentified as applied force or impact and therefore undermine the integrity of the proposed platform.

4.3.5 Updated Fused Deposition Modelling 3D Printing and Sensor Clamping

To improve the reliability of readings generated by the sensor system, the tubing holes were increased in diameter to allow more flexibility and freedom of movement for the tubing when moved by the user (See Figure 4.8). The updates to the design reduced the amount of drift and hysteresis demonstrated in the data and improved the reliability of the sensor readings. The results from this experiment can be seen in section 5.3 and above.

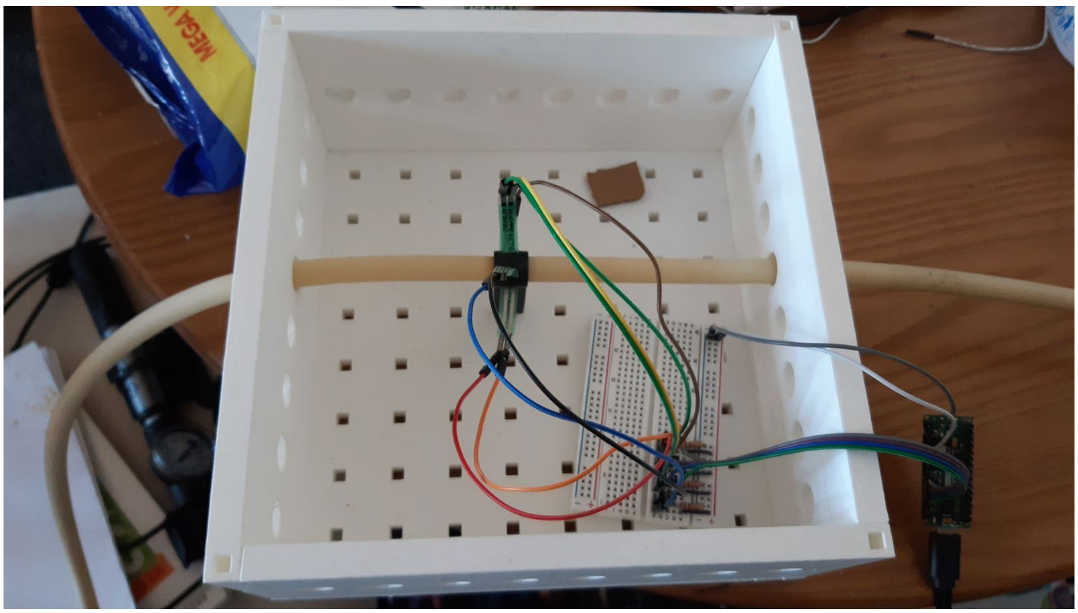


Figure 4.8: Updated design for 3D printed arterial threading box trainer.

4.4 Software Engineering of Arduino and Python Testbed Environment

To generate the data related to the force applied to the sensors, the Arduino Nano was loaded with a script that read in the incoming analogue data from the sensors, looping through each of the sensors to gather an individual reading that was then averaged out, based on the total number of sensors, providing a scalable solution.

When the Arduino was started up, either through the internal serial monitor or an external application, the set-up runs, which contains a loop that cycles through each index of the readings array and defaults them to zero to prevent erroneous results influencing the data transmitted. The incoming voltage data from the sensor was mapped to an analog value between 0 and 1023.

The loop function in the script uses a for loop that checks if the current reading (*i)* is within the array range of the *numReadings* variable defined by the number of sensors. The for loop begins by subtracting the current *readings* index from the total before setting the index as the incoming value from the analogRead function. The index value is then added to the total value to keep a consistent value before incrementing the *readIndex*. When the *readIndex* is equal to the *numReadings* variable, it resets back to zero.

Once the *readings* have been fully recorded, the total is divided by the number of sensors in the array to find the sensor's average value for that loop iteration, which is then printed using the Serial.println function. The code runs within 16.6ms at a refresh rate of 60Hz, which can be reduced to produce more sensitive readings. The Arduino code can be found in appendix 2 on the following:

https://github.com/KieranLathamPhD/ThesisCodeAppendices

It was essential at this stage to know which COM port was used and confirm the baud rate settings used by the Arduino device, as these were required when establishing serial communication later in Python and Unreal Engine 4.

Data sets were collected to test the sensor system and ensure that data regarding the applied force was generated efficiently and provided insight into applied force. A Python script was developed to communicate with the Arduino device, which involves using the COM port related to the Arduino device to communicate the serial data

(Koerner *et al*., 2020). Python was chosen due to its widespread adoption and versatility as a programming language, providing a wide range of resources to support development.

PySerial (Liechti, 2017) was implemented, which allows Python to open serial communication with the device, which requires the Python script to match the COM port and Baud rate of the Arduino device it was trying to open communication with to ensure the data was transmitted correctly, confirmed by printing the output to screen for the user to see.

With serial communication available and Python reading the incoming sensor data, a system can be developed for the organisation and creation of data sets that can be used to analyse and debug the data being generated to ensure its validity. The Python CSV library (Python Software Foundation, 2016) was implemented to provide the functionality needed to create a CSV file at a specified location before making the header array and storing the incoming data as individual rows, with a timestamp to identify when the test was completed.

The script was designed to run for five thousand loops before finishing, to limit the size of the file being created. The developed python script can be found in the appendix 3 on the following:

https://github.com/KieranLathamPhD/ThesisCodeAppendices

4.5 Virtual Reality Learning Environment

4.5.1 Introduction

The virtual Reality Environment produced in this study mostly follows conventional methods to provide an immersive working environment for user training. The communication of real-time sensor data from the Proxy Design Pattern Controller described above, provides a new way of interacting with the virtual environment and controller by extending the functionality from predefined controllers and inputs to allow input from a bespoke controller to drive gameplay in a much more innovative way.

The creation of an immersive virtual learning environment is not a novel concept and does not directly impact the ability to achieve this projects research aims. In the context of this project, the development of a VR environment was completed to provide a working space for data to be communicated, visualised and recorded in real-time. Additionally, in the scope of the project, the virtual environment provides only visual cues regarding the tactile information from the users arterial threading, omitting the additional visual cues provided in the forms of DICOM data visualisation. The reason for this was that existing simulators already provided high fidelity visualisation of DICOM data for simulation, and that the limitation was limited information and visualisation of haptic information in real-time, so the decision was made to focus solely on visualising the change in haptic information to help users develop their muscle memory when navigating an artery.

The Virtual Reality Learning Environment (VRLE) creation involved developing two things: the medical equipment which includes the medical frame, biplane and bed, and the working environment, and was used to provide a realistic working environment in VR. There are various methods that can be utilised to generate a 3D virtual environment (Hurst *et al.*, 2018). The medical equipment props were produced based on a CAD model of the Artis Zeego Biplane provided by Siemens Healthcare (Siemens Healthcare GmbH, 2020).

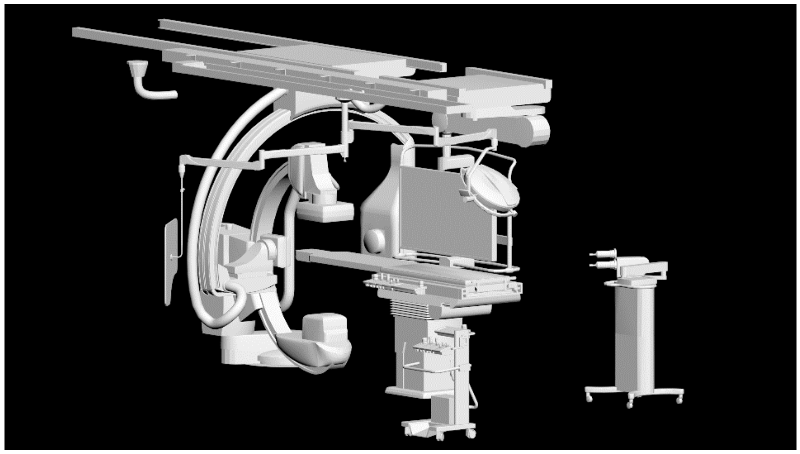


Figure 4.9: CAD model of Siemens Artis Zeego Biplane.

The models provided were not optimised for game engine technology or real-time rendering, with inadequate topology and primitive count, impacting the quality of UV maps, which are crucial to produce ideal texture maps (diffuse, metal, roughness, normal, occlusion) and lighting maps in game-engine. To correct this, the models were optimised in Autodesk 3DS Max 2019, where the geometry was optimised for real-time rendering and UV mapped to make it suitable for a game engine environment (Latham *et al*., 2017), (Hurst *et al*., 2018).

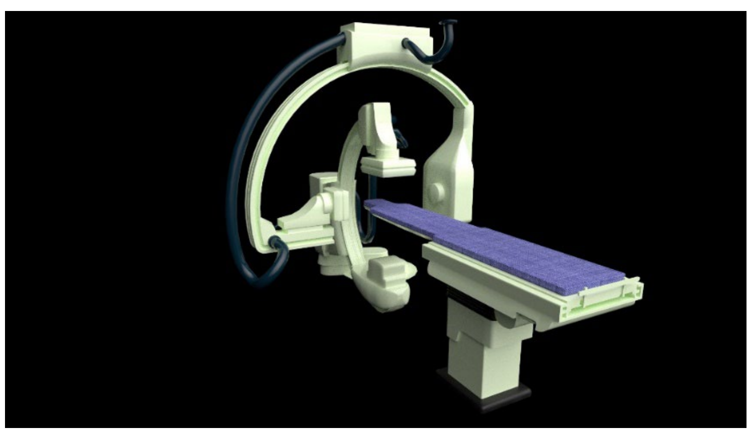


Figure 4.10: Retopologised and textured Artis Zeego in Substance Painter.

Once the model was optimised, texture sets are generated (diffuse, normal, metallic, roughness, and occlusion) inside Substance Painter using physical based shaders for various materials such as plastic, metal, and fabrics, and then applying filters and generators to them such as dust, grunge, and other effects to produce realistic looking textures, to then import into Unreal Engine 4.

4.5.2 Photogrammetry

Initially, the project aimed to utilise photogrammetry to generate the virtual operating theatre using high-resolution images of the real-world operating theatre to generate point cloud data and geometry with a high degree of autonomy (Kraus, 2007). The process involves using structure-from-motion (SfM) to calculate the position and orientation of tie-points in the image set identified from overlapping images (Tobiasz *et al*., 2019). The benefit of photogrammetry is its low cost and accessibility, with users able to use consumer-level equipment to produce the images necessary for photogrammetry and the amount of detail it can capture from the images (Nisha Upadhyay, 2014). In the project's case: a test run was conducted in Agisoft Metashape on the LJMU LIVE Lab where 645 images were used to generate a 3D environment; at high-density, the mesh was rendered at 1.8 million polygons, while the low-density was rendered at 90,000 with 4K (4096x4096) textures that can be used for baking the high-poly mesh onto the low-poly mesh at a later stage in development (Latham *et al*., 2019a).

This method requires calibration on the camera and the images to produce the quality required to generate the optimal number of tie-points based on extracting matching features from multiple photos. Furthermore, SfM cannot inherently derive the scale and orientation of the 3D scene from camera position alone, meaning the user would need to apply scale bars based on available sizes to match the real-world scale. The parameters for decimation are procedural and generated off user-defined thresholds, this offers some control to the user, but can still produce wrong results if there was not enough data. Photogrammetry as a tool for 3D modelling is quite powerful and can produce beautiful results. However, in this experiment, the model produced for this project was low-quality and produced a project size of 10GB, a 3dsmax file of 301MB and a filmbox (fbx) file of 58.3MB. The timeframe for this model took several scans to generate a usable file and any optimisation modifications, the timeframe combined with the quality of the final output; an alternative approach was investigated to develop the environment.

4.5.3 Building Information Modelling and Computer Aided Design

Architectural, Engineering, and Construction (AEC) industries, including cultural heritage, civil engineering, structural health monitoring, often make use of Terrestrial Laser Scanning (TLS), a range-based measuring technique for producing Building Information Modelling (BIM) (Hurst *et al*., 2018), (Tobiasz *et al*., 2019), (Kot *et al*., 2020). Like photogrammetry, TLS involves generating a dense 3D point cloud using high-spec laser scanners that can account for both architecture and terrain and provide orientation and location data in the form of geometric coordinates (X, Y, Z) for the generated point data. The point cloud data was converted into a 3D mesh using specialist software such as Auto Recap, AutoCAD, and Revit.

The final output was a high-quality BIM file comprised of all the captured and processed geometry. A critical difference between the SfM approach discussed previously, and the TLS method for BIM was that this approach takes advantage of structuring the point cloud data and identifying and segmenting respective geometry within the point cloud data, which helps with geometry representation (Aoki *et al*., 2019). BIM is considered a multidisciplinary platform that enables the planning, generation, documentation, and management of an existing or conceptual environment, structure, or building, usually in an offline setting (Tang *et al*., 2019), (López *et al*., 2018).

As these models are often used for offline collaboration between architects, engineers, technicians, and construction companies, they are not optimised for real-time visualisation, requiring extensive development for the real-time visualisation of (Hurst *et al*., 2018). To optimise the environment for Unreal Engine 4, a developer investigated the scene and removed superfluous geometry to reduce the poly count to a more manageable 300,000 polygons before UV unwrapping the geometry and assigning materials inside Unreal Engine 4.

A problem encountered, however, was access to the specialist hardware and software required to produce structured point cloud data. Accessing existing point cloud data allowed for experimentation with inferring geometry from structured point cloud data. The problem identified, however, was how much work had to be done to infer the geometry, and given the complexity of specific machinery or furniture, would be difficult and time-consuming to achieve acceptable results. The issue with this approach was that the time and skill required to investigate the complex equipment and software required to generate and register the structured point cloud and then convert it to geometry to optimise and import into Unreal Engine makes it an undesirable method without the workforce to expedite the process.

4.5.4 Conventional 3D Modelling and Texturing

Conventional 3D modelling and design was considered for the development of the virtual operating theatre due to standardised workflows for efficient development of geometry for real-time rendering and virtual reality.

The steps in making the virtual operating theatre this way involve (a) modelling the architecture (walls, doors, floor, ceiling) and any additional structures or prop; (b) scale it around the medical equipment so that the room does not feel too cramped or empty; (c) UV unwrap all geometry to accurately reflect position and scale in 3D. This was all conducted inside the likes of Autodesk 3DS Max and Houdini FX, which offer effective and industry-standard solutions for the above tasks.

Moving forward from this, the map baking and texturing was accomplished in Substance Painter, using material shaders and layer sets to create texture maps for the environment that give it the graphical appearance of a virtual operating theatre, while the geometry provides the physical representation.

Unlike Photogrammetry, this approach is more manual and involved and requires more understand of workflow and steps to creating necessary geometry and textures. The advantage was full user control over the design, room layout, appearance, and resolution, while the disadvantage was the timeframe that comes with the manual involvement where the designer must make changes that draw out development time.

4.5.5 Procedural Content Generation and Environment Modelling

The decided approach to develop the virtual environment used in the simulator was through procedural content generation (PCG) workflows available in Houdini FX. The benefit of this is the efficiency and speed in which the procedural digital asset developed can create a large amount of geometry of varying complexity based on procedural rules for a wide range of systems (McLennan *et al*., 2020). Procedural Content Generation is more programmatic than standard 3D modelling and design, relying on rules, parameters, and user-defined parameters to function, and is like photogrammetry in terms of automation, in that once the key parameters have been set, the designer can launch the tool and let it build.

The advantage of this over conventional 3D modelling was that the procedural system can be modified in the engine to produce new output instead of having to go back and modify the system in a digital content creation tool. PCG workflows can utilise the methodologies used during conventional 3D modelling in a more procedural and automated way saving development time were certain, repetitive tasks can be taken care of manually.

The procedural system used to create the virtual operating theatre was created using Houdini FX Indie, in which a Houdini Digital Asset (I) was produced that can be imported into Unreal Engine 4 to modify and test the results in real-time, allowing for efficient usability testing and redevelopment if any changes were needed (McLennan *et al*., 2020).

Figure 4.11: Procedural floorplan using a Lindenmayer rule system.

The virtual environment involved using a Lindenmayer System (L-System) to generate a unique fractal layout based on generational growth of a line influenced by procedural rules determining how the geometry changed with each iteration.

Implementing the L-System requires defining the procedural rules that the system runs each time the system iterates through a generation (Lindenmayer, 1968), (Kelly and Mccabe, 2006). These rules can include each generation's step size when iterating, the seed value used to determine what rule gets implemented for that generation, and even the number of *generations* the system loops through.

The result of the L-System was a series of points that the tool then uses to place grids along, sized based on the L-systems step size to maintain correct layout. From this, the grids are fused together to create a floor plan with a uniform cell size, for example, if the step size was 3m then the uniform size of each edge in the grid would be 3m also.

Once the floorplan was created, the geometry was processed in several ways to create the relevant structural geometry: walls, floor, ceiling, and concave/convex corners, which are used to drive other parts of the tools.

The floor layout was split into two different systems: the floorplan as a single primitive was stored for non-procedural design, where it was feasible. Alternatively, the points used to assign the grids are preserved to allow instancing of geometry with tiled textures to allow for optimal mapping and texturing in game. Additionally, the floor prims and points can be referenced when creating the ceiling geometry by considering wall height, which is derived in another sub-network of the tool.

The walls system were created by removing the interior grid edges of the floorplan, leaving only the perimeter, leaving the outer grid edges, with their uniform size intact. Once complete, each edge in the perimeter was carved at the halfway point, which involves taking the first and second point, mapped to 0 and 1, and adding a point at 0.5, this point then identified the centre of the edge, and where wall geometry will spawn.

This was then expanded upon by providing additional user input to modify the appearance of the wall geometry, doors, and windows, such as determining the count and location of doors and window count. Furthermore, for more flexibility in game engine, the point data used to spawn geometry was instanced so that it can be overridden by a designer in Unreal, for custom geometry or gameplay actors.

Information regarding the corner geometry and points was used to identify the shape of the room with the corners, such as interior corners or exterior corners, which was more useful for systems like roofing or pillars, especially when determining the type of geometry to spawn. In this case, the corners were not separated based on normal vector, but were used to append structural load-bearing beams to the environment and breaking up the sharp edges.

The ceiling system considers the height of the wall modules and is a transformed copy of the floor geo or points. This allows for rapid redeployment of the ceiling geo with little strain on the tool.

At this point, most of the building is a point cloud generated from ‘midpoints’ extracted from the layout, with minimal geometry.

These points were assigned a class attribute and *unreal instance* parameter to expose the instancing to Unreal and the developer. This set-up meant that the developer has complete control over the gameplay actors and geometry used to construct the building. Using Unreal Engine 4 with Houdini Engine V2, the developer can import the asset into a scene and begin building procedural layouts for the room. Since the tool does most of the structural work, the developer can simply assign the desired actors or geometry to the digital asset to tailor the environment to their liking.

Figure 4.12: Output of building generator furnished with medical equipment.

From this, two things can happen: the developer can take a more manual approach to the more in-depth design now, focusing on creating the atmosphere and mood of the environment and manually placing the relevant actors, geometry, lighting, effects to create a unique gameplay environment. Alternatively, developers can rely on the digital asset's procedural power and derive most gameplay actors such as lighting, reflection probes, doors, props from existing points and lines created within the tool. In the virtual operating theatre case, the scale was small enough that manual input can be utilised efficiently without drawing out too much development time.

4.6 Serial Communication in Unreal Engine 4

4.6.1 Introduction

Following the creation of the virtual learning environment and the sensor system, Unreal Engine can communicate with the sensor system to retrieve the sensor data generated by the system's force-sensing resistor array. The application uses the UE4Duino libraries, containing functionality designed for serial communication of Arduino devices in Unreal Engine 4 (Villani, 2021). Inside Unreal Engine, to enable serial communication and utilise the data for visualisation, user feedback, and exporting, multiple classes need to be created or adapted to support the functionality.

4.6.2 Gameplay Actor

A gameplay "Actor" inherits from the AActor C++ class and describes any object that can be placed or spawned in a level at runtime or during gameplay. The Actor class is often comprised of "components," which are used to define the functionality of the Actor, such as rendering, interaction, translation; they can also be used to replicate data across a network and communicate with other actors and gameplay framework classes (Epic Games, 2021a).

In the Virtual Arterial Threading Simulator, a simple UActorComponent was created, called BP_Arduino that contains the functionality and scripting of the Actor, including the artificial intelligence, user input, and communication of data from the Arduino device.

An actor component was created to communicate with the Arduino Nano so long as the application was running. The actor consists of three functions that relate to communication and dissemination of incoming sensor data: *"Event BeginPlay," "ReadSensorVal,"* and *"Event EndPlay."*

Event Begin Play launches as soon as the actor spawns during gameplay, whether it be at launch or spawned later via other function or actor. The event begins by storing a reference to the game mode of the world, which was defined either by the project settings or the world settings; this allows the actor to interface and communicate with the Game Mode when working with the sensor data.

The event then opens the serial port, taking in a COM port number and baud rate to set up the communication before confirming the port was open, then creates a reference to the newly created Arduino actor, flushes the port of any data and sends a notification to the screen that the port was opened; likewise, if the port does not open, a message was displayed stating this.

The final task of the event was to trigger an event that reads the sensor data and send it to the game mode, the task looped and runs every 20ms. This provided a buffer for data on the Arduino to completely process.

Read Sensor Val begins by checking there was a valid Arduino actor in the level, if a valid one was found, then the event calls the "*Read Line"* function that reads the current string being generated by the Arduino, such as the sensor data, it then converted this to a float variable before retrieving the game mode sensor variable from the stored reference and updating the variable for the game mode.

The final function in the Arduino actor is End Play, which runs when the game was ended for any reason whatsoever, the purpose of which was to ensure that any critical systems are correctly terminated prior to closing the application to prevent errors. In the case of the Virtual Arterial Threading Simulator, the End Play function ensures that the serial port was correctly closed before switching off the game.

4.6.3 Game Mode Class

In the game mode class, the RunSensorSystem function was called every 20ms as with the ReadSensorVal; the incoming sensor data was added to an array that contains all the sensor readings generated in that session. Here a data structure was also implemented that imported angle data from an Excel spreadsheet that provides additional data regarding the angle.

To save the data results out of Unreal Engine 4 into a CSV file, a C++ “Blueprint Function Library” was created to provide the functionality inside Unreal Engine to save the data. A callable blueprint function called FileSaveArray was created as a static bool that takes a TArray variable and FString variable as arguments. The function uses the SaveStringArrayToFile function from the FFileHelper library to complete the save using the provided TArray and FString arguments (Epic Games, 2021c), (Epic Games, 2021b). The created function was called inside the game mode class and took the sensor value array and a user-defined filename string as arguments for the function. There were several ways in which this function can be called: (1) The array length is used, like the index count in Python, to call the function after a set count. (2) an event timer was set that waits a set period to save the array. (3) Create an input event so the user can manually save the array at any point.

The filename consisted of a defined filename variable and a formatted timestamp to distinguish individual tests; the sensor reading array was saved out to the CSV with that filename and then cleared so the test can reset, and a new array was generated, keeping file size low.

As a safety measure, the save file was automatically called every five thousand frames, same as Python, to limit the file size and reduce the amount of memory being used to manage the data, which is why the array was cleared of data once the data has been saved to disk.

4.6.4 Widget Blueprint Class

The game mode class was then cast to and stored as a reference in the UI widget blueprint class's Event Construct, which runs before spawning the component in-game. The sensor reading and angle variables are received in real-time and update to reflect the changes in the data received from the Arduino.

The widget was then presented in the virtual world as a screen on a virtual monitor for users to refer to during simulation in an equivalent way to how they would refer to a monitor in the real-world scenario. The additional benefit to using the widget approach was that it can be combined with other elements in future studies such as integrating DICOM data or patient vitals that can be positioned to provide users with a robust and informative user interface.

4.7 Python Impact Detection Using Windowed Standard Deviation

The key output in this research was a parameter that can be used to determine a user's level of efficacy during simulated catheterization and threading of an artery. Simulation training commonly provides functionality that monitors specific aspects of a user's performance and records data for supervisors and assessors to use when determining the level of competency in a trainee (Li *et al*., 2017), (Nawka *et al*., 2020), (Loukas, 2016), (Saratzis *et al*., 2017). These parameters often include time taken to complete a procedure or task, volume of contrast medium used, and number of errors (procedure specific). The introduction of a new metric relating to the detection of impact data in a physical simulation could provide supervising practitioners and assessors with additional insights into a trainee's performance during a simulated procedure.

To analyse the sensor data generated and exported from Unreal Engine, a Python program was scripted to receive and analyse the data. The purpose of this was to differentiate the amount of applied force and severity of impacts that are generated in a simulated arterial threading by the user. Initially, the data was analysed using a OneClass-SVM algorithm to identify areas where the applied force or impacts occur based on changes in the data. The algorithm would look at changes in the data as it was read and then distinguish the data based on whether there was applied force or not and classify the various categories. The algorithm identified when the data change exceeded a certain value, such as a 2.5/5/10% threshold and would classify the outliers as applied force, distinguishing the impacts and applied force from idle or non-detecting data, (See Figure 4.16). The thresholds used in this experiment are arbitrarily set at uniform levels of 2.5/5/10% as these will be exposed to the expert users to calibrate and define at the levels they believe to be reflective of competent practice as the scenario being simulated is a complex medical procedure that requires in-depth knowledge.

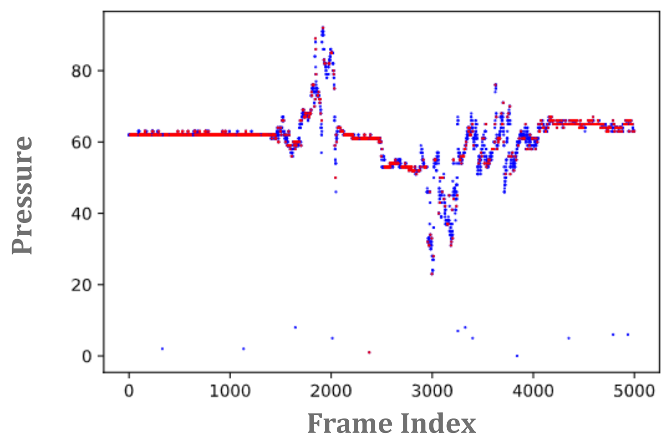


Figure 4.13: example of OneClass-SVM algorithm classifying sensor data into idle (red) data and applied force (blue) data.

The attempt at using OneClass-SVM for anomaly detection in the force-sensor data returned noisy results, while it was able to quantify the amount of anomalous data (applied force), the sensitivity of the algorithm led to some misclassification of data, (See Figure 4.16), where even on the spikes where applied force occurs (as indicated by the blue sections), it was still identifying idle data. Despite this, it was a promising start to producing an object performance metric for the analysis of applied force and impacts in the arterial threading. Moving on from this, a similar approach was considered that would look at using the standard deviation of the data set to identify changes that exceeded a certain threshold.

An early attempt at detecting the differences in applied force was attempted using standard deviation across the entire data set with results being extremely unreliable, as the idle data could change between experiments and any attempt at establishing boundaries that would detect changes in force were met with false positive results inside Unreal Engine.

After additional investigation, it was identified that using standard deviation to detect impacts could be improved to provide more reliable results. Instead of calculating the standard deviation across the entire data set, the standard deviation was calculated across a small range that would be iterated across the data set, allowing for a more in-depth analysis by producing more deviations to assess. For example, if there was a graph of 200 frames and the algorithm splits into two sections of 100 frames, with the first 100 having no change in pressure and the second 100 demonstrating change in pressure, then the graph would calculate the standard deviation of the first graph as having minimal to no deviation, while the second section would show a higher standard deviation. The algorithm would then say that the second window has evidence of applied force or impacts due to changes in pressure and standard deviation.

Based on the idle and active data generated in past experiments, an idle response with no applied force or impact from the user would provide a result with extremely low standard deviation. Therefore, in this case, anything below a standard deviation of 2.5 is an idle response, which also accounts for a general sensor drift and noise generated in this type of sensor systems. From this, additional levels were added, if anything below 2.5 was an idle response, then anything below 5 was a minor response, anything below 10 was a medium response, and anything above 10 was a major response. These boundaries are used to create a "traffic light system" that informed practitioners and supervisors of how much force was being applied and at what level.

To confirm that the system was working as intended, a "print string" function was used to provide the standard deviation values across a series of data points, each one returning a standard deviation for the respective range.

This allowed the data set to be grouped into subsets based on a window size and processed in a '*for loop*' to automatically calculate the standard deviation for each window in the data set.

At this point, the results from the standard deviation were interrogated further by implementing an '*if statement'* to identify whether the standard deviation provided for the window was over a certain threshold and identified those specific windows.

The next step was to build a data frame with the relevant standard deviations so that the results can be assessed to determine the level of applied force and number of impacts. This was achieved by creating a new data frame using the range as the index, and then iterating over each index using a '*for loop'* and adding the standard deviation of the current range to the data frame.

From this point, the thresholds for the standard deviation were applied to visually categorise the various levels of applied force and detected impacts; this was used to quickly visualise the data sets and obtain an approximate representation of the number of impacts that were detected and the level of applied force present in the data set. The next step was to extend the '*if statement'* check conducted earlier to now assess the different thresholds to determine the quantity of impacts and applied force at the various levels (minor, medium, major).

4.8 Testing and User Experience

To assess the effectiveness of the platform and application, end-user testing was conducted to identify how the user perceives and interacts with the system, helping to identify any strengths and weaknesses within the system. End-user testing involved allowing the user to interact with the system and complete an arterial threading simulation to generate the applied force data and occurred impacts.

This provided two outputs, additional data generation, and more importantly, the user was able to provide qualitative feedback during the experiment as to how they feel the system is acting or responding to their input. Secondly, a user experience questionnaire was provided to the user upon completion of the experiment. This provided more formal quantitative feedback regarding several key aspects of the system, its functionality and outward appearance.

At this stage of development, the platform underwent “Alpha Testing” to identify any user experience concerns, possible software bugs, or design flaws that can be implemented before deploying to end-users for further testing and analysis. This form of testing is often done before a product is released to end-users who will test the platform in a real-world environment as part of a “Beta Test”. The alpha test and user experience analysis was conducted internally at Liverpool John Moores University with eligible participants being full and part-time postgraduate researchers and lecturers in the fields of computer science, mathematics, and civil engineering, as these fields are relevant to the design and development of the platform and can provide invaluable feedback. It was expected that at least fifteen to twenty users were required to test the platform and provide user experience responses to help assess the usability of the platform.

4.8.1 Simulated Arterial threading

For the simulation experiment, end-users posed as novice interventional neuroradiologists conducting a simple arterial threading task in a mechanical thrombectomy. They were expected to guide a catheter through the simulated artery and react to the change in physical resistance, with the system recording any impacts or changes to the applied force.

These end-users were not clinically trained, and as such, their opinions were limited primarily to the design considerations of the system as to opposed to the utilisation of the system in practice. Additionally, all users received force value feedback, so results only relate to users who responded to change in the data.

Upon experiencing physical resistance, users were expected to reduce the force they were applying and switch to a smaller catheter as not to put too much force on the arterial bend. The generated data identified how users reacted to the applied force and demonstrated their efficiency by calculating the number of impacts and detecting the applied force.

Users were able to determine how the force (they have applied) affected the artery by the on-screen metric, which changed to indicate that the force was being detected, indicating that the severity is growing.

During the experiment, users could “think aloud” and describe their thoughts on the system, namely (1) how they feel about the procedure, (2) if they feel the system is informative, and (3) whether they feel it is reliable. The “think aloud” method allowed the user to provide qualitative data in-situ and provide direct opinion and feedback on the system as and when something happens.

4.8.2 User Experience Questionnaire

The second part of the study involved users completing a user experience questionnaire (UEQ) that asked about their experience with the device. The UEQ consisted of twenty-six questions with 1-7 Likert scale to gather quantitative feedback regarding the user’s impression of the platform and use these responses to calculate the overall perception of certain aspects of user experience (UX). The UEQ was selected for this task as it was designed for usability assessments on first-time assessments and contains a list of twenty-six different items, (See Figure 4.23).

	1	2	3	4	5	6	7		
annoying	○	○	○	○	○	○	○	enjoyable	1
not understandable	○	○	○	○	○	○	○	understandable	2
creative	○	○	○	○	○	○	○	dull	3
easy to learn	○	○	○	○	○	○	○	difficult to learn	4
valuable	○	○	○	○	○	○	○	inferior	5
boring	○	○	○	○	○	○	○	exciting	6
not interesting	○	○	○	○	○	○	○	interesting	7
unpredictable	○	○	○	○	○	○	○	predictable	8
fast	○	○	○	○	○	○	○	slow	9
inventive	○	○	○	○	○	○	○	conventional	10
obstructive	○	○	○	○	○	○	○	supportive	11
good	○	○	○	○	○	○	○	bad	12
complicated	○	○	○	○	○	○	○	easy	13
unlikable	○	○	○	○	○	○	○	pleasing	14
usual	○	○	○	○	○	○	○	leading edge	15
unpleasant	○	○	○	○	○	○	○	pleasant	16
secure	○	○	○	○	○	○	○	not secure	17
motivating	○	○	○	○	○	○	○	demotivating	18
meets expectations	○	○	○	○	○	○	○	does not meet expectations	19
inefficient	○	○	○	○	○	○	○	efficient	20
clear	○	○	○	○	○	○	○	confusing	21
impractical	○	○	○	○	○	○	○	practical	22
organized	○	○	○	○	○	○	○	cluttered	23
attractive	○	○	○	○	○	○	○	unattractive	24
friendly	○	○	○	○	○	○	○	unfriendly	25
conservative	○	○	○	○	○	○	○	innovative	26

Figure 4.14: Example of the User Experience Questionnaire (Schrepp et al., 2017a).

The UEQ provides an analysis of the user's experience based on the following UX aspects:

- Attractiveness: The user's overall impression of the system. Does the user like it? Is it enjoyable and/or pleasing?
- Perspicuity: Is it easy for the user to understand and familiarise themselves with?
- Efficiency: Can the task be completed by the user without unnecessary effort? Is the interaction smooth and reliable?

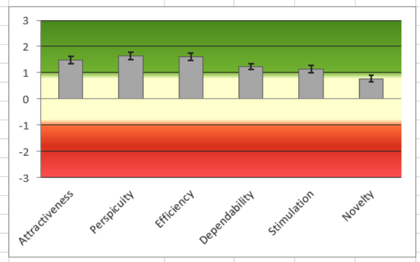
- Dependability: Is the user in control of the interaction? Does the system behave as expected by the user and inspire confidence?
- Stimulation: Does the user feel excited or motivated to use the product? Does the user find it enjoyable?
- Novelty: Is the product at the forefront of its field?

The characteristics identified cover three overall dimensions in user experience: (1) Attractiveness: An overall measure of acceptance by the user that can overlap with pragmatic and hedonic qualities. (2) Pragmatic Qualities: Perspicuity, Efficiency, and Dependability are all relevant to the quality of interaction that relate to the completion of the given task when the user uses the system. (3) Hedonic Qualities: Stimulation and Novelty do not relate to the functionality or ability to complete a task, but describe the aspects related to finding pleasure or being impressed with the system.

The data was analysed to produce a graph showing the overall results and ratings of individual UX aspects on a scale of -3/+3. Anything below zero indicated a negative result, and anything above is a positive result. This helped provide a visual representation of how the users perceived the system and identified areas for improvement, (See Figure 4.24).

Item	Mean	Variance	Std. Dev.	No.	Left	Right	Scale
1	1.6	1.9	1.4	255	annoying	enjoyable	Attractiveness
2	1.9	1.7	1.3	255	not understandable	understandable	Perspicuity
3	0.8	2.3	1.5	255	creative	dull	Novelty
4	1.5	2.7	1.6	255	easy to learn	difficult to learn	Perspicuity
5	1.5	2.2	1.5	255	valuable	inferior	Stimulation
6	1.0	1.7	1.3	255	boring	exciting	Stimulation
7	1.2	1.9	1.4	255	not interesting	interesting	Stimulation
8	0.6	1.8	1.3	255	unpredictable	predictable	Dependability
9	1.4	1.8	1.3	255	fast	slow	Efficiency
10	0.8	2.2	1.5	255	inventive	conventional	Novelty
11	1.0	1.8	1.3	255	obstructive	supportive	Dependability
12	1.7	2.1	1.4	255	good	bad	Attractiveness
13	1.5	2.0	1.4	255	complicated	easy	Perspicuity
14	1.4	2.1	1.4	255	unlikable	pleasing	Attractiveness
15	0.8	2.1	1.5	255	usual	leading edge	Novelty
16	1.5	1.9	1.4	255	unpleasant	pleasant	Attractiveness
17	1.6	2.1	1.5	255	secure	not secure	Dependability
18	0.8	1.7	1.3	255	motivating	demotivating	Stimulation
19	1.7	1.9	1.4	255	meets expectations	does not meet expectations	Dependability
20	1.7	1.8	1.3	255	inefficient	efficient	Efficiency
21	1.7	1.9	1.4	255	clear	confusing	Perspicuity
22	1.9	1.2	1.1	255	impractical	practical	Efficiency
23	1.3	2.6	1.6	255	organized	cluttered	Efficiency
24	1.2	1.8	1.3	255	attractive	unattractive	Attractiveness
25	1.5	1.8	1.3	255	friendly	unfriendly	Attractiveness
26	0.7	2.2	1.5	255	conservative	innovative	Novelty

UEQ Scales (Mean and Variance)		
Attractiveness	1.473	1.31
Perspicuity	1.642	1.29
Efficiency	1.607	1.10
Dependability	1.243	0.83
Stimulation	1.135	1.13
Novelty	0.774	1.17



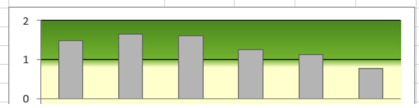


Figure 4.15: Example of the data analysis of user experience based on UEQ assessments.

4.9 Conclusions

The work completed in this chapter demonstrates a working prototype of the arterial threading simulator designed to achieve the goal of calculating and assessing haptic information for end-users. It also highlights the various workflows and technologies explored in achieving this goal.

The design of the proxy pattern controller allowed for a simple, yet effective method of receiving and calculating haptic information and changes in the application of force from a user during arterial threading.

The development of an immersive virtual environment was not paramount to achieving the goals of this research project, rather serves to demonstrate, in a real-time environment, how the data can be integrated and assessed, in line with growing demand for more real-time immersive learning platforms. In this case, the decision was made to use a methodology that expedited the design of said immersive environment to allow for more focused development on the hardware design of the platform and analysis of data to complete project objectives. Additionally, the virtual learning environment focused only on provided information regarding haptic interaction from the user and did not include visual cues such as DICOM, this decision was made to allow users to focus purely on the change in tactile resistance without distraction, allowing them to concentrate on the physical aspect of the simulation., since visual simulation is already a major part of simulation training.

The testing of the platform is limited by a number of factors, including a lack of medical practitioners involved in testing to provide formal and qualitative validation and assessment of the platform; while manual calibration and repeatability was completed to ascertain the repeatability and stability of sensor data, a mechanical examination was not conducted. Furthermore, the application only tests for applied pressure at a single point of the simulated artery and does not account for the difference in physical characteristics between inserting the catheter and removing the catheter from the artery. To enhance this proof-of-concept simulation and make it potentially usable as a simulator for clinical training, future iterations would benefit immensely from mechanical validation studies to confirm repeatability and stability;

modelling the insertion and retrieval stages independently could provide better understanding of how the sensors are expected to react to changes in force. Lastly, adding additional sensor arrays along the curve could provide entry and exit data points to correlate with the apex point (currently captured) to provide a more in-depth picture of the haptic information and changes in tactile resistance throughout the insertion.

CHAPTER 5 RESULTS

5.1 Introduction

The collected data throughout the testing of the proposed virtual arterial threading simulator will be utilised to assess the system's ability to identify changes to the force-sensor data when applied force occurs. The testing is conducted across four phases:

1. Initial System Set-up: This involved conducting applied force tests on the initial designs to determine the quality and efficiency of the data being collected to identify a suitable material and sensor set-up for the platform. The results here will help identify the optimal set-up for the box trainer.
2. Idle testing: This involves leaving the sensor system in an undisturbed state to see how the sensor data changes throughout an experiment across a range of bends. The results here will indicate whether the force-sensor data is reliable enough to provide a baseline of the idle state, which will enable the platform to differentiate between the idle and active states.
3. Active testing: This stage involved applying force to the sensors by manoeuvring a catheter through the tube and triggering a response from the sensors across multiple bends. The data produced here will demonstrate how the system responds to the applied force across varying bends and levels of force and the reliability of detecting these changes in data format.
4. Real-time testing: The testing at this point will be conducted in Unreal Engine to produce replicates of the data output of the active testing in a real-time environment for virtual reality simulation. The generated data will be analysed to determine whether the output is of the same fidelity as, or higher than the active testing to ensure that the data is still reliable enough.
5. Impact Detection: Data generated in Unreal Engine will be analysed using an anomaly detection algorithm based on standard deviation to identify the distinct levels of applied force and impacts that occurred in the data set. The results here will demonstrate the platform's ability to analyse force-sensor data and identify areas of impacts and applied force and quantify the total amounts based on level of force.

5.2 Preliminary Experiment Results

5.2.1 Initial Experiment Results

The initial experiments took place using the first prototype, which involved using an FSR to detect movement within a 12fr catheter from a 6fr microcatheter. During the experimental work, a user manually held the sensor to test the interaction. The reason for this was to determine the quality of the sensor data being communicated from the sensor to the device to see how the position of the sensor affected the reading of the sensor data and the difference in results.

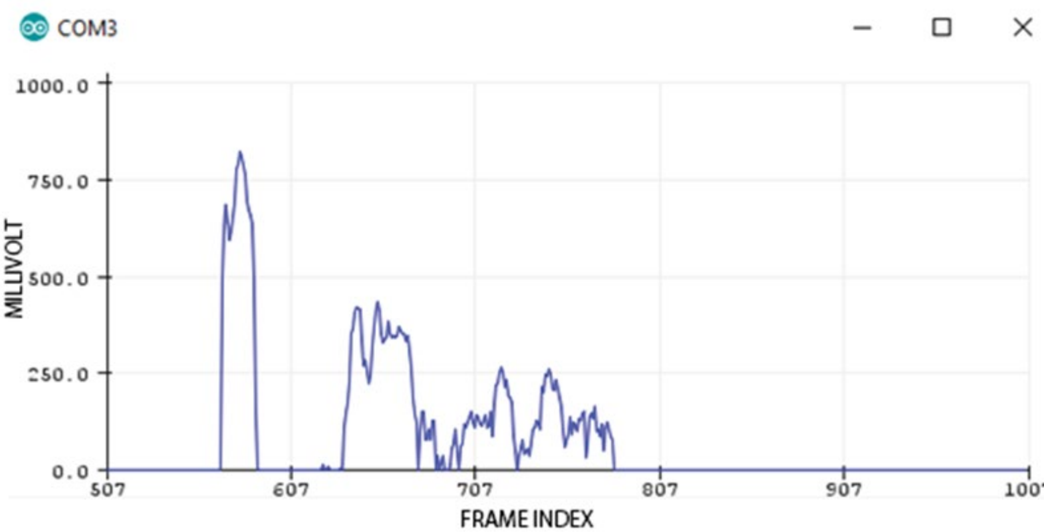


Figure 5.1: Initial FSR data experiment (manual application to catheter)

As the graph in Figure 5.1 shows, there are inconsistent and noisy spikes, the issue is it only detected a small amount of force, with the graph mapped from 0 to 5,000, and the spikes are influenced more by the hand, than the actual microcatheter and this does not demonstrate the intended behaviour of the sensor system. The intended behaviour for this experiment was more consistent spikes in the data when the catheter was inserted into the tubing to show that it could consistently read in the data being communicated from the sensors.

The data in Figure 5.2 indicates that some pressure is being detected, albeit, very faint readings, by the sensor. The sensor readings are inconsistent with the arterial navigation being conducted.

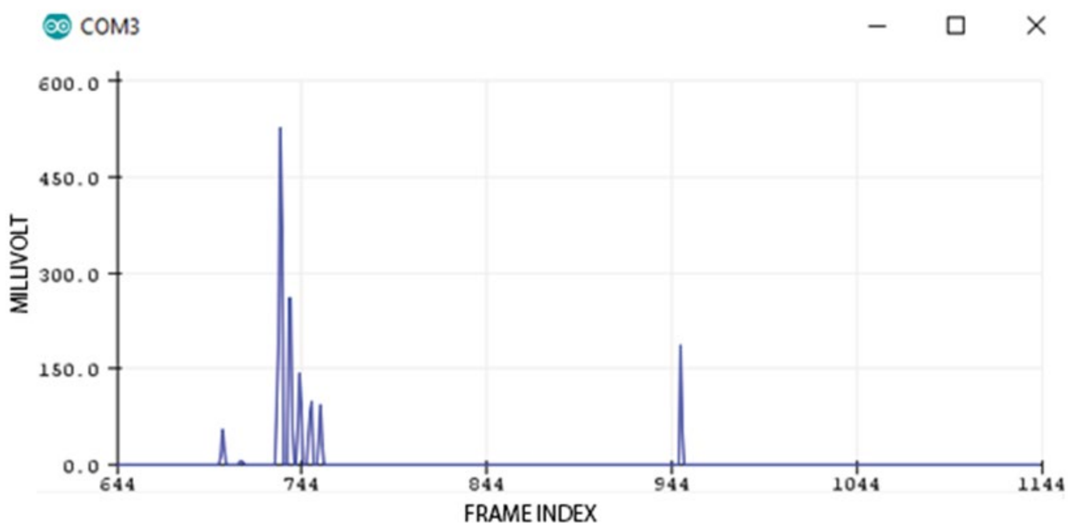


Figure 5.2: Initial FSR experiment with sensor attached to tubing via adhesive tape

The readings in Figure 5.3 indicate that the sensor data being read is affected by the angle of the tube where the sensor is placed. In this scenario, the sensor was on the outside of the bend, as opposed to being taped to the side of the bend.

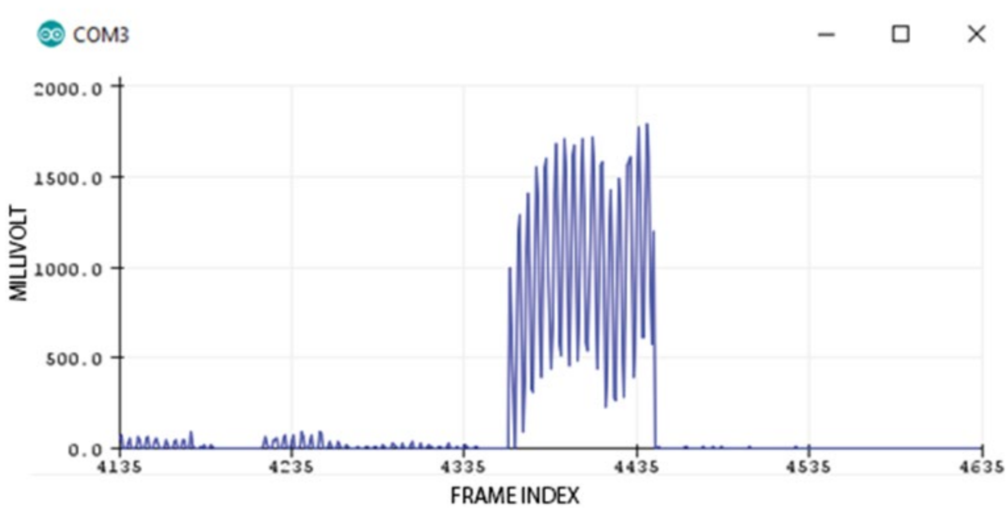


Figure 5.3: Initial FSR experiment with tube rotated to correct sensor position on bend.

As indicated by the above data sets, using the catheter as the tube to detect pressure during arterial navigation is not a feasible idea, as the sensor has extreme difficulty detecting pressure.

5.2.2 Polyurethane tube tests

After some initial experimentation with a catheter and microcatheter, the decision was made to switch to simulating the artery using polyurethane tubing. The change in material provided the system with more consistent sensor readings in comparison to the catheter and microcatheter tests (See Figure 5.4).

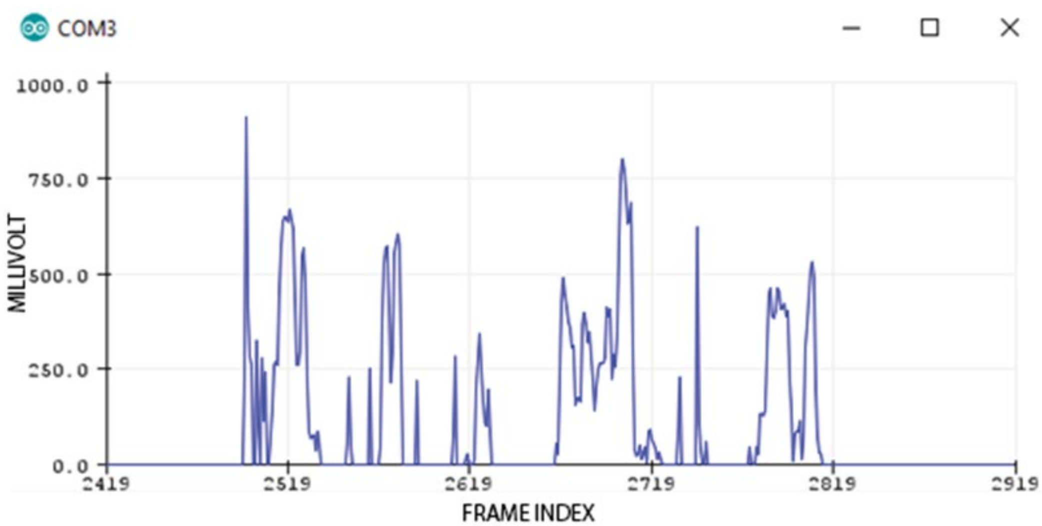


Figure 5.4: *FSR experimentation with Polyurethane tubing.*

As Figure 5.4 demonstrates, the sensor has better success at detecting applied force through the polyurethane tubing and produced the following graph when force was applied to the bend. The issue however is the noise in the spikes indicating inconsistent readings; it is likely the sensor is still having some issues with the thickness of the material and therefore applied pressure may not accurately reflect the applied force by the user.

5.2.3 Preliminary Experiment Results

Eventually, it was determined that the issue with the system not detecting enough data was the polyurethane, and the tubing was changed to Neoprene. The catheter was inserted into the simulated artery and removed multiple times to identify whether the sensors picked up the movement and therefore validate the feasibility of force-sensing resistors for the monitoring of applied pressure during the arterial navigation.

In Figure 5.5, the data picked up by the sensor does not indicate any form of pressure or applied force, only a brief indication of noise.

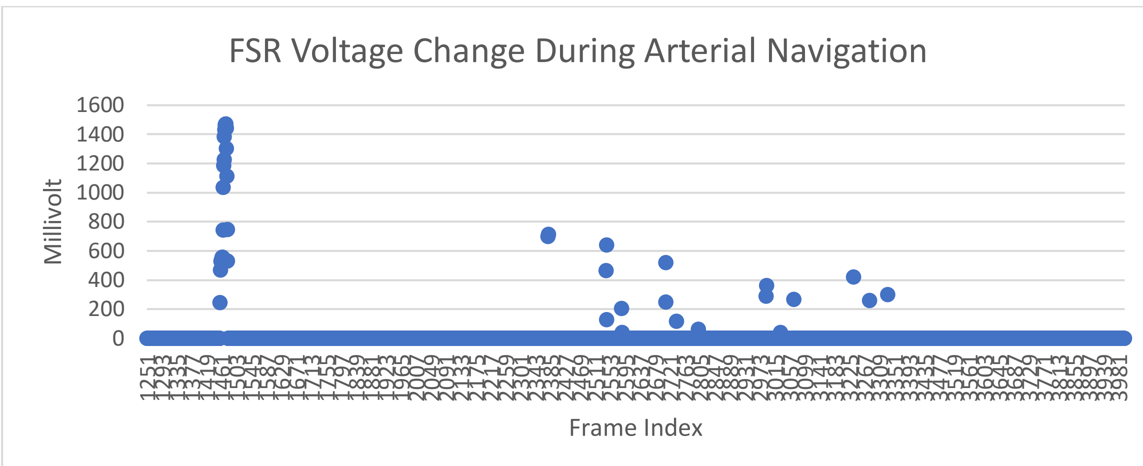


Figure 5.5: Initial test using an FSR and Neoprene tubing (No evidence of impact).

After a slight rotation of the bend to position the sensor more on the apex, the sensor provided more substantial evidence of impact, as shown in Figure 5.6, although, still noisy, and hard to distinguish individual spikes.

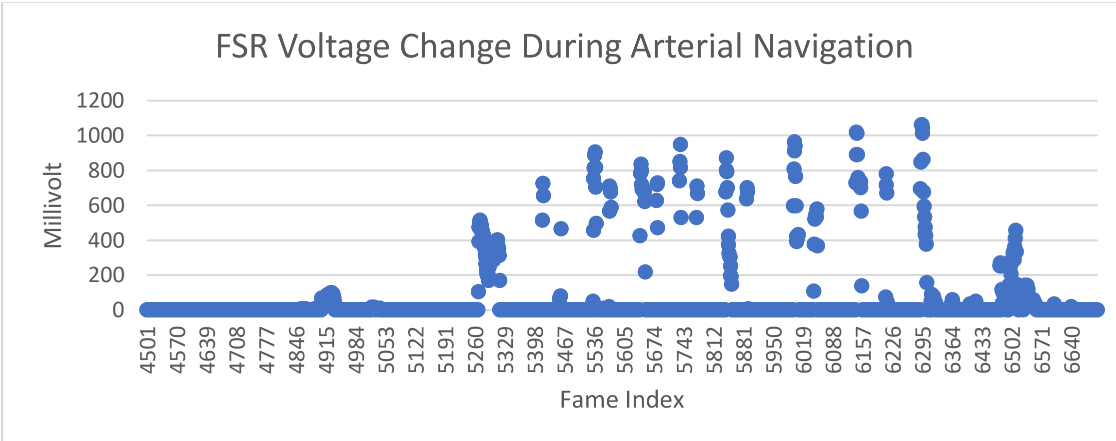


Figure 5.6: The second test using an FSR and Neoprene tubing (Noisy indication of impact).

As shown by Figure 5.7, when the sensor is placed in the correct location, it provides a clear indication of applied force, with sharp curves indicating the change in voltage when force is applied to the area the sensor is placed on. This indicates that the FSR system can detect applied force during arterial navigation.

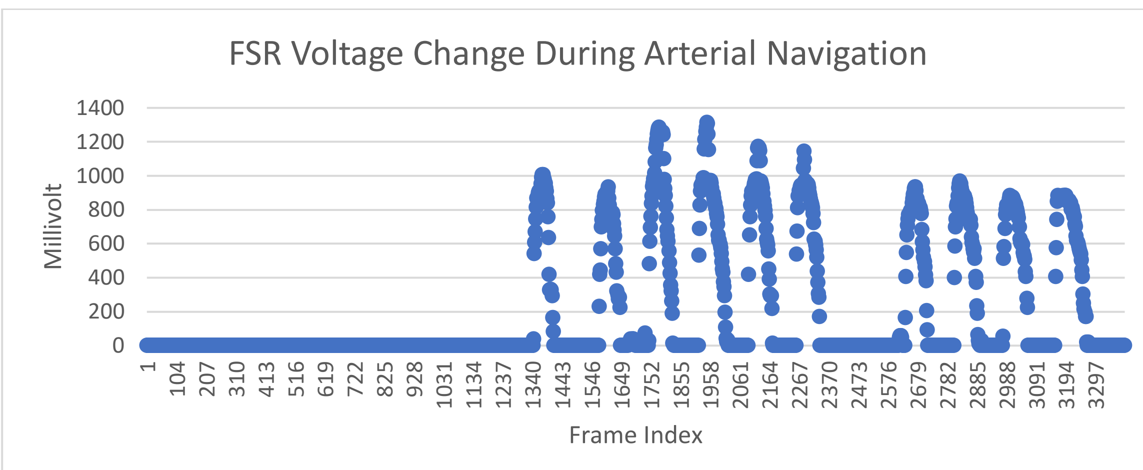


Figure 5.7: Third test using single resistor and Neoprene tubing (Conclusive evidence of impact).

The data in Figure 5.7 also highlights a limitation, namely a single sensor cannot be placed effectively to detect force, since the practitioner could insert the catheter at a different angle that leads to the catheter either pressing near the sensor or missing it altogether reducing the amount of usable data. Adding additional sensors allowed the software to produce 240 samples per second, sixty samples per sensor, then averaged the results to provide a single reading.

The data shown in Figure 5.8 demonstrates an improvement in the collection of data from the system with the implementation of additional sensors to cover the different sides of the tube. Due to the improved coverage, the system was able to identify five spikes in the voltage during arterial threading.

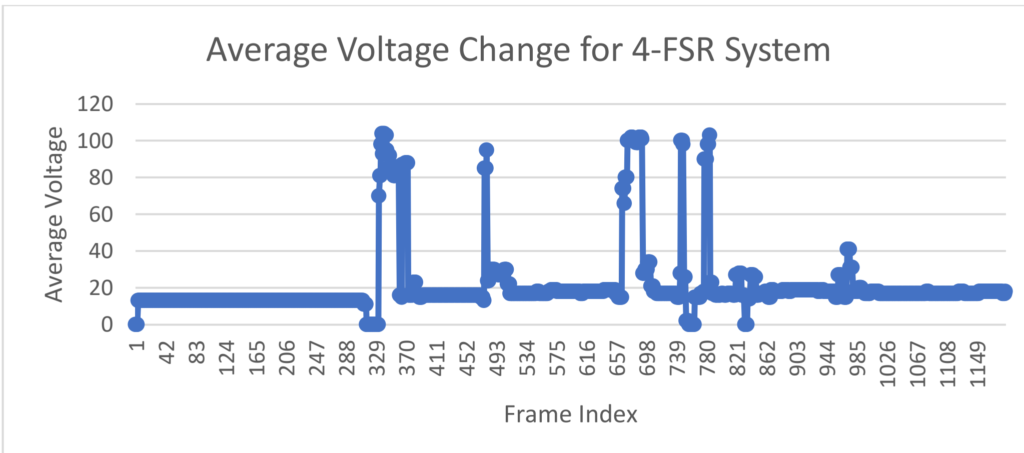


Figure 5.8: Data spike caused by changes in the average value of all four sensor readings.

5.3 Idle Results

Each bend was tested one hundred times to obtain an accurate measure of stability in the sensor data at different angles. These included 0, 9, 16, 27, 37 degrees and their negative counterparts, resulting in 4.5 million values. The data collected through idle experimentation was analysed using a Pearson Rank Correlation that identified a correlation of 97% between the angle of the simulated artery and the average pressure received in an undisturbed environment.

Initially, the idle results in this stage indicated the sensors were exhibiting hysteresis and sensor drift caused by an external force other than the user, causing certain data sets to fluctuate and produce unreliable readings, (See Figure 5.9).

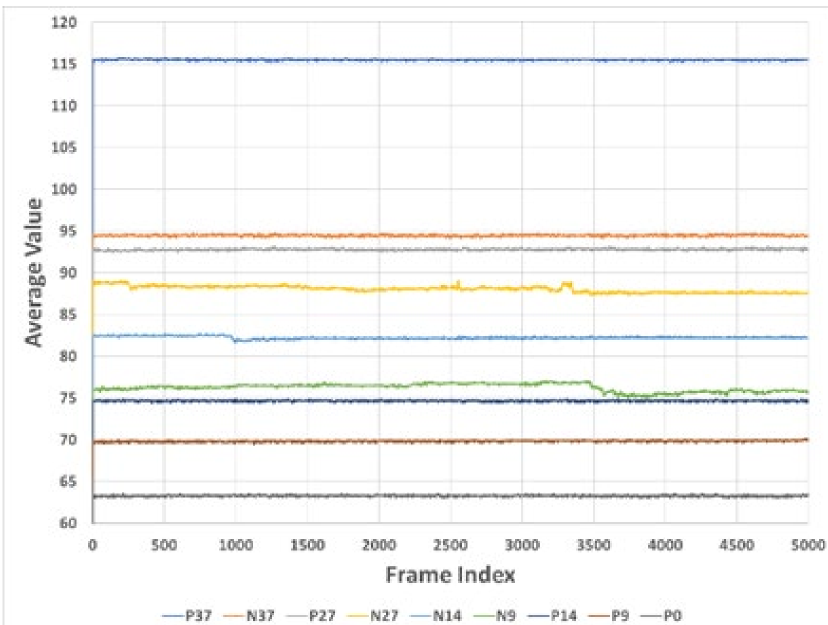


Figure 5.9: Initial idle results for sensor system.

Hysteresis and drift are common issues with force-sensing resistors, as other researchers have found (Flórez and Velásquez, 2010), (Paredes-Madrid *et al*., 2017), (Paredes-Madrid *et al*., 2018), (Lee *et al*., 2015); in this situation, the issues are caused by a flaw in the system design that means the tubing used for the arterial bend is being gripped by the frame and over time the tube is shifted slightly to return to a more natural shape.

A slight modification to the frame design was carried out to expand the entry holes from 1cm in diameter to 1.5cm in diameter, which was enough to reduce the hysteresis on the sensors.

The updated system allows the tubing to retain its shape and position when updated and demonstrates a reduction in hysteresis and drift, as seen in the previous experiment presented in section 5.2. Further results show the reliability of the linear sensor data in an undisturbed state that can potentially be used as a baseline for identifying changes in the data during simulation, (See Figure 5.10).

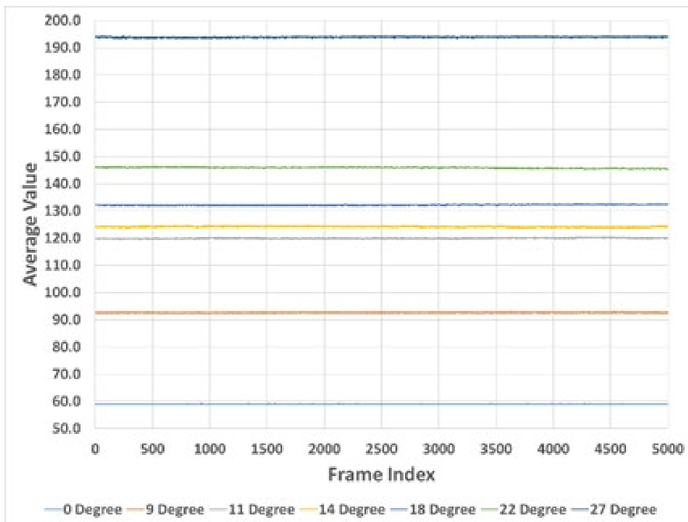


Figure 5.10: Updated idle results for sensor system.

5.3.1 Evaluation of offline sensor results with no applied force

Figure 5.9 shows the stability across several bends in the initial stage of development; Figure 5.10 demonstrates the stability of sensor data across multiple bends following system redesign and optimisation. The most important observation to note, is that even in the initial tests, the results demonstrated 97% correlation between idle sensor value and bend angle in the sensor system. The updated design reduced the amount of deviation in idle results, making them more reliable and indicative of idleness in the data sets.

5.4 Active Results

The results for the applied force data collection in an offline Python environment demonstrated that the system could detect changes in the applied force as the user changes the amount of pressure they apply to the catheter, (See Figure 5.11).

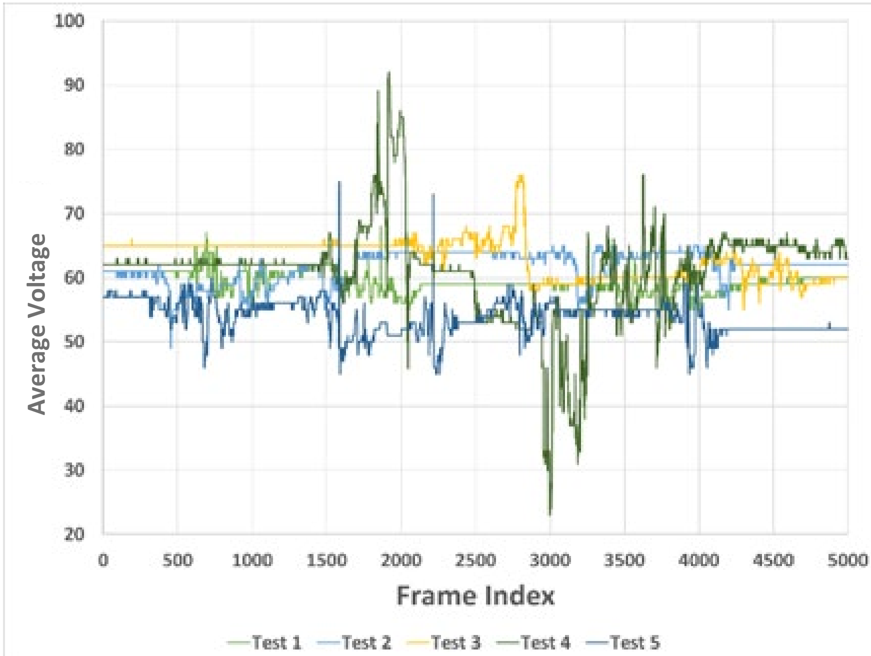


Figure 5.11: Sensor reading results for applied force.

Under normal operating conditions, the sensor data shows no deviation or change, as seen in Figure 5.10, while the results in 5.11 show deviation and change in the readings, this is due to the applied force generated by the user. Interestingly, the slight fluctuation leading up to or following an impact dissipates as the applied force is reduced. While the data can appear noisy when multiple impacts happen in quick succession, the system manages to return to an idle state reliably, with more controlled applications of force resulting in more efficient results.

5.4.1 Evaluation of offline sensor results with applied force

As the active applied force data shows, the system can effectively detect and record the changes to applied force in simulated arterial threading. The changes in data demonstrate how the user's applied force affects the readings when compared to idle results. The data shows the different patterns that emerge from distinct levels of applied force: small fluctuations near the beginning or end of a spike indicating insignificant amounts of applied force, while larger fluctuations demonstrate heavier force, with spikes indicating severe impacts and levels of force. The contrast between idle results and applied force results indicates that the average sensor value changes to reflect the level of force applied and reinforces the idea that applied force and impact data can be determined by identifying the amount of force and changes in the data.

5.5 Real-Time Results

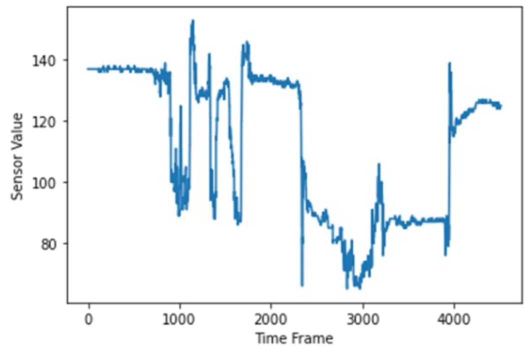
The Virtual Arterial Threading Simulator was tested by a total of twenty-six users, in the scenario, the arterial tube was manipulated into a position that would provide some level of resistance to the operator that they would need to acknowledge and respond to by adjusting the amount of pressure they apply to the catheter. As the operator slides the catheter through the artery, the FSRs will detect the catheter's movement and react to it, with a larger amount of applied force resulting in a higher value being detected. Once the catheter has reached the end point of 20cm, the operator will then have to "retrieve" the catheter, by removing it from the simulated artery.

These two tasks represent the first and last part of a MT procedure, (first) navigating up the artery to the site of the thrombosis, and (last) withdrawing the catheter once the thrombosis has been contained. Along with the haptic cues in the form of the tactile resistance of the simulated artery, users had a view of the virtual operating theatre, which had a visual cue in the form of a live reading of the applied force. A steady and low-impact reading would have little change in the reading, indicating effective manipulation of the catheter and acknowledgement of the physical sensation indicating resistance in the artery; inversely, a noisy and high-impact reading would show rapid and large change in the reading, indicating ineffective handling of the catheter and a lack of regard for the tactile resistance being communicated to the user by the artery and catheter.

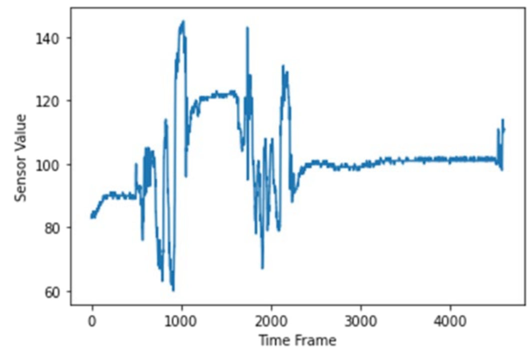
The tests conducted were used to gather data from end-users that would be used to complete the data analysis and performance monitoring described in section 4.7. The tests were conducted on three separate occasions, with time between to ascertain whether users who repeated the assessment could recall their previous experience and improve the way in which they responded to the physical resistance presented by the simulated artery during an assessment. Change in their performance would be identified following the data analysis, which would show the difference in results; ideally, users repeating the task should score lower on their second or third round.

5.5.1 Data Collection Phase 1

Initial collection of sensor data from the VATS box trainer began in June 2021 and consisted of six participants. The data sets generated throughout the simulation provide indication of various user behaviours regarding applied force during catheterisation and retrieval. Firstly, there are the users who exhibit excessive force and inadequate control early on (See Figures 5.12a and b).



(a)

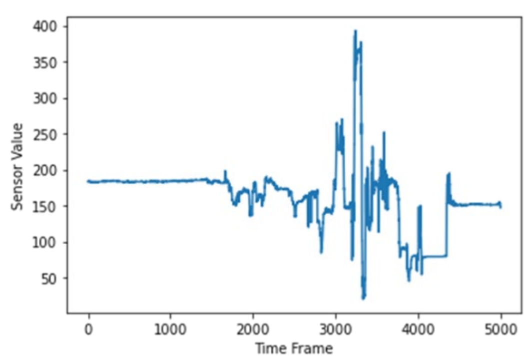


(b)

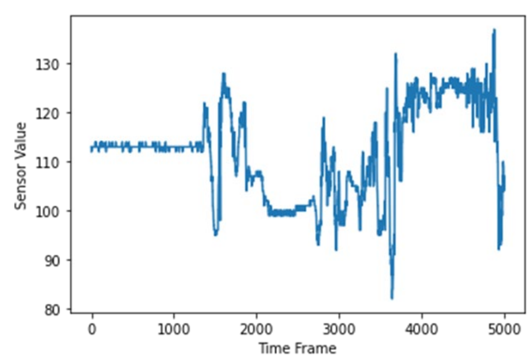
Figure 5.12: a) Graph demonstrating excessive force early with some improvement in latter half, *b)* Excessive force in first half, with effective control near the end.

This is demonstrated by large fluctuations and spikes within the data sets during the first half of the scenario, with potentially improved control further in once the user has settled down and figured out how to use the catheter, though control can remain inadequate in some cases.

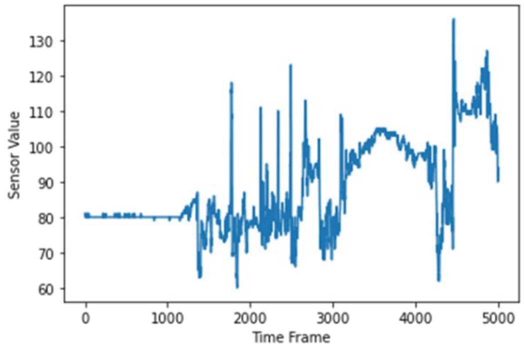
Secondly, there are users who demonstrate delicate movements early on and try to avoid applying excessive force during catheterisation, but upon retrieval or shortly prior, would apply more force or retrieve the catheter at an accelerated pace, causing more disturbance and spikes in the latter half of the scenario (See Figures 5.13 a-c).



(a)



(b)



(c)

Figure 5.13: a) Initially smooth application of force leading to excessive force midway, *b)* Initially effective in control followed by excessive force, *c)* Effective control at insertion that turns excessive shortly in.

This demonstrates two areas of concern, the first being the response to resistance causing massive amounts of noise and fluctuations, indicating impacts, and the intensity of noise in the latter half of the experiment showing aggressive tendencies on retrieving the catheter.

The last behaviour noted was where the user managed to identify the change in applied force through the visual prompt and tactile resistance of the catheter, and responded with a reduction in force before continuing, which led to indications of control following by some fluctuation and spikes before another period of stable control (See Figure 5.14).

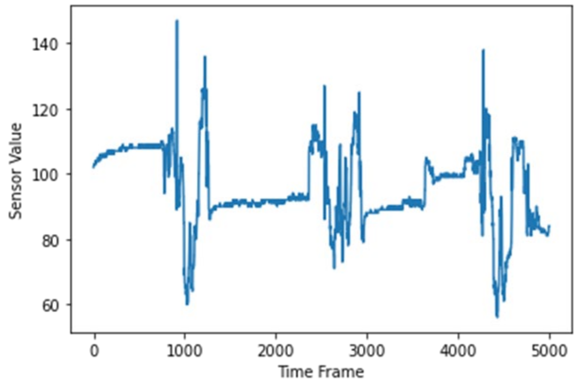


Figure 5.14: Indication of excessive force beginning, middle, and end, with some effective control in between.

This is an interesting pattern that demonstrates the user can respond to the change in physical resistance and the numerical indication, and that at times when applied force gets too high, they can adjust to it accordingly.

5.5.2 Data Collection Phase 2

The second round of data collection took place in February of 2022 and involved sixteen participants. Due to the increase in participants, there were more user behaviours demonstrated that showed how different users responded to the platform and subsequent interactions. Similar to the initial data collection, there are experiments were users demonstrated applied force during the early stage of the experiment, with indications of excessive force or impacts prior to them either noticing the resistance and adjusting behaviour or continuing with minor change (See Figures 5.15 a-h).

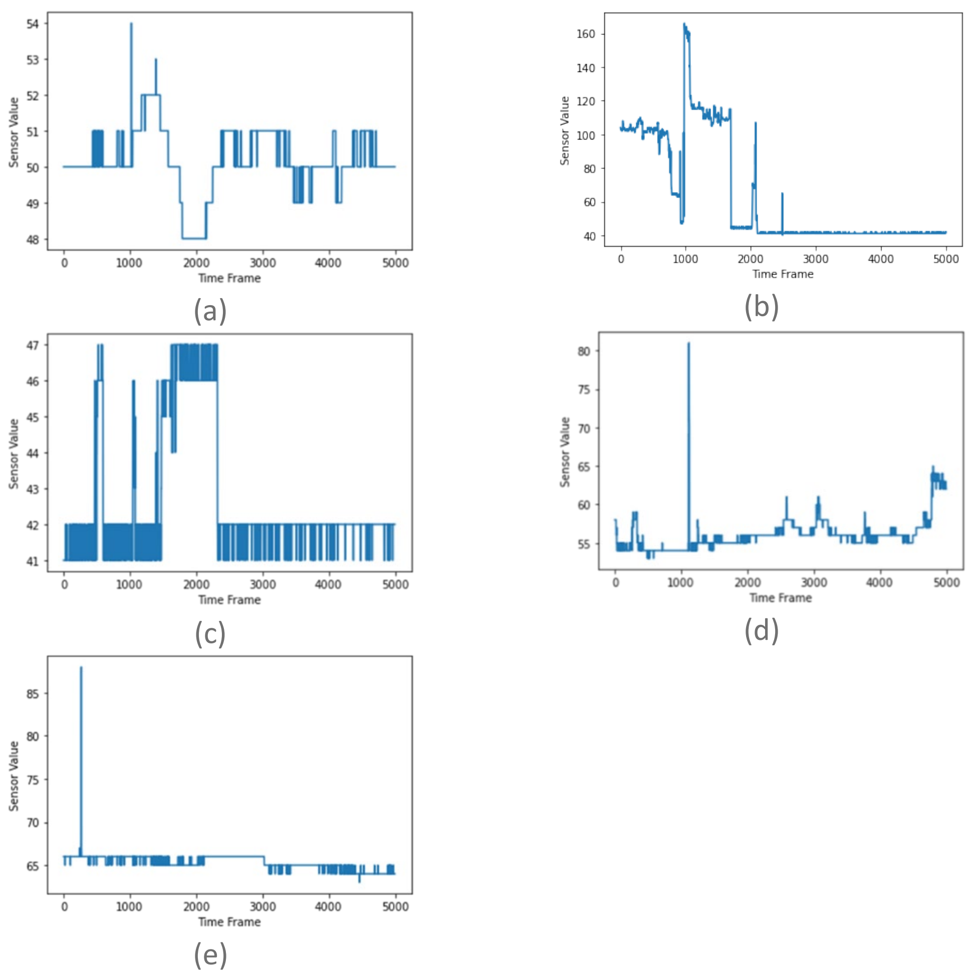
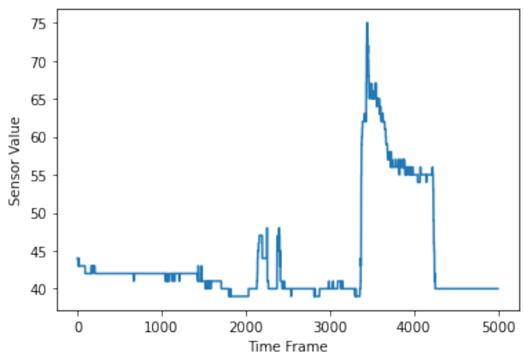


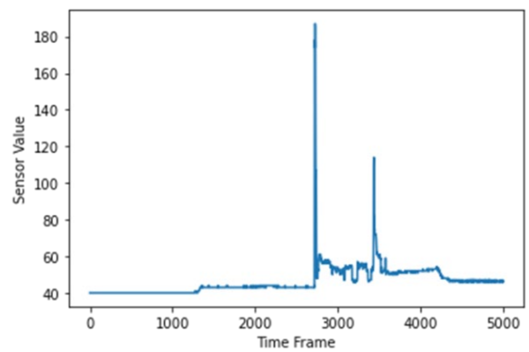
Figure 5.15: a) A follow-up attempt showed better control with only minor disturbance near start, *b)* Indication of excessive force early on with effective control following, *c)* Low-level force applied early on in experiment, *d)* Indication of impact at the outset with adequate control throughout, *e)* Indication of impact at the outset but effective control further in.

Similar to the original collection, these indications of force are due to a lack of knowledge or consideration for the implications that excessive force has on patient safety, and indicates the user is not familiar with the tactile sensation.

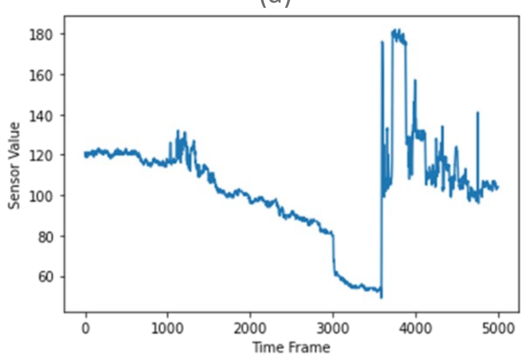
Several users also demonstrated excessive control during the later stages of the scenario, showing effective control during insertion and navigation, but then upon retrieval, accelerating movement and trigger more of a response from the artery sensors (See Figures 5.16 a-h).



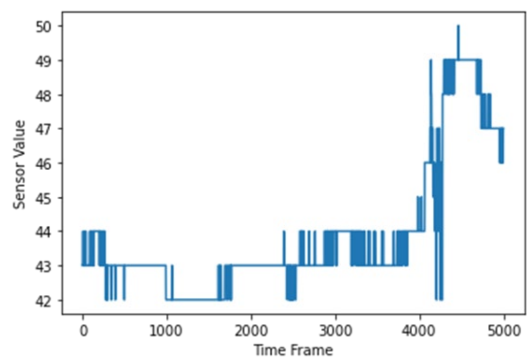
(a)



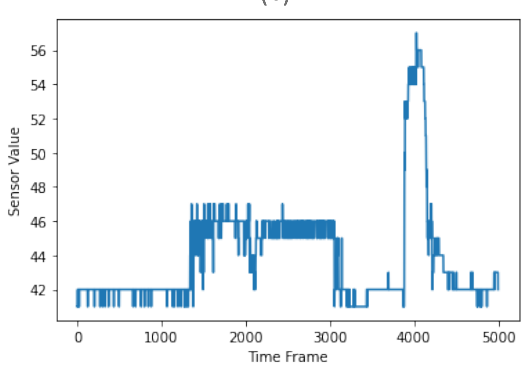
(b)



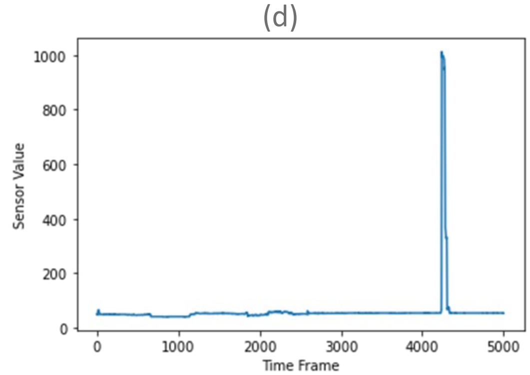
(c)



(d)



(e)



(f)

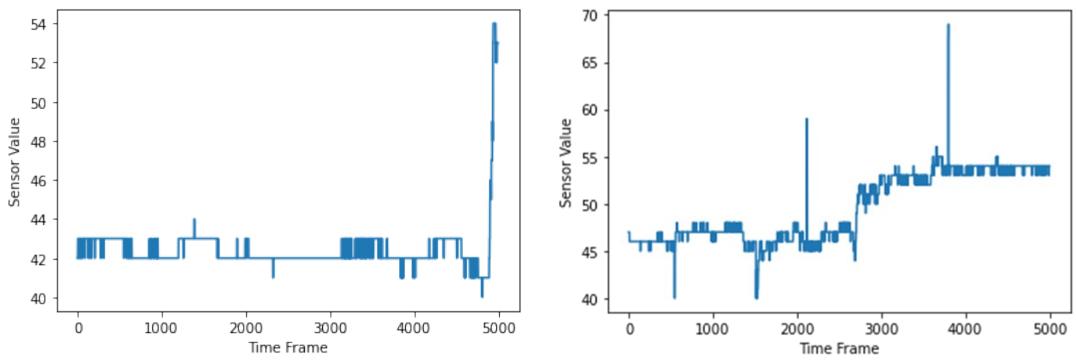


Figure 5.16: a) Effective control at first with excessive force occurring in the later stages of the test, *b)* Signs of excessive force near midpoint of experiment*, c)* Moderate force early on, with extreme force near end of test*, d)* Effective control early on with applied force and impact occurring near end*, e)* Evidence of control during most of the test with indication of force near the end*, f)* Smooth control during most of the test with extreme force applied near end*, g)* Effective control during test with impact occurring at the end*, h)* Demonstrable controlled force during experiment, with small spikes occurring several times*.*

This indicated that some users held a misconception that because they had already got past the point of resistance in the artery, retrieving it will be smoother and less risky, but in fact, retrieving led to more fluctuation in the data.

Some users also demonstrated effective control during the start and end point of the experiment but showed excessive force during the mid-point of the experiment (See Figures 5.17).

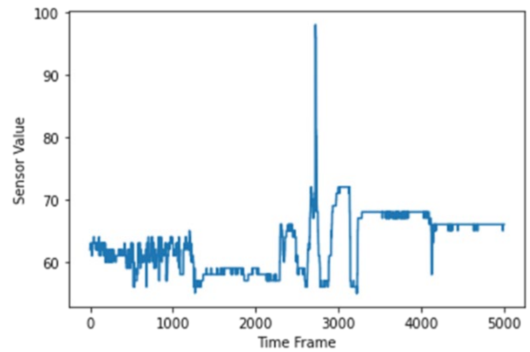


Figure 5.17: Moderate force applied early on with signs of extreme force midway.

This is due to users being careful to insert or pull-out, but once inside, just push forcefully, and fight through any resistance, leading to the spikes in the data.

The inverse is also true for users who maintain effective control during the midpoint of the test but demonstrate excessive force at the beginning and end of the test (See Figure 5.18 a-b).

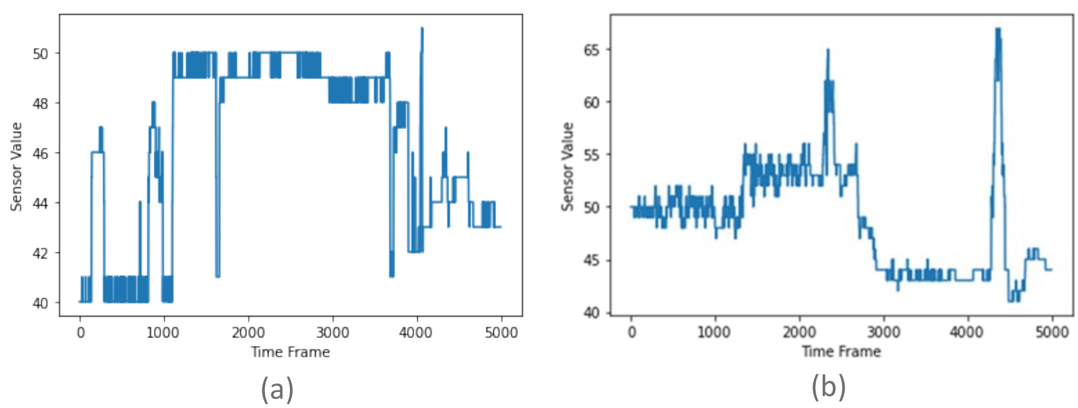


Figure 5.18: *a)* Indication of impact near start and end of experiment with moderate control during middle, b) Indication of moderate force at onset, with major force near end.

The figures above show users who initially struggle to gain control of the catheter but manage to do so part way in, with indication of applied force near the end indicating that some users are finding it tricky to effectively insert or retrieve the catheter.

5.5.3 Data Collection Phase 3

The final stage of data collection took place in March of 2022 and involved four participants. During this stage, similar to the previous studies, there were distinguishable behaviours identified in the participants. One of the users demonstrated effective control during the start and end of the experiment with an indication of excessive force midway (See Figure 5.19).

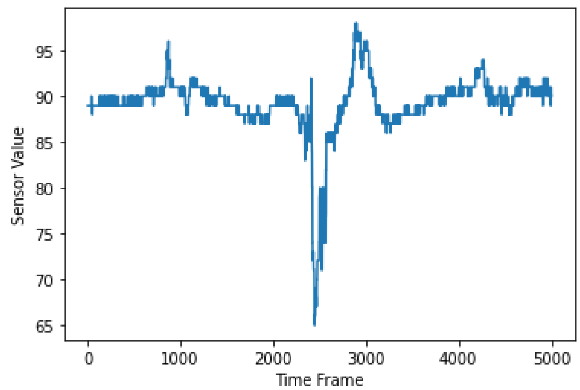
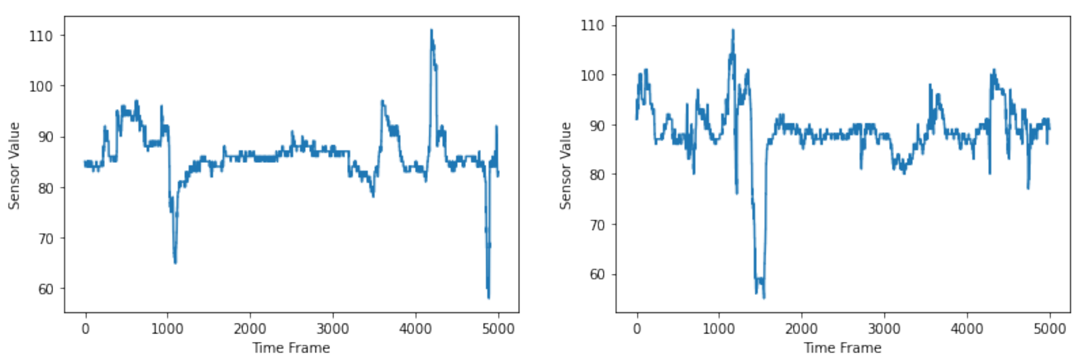


Figure 5.19: Indication of extreme force halfway through test.

This indicated, similar to the previous studies, that the user had no trouble inserting or removing the catheter, but misread what the tactile resistance was telling them, and chose to force their way through the resistance.

Other users showed signs of struggling to control the catheter during the start and end, but inverse to the previous user, demonstrated effective control during the mid-point of the experiment (See Figure 5.20 a-b).



(a) (b)

Figure 5.20: a) Evidence of excessive force in the beginning and end, *b)* Signs of excessive force in the early and late stages of the test.

This, while hard to prove with such a small number of data sets, potentially indicates that while some users struggle during the insertion and retrieval, a task not even state-of-the-art simulators cover, the user can still demonstrate effective manipulation of the catheter during the main bulk of the scenario, responding to the change in resistance.

Lastly, a user showed signs of struggling to control the catheter early on but gained control and showed adequate response to tactile resistance and adjusted their behaviour when manoeuvring the catheter (See Figure 5.21).

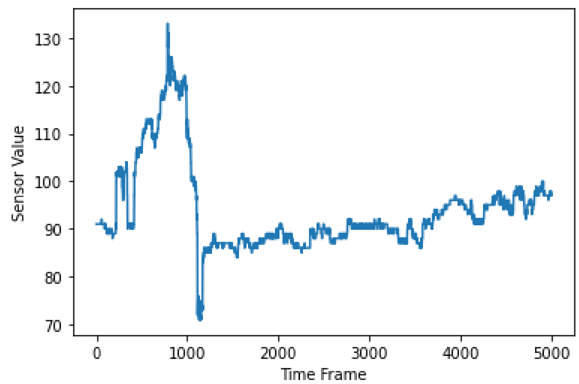


Figure 5.21: Sign of excessive force early on with low level applied force throughout.

The figures above demonstrate the platform’s ability to read the sensor data in real-time from the Arduino platform into Unreal Engine and record it to a comma-separated value (CSV) file for external data analysis.

Using the same principles as previous stages of the sensor testing, the more movement in the data, the more indicative it is of applied force or an impact. From this, end-users can access this data in an external software package such as Microsoft Excel, R, MATLAB, or Python (The graphs in this experiment where generated using Jupyter Notebook Python).

The graphs give the end-user a visual indication of how the trainee performed during the scenario (less movement in the data values = less applied force and impacts) but they also highlight the complexity of the scenario being simulated. Many users indicated early problems controlling the amount of force they apply to the catheter during arterial navigation, which was to be expected for novice users. Some of these users were able to correct the control on the catheter before the end of the experiment, leading to better responses later in the tests. Inversely, some users approached the scenario with cautiousness and for the first part, demonstrated effective control of the catheter during insertion to the full 20cm, however upon retrieval, they assumed since there was less resistance, that they could withdraw the catheter in a rushed manner, which inadvertently caused arterial shearing, where the catheter scraped against the arterial wall, which in this case, applied force to the sensors, indicating excessive force. While most tests demonstrate some level of applied force and impacts, this is expected of a group with no experience of arterial threading, mechanical thrombectomy, or minimally invasive surgery.

The real-time sensor data can also be seen in-game during simulated arterial threading on the in-game monitor or user interface (depending on whether it is in VR or not), (See Figure 5.22). This allows the user to make proactive adjustments to their applied force in real-time as opposed to retroactively adjusting their pressure after the fact. The results also demonstrate the effectiveness of the save system used to export the sensor data, with the user being able to restart and save at any given point.

Figure 5.22: Sensor results displayed in-game.

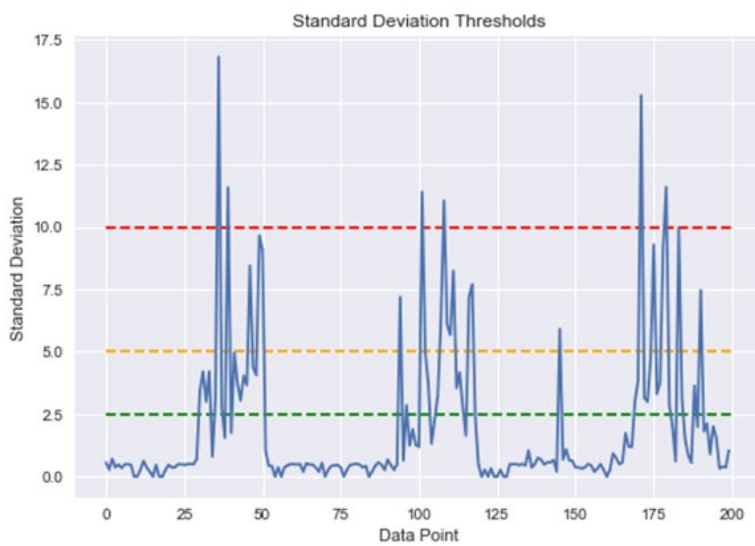
5.5.4 Evaluation of real-time sensor results

The results for this section demonstrate the platform's ability to read and record applied force data in Unreal Engine 4 at the same quality and resolution as the offline version, despite differences to the code. From the data it is evident that there is significant difference between the idle data and applied force data, with patterns visible to suggest applied force and impacts have occurred. The advantage of being able to obtain results at the same level of fidelity in real-time is that the user can be presented with this data in a much more user-friendly way, with the user being able to decide what bend they are testing to support arterial threading. This reinforces the belief that the sensor system can be integrated into an immersive real-time environment for visualisation and presentation to the user. As the data is continuously running and being stored into an array, the save function acts as a failsafe to prevent continuous storing of data that would potentially use up resources or crash the application.

5.6 Impact Detection Results

Using Python, the results were analysed to identify the application of force, and the level of force, applied during a simulated arterial threading test, show that it can visualise, and plot detected impacts based on the amplitude of standard deviation.

Given the test results have a length of five thousand, the standard deviation can be refined by increased window size and calculating the standard deviation of a broader range of values, which removes much noise from the graph while retaining the most pertinent data points. This is due to the standard deviation being greater where impacts occur and smaller where data is idle. In the graph below, the data has been refined to a window size of twenty-five, meaning that the standard deviation has been calculated for every twenty-five data points, producing a total data set size of 200, as seen in Fig. 5.23.




```
Minor Impacts: 30
Medium Impacts:  15
MajorImpacts: 6
```

Figure 5.23: Windowed SD plot graph refined to two hundred points.

Due to the size of the data sets, the data can be refined by increasing the window size used to calculate the standard deviation of a given point in the data set, improving the compute time, and reducing any false positives that may occur. In the case of Figure 5.23, there are only four distinct areas of impact and applied force, but the results show a total of fifty-one impacts. By reducing the sensitivity of the analysis, the algorithm will reduce the number of data points being analysed and condense the data. The plot will retain the most extreme deviations, thus maintaining the structure of the data set and will reduce the number of false-positive impact detections. The purpose of this is to account for the noise and fluctuation that occurs within the sensor readings leading up to and following an impact (which in the past has created multiple false positives) and narrow the results down to the major points. (See Figures 5.24 a-d).

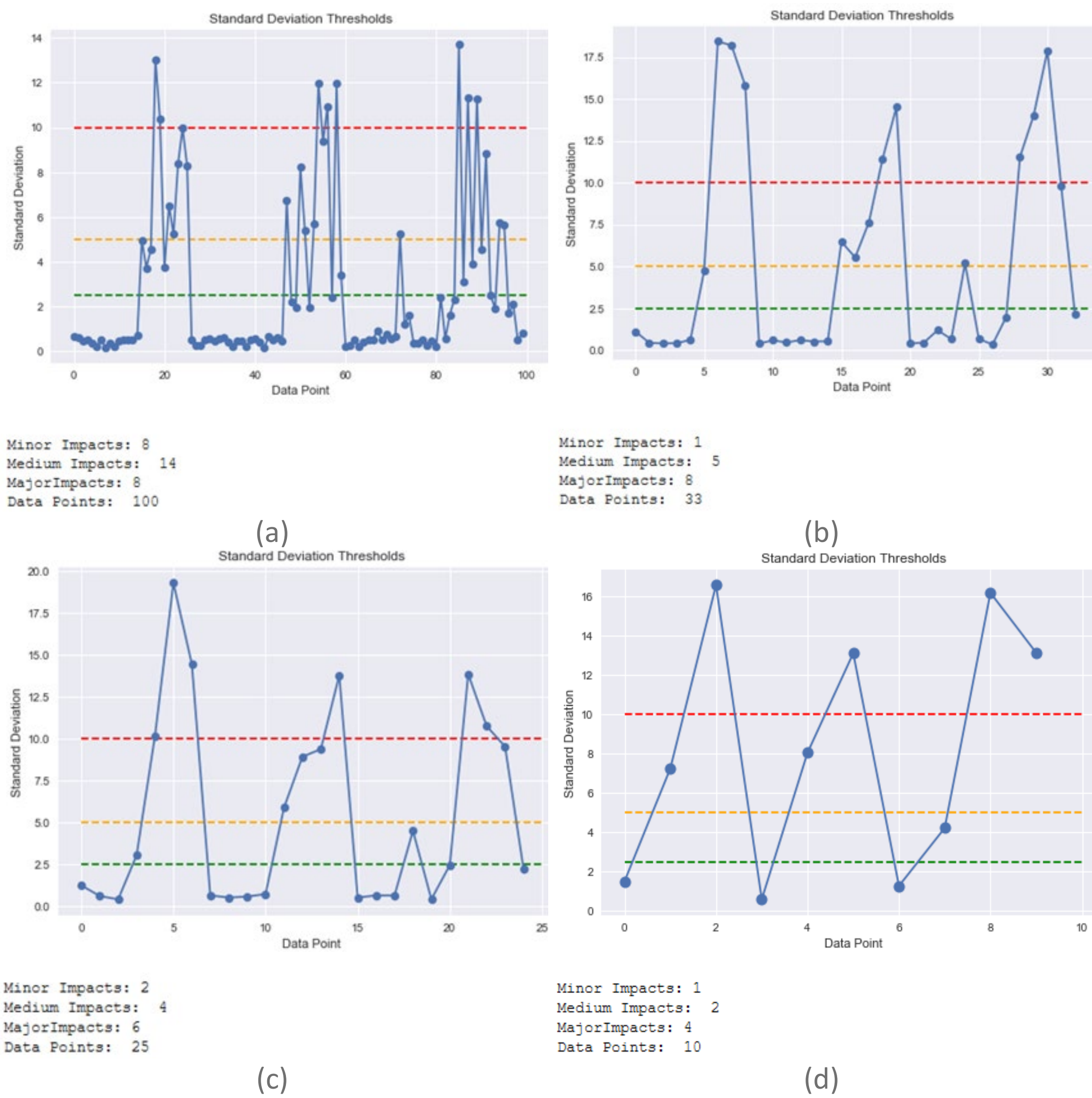


Figure 5.24: a) Windowed SD plot graph refined to one hundred points, *b)* Windowed SD plot graph refined to thirty-three points, *b)* Windowed SD plot graph refined to twenty-five points, *c)* Windows SD plot graph refined to twenty-five points, *d)* Windowed SD plot graph refined to ten points.

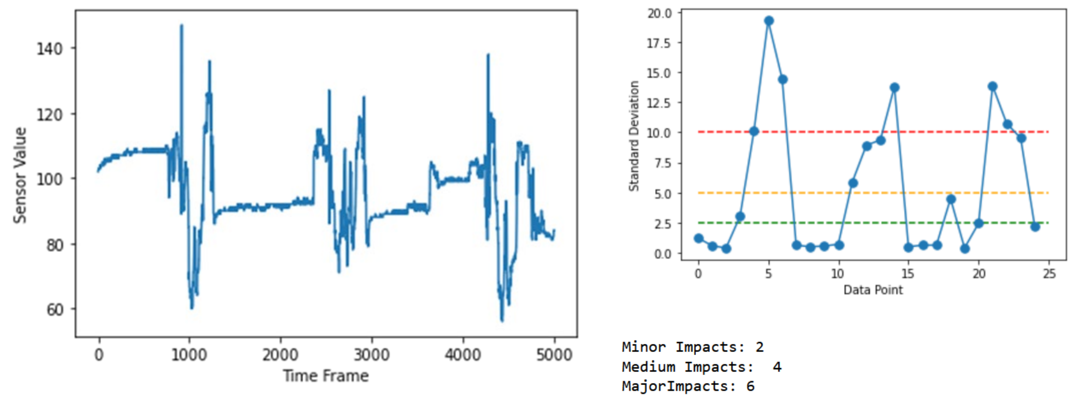
As the graphs on the previous page demonstrate (See Figure 5.24 a-d); the number of detected impacts is reduced as the window range increases. However, the scatter points and curves remain the same, structurally speaking, with the most prominent impact points remaining, while removing any redundant or noisy data points by incorporating them into a larger deviation window.

The benefit of reducing the sensitivity of the algorithm to only capture key impact points is that while there is a lot of data being removed, some of it is caused by the fluctuation following on from the initial impact or caused by minor impacts prior to the main impact, so being able to narrow it down to the most crucial impacts can create a clearer picture for trainees and supervisors.

The result of this is the data points returned from the algorithm can be as concise as the supervisor requires them to be and allows them to adjust the difficulty of the simulation for the trainee by making it more sensitive to applied force and impacts as their skill improves to ensure their level of skill continues to improve.

In this test scenario, the resolutions seen in Figures 5.24 *b* and *c* are optimal as they reduce a lot of the noise and detections into the most prominent aspects and provide simpler output for practitioners to explore and still provide valuable information regarding applied force and impact. The act of refining the data set involves finding a balance between reducing the data set to an efficient number of data points, while retaining the key structure that indicates where impacts and applied forces have occurred. In the graph below, a window size of two hundred has been selected.

When the data is exported from Unreal Engine and analysed to produce the data points, it is worth noting that two key features can be considered: firstly, the timeframe remains the same, just remapped to fit better with the output dataset, so a range of 0-5000 in the original dataset is equal to 0-25 in a processed and analysed dataset; this also means that the pattern of the analysed dataset, regardless of resolution, should match the exported dataset it originated from (see Figure 5.25). This means that users exploring the data can compare analysed data points with the time frames of the original data sets.



(a) (b)

Figure 5.25: Side by side comparison of exported force sensor data and analysed dataset. (a) exported sensor data showing excessive fluctuations three times with a small spike; (b) analysed dataset showing the moving average across the dataset.

At this resolution, the data set consists of just twenty-five key data points that demonstrate the changes in data, however, the structure still lines up with the resolutions of previous graphs, (See Figure 5.25).

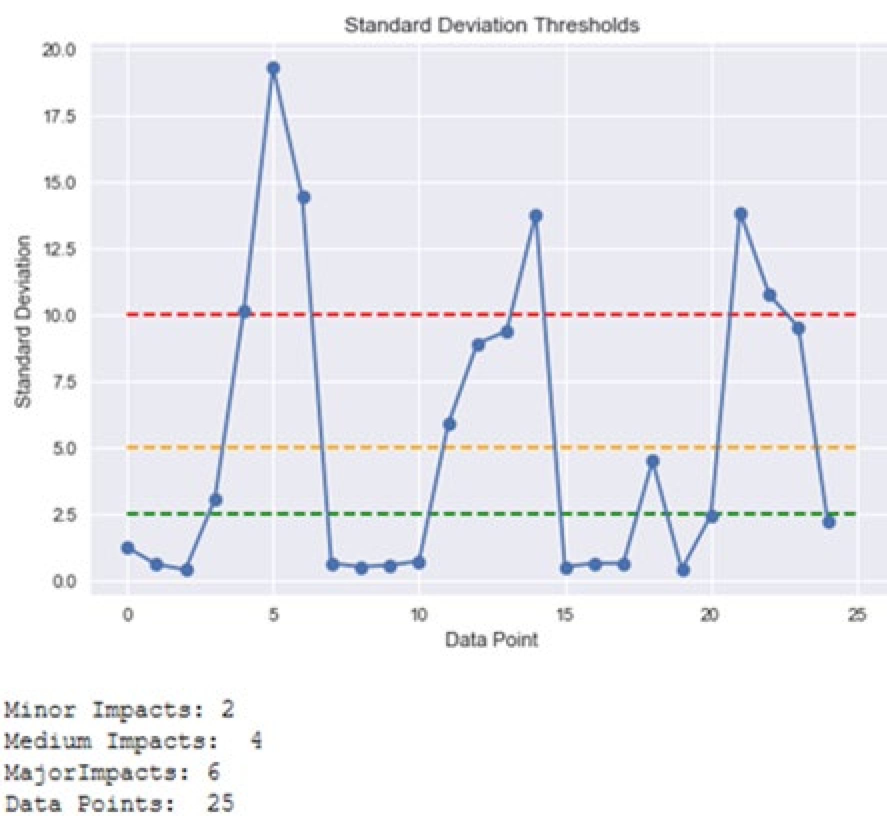


Figure 5.26: Windowed SD plot graph with detection thresholds.

At this point, the thresholds described in the methodology can be applied to the graph to visualise further the nature of applied force evident in the plotted data. With the thresholds plotted on the graph, the data points are distinguishable by where they sit in relation to the threshold boundaries.

This makes it easier to determine which points are low, medium, or high impacts, helping improve the readability of the data. These thresholds can be adjusted, and change based on how the data is refined. Beyond the visual element of distinguishing impacts, the thresholds are also used to programmatically filter the impacts with a loop that increments the total number of low, medium, and high impacts based on the amplitude when they register, (See Figure 5.26).

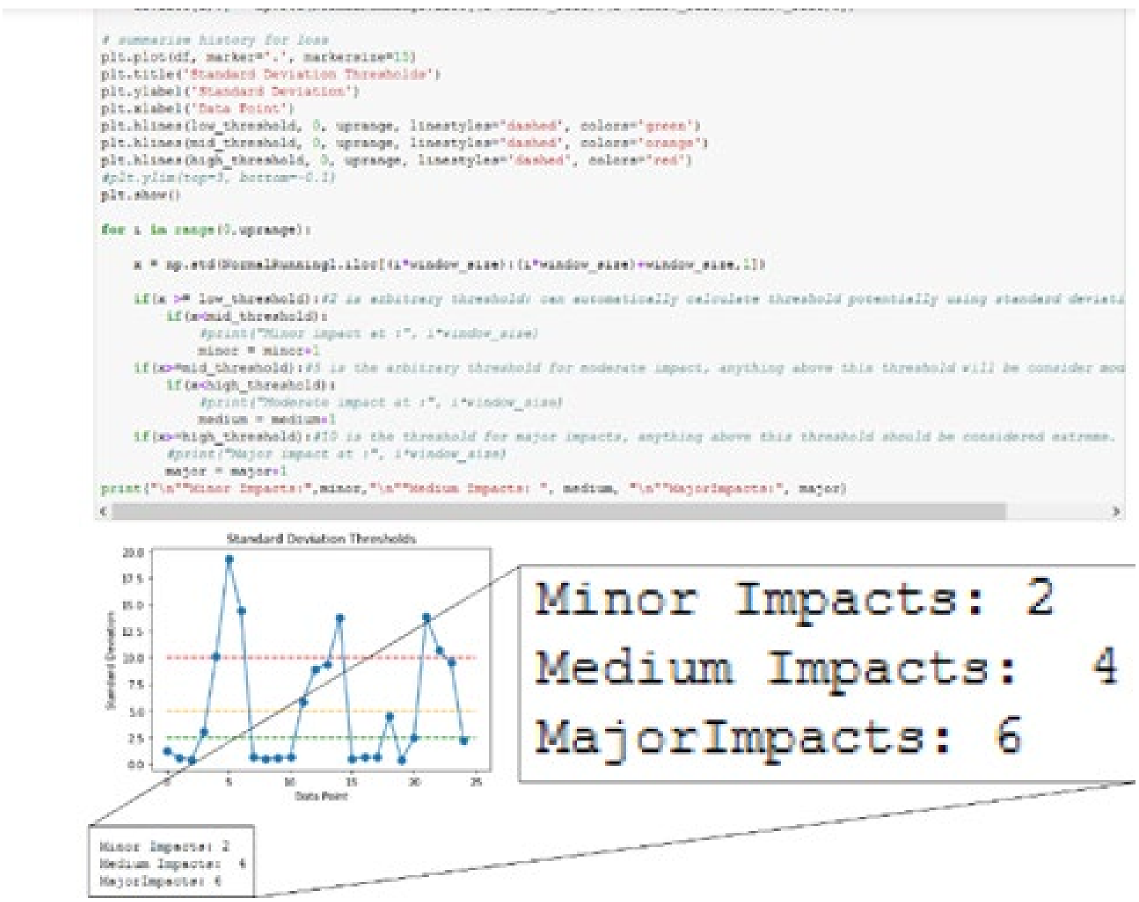


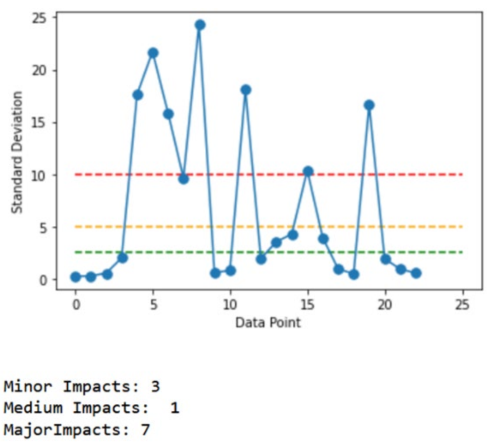
Figure 5.27: Impacts detected and itemised by intensity.

The results above show the total number of impacts detected by the system and filters them based on intensity. Knowing that the window size for this experiment provided twenty-five data points, the figures show that 8% of detected points were minor impacts, 16% were medium impacts, and 24% were major impacts. The figures indicate that an impact occurred 48% of the time during the simulation test, with the remaining 52% implying either no applied force or impact was detected, or the device was left in an idle state.

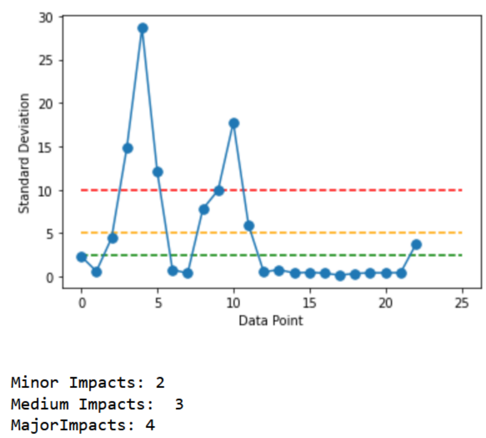
5.6.1 Data Analysis Phase 1

Each of these graphs correlate with those recorded in Section 5.5 and are listed in the same order. For the data analysis, a resolution resulting in twenty-five data points was used. While the data collection demonstrated a visual representation of the applied force, the calculation of the standard deviation of the movement and addition of thresholds provides a more concise picture of what happened during the scenario.

During the analysis of the first stage of collection, all of the users demonstrated excessive levels of force, with the majority of users scoring a large number of medium to major impacts. Similar to the data collection, user behaviour can be distinguished, with some graphs showing a higher concentration of impacts scored towards the start of the experiment (See Figures 5.28 a-b).



(b)



(c)

Figure 5.28: a) Analysis identified several major impacts, of which four occurred early on in quick succession, *b)* Signs of major impacts during early stages.

The indication of applied force and impacts is corroborated by the use of the thresholds which help show the frequency of deviations due to applied force and the amplitude of these deviations.

Additionally, the users who demonstrated inadequate control throughout the scenario can also have the fluctuation and noise produced by their applied force calculated to indicate the frequency of higher impact scores and the amplitude, which is showing where users' force began to increase or fall (See Figures 5.28 a-d).

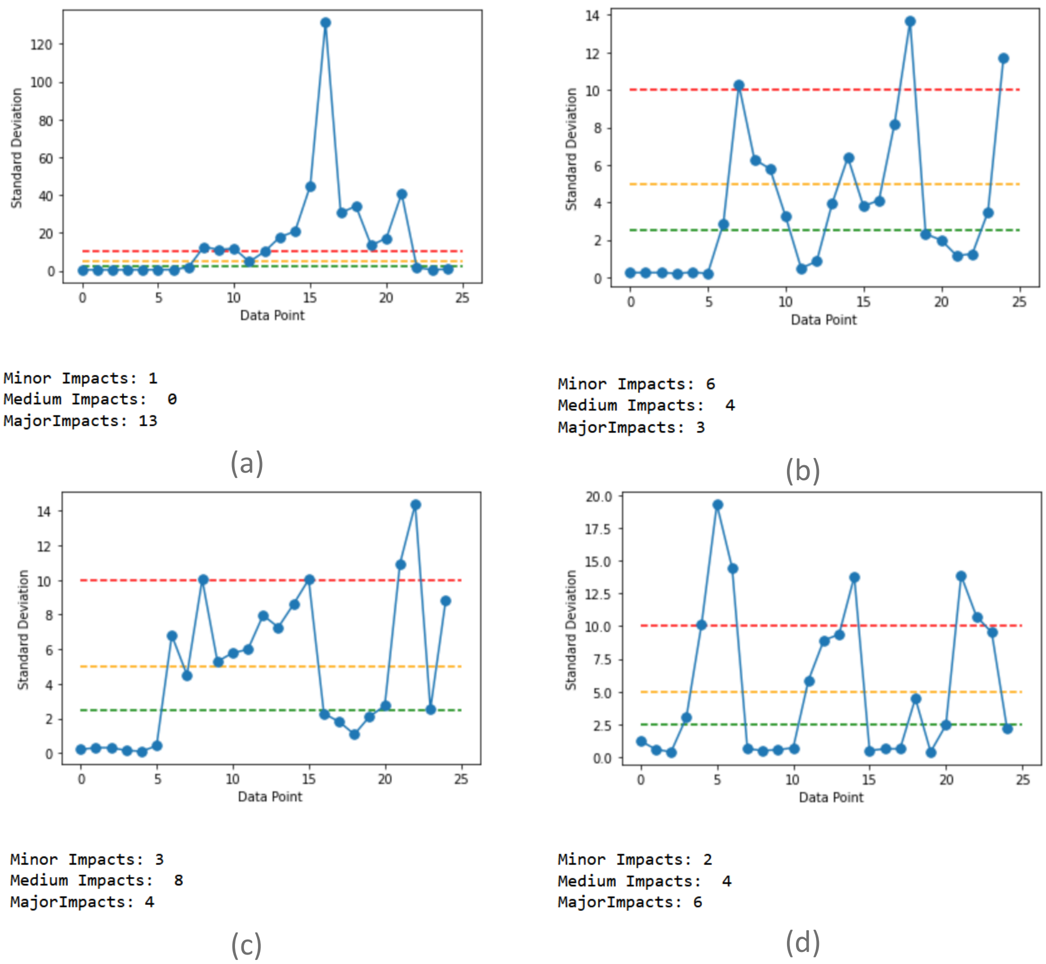


Figure 5.29: a) Indications of numerous major impacts in the later stages, *b)* Indication of moderate number of medium-major impacts, *c)* Analysis several medium impacts through the scenario, *d)* Indications of minor scores following major scores.

These users tended to score a higher number of medium-major impacts on the experiment, due to the lack of experience and knowledge of the procedure and how best to interact with the catheter and respond to changes in applied force.

5.6.2 Data Analysis Phase 2

The data analysis conducted during the second stage of testing further demonstrated the various behaviours and trends that were the source of most impacts that occurred during the relevant test. For example, users described as demonstrating excessive force in the early stages of the experiment tended to score more impacts in the same region, with the frequency of high-amplitude spikes being higher in such a short space of time, with the majority of users in this group scoring most of their major and minor impacts early on prior to gaining effective control of the catheter (See Figures 5.29 a-d).

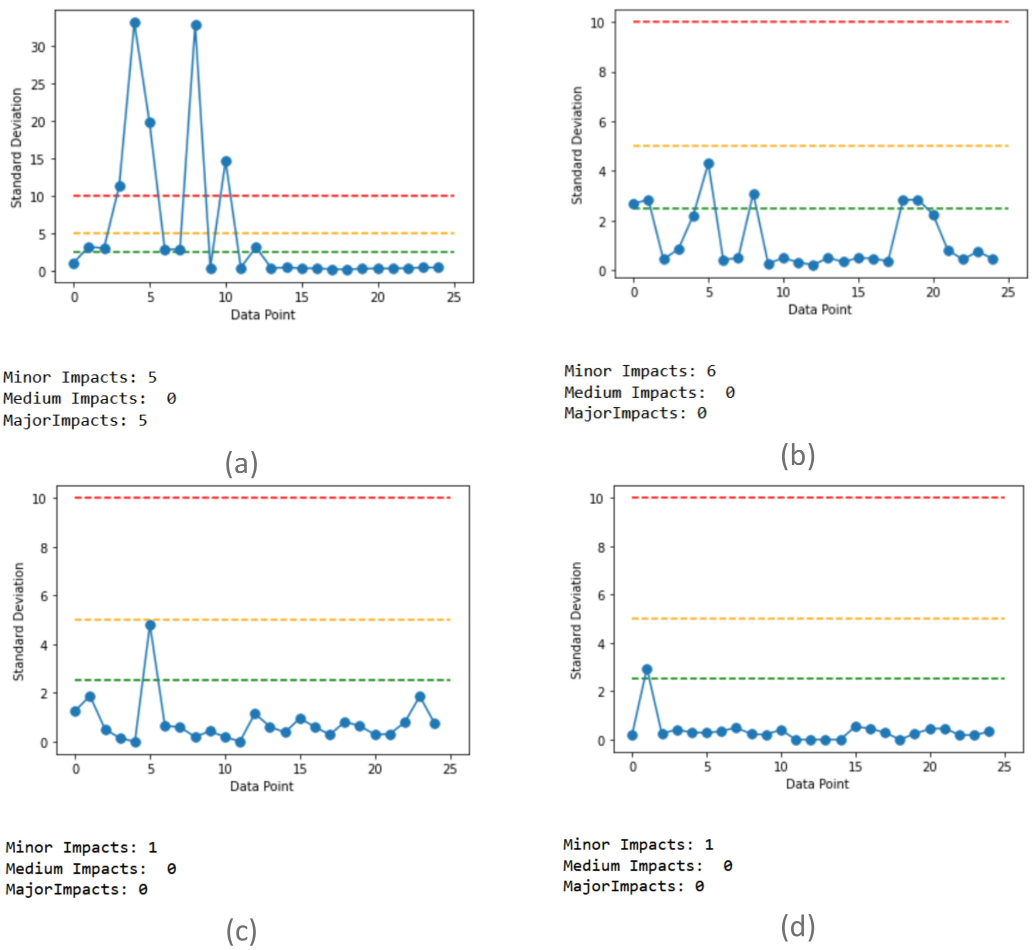
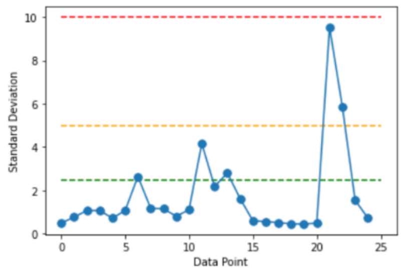


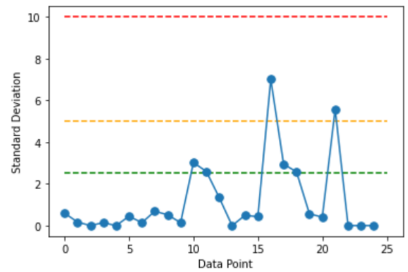
Figure 5.30: a) Signs of major impacts during first part of experiment, b) several impacts scored at a minor level, c) single minor impact scored during experiment, d) single minor impact scored near beginning of test.

Similarly, users who demonstrated inadequate response to tactile resistance during the later stage of the experiment were shown to score more impacts in the same region during analysis. Due to the response being from shearing and not direct impact, the impact scores are mostly minor to medium, with one exception being a major that is potentially a misread by the system (See Figures 5.30 a-f).



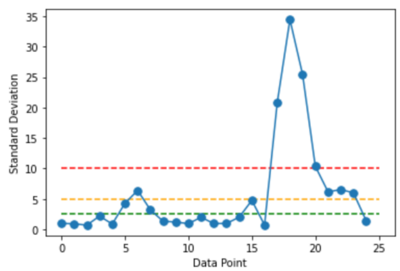

```
Minor Impacts: 3
Medium Impacts:  2
MajorImpacts: 0
```

(a)



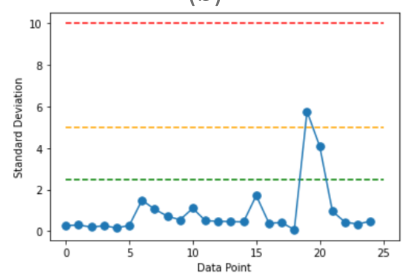

```
Minor Impacts: 4
Medium Impacts:  2
MajorImpacts: 0
```

(b)



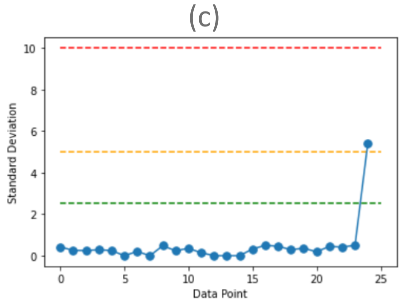

```
Minor Impacts: 3
Medium Impacts:  4
MajorImpacts: 4
```

(c)



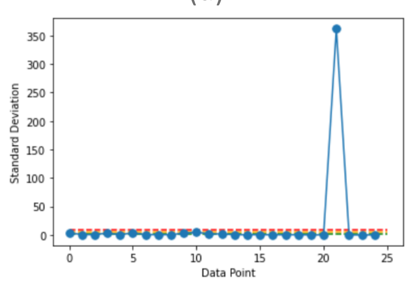

```
Minor Impacts: 1
Medium Impacts:  1
MajorImpacts: 0
```

(d)




```
Minor Impacts: 0
Medium Impacts:  1
MajorImpacts: 0
```

(e)

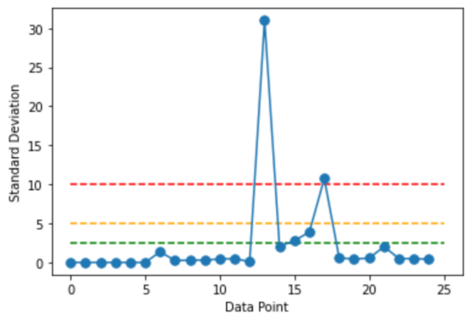



```
Minor Impacts: 5
Medium Impacts:  0
MajorImpacts: 1
```

(f)

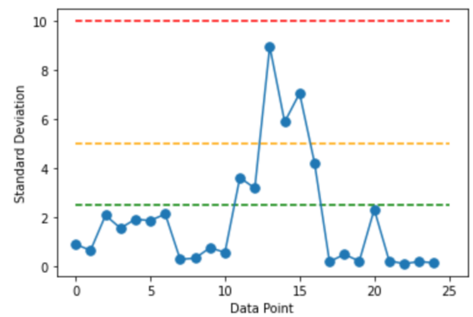
Figure 5.31: *a)* User demonstrated few minor-medium impacts, *b)* User demonstrated moderate force during later stages, *c)* User produced several impacts during test, primarily towards the end, *d)* Demonstration of single medium-minor impact scored, *e)* Single medium impact scored at end of test, *f)* Several minor impacts scored with one major near end.

Users who demonstrated a forceful response to the resistance in the artery also triggered several major and medium impact scores, this indicates that the resistance of the tube being met with more force is likely to push the impact score higher as the amplitude of the force increases (See Figures 5.31 a-b).



Minor Impacts: 2
Medium Impacts: 0
MajorImpacts: 2

(a)



Minor Impacts: 3
Medium Impacts: 3
MajorImpacts: 0

(b)

Figure 5.32: a) User demonstrated two minor and major impacts during experiment, *b)* Several indications of minor-medium impacts scored partway through.

There were several instances of users who were able to effectively navigate the artery without triggering an impact, which is evident by the lack of impact scores on the relevant tests, which indicate the user was manipulating the catheter gently, easing it in slowly as not to disturb the artery and adjusting their behaviour at the first hint of resistance (See Figures 5.32 a-d).

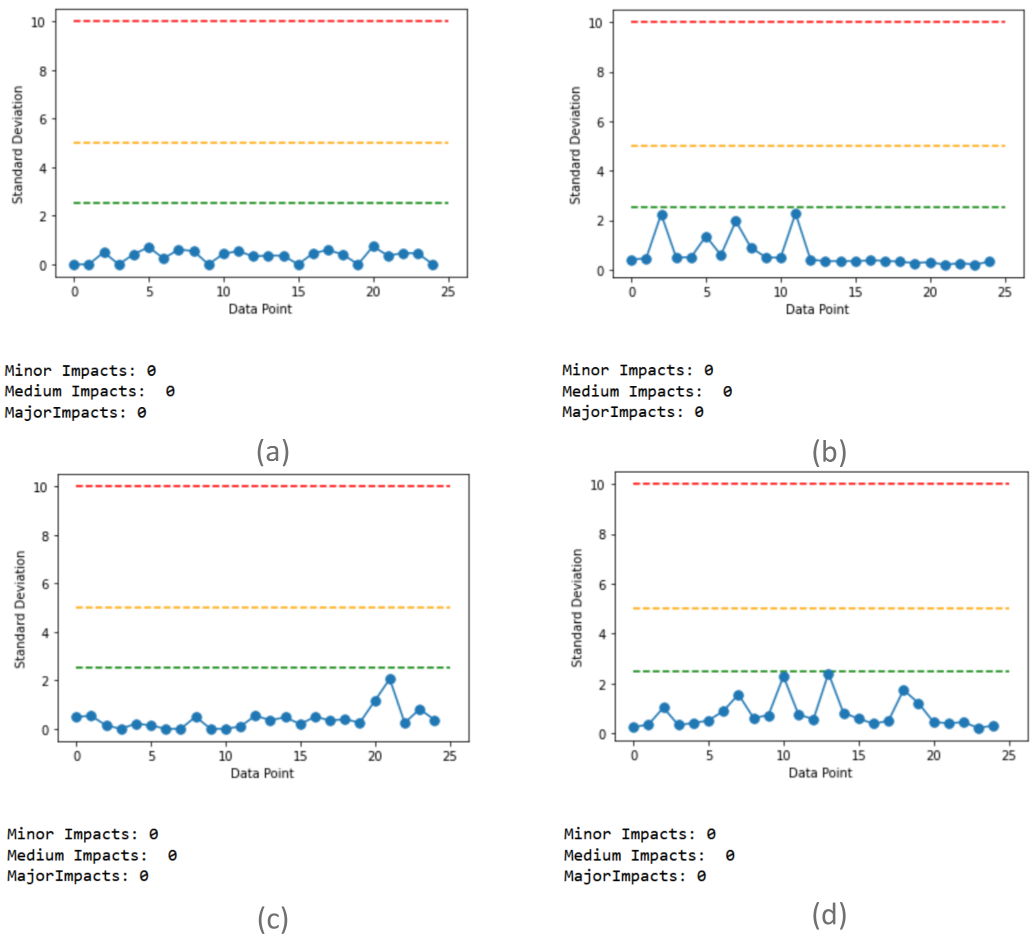
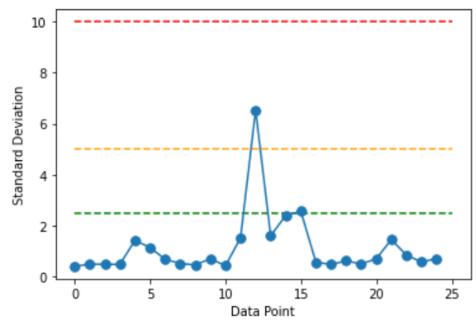


Figure 5.33: a) User demonstrated control responding to resistance, *b)* No impacts scored during experiment, *c)* No impacts scored due to effective control of catheter, *d)* No impacts scored due to effective control of catheter.

5.6.3 Data Analysis Phase 3

The analysis of the data collected in the third stage of testing further confirmed the user behaviours, but also highlighted how low-level amplitude in the fluctuation could indicate lower levels of applied force. The user who demonstrated applied force part way through the experiment only produced enough force to trigger a minor-medium response in the data analysis, with the majority of data points occurring below the detectable threshold (See Figure 5.33).

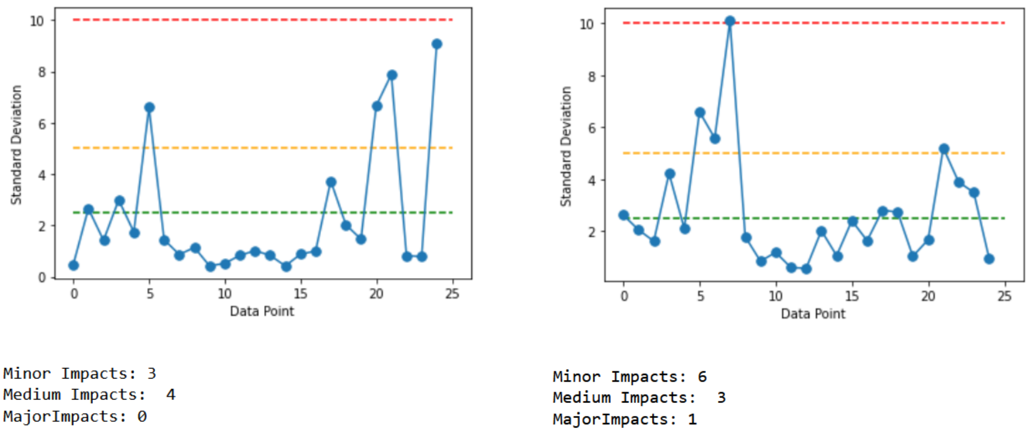



```
Minor Impacts: 1
Medium Impacts:  1
MajorImpacts: 0
```

Figure 5.34: Analysis indicates that the user demonstrated only a single minor and moderate impact.

This indicates that while the initial data set showed a large spike in the data, the actual frequency and amplitude of the data was not strong enough to imply a major impact and was brought under control quite quickly.

Users who demonstrated applied force and impacts at the start or end of the scenario, demonstrated the user's ability to control the catheter during the main navigation portion of the scenario with minor-medium impacts occurring (See Figures 5.34 a-b).

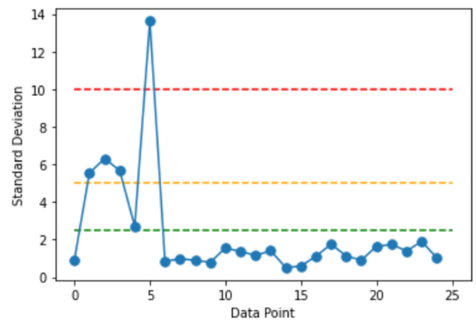


(a) (b)

Figure 5.35: a) Signs of excessive force during insertion and retrieval stage of the scenario, *b)* User produced several impacts during the start and end.

This demonstrates that the start and end steps of the scenario can be quite cumbersome for some users and be the point where some users struggle and use more force to account for change.

The user who demonstrated frequent spikes and noise in the insertion stage of the procedure triggered impact scores across each threshold due to the frequency of excessive application of force (See Figure 5.35).




```
Minor Impacts: 1
Medium Impacts:  3
MajorImpacts: 1
```

Figure 5.36: Analysis shows user several impacts in early stages of the scenario.

This demonstrated that the user was able to find the correct amount of force to apply to the catheter during navigation, but that like most users, had some issues getting it in.

5.6.4 Evaluation

The results from the impact detection show that the system can take in data produced by a virtual simulation in Unreal Engine and automatically detect the different impacts and applied force demonstrated during the tests and list the various levels of impact as well as visually display them, which can help to inform the supervising practitioner about the trainee's performance.

The ability to refine the data set and reduce the number of datapoints in a graph allows for an efficient representation and assessment of the data set. The window size can also be identified as a sensitivity parameter, a lower window size will produce a more sensitive reading, while a higher window size will produce a less sensitive reading with fewer detections. Given the size of the data, a window size of 200 or 250 is suitable for this detection with the shape of the graph staying mostly consistent up to this point. The resolution of the data set can be manipulated to adjust the sensitivity of the anomaly detection when identifying areas of impact and applied force and can be adjusted for data sets of varying sizes if needs be, however for modularity and size, the system is designed to limit itself to five thousand values.

5.8 User Experience Questionnaire Results

Following from the data analysis, the platform's usability characteristics were assessed by users through a UEQ to determine the level of performance in different areas: attractiveness, perspicuity, efficiency, dependability, stimulation, and novelty. The users were asked to thread a catheter through a simulated artery using as much force as they felt was necessary to bypass the apex of the bend and then retract the catheter after reaching a defined point 20 cm from entry. Following this, their data set was analysed to identify the level of applied force and number of impacts that occurred during the threading simulation. A User Experience Questionnaire was completed by the user which was then analysed using the UEQ analysis spreadsheet to determine the performance of each characteristic.

The results of the data analysis, as mentioned earlier, are converted to a scale ranging from -3 (horribly bad) to +3 (extremely good) and plotted on a bar chart. These provide indication as to whether users positively or negatively perceived the platform and can be interpreted to indicate the strengths of the platform and any areas for improvements. The bar charts are also accompanied with error bars to indicate the standard deviation of results, (See Figure 5.38).

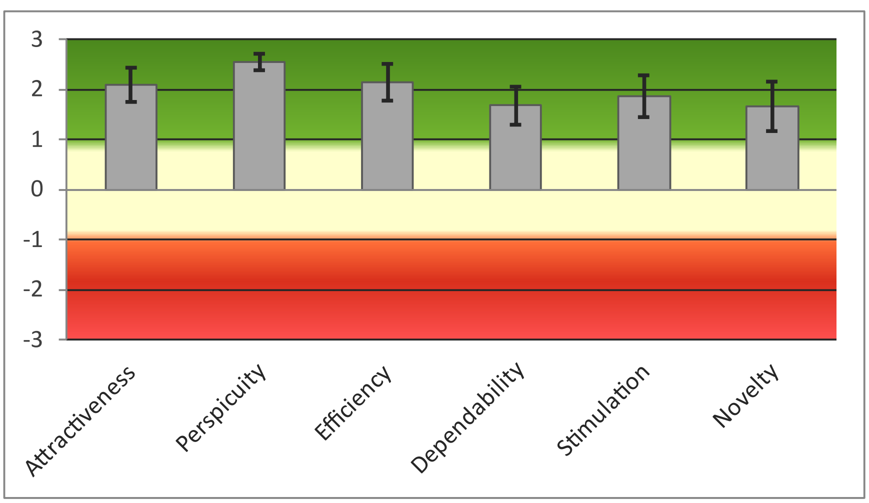


Figure 5.37: Graph demonstrating the results for the six different usability scales.

While the individual scales provide an effective insight into the core usability characteristics for the platform, these can be analysed further to obtain an overall performance metric for the different usability qualities: attractiveness, hedonic, and pragmatic, (See Figure 5.39).

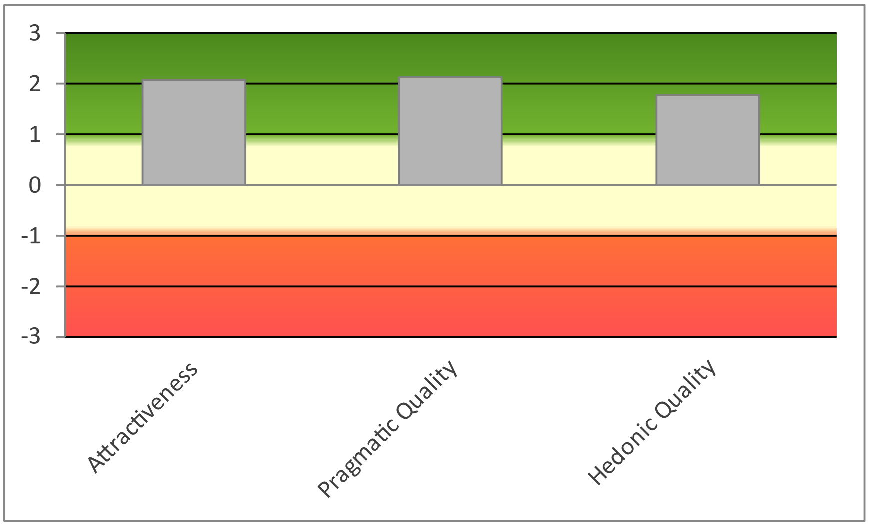


Figure 5.38: Graph showing the means of three usability characteristics of the platform.

Fifteen independent users who had tested the platform provided answers to the UEQ; these results were analysed using Cronbach's Alpha-Coefficient to calculate the consistency of the answers received for individual categories. Given that the questionnaire items pertain to distinct categories within the questionnaire, there are a total of six Alpha-Coefficients used to indicate whether the answers received for that category are reliable, (See Table 6).

Table 7: Table showing Cronbach's Alpha for UEQ responses.

Category	Cronbach's Alpha Coef	Internal Consistency
Attractiveness	α = 0.84	Reliable
Perspicuity	α = 0.03	low
Efficiency	α = 0.76	High
Dependability	α = 0.63	Moderate
Stimulation	α = 0.74	High
Novelty	α = 0.80	Fairly high

The results shown in Table 6 demonstrate the consistency of each UEQ category, with attractiveness and novelty showing an α value > 0.80, efficiency and stimulation showing an α value > 0.7, dependability showing an α value > 0.6.

- The categories where α > 0.80 demonstrates a very high consistency between user responses and that users are in strong agreement about the category, in this case, users strongly agreed that the platform was highly attractive and novel, and that the UEQ results for these scales are very reliable.
- The categories where α > 0.70 demonstrates a high amount of consistency between user responses and that users mostly agree in their responses, in this case, users mostly agreed that the platform was efficient and stimulating and that the UEQ results for these scales are reliable.
- The categories where α > 0.60 demonstrates a moderate amount of consistency between user responses and that users were in modest agreement about a category, in this case, the dependability results indicate that a) the platform needs to be improved, or b) the question items were misinterpreted by users.
- The confidence alpha for perspicuity came back with an extremely low value that indicates the reliability could not be correctly estimated. In this case, it is advised that a low sample size (*n* = 15) can cause sampling errors and might not indicate a problem with the UEQ scale in question.

5.8.1 Evaluation

The results from the user experience study demonstrate that most users had a positive experience with the virtual arterial threading simulator platform. The scales that had the highest ratings were perspicuity and efficiency, with users feeling the platform was quite easy to use and clear to understand. Most users quickly understood how to perform the task, how to interpret the data on screen, and the results from the analysis with little obstruction from errors or faults. Out of the scales, the ones that show the least deviation and most consistent responses are perspicuity and attractiveness.

The important observation here is that the low sample size can have a negative effect on the consistency of the UEQ scale, which can contradict the confidence of the results, specifically, perspicuity was the highest rated scale, while the consistency, due to a small sample size of fifteen users, implied the results were inaccurate, so for future studies, the sample size should be increased to improve the accuracy of consistency and confidence measurements.

When evaluating the results provided, it is important to consider the different biases relevant to these types of questionnaires. As responses are provided by a variety of participants with different mindsets or level of knowledge, their response style can differ from one another. In some cases, users might prefer to avoid giving extreme answers or prefer to give them, also known as *extreme response bias*; other users might be more likely to provide positive responses to the questionnaire items, also referred to as *acquiescence response style* (Park and Wu, 2019).

An additional concern with Likert scales is the *dumping ground* that is the midpoint; in certain cases, such as users not understanding how the question relates to the system or are ambivalent towards the subject matter, they may choose the midpoint as an answer, which demonstrates a neutral opinion on the topic, even though they may not actually feel this way (Chyung *et al*., 2017). Throughout this study, several participants expressed confusion as to how certain items in the questionnaire applied to the system being assessed or demonstrated insufficient understanding of the context of the device and opted to indicate a neutral stance. It is important that the context of the question items is interpreted correctly by the user to ensure answers from users are consistent with one another to improve the reliability of the UEQ scales.

This is where the overarching groupings are useful; by grouping scales into attractiveness, pragmatic, and hedonic qualities, an overall metric can be obtained regarding the pragmatic qualities of the user's experience (task relevant aspects) and the hedonic qualities of the user's experience (non-task related aspects). This can help clarify an overall opinion on different qualities of the platform based on the individual scales.

CHAPTER 6 DISCUSSION

The findings in this thesis support the hypothesis that a platform can be designed to provide physical resistance when simulating arterial threading, monitor the data for applied force and impact, provide the operator with this information in an immersive way, and analyse the impacts and applied force. The findings relate to simulation trainers' problem in neuroradiology, namely the lack of effective haptic feedback in the form of physical resistance, either digitally or inherently produced, parallel to simulation training platforms in other fields and how users can interpret the data regarding the applied force.

The methodology described and tested can provide a way for experts to expand on the existing performance metrics they use to assess new practitioners by allowing them to factor in applied force and impacts in arterial threading, which, while a crucial competency, is not demonstrable in state-of-the-art simulation training platforms. The methodology could allow for the reduced usage of cadavers, dummy models, and live practice to attain arterial threading skills and provide a quantifiable metric regarding a practitioner's performance.

The force-sensing system, virtual learning environment, and impact detection produced data that demonstrated the system's ability to provide information that indicated where a user had applied enough force to cause an arterial impact. This information was demonstrable in spikes and fluctuation to data and indicated where no additional force had been applied in the form of linear data. With the impact detection system, this is converted to data points that indicate the impacts in a more user-friendly manner and more accurately quantifies the number of impacts that have occurred, and the level of force applied, which can be used to track a user's performance throughout numerous experiments.

What can be derived from this work is a system that can tell the difference between the distinct levels of force and detect the number of impacts that occur during simulated arterial threading conducted in a real-time environment. Providing practitioners with this knowledge can improve the quality of training they receive and enhance their ability to navigate a patient's arteries safely and efficiently.

Furthermore, supervising practitioners can use this data to inform their decision making regarding their trainee's performance and level of competency during training by analysing how many impacts occur, how often they occur, and the severity of them. The findings of this project address the gap in literature relating to haptic feedback in Neuroradiology training, specifically MT, by identifying a way to detect and measure the incoming force applied by a practitioner and then analyse the data to determine if extreme levels of force are being applied or if they are impacting the artery wall. The identified literature focuses on the task autonomy of practitioners and task breakdown of the procedure into manageable sections that can be recorded for performance monitoring purposes on a step-by-step basis but fails to discuss the importance of haptic feedback in training. The result can help practitioners develop their arterial threading skills and improve their efficiency in a risk-free virtual environment.

The findings demonstrate that simulated arterial threading with physical resistance is possible for simulation training platforms. Thus, the proposed method would reduce the resources required for training this skill and reduce pressure by removing the need to practise on patients. Furthermore, the data produced by this system can be used as a performance metric, supporting training and assessment of practitioners by analysing the number of impacts in a simulation, the duration, and any changes to this data over a period, which would help make a more comprehensive training platform. The aim of creating a Virtual Arterial Threading Simulator that can integrate the sensor data from a proxy controller that provides physical resistance into a virtual learning environment to disseminate impact data is also reinforced by the findings of this thesis. There is sufficient research to suggest that a high-fidelity VR simulation training platform will increase the trainee's engagement, spatial awareness, and sense of presence during simulated MT training.

CHAPTER 7 FUTURE WORK AND CONCLUSIONS

With the technological advancements in immersive technologies, there is an opportunity for medical institutions to enhance the quality of training that resident surgeons receive to expedite the development of core and sub-specialist skills in interventional neuroradiology. As mechanical thrombectomy is a complex procedure performed primarily on critically ill stroke patients in a time sensitive manner, it is rare for trainees to get practical experience in this procedure, hence the importance that simulation platforms are developed to provide trainees with the ability to develop the relevant skills and confidence to safely perform these procedures. A summary of the research completed in this thesis is presented within this chapter. The key contributions to novelty and the future possibilities are also discussed in detail.

Many examples of virtual reality for surgical simulation demonstrate the ability to recreate the steps of complex procedures, simulate the relevant instruments and anatomy, and visualise the complex imagery needed to build a resident's confidence and knowledge of a procedure. However, in cases like interventional neuroradiology, there are significant weaknesses in the curriculum due to the time-sensitive and minimally invasive nature of certain procedures that means novice practitioners struggle to build their confidence and fine-motor skills regarding key procedures such as mechanical thrombectomy. Developing a system to provide users with the opportunity to attain this skill will support their training and development as they get used to the different physical sensations and resistances offered by the arterial system.

7.1 Future Research

While the proposed methodology can monitor and assess applied force in simulated arterial navigation, there still exist avenues of research that can improve the output quality and make for a more robust system.

The primary limitation of the system is the lack of mechanical validation of the sensors used in the platform and characteristic evaluation of material used in the platform. Future research is required to validate the sensors and identify the level of repeatability and stability for this type of application, this can be used to also create a model of the pressure expected during the insertion stage of the experiment and the clot-retrieval stage of the experiment, which could be used to infer which applied force indicators provide indication of applied force.

Standardised procedural-based simulators use patient-specific DICOM files that provide the practitioner with real-life case studies on which to practise. DICOM files are medical image sets produced during computerised tomography angiography (CTA) or Medical Resonance Imaging (MRI). DICOM integration in simulation training allows practitioners to practise procedures with differing challenges based on real-world scenarios. There is research showing that angiographic volumes based on DICOM files can be enhanced to provide better depth perception and understanding of the vascular structure that practitioners routinely operate on through the application of view-based chroma and alpha mask to provide better perspective visualisation of the arterial network they are working in (Drouin *et al*., 2020). So, the integration of DICOM combined with a system for visualising the depth and structure of the arterial network could provide a powerful training tool for practitioners in the VRLE.

In addition to this, the arterial bend being simulated is currently assigned manually with only 2 degrees of freedom being manipulated. In a live practice, the practitioner would work with more complex bends that requires more intimate knowledge and interaction. The manual approach of assigning a bend could be made more procedural by analysing the bend in the DICOM data and adjusting the positions of the tube and sensors using step motors based on the curvature to recreate the bend as it would be represented in the game engine environment, thus allowing for patient-specific cases to be recreated that the practitioner can use to practise.

Additionally, the real-time communication and visualisation of sensor data can be investigated further for latency and identify any optimisations to the framework used to communicate, visualise, and record real-time sensor data. In the VRLE, it currently focuses on the visual dominance of the user with information regarding the experimental procedures visualised on screen. An ideal path would be to incorporate an avatar of the user and their hands to provide users with a sense of body ownership and hand tracking. There is research to support this, suggesting that a sense of body ownership and hand tracking would enable the user's movements and interactions to be mapped in real-time to further enhance the engagement and immersion of the simulation (Ogawa *et al*., 2020).

A limitation in the platform is that the thresholds that distinguish the various levels of applied force in the data analysis are arbitrarily set based on initial testing with the objective being to demonstrate a clear ability to distinguish the different changes in applied force. As with any expert system for teaching, learning, and assessment, the expert practitioner has full access to these parameters and can tune the system to their own standards. Expert practitioners will have a deeper understanding of the output of the data analysis if they are able to test the platform and adjust parameters to better fit their expectations so they can provide more accurate feedback to the training practitioner.

Currently, the platform lacks formal validation and assessment from clinical practitioners that would provide qualitative evidence. Potential future research can expand on the user study conducted here and work with expert practitioners across the twenty-four stroke centres in England to identify what expert users consider to be the correct thresholds for the platform when training new practitioners. The outcome would be that the data provided can be used to reach a consensus on what the ideal thresholds for distinct levels of impact and applied force and sensitivity of the system should be, which will improve the reliability of the novel system by incorporating expert feedback to improve the quality of the objective performance metric it produces.

In addition to this, alpha-testing was aimed at members of the Faculty of Engineering and Technology (computer science, mathematics, civil engineering and built environment), meaning that the context of user feedback was more about identifying any potential user experience concerns, design flaws, or software bugs from peers in a development context. Future research coinciding with the previous point about exposing expert users to the platform could involve exposing the platform to practicing residents who would be able to complete a beta test and provide user feedback in the context of real-world deployment with actual end-users, which would improve upon existing user experience outcomes.

7.2 Conclusion

The findings of this research project confirm that sensor data and game engine technology can be combined to produce a tactile VR controller that can provide physical resistance during simulated arterial navigation and analyse the applied force from a user to produce an object score regarding their applied force. The outcome is achieved by integrating incoming sensor data into gameplay variables that can be presented to the user to inform them of what they are doing regarding the force they are applying to allow for real-time behaviour adjustment. The resulting data is analysed externally to provide an objective metric about the trainee's applied force by analysing the changes in force-sensor data in segments across a data set.

The novelty of this platform is the obtaining of information regarding applied force in relation to physical resistance during simulation and the calculation of an objective parameter to indicate how well a user responding to the resistance and adjusted their applied force. The significance of this is the ability for expert practitioners who originally could not visualise how a user was interacting with an artery during simulation training, now have a parameter generated from user interaction to inform them of the practitioners performance regarding the physical application of force. With further investigation and validation, the work completed here can enhance simulation training for practitioners and improve the ways in which practitioners develop an understanding of the physical aspects of mechanical thrombectomy by providing indication of their threading quality.

The project aims and objectives were addressed by creating a novel platform that integrated sensor data from an Arduino system into a real-time game engine environment that can be used to provide practitioners with a virtual learning environment in which to practise arterial threading in a risk-free environment while producing physical resistance when the practitioner applies force. The system also addresses the aims by allowing arterial threading to occur at several different angles and positions, allowing for different arterial bends to be simulated by the practitioner. Furthermore, the impact detection system using a windowed standard deviation achieves the objective of providing practitioners with a quantifiable metric derived from the applied force data produced by the system as a whole and can be used to support training and assessment of trainee interventional neuroradiologists during their sub-specialist training.

The significance of the findings in this study is that the Virtual Arterial Threading Simulator is a low-cost and small-form factor system, which provides practitioners with a reliable way of measuring and recording how much force is being applied during simulated arterial threading with physical resistance; an aspect of simulation training that current state-of-the-art box trainer simulators lack. The integration of real-time time-series data into an application that can monitor the amount of force being applied and determine whether an impact occurred implies that Neuroradiological training programs can be extended beyond a focus on task autonomy and task composition, and in the future, support the attainment of crucial fine-motor skills.

Additionally, the ability to record and analyse the data means that it can potentially be used as an objective performance indicator, with experts assessing the efficiency of a practitioner's arterial threading skills. This performance metric can be combined with additional measures of success already present in MT simulation training to gain a better understanding of their progress throughout their training.

The project has contributed a system that can simulate an arterial bend through a proxy pattern controller and simulate the physical resistance that goes with it. The project has also contributed a method utilising serial communication of sensor data and integrating it into a real-time environment that can be used to monitor and assess the applied force on an arterial bend, in which the data can provide insight into the application of force and help to identify when practitioners are too forceful during navigation. The applied force data can be graphically represented in real-time to the user so they can actively inform their applied force and make efforts to improve the quality of applied force. The approach used to develop the proxy pattern control box trainer is a small-scale solution when compared to industry standard counterparts and can be reconfigured to fit different scenarios and layouts. The layout of the sensors and tubing can also be modified to allow different situations to be tested and see how users perform with different extremities and resistances.

By conducting data analysis using the standard deviation of a moving average across sub-sections of a data set for anomaly detection, an assessment tool has been developed that can identify how many impacts occurred and the level of force that was applied by the user, providing a novel metric to assessors that can inform them of the quality of applied force being exhibited. Being able to quantify the number of impacts and amount of applied force a user exhibited during simulation will support training and assessment of novice residents in interventional neuroradiology and mechanical thrombectomy and help supervisors determine their capability in practice.

The technology used and tested in this research has further applicability beyond mechanical thrombectomy in the medical simulation training, as identified in section 2.2.4. A correctly calibrated force-sensitive resister can be used to ascertain levels of applied force and impacts, and even correlated with additional sensors, including optical sensors, to provide determine proximity and calculate relative forces to prevent collisions. This could be beneficial beyond medical simulation training, in fields such as robotic-assisted surgery, and engineering and construction by providing valuable force sensor data to relevant algorithms or systems to help improve operational safety and efficiency.

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APPENDIX 1 – PARTICIPATION INFORMATION SHEET AND USER CONSENT FORM

LIVERPOOL JOHN MOORES UNIVERSITY

Participant Information Sheet for End-User Participants

LJMU's Research Ethics Committee Approval Reference:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study User Experience Assessment of Arterial Threading and Applied Force Simulator

You are being invited to take part in a study that will involve you conducting the arterial threading of a simulated artery that will be used to detect the level of applied force and then completing a user experience survey. Before you decide it is important for you to understand why the study us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

1. **Who will conduct the study?**

<u>**Study Team**</u> Mr Kieran Latham – PhD Student
Principal Investigator: Mr Kieran Latham – PhD Researcher
Co-investigator: Prof Patryk Kot – Director of Studies

School/Faculty within LJMU: Department of Civil Engineering

Collaborating Institutions: The Walton Centre NHS Trust

2. **What is the purpose of the study?**

The purpose of this study is to assess the usability of the "Arterial Threading and Applied Force Simulator" platform developed as partial fulfilment of the requirements for Doctor of Philosophy at Liverpool John Moores University. The study will look at how the user interacts and respond to the system during simulated arterial threading and how the system reacts to the applied force and communicates with the user. The study seeks to acquire qualitative responses from the end-user through the completion of a User Experience Questionnaire.

This study hopes to answer the following questions:

Does the **system** reliably respond to user input regarding applied force?
Does the **system** present the information regarding applied force efficiently?
Is the **system** considered a novel approach to the task of arterial threading?
Does the **user** respond to the information in a positive manner?
Does the **user** find the platform easy to use?
Does the **user** feel that they are in control of the interaction?

[LJMU Participant Information Sheet]
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Figure 6.1: Participant information sheet page 1.

3. **Why have I been invited to participate?**

   You have been invited to take part in this study due to being over the age of 18 and are able to interact with a computer and hardware related to this study.

4. **Do I have to take part?**
   No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time by informing the investigators without giving a reason and without it affecting your rights.

5. **What will happen to me if I take part?**

   We will talk you through the study procedures and give you the chance to ask any questions. Your involvement is not expected to exceed ten minutes per experiment and you can participate up to three times, totalling a maximum of thirty minutes. You will be asked to conduct a simulated arterial threading under the guidance of the principal investigator that involves guiding a catheter through a tube, generating force-sensor data in semi-public environment. The test will take up to five minutes at most, and you will be expected to complete a questionnaire following the simulation to provide quantitative feedback on the experience and the experimental setup.

6. **Will I be recorded and how will the recorded media be used?**

   No, you will not be recorded, and no audio and/or visual recording devices will be used to record participation at any point.

7. **What are the possible benefits of taking part?**
   Whilst there will be no direct benefits to you for taking part in this study, partaking in this study will provide data that can be used in future publications regarding the work done on this research programme and help identify areas of improvement and potentially identify future research questions.

8. **What will happen to the data provided and how will my taking part in this project be kept confidential?**
   The information you provide as part of the study is the **study data**. Any study data from which you can be identified (e.g. from identifiers such as your name, date of birth, audio recording etc.), is known as **personal data**. This includes more sensitive categories of personal data (**sensitive data**) such as your race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation.

   Your participation in this study will not involve the collection of personal data

   When you agree to take part in a study, we will use your personal data in the ways needed to conduct and analyse the study and if necessary, to verify and defend, when required, the process and outcomes of the study. Personal data will be accessible to the study team. In addition, responsible members of Liverpool John Moores University may be given access to personal data

[LJMU Participant Information Sheet]
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Figure 6.2: Participant information sheet page 2.

for monitoring and/or audit of the study to ensure that the study is complying with applicable regulations.

When we do not need to use personal data, it will be deleted or identifiers will be removed. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed). However, your consent form. will be retained for 5 years.

9. Limits to confidentiality

Please note that confidentiality may not be guaranteed; for example, due to the limited size of the participant sample, the position of the participant or information included in reports, participants might be indirectly identifiable in transcripts and reports. The investigator will work with the participant in an attempt to minimise and manage the potential for indirect identification of participants.

10. What will happen to the results of the study?

The investigator intends to include the results as part of their PhD thesis to demonstrate robustness and repeatability of the experimental setup and also potentially publish a journal article based on these results.

11. Who is organising and funding the study?

This study is organised by Liverpool John Moores University and co-funded by The Walton Centre NHS Foundation Trust. The Walton Centre NHS Foundation Trust is looking at experimental work in tactile feedback for simulated neuroradiological procedures.

12. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the Liverpool John Moores University Research Ethics Committee (Reference number: **21/CIV/**).

13. What if something goes wrong?

If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The investigator should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk) and your communication will be re-directed to an independent person as appropriate.

14. Data Protection Notice

Liverpool John Moores University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study *[If LJMU is not the sole Data Controller this will need to be revised and the other data controller added. An explanation provided in the ethics application].* This means

[LJMU Participant Information Sheet]
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Figure 6.3: Participant information sheet page 3.

that we are responsible for looking after your information and using it properly. Liverpool John Moores University will process your personal data for the purpose of research. Research is a task that we perform in the public interest. Liverpool John Moores University will keep identifiable information about you for 5 years after the study has finished/ until 2026.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at by contacting secretariat@ljmu.ac.uk.

If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

15. Contact for further information

Name of P.I.: Kieran Latham
Address: James Parsons Building, Byrom Street, Liverpool L3 3AF, United Kingdom
Email: K.Latham@ljmu.ac.uk
Tel No: 0151 231 2121

Thank you for reading this information sheet and for considering to take part in this study.
Note: A copy of the participant information sheet should be retained by the participant with a copy of the signed consent form.

[LJMU Participant Information Sheet]
Version 1.0 date: 17/11/2021

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Figure 6.4: Participant information sheet page 4.

LIVERPOOL JOHN MOORES UNIVERSITY

PARTICIPANT CONSENT FORM [Academic Student, Researcher, and Staff]

Study title: User Experience (UX) Assessment for Virtual Arterial Threading Simulator
Research Ethics Committee Reference Number: 21/CIV/

Principal Investigator: Kieran Latham
LJMU postgraduate research student
LJMU Email address: K.Latham@ljmu.ac.uk
LJMU School/Faculty: School of Civil Engineering and Built Environment
LJMU Central telephone number: 0151 231 2121
Supervisor Name: Patryk Kot
LJMU Email address: P.Kot@ljmu.ac.uk

If you are happy to participate, please complete and sign the consent form below

		Please initial
1.	I confirm that I have read the information sheet dated………………. (version 1.0) for the above study, or it has been read to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand what taking part in the study involves	
3.	I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions I can withdraw from the study at any time, without giving a reason and without penalty or my legal rights being affected.	
4.	I have been advised about potential risks associated with taking part in this study and have taken these into consideration before consenting to participate	
5.	I agree to joint copyright of the generated sensor data to Kieran Latham.	
6.	I give permission to the investigator to take a copy of my completed user experience questionnaire and to use the responses for academic publication.	
7.	I understand that parts of our conversation will be used verbatim in future publications or presentations and that all efforts will be made to ensure I cannot be identified in reports or any further outputs	
8.	I agree to take part in this study	

Name of Participant   Date   Signature

For participants unable to sign their name, mark the box instead of signing ☐

I have witnessed the accurate reading of the consent form with the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely

Name of Investigator   Date   Signature

Name of Person taking consent   Date   Signature
(if different from investigator)

Participant consent form Version No. 1.0 Date: 17/11/2021   Page 1 of 1

Figure 6.5: Participant consent form.

APPENDIX 2 – CODE REPOSITORY

https://github.com/KieranLathamPhD/ThesisCodeAppendices