Development of an Integrated Catheter Insertion Training Simulator and Performance Monitoring System

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Abstract

Catheters are used in a wide range of procedures such as insertion of stents or drains and are increasingly utilized. Currently experience or judgement is used in intravenous catheter selection and, while this can be a reasonably successful approach, it is felt that improvements could be made by utilizing a combination of historical data analysis and machine learning algorithms and Artificial Intelligence (AI) to improve catheter selection performance and assessment in early-stage catheterization training.

Current training lacks consistency, is expensive, and requires access to a both surgeons and test cadavers. There is therefore a requirement for research to cover means to improve and standardize catheter selection and catheterizationassessment methods, especially in emergency situations. An system with automated wall-hit detection and evidence-based catheter selection could provide additional practice time to medical students in their initial training. Combining this performance tracking to give consistent, qualitative feedback to students and instructors can potentially reduce training times and subsequently improve catheterization performance and patient outcomes.

This study covers the conceptualization, initial modelling, and requirements definition for such an application. Key to this is establishing performance metrics and a means to assess them. There are two critical performance measures in catheter insertion: 'wall-hits' or the number of times the catheter tip hits the side of the vein and procedure time. Establishing feedback loops in the training system reinforces learning by enabling real-time awareness and faster correction of mistakes.

While the application would initially be aimed at monitoring performance during training, this could be expanded to monitor performance throughout medical use of intravenous catheters. Several risks and challenges remain in the development of a solution, and are subject to ongoing research.

Keywords: Catheterization, Training, Artificial Intelligence, Medical Simulation.

1. INTRODUCTION

1.1 Background

Intravascular catheterization is a complex, time-critical medical technique that underpins minimally invasive procedures from angiographic imaging to angioplasty and stent fitting. Typically, the procedure involves the placement of a substance or device in the patient's vascular system by means of a catheter and guidewire combination, introduced via a cannulation site typically via the femoral or subclavian vein, described in detail by Goldmann and Pier (1993).This task requires selection of a catheter and guidewire combination that best suits a given procedure, patient, and surgeon and is a particularly complex procedure (Myler, Boucher, Cumberland, & Stertzer, 1990).

Trainees in cardiac catheterization program must follow specific steps delineated in the Core Cardiovascular Training Statement (COCATS) 4 training requirements (King et al., 2015) to gain appropriate experience in the cardiac catheterization lab. COCATS 4 Taskforce 10 (King et al., 2015) outlines a structured, three phase framework for training in cardiac catheterization and is endorsed by the Society for Cardiovascular Angiography and Interventions. The framework outlines milestones in knowledge and skill requirements in a detailed timeline. The ability to perform a Right Coronary Artery (RCA) Catheterization is a requirement of the first phase of COCATS 4 (King et al., 2015), expected to be complete after 24 months of medical training. This procedure is the focus of this study, and we believe supporting early phase training can improve performance.

While there is a training framework for catheterization, there is currently no defined catheter selection procedure or framework in place at Miami Valley Hospital and literature searches did not discover any such standards in place in the wider angiographic community. The current catheter selection process is largely down to the experience of the Surgeon and their familiarity with certain shapes and sizes of catheter which can lead to inconsistencies in performance and localization of best practice.

Catheterization training is either conducted on cadavers or simulation-based in the initial stages and highly reliant on expert mentors to assess performance. The requirement for expert oversight limits the amount of time available for training, even in the early stages. Barsuk et al. (2009) demonstrated that Cardiac Catheterization simulation training can increase both the skill and self-confidence of trainees. In a subsequent study Barsuk et al. (2010) also investigated the long-term effect of simulation on training with between 82.4% to 87.1% of trainees maintaining their performance up to one year after training.In addition, catheterizationtraining using ultrasound guidance was shown to improve catheterizationperformance in emergency technicians to 0.970 (95% confidence interval, 0.956–0.983), which was close to the level expected of surgeons (Duran-Gehring et al., 2016)

Throughout related literature, Right Coronary Arterial (RCA) Angioplasty is highlighted as a particularly complex procedure from the perspective of catheter selection with several consideration influencing the choice (Myler et al. 1990). Understanding the nature of the tasks involved in the process is an important aspect to design a useful training system. As such, it is important to understand the factors that relate to successful catheterization.

There are limited examples of research into improved catheterization training in the literature. Wang et al. (2018) focus on the implementation of a VR catheterization training system to mitigate problems arising from the use of additional x-ray shielding by surgical teams. In 2020, Guo et al., demonstrated a machine learning approach for the assessment of difficulty levels in a specific catheterization task. This approach utilized machine learning to classify the aortic arch geometry to establish a difficulty associated with performing the required catheterizationon the patient. In 2009 Sarkar and colleagues. studied the problem of Catheter Selection, specifically considering coronary angiography and intervention in anomalous Right Coronary Arteries (RCA). Based on the 24 interventions included, this study defined a catheter selection framework for anomalous RCAs for 4 different takeoff types. The study also suggests that characteristics of the angiographic procedure, such as the initial trajectory, angle at takeoff, aortic root dimensions, configuration of the ostium, and the location of the procedure are important aspects that influence the selection of a guide catheter (Sarkar et a., 2009).

While Sarkar et Al. show that historical data can predict optimal catheter selection for a given procedure, they only highlight the successful catheter and give both a procedure time and list the number of attempts. This analysis does not consider other factors such as 'tip strikes', which could be another important factor in catheter selection. In their 2011 paper, Riga and colleagues define the Imperial College Complex Endovascular Cannulation Scoring Tool (IC3ST) to assess catheterization performance, defining seven elements to be scored by an expert observer. The IC3ST catheterization scoring framework is shown in Table 1.

Catheter Use	**1** Inappropriate use of catheter, failure to recognize catheter unsuitability	**2**	**3** Inappropriate catheter use initially but recognizes and rectifies error within a reasonable timeframe	**4**	**5** Correct catheter use to full advantage
Wire and catheter manipulation	**1** Excessive & uncontrolled	**2**	**3** Makes clumsy movements on occasion	**4**	**5** High degree of finesse
Contact wit the vessel wall/vessel trauma (wall hits)	**1** Excessive force and multiple dragging of the catheter tip along the vessel wall	**2**	**3** Some contact with the vessel wall but swift correction	**4**	**5** Minimal contact with the vessel wall, careful placement of wire and catheter
Areas of specific embolic potential	**1** No respect for areas of danger – embolization risk HIGH	**2**	**3** Recognition of potential areas of danger – embolization risk MODERATE	**4**	**5** Full awareness of areas of danger – embolization risk LOW
Vessel cannulation	**1** Failure to cannulate and maintain position>3cm into target vessel	**2**	**3** Successful wire cannulation but inability of the catheter to follow	**4**	**5** Successful cannulation with wire and catheter >3m into target vessel
Overall time and motion	**1** Slow, makes many unnecessary movements	**2**	**3** Efficient but some unnecessary movements	**4**	**5** Maximum efficiency and clear economy of movement
Flow of procedure	**1** Stops frequently and needs to discuss the next move	**2**	**3** Demonstrates some forward planning	**4**	**5** Has obviously planned course with efficiency
General Score	**1** **Poor**	**2**	**3** **Competent**	**4**	**5** **Clearly Superior**

TABLE 1: Imperial College Complex Endovascular Cannulation Scoring Tool (IC3ST), reproduced from (Riga et al., 2011).

The IC3ST represents a baseline performance metric that has credible historical use and although its current implementation requires assessment by a 3rd party expert could provide the basis for catheterization assessment within an automated or non-expert training system.

Understanding catheter deflection and the potential space envelope achievable is a key aspect of any system to predict optimal catheter selection for a given patient and procedure. A finite element method for predicting the shape of any given catheter and guidewire combination as function of the relative position of the two elements is described by Li et al. (2011). This method is detailed but also requires accurate information on the mechanical properties of the catheter and may be less accurate given any variability in shape due to temperature changes.

A computational, predictive approach to catheter selection is described by Rauf, et al. (2016), where, again, the RCA is scanned by means of a pre-procedural MRI to determine the dimensions of the RCA geometry. This information is then combined with deflection predictions for specific catheters to make a prediction as to the optimal catheter for a given RCA geometry and procedure. Rauf et al. (2016) continue to define the significant parameters of the RCA as: Coronary Arteries Curve Angle (CACA), Distance of the Ostium from the Aortic Valves (DOAV), and Aorta Diameter (AD) and conclude that the calculation of the dimensions of the aortic arch curve were found to be important factors in optimized catheter selection.

Zhang, et al. (2017) took a different approach to improving catheterization performance, detailing a system that utilizes a braking system on detection of a potential wall hit. This approach has the potential to mitigate wall-hits but does not provide a means to improve catheter selection and would potentially slow procedures down in order to achieve success.

To achieve a catheter selection and wall-hit classification system requires access to existing data on the outcomes of catheterization procedures and ground-truth of wall-hit situations to train the image classification system. There are significant challenges in the design, build and implementation of such a system. This problem has the potential to be both computationally intensive and require analysis of large datasets to deliver optimal catheter selections, robust and credible performance assessment, and timely and precise feedback to improve training outcomes and therefore improve performance and patient outcomes in the long term. Artificial Intelligence can provide the means to interpret big data and provide useful insights that otherwise would not be realized (Najafabadi et al., 2015). We believe that utilizing AI and Machine Learning (ML) to analyze performance and provide real-time feedback to improve training outcomes, decision-making and reinforce best practice. In addition to this, there is a need to implement the performance assessment in a training environment that may not have access to expert oversight.

There is clearly a research gap in the area of catheterization selection training, especially for emergency situations and where pre-existing MRI scans are not available. Catheterization training also requires expert oversight to classify wall-hits which is both costly and a highly limited resource. This paper conceptualizes an approach to bridge these research gaps and details elements of a prototype system that could be implemented to standardize catheter selection training. In addition to improving training by providing a standardized means to guide catheter selection in an evidence-based approach, the system could replace the need for expert oversight to assess wall-hits, allowing trainees time to practice without expensive senior surgeons to be present. The AI-based wall hit detections system would enable the performance of trainees to be tracked and qualitative performance metrics could be established in line with the requirements defined in COCATS 4 (King et al., 2015). Neither of these approaches have been considered in literature and their implementation could benefit trainee physicians undertaking early-phase catheterization training. Additionally, improving catheter selection and insertion performance through improved training has the potential to deliver a range of benefits to patients and surgeons. These could range from reducing complications arising from wall hits to reducing the procedure time and hence reduce the radiation exposure for the surgical team. In addition to these performance improvements, there is potential for cost savings, with Miami Valley Hospital alone performing approximately 3000 endovascular procedures each year the reduction in wasted time and materials, as well as secondary treatment required due to complications could lead to significant cost reductions.

While there are other approaches to catheterization training and assessment detailed in the literature, these focus on the use of virtual reality or difficulty assessment. Our approach focuses on improved catheter selection in the early stages of catheterization and using image classification to identify wall-hits in a catheterization simulator. In can be used in conjunction with existing training and assessment methods, as described in the literature. Alternative approaches for catheter selection improvement have been put forward (Rauf, et al., 2016) but these require pre-existing MRI scans of the patient. While this solution is potentially more accurate, the reliance on the MRI scan precludes this approach from use in emergency situations and does not include a means to assess wall-hits, in simulation or in a catheterization procedure.

1.2 Aim

The specific aim of this study was to determine the design requirements for a dynamic decision support and training tool for use in cardiovascular education and practice. A key goal of this study was the analysis of the requirements for all system elements such that a credible, usable, human-centered experience can be developed. This process includes broad consideration of the human-system interaction elements both in terms of the computer-based and physical interactions with the training system. The specific aim was to define the top-level design rules and requirements for low-cost, medium fidelity training applications.

1.3 Scope

This paper covers the conceptualization and development of initial design requirements and rules for the system. There are two main elements in the proposed training system. Firstly, the physical simulator and secondly the partner application. The interaction between the user and both these elements will be key to the implementation of a successful training system, however this paper focuses on the design of the Human Computer Interface (HCI) elements. This paper will examine the design of these elements and interactions from a Human Factors (HF) perspective from concept development to initial design requirements.

It is important for the credibility of the system that both the physical simulator and training application are representative of the tasks, protocols, and environment that the simulator will be used in. As such this study considers the goals and processes defined in the COCATS4, Task force 10 training framework (King et al., 2015)and specific design elements will utilize the language and appearance of similar medical training applications where possible.

2. CONCEPT

As stated in the scope, this study focuses on design requirements for a low-cost simulator with the Catheterization of the RCA as a testbed procedure. The purpose of the simulator is to be both a low-cost, low-fidelity training system and a decision support tool for practitioners. Although these uses might at first seem to require entirely different approaches, the fundamental task being performed is the same in both cases. Within these two applications there are two main functions of the proposed catheter selection and performance assessment tool: To provide catheter selection advice, and to assess practitioner performance.

These are somewhat easier to conceptualize as separate applications but much of the functionality is common. As a decision support tool, the key function is to provide the practitioner with advice on the best catheter for a particular task, while as a training tool, both this and the performance feedback are required functionalities. These concepts are summarized in Figures 1 and 2.

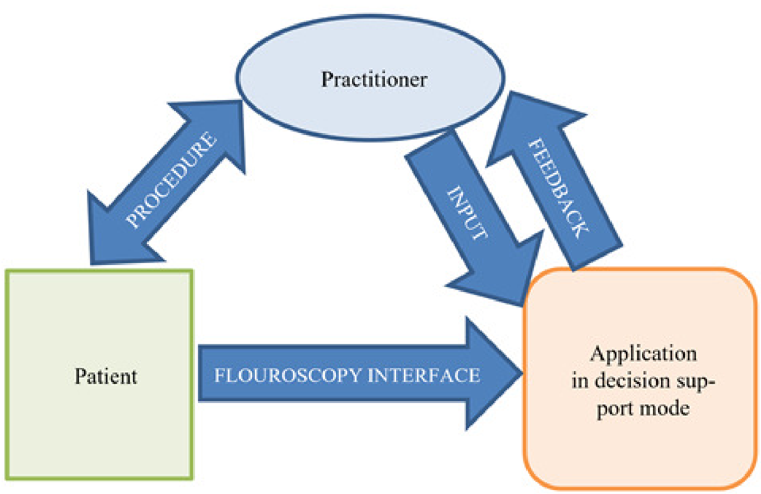

FIGURE1: Catheterization Training Simulator Concept Diagram.

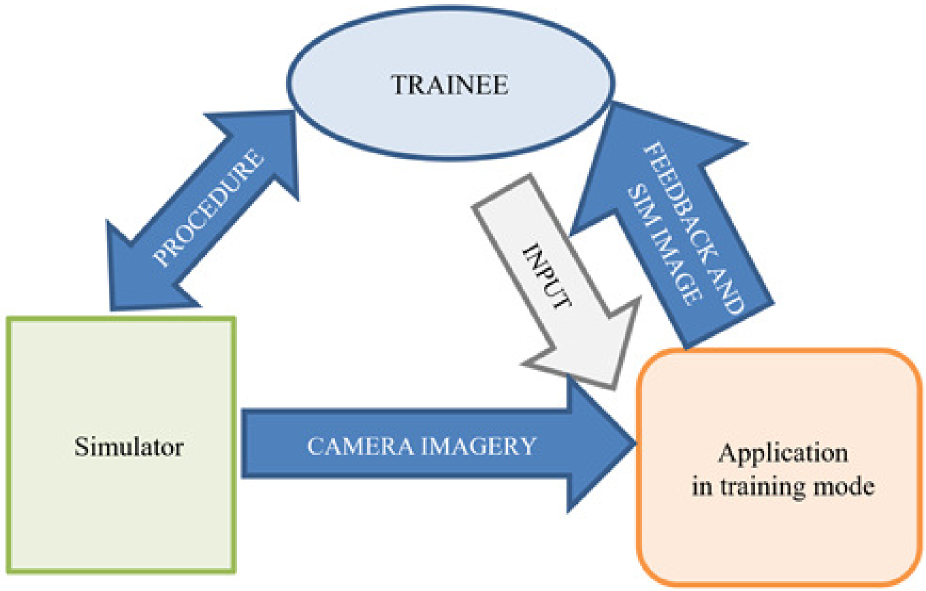

FIGURE 2: Catheterization Decision Support Concept Diagram.

As these two diagrams illustrate, although there are differences in the functional elements of the system in either configuration, the system design and driving requirements are common. The key differences of the concept as a training aid and as a decision support tool is the need to simulate as close as possible to the fluoroscopic display in the training mode and a need to integrate the fluoroscopic display to assess performance in the decision support mode. The Trainee input is shown in grey, as in a more complex simulator, parameter inputs would be required but for our testbed, only the RCA procedure is being conducted by the. A such, there is limited scope for varying the parameters of the 'patient' as it is difficult to vary the geometry of simulated vascular elements and other aspects such as age, criticality and catheter entry location cannot be varied, especially in a low cost simulator. As a result, no catheter selection output advice is required from the application.

Additionally, the nature of the performance feedback given to professional practitioners by adecision support tool will need to be different to that given to trainees in the training mode. This is key to establishing trust and eventually continuing use of such a tool by the practitioner community. The commonalities between these modes are defined in the unified training concept interaction model as shown in Figure 3. This combines all the system interaction requirements that were then analyzed further to develop design rules.

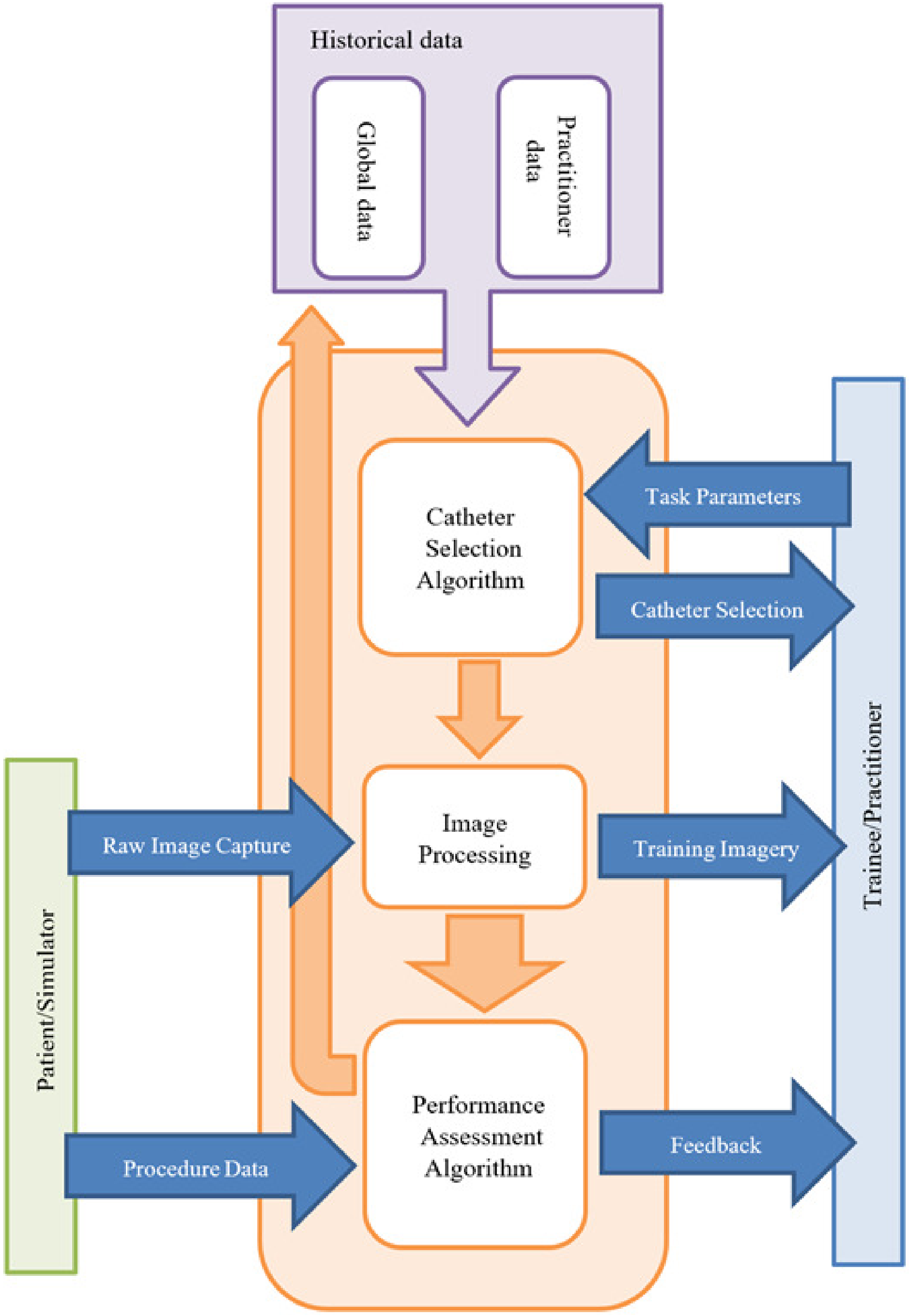

FIGURE 3: Catheterization Decision Support Concept Diagram.

The proposed concept for the training and decision support algorithm centers on the catheter selection and performance assessment algorithms. It is proposed that ML algorithms that can take input parameters as well as historical data for both the practitioner and global procedure data and predict one or more potentially optimal catheters.

This model shows the information in a sequential manner ,although there is potential for catheterization to be a dynamic procedure requiring this to have more complex interactions with practitioner decision making, this simplified model outlines the basic requirements that are needed at any point in that dynamic process. This conceptual model combines the display simulation/fluoroscopy integration elements for simplicity, but these concepts are explored separately in the detailed design requirements section. The inputs and outputs detailed in this model are further examined to determine detailed system requirements for the catheter training and decision support application.

3. DETAILED DESIGN REQUIREMENTS

The following requirements are initial estimates of the requirements and may be subject to change during design development and evaluation.

3.1 Catheter Selection Algorithm

Task Parameter Input: To enable the application to select a suitable catheter for a given procedure, that procedure must be parameterized to enable user input into the application. The initial parameterization process was conducted with subject matter experts at the Miami Valley Hospital, Dayton, Ohio and resulted in the following high-level requirements for input data in the application:

- Type of procedure.
- Entry point.
- The location of the procedure.
- The size of the patient(length, mass).
- Age of the patient.
- Sensitivity to wall hits.
- Sensitivity to time (emergency situation or otherwise).

Catheter Selection Output: In both the Decision Support mode and the Training mode, when implemented on complex training scenarios, the application will provide a minimum of one or more potential catheter guidewire combination matches for a specific procedure. This will include a selection derived from the global data and, in the event of a discrepancy, a supplemental option derived from the practitioner specific data. To support these selections and provide additional information to the practitioner, a success probability will be given. As well as providing an estimate of the potential difficulty of the procedure, this approach provides a delta between global performance and the preferred option of the individual. As there are many different catheter manufacturers, producing many different models, it may be necessary to have parametric output as well as a specific catheter selection, the application will provide information to enable the nearest match in the available stock to be determined by the practitioner. The following parameters should be provided upon interrogation of the selected catheter option:

- Tip length.
- Shape description (imagery).
- Radius of shape elements.
- Thickness of catheter.
- Stiffness of catheter and guidewire.

3.2 Data Requirements

There are potential issues regarding the storage and use of procedural and individual data that may require additional security considerations in the implementation of such an application. In addition to this, there are specific functional requirements for input data to be used by the application.

Global Data: In order to build a ML algorithm capable of predicting suitable catheters for a given procedure, historical data is required to train the model. The eventual aim would be to utilize the high-fidelity data available within the application to update and refine the model. In the absence of this data, the initial model will be trained using data from the Mid Atlantic Group Interventional Cardiology (MAGIC) database. If possible, this will be supplemented with high fidelity data from partner organizations as the application is developed.

Practitioner Data: To account for practitioner preferences and skills, some account of the specific performance of the individual users, the application will maintain a record of the procedures, catheters used, and outcomes. This will be used to tune the suggestions and provide long term analytics to the application user. There are important trust considerations with such performance tracking data that may impact the trust of users and potentially the success of the product.

These are the manuscript preparation guidelines used as a standard template. Author must follow these instructions and ensure that the manuscript is carefully aligned with these guidelines including headings, figures, tables, and references. Manuscripts with poor or no typesetting are not preliminary approved and consider for review.

3.3 Image Processing

The training mode of the application requires image processing and display manipulation to ensure the training experience is as close as possible to a real catheter insertion procedure. The position of the catheter in the simulator will be relayed to the trainee through a video screen and various transforms will be applied to ensure the view is as representative as possible. This will not be required for the Decision Support mode of the application. The image capture and display are important components of the training system. An example of the raw image data from the low-cost simulator that will be available to the application is shown in Figure 4. The image output from the application should attempt to mimic, as far as possible fluoroscopic imagery in terms of frame rate, display resolution, field of view and contrast. The raw visual images captured in the simulation are very different to greyscale, low-resolution (spatial and temporal) fluoroscopic images available in surgery and as such, additional processing will be required to achieve a representative display and ensure credibility of the simulation.

FIGURE 4: Example simulator image.

3.4 Performance Assessment

Parametric Procedure data. The performance assessment algorithm will compare the procedural data with historical data to establish not only if the procedure was successful but also how it compared with both global and practitioner specific procedures. The IC3ST framework (Riga et al, 2011) was developed to assess catheterization success but this tool is reliant on the presence of a subject matter expert. The application will utilize quantitative data from the procedure, which is a subset of the initial metrics of the IC3ST (Riga et al, 2011), as follows:

- Wire and catheter manipulation – total movement (mm)
- Contact with vessel wall (number of hits)
- Vessel Cannulation – was the procedure successful (yes/no)
- Overall time of procedure (seconds)

While the Vessel Cannulation success and time of procedure can be recorded by the application or input by the practitioner respectively, the wire and catheter manipulation, and contact with vessel wall metrics are harder to determine. It is proposed that these are assessed by use of a ML algorithm that can determine the total distance of movement of the wire and catheter, and the number of catheter contacts with the vessel wall. To do this, the algorithm requires access to the image data from the procedure.

The proposed system will utilize a ML algorithm to assess wall hits and total movement of the wire and catheter. A transfer learning approach, based on the VGG16 image classification model (Simonyanet al., 2013), fined tuned on catheterization wall-hit image data using a process outlined by Rosebrock (2012) and the Keras ML library (Chollet, 2015) was implemented in python by the authors. This model was developed using a set of 320 images (160 'hit', 160 'no hit') captured on the low-cost simulator. The images data were split into a training set (60%), validation set (20%) and evaluation set (20%).The model training resulted in a mean training accuracy of 97.9% with an associated validation accuracy of 88%. The model was then tested using set aside test images and the associated image classification results are presented in Table 2.

N=64	Predict Hit	Predict No Hit	Total
Actual Hit	30	2	32
Actual No Hit	3	29	32
Total	33	31	64

TABLE 2: Confusion matrix of catheterization image classification.

This shows the successful training performance generalized well to the test data with a 93.8% True Positive rate and a 90.6% true negative rate, and a testing accuracy of 92.2%. This translates to a precision of 0.94 and a recall of 0.91, along with an f-1 score of 0.92 on test data from the catheterization simulator. This study demonstrates that vascular wall hits can be detected using a deep learning classification model. These results are in line with the expected performance of the VGG16 model and broader state-of-the-art for image classification. Although comparable to other image classification models requires comparison to the success rate of human assessors to determine if this approach will be suitable for such an application or if an alternate method for vessel contact assessment, such as reverting to human assessment, is required.

The application will require output assessment feedback specific to each user type. While both require some level of comparison to both global and individual historical data, the content and frequency of the feedback will be user specific.

In the case of the trainee, the feedback can be a direct comparison to required performance criteria for cannulation success, and to historical data for vessel contact and time performance. In addition to this, the trainee would be provided with trend analysis on their own performance specific to the procedure parameterization.

When used as a decision support tool by professional practitioners, there are further considerations when giving performance feedback. Surgeons may be unwilling to use such an application if it is highlighting areas of weakness, which they may be directly assessed against. It may seem that this is a desirable function of the application, but such information may result in resistance or resentment among the potential user community, which must be avoided if such an application is to be successful.

4. DISCUSSION

This study has defined a conceptual model and initial information requirements for a catheterization training and decision support application. The information requirements themselves can be met with available historical data and further developed as the application produces data. Although this study defines a design framework and associated requirements, there are still significant risks and challenges that need to be reduced and mitigated to develop the application.

Firstly, there is a visual difference between the raw simulator imagery and the fluoroscopy imagery. While ensuring a representative frame rate, field of view and resolution is achievable through commercial video processing methods, the contrasts between tissue areas and blood vessel maybe somewhat harder to achieve. This will require contrast adjustments and potentially localized image manipulation;however, any solution must be compatible with near real time image processing.

The second major risk is the ability of ML algorithms to select a suitable wire-catheter combination given the parameters defined. There is no standard performance metric for catheter selection as this is currently conducted based on individual preference and without rigorous training or selection requirements. As such the performance of the application needs to be compared to the success rate of historical data. For this reason, it is important that a scalable development process is used, starting on low fidelity simulators to ensure the advice given results in performance at least as good as existing procedure results, subject to the same assessment criteria. The development application should always be defined as an advisory system as the predictive ability of the algorithm will only ever be able to be successful if the procedure involved is representative of existing data in the historical database. In addition, the system should be fully compliant with all guidance in COCATS 4 (King et al., 2015).

There are additional risks associated with automation in the performance assessment elements of the application. Both the total wire-catheter movement and the vessel wall hit count are dependent on ML algorithms. To some extent, the initial research into the wall hit algorithm has somewhat reduced this risk, although this initial use of a 2D CNN did not generalize well and as a result, further development is required.

The final challenge involved with the application development is the need to store information and provide feedback that might be sensitive and subject to specific security requirements, especially in the case of professional practitioners who will be primarily using the application as a decision support tool. While these risks and challenges are not insignificant, the initial results are promising and there are potential alternative solutions that may be employed if successful resolutions cannot be achieved.

Future research will ideally include the design and build of a prototype training system with integrated AI-based catheter selection model and wall-hit image classifier. Once working prototype is available, a between-subjects, repeated measures experiment to test if the simulator improves performance in a representative population is proposed. A control group will conduct an initial training based on traditional methods, while the experimental group will use the training simulator. A final one-way ANOVA performance assessment against a suitable baseline test will be used to judge any variation due to the catheter insertion simulator.

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