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3D SIMULATION FOR INTERVENTIONAL CARDIOLOGY PROCEDURES - FACE AND CONTENT VALIDITY

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3D SIMULATION FOR INTERVENTIONAL CARDIOLOGY PROCEDURES - FACE AND CONTENT VALIDITY

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Abstract

Introduction: Three-dimensional (3D) model simulation provides the opportunity to manipulate real devices and learn intervention skills in a realistic, controlled, and safe environment. To ensure that simulators provide a realistic comparison they must undergo scientific validation. We aimed to evaluate a 3D-printed simulator SimuHeart® for face and content validity, to demonstrate its value as a training tool in interventional cardiology.

Methods: We recruited healthcare professionals working in interventional cardiology from sixteen hospitals across Portugal. All participants received a 30-minute theoretical introduction, 10-minute demonstration of each task and then performed the intervention on a 3D-printed simulator (SimulHeart®) for 2 hours. Finally, a post-training questionnaire testing the appearance of the simulation, simulation content and satisfaction/self-efficacy was administered.

Results: We included 56 participants: 16 “experts” (general and interventional cardiologists), 26 “novices” (cardiology residents), and 14 nurses and allied professionals. On a five-point Likert scale, the overall mean score of face validity was 4.38 ± 0.35, while the overall mean score of content validity was 4.69 ± 0.32. There was no statistically significant difference in the scores of “experts” and “novices”. Participants reported a high level of satisfaction/self-efficacy, 60.7% considered it strongly improved their skills. The majority (82.1%) agreed or strongly agreed that after the simulation they felt confident to perform the procedure on a patient. Additionally, 96,4% “agreed” or “strongly agreed” that the simulator should be integrated in the cardiology residency curriculum. The mean score (on a 10-point Likert scale) in general terms for the use of the model in training was 9.41 ± 0.80.

Conclusion: Our 3D-printed simulator showed excellent face and content validity. 3D simulation might play an important role in interventional cardiology training programs. Further research is required to correlate simulator performance to clinical performance in a real patient.

Keywords: Education, Revascularization, Percutaneous coronary intervention, 3D-printing, Patient-specific simulation, Simulation training

1. Introduction

Simulation has been used for training in professions that require precise cognitive and physical tasks in high-risk environments, with potentially fatal complications. Currently, many non-medical professions require simulation as part of routine training or maintenance of competency and annual skills assessment (1). Multiple high-fidelity medical simulators have been developed, over the past decade, to address the 21st century challenges of rapid expanding new technologies, restrictions in work hours and a demand by regulatory bodies for simulation to be implemented in the medical field (2).

Interventional cardiology (IC) is a fertile field in which simulation can blossom, because of its highly complex procedures with a long learning curve and that involve life-threatening complications that are prone to a variety of medical errors (3). By using simulation in IC, the traditional approach "see one, do one, teach one" can be replaced with "learn the operation before the operation room" (4). However, an international survey of 172 cardiologists showed that only 48% had already participated in simulation training, even though 91% considered it to be "necessary" in cardiology (5). The importance of patient safety and prevention of medical errors define the rationale for simulation training – the prevalence of medical errors became evident since the publication of the institute of Medicine's report "To Err Is Human"(3).

Three-dimensional (3D) model simulation is a growing novel tool that can be used for educational purposes, training, or individualized medicine, and even patient empowerment. Its versatility allows to solve several shortcomings of clinical simulation, allowing to standardize a simulation platform with educational cases that are cheaper and more practical than traditional or cadaveric training (6). Simulators based on 3D printing offer an alternative way of learning in an immersive reality with real materials where trainees can make mistakes, repeat, and learn percutaneous intervention skills in a controlled, safe, and realistic environment.

Many studies have shown improvement in operator skills using simulations over traditional mentor-based training in specific IC skill sets (7, 8, 9, 10). Simulator-based training in coronary angiography improved operator skills compared with traditional mentor-based training – namely, there was a shorter procedure time, lower radiation dose, and a higher global procedure skill score (7).

The Education and Training European Association of Percutaneous Cardiovascular Interventions (EAPCI) published a recommendation for simulation sessions to be incorporated in training centers of IC (11) and the accreditation council for graduate medical education mandates that cardiovascular fellowship training programs include some component of simulation as part of fellow training (2). Therefore, it is expected that simulations will be incorporated into future training programs and certification examinations for interventional cardiologists.

To ensure that simulators provide a realistic comparison to real-life environment they must undergo scientific validation, according to different levels of evidence, following Kirkpatrick model for evaluating the effectiveness of training (12). This study aims to evaluate the 3D-printed simulator SimulHeart® for face and content validity.

2. Material and methods

This article was written following the author guidelines by the Medical Education Journal (https://onlinelibrary.wiley.com/page/journal/13652923/homepage/forauthors.html).

Participants:

This study recruited participants from four interventional cardiology simulation courses that occurred between November 2021 and November 2022. All individuals worked in cardiology, including medical residents, interventional cardiology fellows, sub-specialists in IC, nurses, and technicians. “Experts” were a group of interventional cardiology fellows and specialists. “Novices” included cardiology residents and nurses and allied professionals - NAP (including cardiology and radiology technicians). All of them performed a simulation protocol on a SimulHeart® 3D printed simulator. Study design was reviewed and approved by the local research ethics board. Participants were asked to provide written informed consent before enrolment.

Simulation protocol:

The simulation protocol started with a 30-minute theoretical introduction. Beginners were briefed on diagnostic coronary angiography and simple coronary intervention procedures, and fellows/sub-specialists were exposed to percutaneous coronary interventions (PCI) in complex bifurcations, calcified lesions, left main, post-transcatheter aortic valve implantation (TAVI) and intravascular imaging.

The simulation required the participants to perform the following tasks: selective catheterization of left and right coronary artery by radial or femoral access; PCI of calcified lesions with rotational atherectomy and/or litoplasty; PCI of bifurcation lesions and left main with provisional or two-stent techniques; PCI in a post-TAVI context and to perform and interpret intravascular imaging (with ultrasound or optical coherence tomography). All participants received a demonstration of each task and then attempt to perform it for two hours.

Table 1. Tasks performed in the SimulHeart® 3D printed simulator.

Tasks performed:
Selective catheterization of left and right coronary artery by radial or femoral access;
PCI of calcified lesions with rotational atherectomy and/or litoplasty;
PCI of bifurcation lesions and left main with provisional or two-stent techniques;
PCI in a post-TAVI context and intravascular imaging interpretation (with ultrasound or optical coherence tomography)

After each attempt participants were given oral feedback by the trainer. In the end, a 30-minute debriefing session was performed.

Simulator:

The 3D printing process is a complex three-step procedure (image acquisition, segmentation and printing); its detailed explanation is out of the scope of this article and reviewed elsewhere (13, 14, 15).

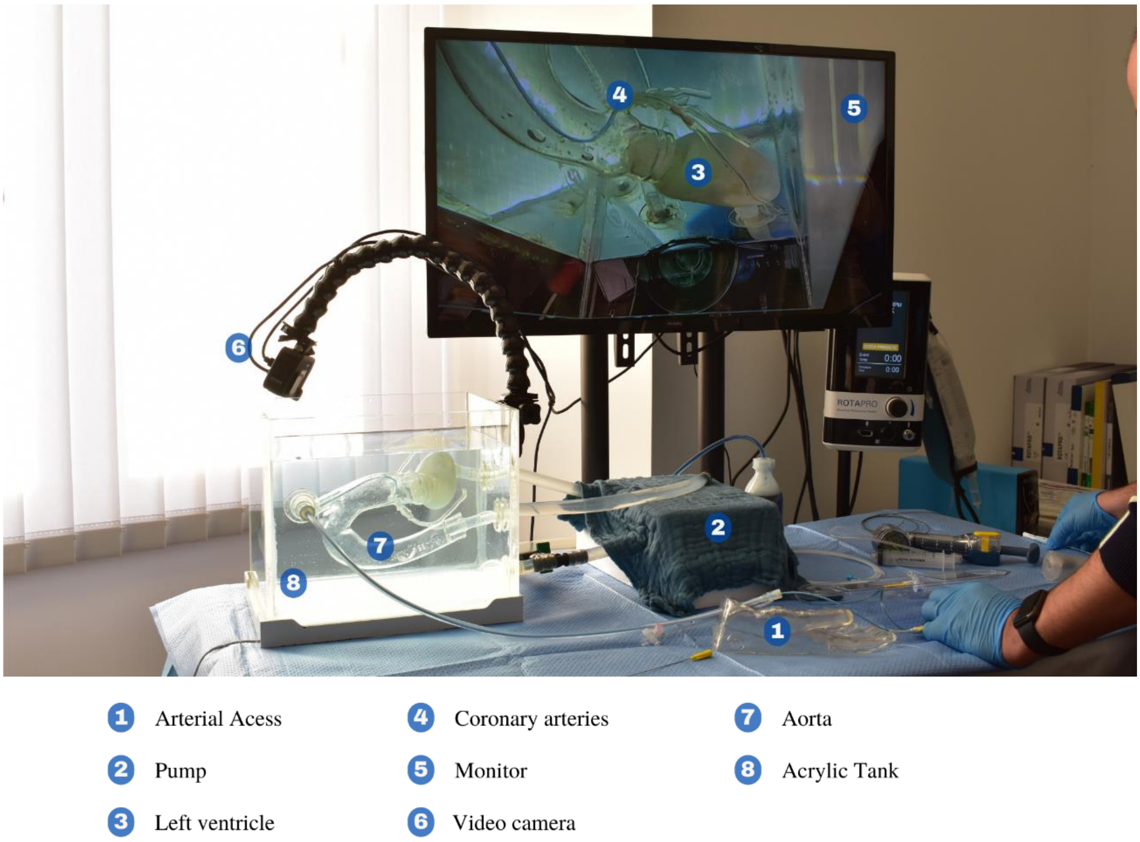

Figure 1. The SimulHeart® Simulation setup

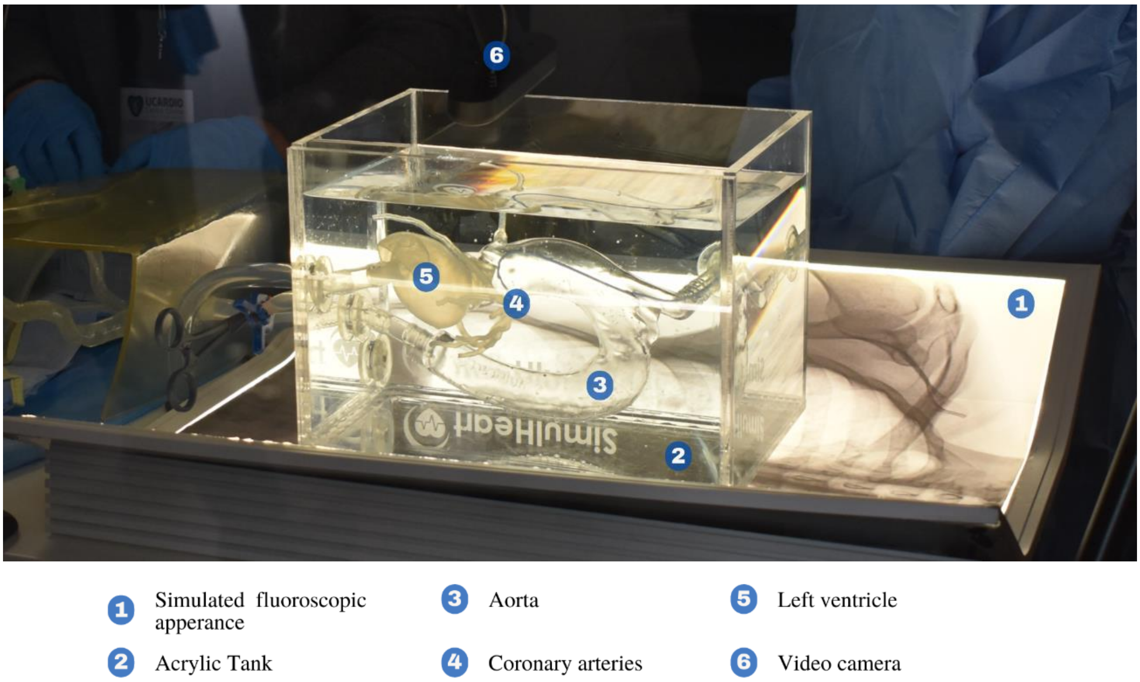

Figure 2. The SimulHeart® components.

For the development of the coronary model, two-dimensional angiography data of a real patient was rendered into a 3D volume depicting the proximal left coronary artery using CAAS-QCA-3D software (16) (Pie Medical Imaging BV, the Netherlands) and digitally added parts to the model to connect it to the simulator. The coronary anatomy was then printed in 3D using a stereolithography printer to obtain a final patient-specific coronary artery model made of custom hybrid flexible material of polyethylene and siliconized rubber, with a dual-layered design and filled with fluid. Finally, the coronary 3D-model was connected to our custom-made interventional cardiology simulator, the SimulHeart® (Coimbra, Portugal). The simulator (as shown in fig.1 and fig.2) is composed by an acrylic water tank, which is filled with water and where the 3D-printed vascular anatomical structures are inserted. The whole vascular structure is connected to a pumping system to simulate the arterial pressure of a patient, generating an authentic environment during the intervention. Its main features besides the 3D-printed vascular anatomy, include radial and femoral access sites that enable the use of actual diagnostic and interventional devices with realistic haptics feedback. The simulation was performed without ionizing radiation. Participants monitored the simulated procedure through a monitor, and usual projections were obtained by moving a video camera.

Questionnaire (research tool):

A post-training questionnaire was administered to all participants (appendix 1).

The questionnaire was developed by the research team, based on a literature review, and with the collaboration of a panel of specialists in IC from different Portuguese centers. The "expert group" met on two occasions, the first to brainstorm possible questions on face and content of the model and satisfaction with the course, and a follow-up meeting to decide the final items to be included on the questionnaire. The questionnaire involved three main areas: a) Appearance of the simulation with 13 items; b) Simulation content with eight items and c) Satisfaction and self-efficacy with seven items.

The simulator was assessed for face and content validity and learner satisfaction and self-efficacy, in concordance with definitions published in the literature (12, 17). Face validity is an assessment of realism, in which a defined group of subjects are asked to judge the degree of resemblance between the system under study and the real environment (17). Content validity examines the level to which the system covers the subject matter of the real performance (17). The evaluation is carried out by reviewing each item to determine whether it is appropriate for the test and by assessing the overall cohesiveness of the items, such as whether the test contains the steps and skills that are used in a procedure. The reliability of an evaluation instrument relates to its ability to provide consistent results with minimal errors of measurement. Test–retest reproducibility and internal consistency are the most used methods for estimating internal reliability (18).

Face and content validity were evaluated using "experts" (level V) and "novices" (level III) operator assessments of the simulator. This expertise difference was based on criteria established by EAPCI core curriculum for percutaneous cardiovascular interventions(11), where level V is defined as "Performance as the first operator without supervision and ability to teach/supervise more junior colleagues" and level III is "Performance as the first operator with reactive supervision, i.e., on request and quickly available". Using five-point Likert scale participants evaluated 13 aspects of the appearance of the simulator, eight domains of the content, and seven domains of satisfaction and self-efficacy. Higher scores indicated a more favorable assessment. Thresholds were set *a priori* as mean scores of <3.0, 3.0-4.0, and >4.0 for "unacceptable", "moderately acceptable" and "good", respectively. The literature lacks consistency on the thresholds used for the validation criteria of simulators, however, the majority of studies used similar thresholds and adapted them to a five-, seven-, or ten-point Likert scale (19, 20).

Statistical analysis

All data were collected and stored in a de-identified manner using a Microsoft Excel spreadsheet (2011, Microsoft, Redmond, WA, USA). Continuous data were described using mean ± standard deviation or median (interquartile range), according to the normality of the distribution. Categorical data were represented by frequency and proportion. Statistics were calculated using the IBM Statistical Package for Social Sciences, v28.0 (SPSS). An alpha of 0.05 was set for significance of all statistical tests.

3. Results

Fifty-six participants completed the study: 16 “experts”, 26 “novices” and 14 NAP from sixteen hospitals across Portugal. No participant had prior experience with the SimulHeart® simulator. Sociodemographic characteristics are explained in table 2.

Table 2. Participants sociodemographic characteristics

	Total	**Novice**	**Experts**	**NAP**
(n)	56	26 (46.4%)	16 (28.6%)	14 (25%)
Gender	F – 25(44.6%) M – 31(55.4%)	F – 13(50%) M – 13(50%)	F – 4 (25%) M – 12 (75%)	F – 8(57.1%) M – 6(42.9%)
Age	Mean: 35.6 ([26-60]	Mean: 29.3 ([26-35])	Mean: 31.1 ([31-60]	Mean: 44.3 ([30-55])

The questionnaire showed good values of internal consistency, with a global reliability of 0.93, measured by Cronbach’s alpha. The items of face, content, and satisfaction showed an internal consistency of 0.85, 0.81, and 0.87, respectively.

The overall mean score of face validity was 4.38 ([SD 0.35]) (with classifications varying from 2 to 5). The individual frequencies of the items that evaluated face validity are described in fig.3.

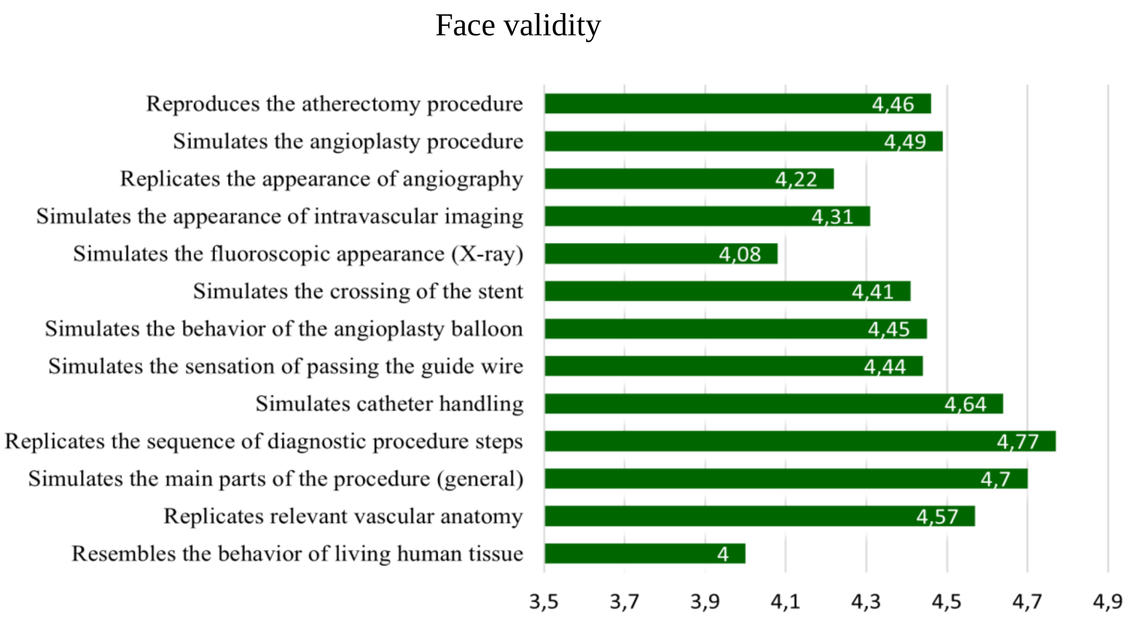

Figure 3. Mean face validity of individual items of the post-simulation training questionnaire

The overall mean score of content validity was 4.69 ([SD 0.32]) (only varying between 4 to 5 classifications) – fig.4.

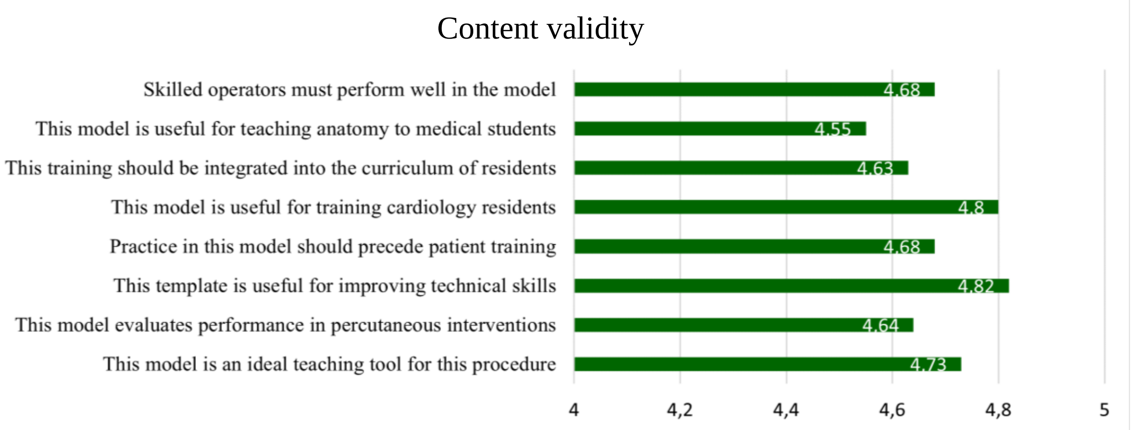

Figure 4. Mean content validity of individual items of the post-simulation training questionnaire.

In both face and content validity, there was no statistically significant difference in the scores of “experts” and “novices”.

Optional written narrative qualitative assessment by participants showed several common themes. Participants found the simulator to be “realist”, have “good fidelity” and be an “enriching formative experience”. Some participants, however, considered that the course should have “more hours of individual training”.

In the questionnaire satisfaction and self-efficacy were also measured, 80.4% strongly agreed that the course was well executed and interactive, 75.0% strongly considered the course improved their theoretical knowledge, 60.7% also considered it strongly improved their technique. After the simulation training, 67.9% strongly agreed that they felt confident to explain the procedure to a patient, and 82.1% agreed or strongly agreed that they felt confident to perform the procedure on a patient. The majority of participants (85.7%) strongly agreed they would recommend the course to colleagues.

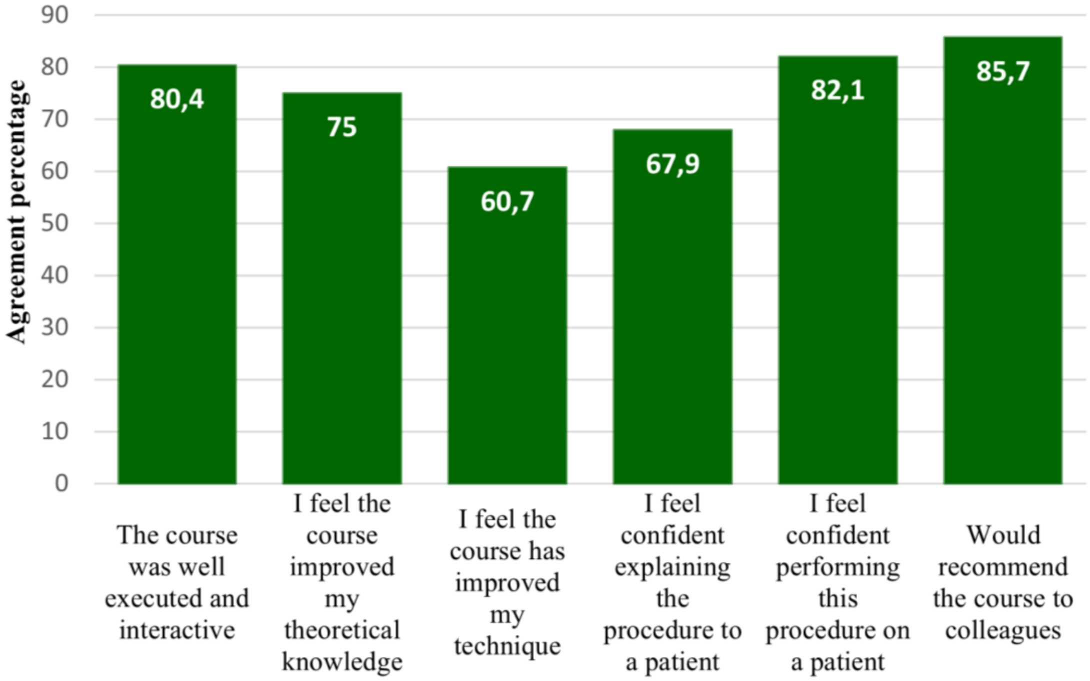

Figure 5. Agreement percentage on satisfaction and self-efficacy of individual items of the post-simulation training questionnaire.

The mean score (on a 10-point Likert scale, with 1 being not relevant and 10 very relevant) in general terms for the relevance of using this model in training was 9.41 (SD 0.80, Range [7-10]).

4. Discussion

Simulation is breaking barriers in the modern era of medical and surgical education. A 2019 study with Simbionix Angio-Mentor (Simbionix USA, Cleveland, Ohio) documented a significant improvement of skills in real-world practice (coronary angiography in patients) after simulator-based training(7). According to Popovic et al., the simulation group showed significant improvement in respect to contrast use, procedural time, fluoroscopic time, and global performance score in coronary catheterization in patients in the cardiac catheterization lab, after four hours of high-fidelity simulation training, in comparison to a control group. These findings documented an improved intra-operator performance in the clinical setting before and after simulation training demonstrating the impact of simulation on the transference of skills to real-life practice. They concluded that “simulation can be used as an assessment tool by defining a mastery threshold ensuring all individuals have reached a predefined level of proficiency to allow a safe patient care”.

With ever increasing pressures on surgical performance, the profession is eagerly looking for training systems that are novel, reproducible, and validated. The reality is trainees are operating less than ever before (21) due to shortened training programs, reduced working hours (22), and advancement of medical and minimally invasive techniques, therefore the application of 3D simulation technology is evident. Advancing 3D printing technology has been incorporated into cardiology training. This is particularly important in training for minimally invasive percutaneous procedures which are complex and leave little space for error. In this area a valid 3D simulator may reduce the learning curve and improve patient safety. This modality of simulation affords a unique opportunity for trainees to practice reality-based surgical skills without any risk to the patients.

While there are studies on 3D simulators for patient-specific percutaneous interventions (13, 23, 24, 25, 26, 27, 28, 29, 30), there is minimal data in the literature on the validation of 3D model simulators for training in cardiology. Common benchmarks on which simulators are judged include reliability, face, content, construct, and predictive validities (31). Even though there are some validated training devices and protocols for coronary angiography, the area has few well-established or validated tools.

This study showed that the SimulHeart® simulator for percutaneous interventions met the criteria for both face and content validity at a “good” level, based on the predefined definitions of validity. The simulator presents excellent realism and simulation of the procedure steps.

However, there is room for improvement. The criteria with the lowest scores were “resembles living human tissue”, with a mean score of 4, and “simulates the fluoroscopic appearance (x-ray)”, with a mean score of 4,08. These items would score higher if the simulation took place in an actual catheterization laboratory, with radiation and sterile drapes. That environment undoubtedly lacks practicality for widespread practical courses.

Despite the possible limitations, the vast majority of the participants (96,4%) “agreed” or “strongly agreed” that the training in the simulator should be integrated into the cardiology residency curriculum. Furthermore, the improved subjective confidence of “novices” participants suggests a benefit from training in the simulator and supports its use as an educational tool.

The categorization of participants as “experts” or “novices” was based on the definition of the EAPCI curriculum and was self-reported in the questionnaire by the participants. One of the limitations of our study was overall participant number was low (n=56), a more significant sample could have more statistical power to detect differences between groups and to evaluate construct validity. Expanding the study to a larger number of participants would be reasonable based on our results.

Despite not being able to measure it in the present course, for future investigation construct validity should be performed on the model.

5. Conclusion

The SimulHeart® simulator built by 3D CardioSolutions showed a good level of face and content validity. There was an improvement in satisfaction and efficacy, as well as improved confidence. Both “experts” and “novices” participants agreed that training in the simulator should be incorporated into the cardiology residency curriculum.

Based on our study, we suggest training in this simulator could be used in interventional cardiology for medical residents, fellows, and allied professionals to gain experience and skill in a safe environment.

Despite its benefits, there are still some obstacles to integrating simulation training in medical education programs, including high costs, limited access to simulation models, and lack of standardized curriculum incorporating simulation in IC.

Some limitations of our study should be considered such as the categorization of participants and subjective measurements being self-reported, and the simulator lacking construct validity to be able to recommend this simulator for the evaluation of participants' operative skills. Further research is required to correlate simulator performance to clinical performance in a real patient.

6. List of abbreviations

3D - Three-dimensional

CAAS-QCA - Cardiovascular Angiography Analysis System Quantitative Coronary Analysis

EAPCI - Education and Training European Association of Percutaneous Cardiovascular Interventions

IC - Interventional Cardiology

NAP- Nurses and allied professionals

PCI - Percutaneous Coronary Interventions

TAVI - Transcatheter Aortic Valve Implantation

7. Appendix

English version of the Portuguese Questionnaire

Demographic Questionnaire

1- Age: ______ years

2- Genre: ○ Female ○ Male

3- Hospital:
____

4- Categoria Profissional:
○ Medical student ○ Cardiology resident ○ Cardiologist (fellow) ○ Subspecialist in Interventional Cardiology ○ Nurse ○ Cardiopneumology Technician ○ Other: ________________

Evaluation questionnaire of the training with 3D model in percutaneous interventions

Indicate your level of agreement/disagreement with each of the following statements:

1- Appearance of the model:	**1 Totally disagree**	**2 Disagree**	**3 Nor agree nor disagree**	**4 Agree**	**5 Totally agree**	**Not aplicable**
Resembles the behaviour of living human tissue						
Replicates relevant vascular anatomy						
Simulates the main parts of the procedure (general)						
Replicates the sequence of diagnostic procedure steps						
Simulates catheter handling						

Simulates the sensation of passing the guide wire						
Simulates the behaviour of the angioplasty balloon						
Simulates the crossing of the stent						
Simulates the fluoroscopic appearance (X-ray)						
Simulates the appearance of intravascular imaging						
Replicates the appearance of angiography						
Simulates the angioplasty procedure						
Reproduces the atherectomy procedure						
2- Content of the model:	**1 Totally disagree**	**2 Disagree**	**3 Nor agree nor disagree**	**4 Agree**	**5 Totally agree**	**Not aplicable**
This model is an ideal teaching tool for this procedure						
This model evaluates performance in percutaneous interventions						
This template is useful for improving technical skills						
Practice in this model should precede patient training						
This model is useful for training cardiology residents						
This training should be integrated into the curriculum of residents						
This model is useful for teaching anatomy to medical students						
Skilled operators must perform well in the model						
3- Satisfaction and self-efficacy	**1 Totally disagree**	**2 Disagree**	**3 Nor agree nor disagree**	**4 Agree**	**5 Totally agree**	**Not aplicable**
The course was well executed and interactive						
I feel the course improved my theoretical knowledge						
I feel the course has improved my technique						
I feel confident explaining the procedure to a patient						
I feel confident performing this procedure on a patient						
Would recommend the course to colleagues						

4. 4. In general terms, how would you rate the training using this model (on a score from 1 to 10, with 1 meaning not at all relevant and 10 being very relevant): ______________________

5. Suggestions or Comments:

____

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9. Conflict of interest

The authors report no competing interests.

10. Author Contributions

CS and MOS contributed equally to the conceptualization, writing and revision of the work. JBR and LG contributed to the writing – review and editing of the work.

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