FACULTAT
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Develop anatomical devices using 3D technology to improve learning in medicine studies.

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Tell me and I will forget,
show me and I will remember,
involve me and I will understand.

(Dime y lo olvidaré,
muéstrame y lo recordaré,
involúcrame y lo entenderé.)

Benjamin Franklin

ABSTRACT

Background: Integrating theoretical knowledge with practical application is vital in medical education. Though 3D-printed models are not utilised in medical classrooms, advancements in 3D printing technology offer customization, cost reduction, and the elimination of animal sacrifices. Incorporating 3D printing in medical education could enhance precision, safety, skill development, and cost-effectiveness, particularly in anatomy and suturing training.

Objectives: Design a 3D prototype using printing technology. Evaluate two prototypes: inguinal hernia and suturable skin. Determine if the skin prototype enhances suturing techniques and improves training, leading to better learning and technique acquisition for future doctors.

Materials and methods: The inguinal hernia prototype underwent CT imaging, 3D reconstruction, printing, and validation. Specialists evaluated similarity, texture, and cutting resistance using a Likert scale. The suturable skin model followed a similar process and was validated with the System Usability Scale (SUS). Applicability and usability were assessed through a clinical trial with third-year medical students using questionnaires and the SUS scale.

Results: The skin and aponeurosis prototypes were satisfactory, while the hernia prototype showed partial results. Muscular tissue and fat prototypes had unfavourable outcomes. Students found the prototypes useful, but the surgeon did not. Technological specialists evaluated the prototypes positively.

Discussion: 3D-printed models are valuable for diagnosis and surgical planning, but more research is needed on integrating 3D printing in to medical education. Students prefer 3D models over cadavers. Further exploration is required to fully harness the potential of 3D printing in medical training.

RESUM

Antecedents: Integrar el coneixement teòric amb l'aplicació pràctica és vital en l'educació mèdica. Tot i que els models impresos en 3D no s'utilitzin a les aules de medicina, els avanços en la tecnologia d'impressió 3D ofereixen personalització, reducció de costos i la eliminació dels sacrificis animals. La incorporació de la impressió 3D en l'educació mèdica podria millorar la precisió, la seguretat, el desenvolupament de habilitats i l'eficiència econòmica, especialment en l'educació anatòmica i el entrenament en sutures.

Objectius: Dissenyar un prototip tridimensional utilitzant la tecnologia d'impressió. Avaluar dos prototips: hernia inguinal i pell suturable. Determinar si el prototip de pell millora les tècniques de sutura i l'entrenament, conduint a un millor aprenentatge i adquisició de tècniques pels futurs metges.

Materials i mètodes: El prototip de la hernia inguinal es va sotmetre a imatges de TC, reconstrucció 3D, impressió i validació. Els especialistes van avaluar la similitud, la textura i la resistència al tall utilitzant una escala Likert. El model de pell suturable va seguir un procés similar i es va validar amb l'Escala d'Usabilitat del Sistema (SUS). L'aplicabilitat i la usabilitat es van avaluar mitjançant un assaig clínic amb estudiants de medicina de tercer any, utilitzant qüestionaris i l'escala SUS.

Resultats: Els prototips de pell i aponeurosi van ser satisfactoris, mentre que el prototip de la hernia va mostrar resultats parcials. Els prototips de teixit muscular i greix van obtenir resultats desfavorables. Els estudiants van trobar els prototips útils, però el cirurgià no ho va fer. Els especialistes tecnològics van avaluar positivament els prototips.

Discussió: Els models impresos en 3D són valuosos per al diagnòstic i la planificació quirúrgica, però cal més investigació sobre la integració de la impressió 3D en l'educació mèdica. Els estudiants prefereixen els models en 3D en comptes de cadàvers. Cal explorar més a fons el potencial de la impressió 3D a la formació mèdica.

RESUMEN

Antecedentes: Integrar el conocimiento teórico con la aplicación práctica es vital en la educación médica. Aunque los modelos impresos en 3D no se utilizan en las aulas de medicina, los avances en la tecnología de impresión 3D ofrecen personalización, reducción de costos y la eliminación de los sacrificios animales. La incorporación de la impresión 3D en la educación médica podría mejorar la precisión, la seguridad, el desarrollo de habilidades y la eficiencia económica, especialmente en la educación anatómica y el entrenamiento en suturas.

Objetivos: Diseñar un prototipo tridimensional utilizando tecnología de impresión 3D. Evaluar dos prototipos: hernia inguinal y piel suturable. Determinar si el prototipo de piel mejora las técnicas de sutura y potencia el entrenamiento, lo que conduce a un mejor aprendizaje y adquisición de técnicas para futuros médicos.

Materiales y métodos: El desarrollo del prototipo de hernia inguinal incluyó cuatro fases: imágenes de TC, reconstrucción 3D, impresión 3D y validación del prototipo. Los especialistas evaluaron el modelo impreso utilizando una escala Likert, evaluando su similitud, textura y resistencia al corte. El modelo de piel suturable siguió un proceso similar y se validó utilizando la Escala de Usabilidad del Sistema (SUS). La aplicabilidad y usabilidad de ambos prototipos se evaluaron a través de un ensayo clínico con estudiantes de medicina de tercer año. Se utilizaron cuestionarios y la escala SUS con fines de evaluación.

Resultados: Los prototipos de piel y aponeurosis arrojaron resultados satisfactorios, mientras que el prototipo de hernia inguinal mostró resultados parciales. Los prototipos de tejido muscular y grasa obtuvieron resultados desfavorables. Los estudiantes encontraron los prototipos útiles, mientras que el cirujano no. Sin embargo, los especialistas tecnológicos evaluaron positivamente los prototipos. **Discusión:** Los modelos impresos en 3D han demostrado su valor en medicina para fines de diagnóstico y planificación quirúrgica. Sin embargo, existe una falta de estudios que se centren en la integración de la tecnología de impresión 3D en la educación médica. Los estudiantes muestran una preferencia por utilizar modelos en 3D en lugar de cadáveres. Se requiere más investigación para desarrollar modelos y aprovechar plenamente el potencial de la impresión 3D en la formación médica.

INTRODUCTION

Currently, in the medicine workshops at the University of Vic-Central University of Catalonia (UVic-UCC), theoretical elements of knowledge are combined with their application in a practical environment. In some subjects of the medical degree, cadavers or animals, such as pigs, are used to simulate human structures and characteristics to make them more realistic, such as touch, pressure, and texture, among others. To understand anatomy, medical students must use cadavers or experimental animals, as anatomy atlases do not provide the necessary three-dimensionality to assimilate the different structures.

Inguinal anatomy is even more difficult to understand due to its many layers. Nowadays, the use of 3D-printed models is very limited or non-existent in medical classrooms, and human cadavers (donated to science) or pigs (purchased from meat industries) are used in practical classes.

3D printing, also known as additive manufacturing, is a set of processes that produce objects by adding material in layers that correspond to the successive cross sections of a 3D model. The use of this technology as a teaching tool can contribute to improving learning for better **diagnosis, planning, treatment, rehabilitation, and health education** in a personalized way.

Students in the third academic year of the medicine degree at UVic-UCC take the Digestive and General Surgery subject, which includes a workshop about inguinal hernias. According to the curriculum of the subject "Provision, Processing and Elimination System. Digestion, Metabolism, and Detoxification", students learn about inguinal hernia **through PowerPoint slides** that provide information about this pathology and the recommended bibliography by professionals. This pathology, which is simple for surgeons, is highly complex for students, who need to first understand the anatomy of the hernia in order to comprehend the types of applicable surgery. Given this difficulty, the possibility of using technology and 3D abdominal printing to reproduce an inguinal hernia with the correct visualization of anatomy and attempting to simulate the texture of the different layers of the human abdomen is the aim of this study. In the medical profession, there is an ongoing consideration that sensory information (vision, touch, hearing and smell) also requires integration into the learning process.

To this day, 3D technology has experienced significant advancements in various medical fields, including the treatment of complex congenital heart diseases. In surgical planning, the heart is reconstructed and printed in 3D to provide a detailed visualization of both intracardiac and extracardiac structural abnormalities. [1] The process starts with an imaging test (such as Computed Tomography/CT or Magnetic Resonance Imaging/MRI), [2] from which images are extracted to reconstruct the heart, and specialized computer technology is used to visualize 3D images that simulate the structures to be analysed and the prosthetics to be used in each case. It has also been used during the COVID-19 pandemic to print protective materials in intensive care units, such as face shields or connectors for non-invasive ventilation systems. [3] Another medical specialty that has incorporated 3D printing is maxillofacial surgery. A systematic review on the usefulness of 3D printing of bone models in craniofacial surgery concluded that hospitals should invest in 3D printers for both educational and surgical purposes, as the results were satisfactory for training, simulation, and planning of oral and craniofacial surgical interventions.[4] Another author studied the effectiveness of using polyetherketoneketones (PEKK) in medical implants. It was found that the use of PEKK provided increased design freedom, incorporation of materials, antibacterial drugs, and improved bioactivity provided by porous designs like cancellous bone. Increased mechanical strength was also observed, which is important for material performance. [5] In the field of orthopaedic and trauma surgery, 3D printing addressed five concepts of surgical management: virtual visualization of tibial plateau fractures, 3D printed portable fracture models, pre-contouring of osteosynthesis plates, 3D printed surgical guides, and intraoperative 3D imaging. The results showed that this technology could reduce surgery time, decrease blood loss, and reduce fluoroscopy frequency, although no differences were found in functional outcomes. [6] Finally, a meta-analysis of 58 articles on the surgical treatment of post-traumatic orbital fracture reconstruction demonstrated positive results, including reduced surgical time, improved orbital volume symmetry, and enhanced management of diplopia and enophthalmos. [7]

There was a study conducted to evaluate first-year medical students and teachers' use of 3D-printed heart models in anatomy education. The results showed benefits in terms of accessibility, consistency, and the potential for evaluating anatomy, although further research is needed for their use in summative assessments. [8]

In another pilot study, a 3D-printed silicone suturing trainer was developed. The results indicated that the silicone trainer achieved better outcomes compared to porcine tissue. The students perceived this technique as improving their suturing skills significantly. [9]

Although 3D printing alone was a more satisfactory technique compared to conventional methods, being a safer, more accurate, and more effective complement, evidence on the routine use of 3D printing in the healthcare system is still limited, and 3D printing of soft tissues remains a challenge in medicine. 3D technology offers customization and reproduction of physiological and pathological structures of the human body. Replacing an animal specimen with a synthetic model also reduces the costs associated with caring for, feeding, and maintaining a farm animal, and it is also more ethical as it eliminates the need to sacrifice an animal for surgical practice.

Another advantage of a 3D-printed model is the durability of the material used for printing, which has a longer lifespan and a consistency like a human being compared to an animal. Animal specimens need to be preserved in refrigerators to prevent decomposition, and once they are used, they must be discarded. On the other hand, a 3D-printed model only needs to have the movable block changed, and the static model (adaptability) can last for years with minimal maintenance, reducing costs.

3D printing is a revolution of recent years, and there is no better way to use it than in the field of education, as it will create better professionals by increasing their precision in surgical skills, ensuring safety for both the professional and the patient, improving surgical and technical skills, and enhancing cost-efficiency for the university.

HYPOTESIS

3D printing of anatomical models for inguinal hernias can be a complementary resource to pig models in the workshop where abdominal wall pathologies and hernias are explained. Additionally, students can benefit from a skin model for suture practise. The use of this technology will enhance the learning of abdominal anatomy and the complexity of inguinal hernias and their treatment, as well as improve students' skills in suturing techniques.

OBJECTIVES

Overall objective:

The overall objective (1) is to **design a three-dimensional prototype** in the beta phase using 3D printing technology and validate the prototype.

Operational objectives:

Another objective is to **evaluate two prototype designs in three dimensions** in the beta phase using 3D printing technology. The first one is the inguinal hernia, and the second one is suturable skin (2).

The secondary objectives are (3): **determine if the use of prototype skin improves applicable surgical techniques** (suture) and **improve the training** of future doctors using 3D technology, acquiring greater learning and technique.

MATERIALS & METHODS

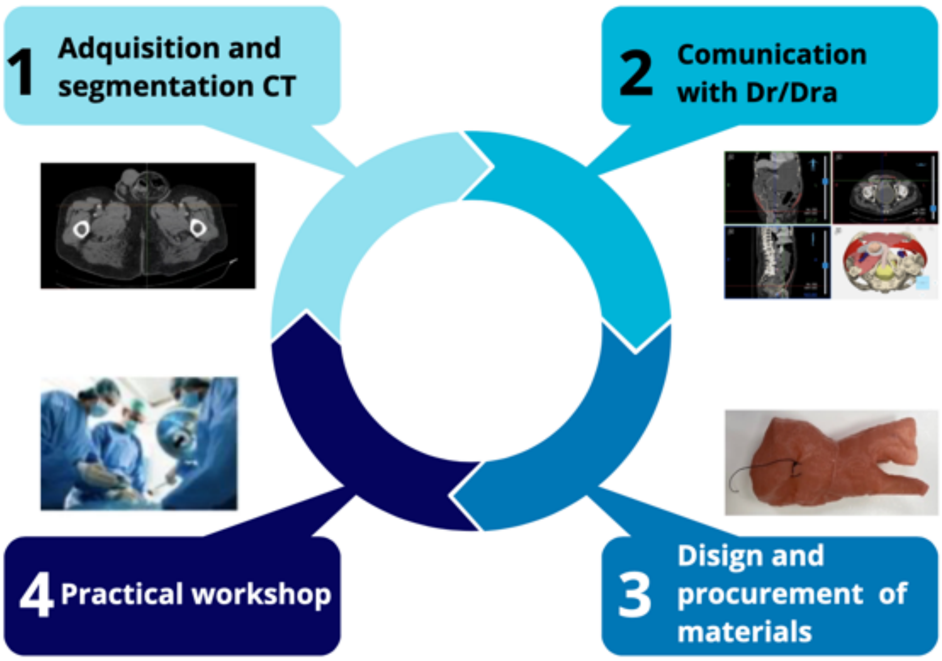
OBJECTIVE 1 & 2: PROTOTYPE DESIGN AND VALIDATION

1. BETA PROTOTYPE OF HERNIA INGUINAL

Development of a beta prototype of inguinal hernia anatomy using 3D printing technology.
The process consisted of four phases:

- **Obtaining an image** of the inguinal hernia through CT imaging
- **3D reconstruction**
- **3D printing**
- **Prototype validation**

The design of the abdominal prototype of the inguinal hernia follows regulations 1 and 2 of medical devices (EU Regulation 2017/745 of the European Parliament): creation and manipulation.



1.1 PROTOTYPE DESIGN

Obtaining the image*:* The image was selected by experts from the General Surgery Team at Sant Joan de Deu-Althaia Hospital (HSJD-Althaia). Finding CT images of an inguinal hernia was challenging due to the fact that its diagnosis is clinical and imaging tests are not typically used.

Three suitable CT scans were found to be suitable for reconstruction by the engineer (Figure 1). An important point to consider is that CT cuts must range from 0.5mm to 1.5mm to import the correct images for reconstruction.

Avinent is a company based in Manresa, Spain, that utilises 3D printing technology to provide innovative solutions across various industries. Their expertise lies in leveraging advanced 3D printing techniques to create cutting-edge, customised, and high-precision products. Avinent was the company responsible for the 3D reconstruction of the prototypes and carried out the printing because it is the company that has an agreement with the hospital to perform 3D reconstructions for complex surgical cases.

The three CT studies were securely sent to Avinent's platform in DICOM format, ensuring patient anonymity. The studies had a diagnostic orientation, specifically focusing on inguinal hernias, and specified that the requested product was a personalised anatomical model for medical students at UVic-UCC. This information (Annexe 1) is crucial for the company to apply the appropriate level of quality control.

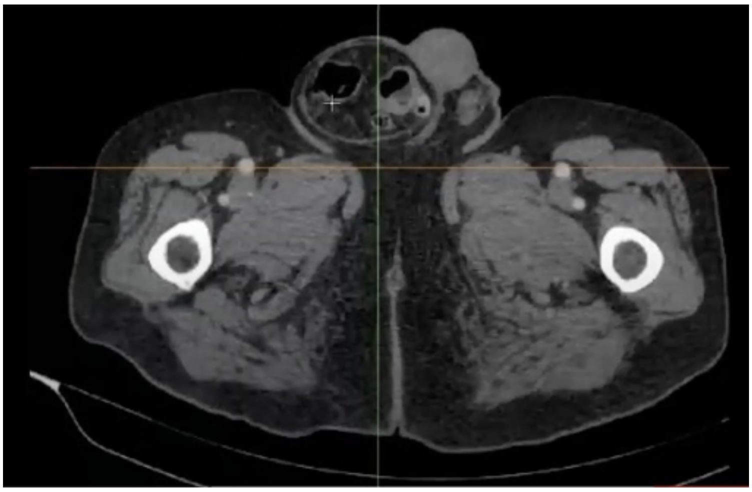


Figure 1: CT Helix Abdomen Simple Axial Section – Inguinal Hernia.

3D reconstruction by segmentation of the CT image: First of all, the biomedical engineer from Avinent receives the CT scan in DICOM format and classifies the product as Class I (surgical planning model) according to *Annexe 1.* Secondary, the CT scan images are imported into certified software for designing, diagnosing, and planning medical and surgical procedures, specifically the Mimics Materialise software®, to create the final virtual design (Figures 2 and 3).

The engineer, with the information provided by the responsible surgeon, made an initial proposal based on the design requirements. In a meeting between the doctor and the 3D specialist, they discussed the specific structures that should be visible in the inguinal hernia surgery technique, including factors such as size, hardness, flexibility, density, colour, and textures (measured using the Shores scale). The doctor's input was essential in determining how the prototype should resemble the physical characteristics of the real human body. During the validation process, incisions and sutures were performed to assess the material's resistance. All these model iterations were conducted using the Mimics Viewer Materialise software, with annotations documenting the necessary corrections to be made.

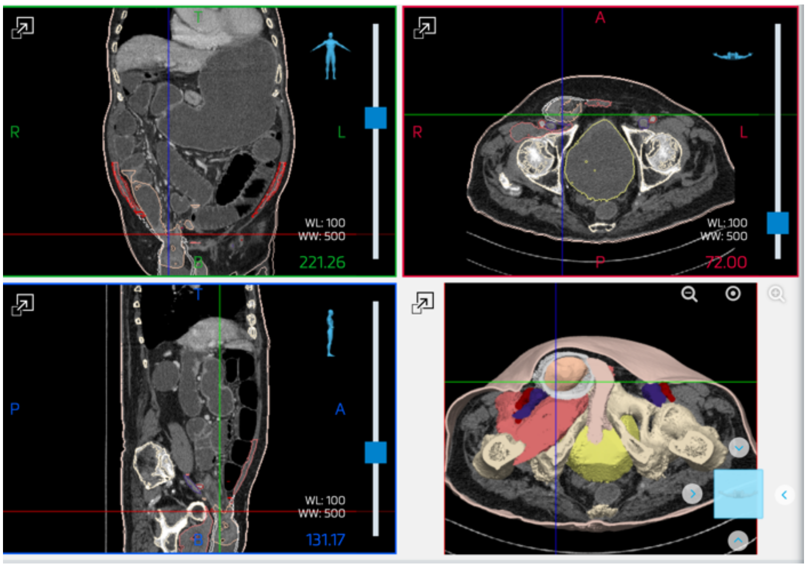


Figure 2: 3D reconstruction of an inguinal hernia using Mimics Materialise software. Different CT projections and anatomical structures of interest are marked in different colours.

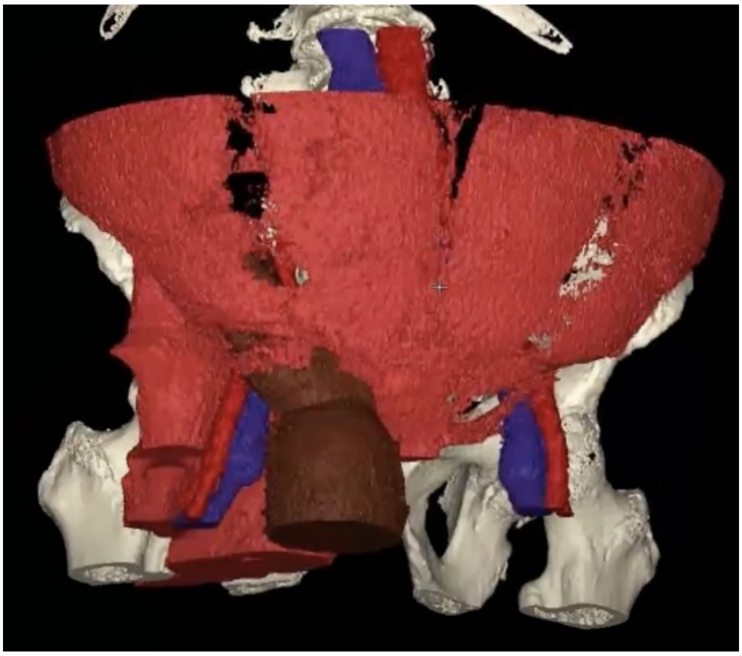


Figure 3: 3D visualisation of the muscles of the abdominal wall, hernia, blood vessels, and bones.

3D printing: Two types of 3D printers were used:

- Silicone 3D printer: The Project Silicone Printer, which utilised AMSii and Silbione technology from Elkem, provided us with silicones that could achieve shores ranging from 0 to 90K.
- Reverse silicone printing: The Stratasys J850 Techstyle from Avinent allowed us to acquire structures in different colours and with shores exceeding 40K. It allows us to make the moulds of the different fabrics to carry out the 3D printing technique by moulding.

1.2 VALIDATION

The validation was carried out by different professionals from different disciplines: a specialist physician in general surgery, a biomedical engineer, and a technology and materials engineer. In this phase, three areas were evaluated to determine if the product was of good quality: similarity, texture or density, and resistance to cutting or tearing. A Likert-type scale was used, where 1 represented 'not suitable' and 5 represented 'suitable'. The final score for each area evaluated was determined through consensus among the three professionals. The minimum average score required for the product to be considered valid was 3.

2. PROTOTYPE SKIN SUTURABLE

2.1 DESIGN OF SUTURABLE SKIN

The creation of suturable skin involves several critical steps. Firstly, a 3D model is created using software such as Autodesk Fusion 360, SolidWorks, or certified software such as Mimics Innovation Suite® (MIS®), which allows for the import of medical images (DICOM) and segmentation of anatomy to create precise 3D models. In our case, we have used MIS software.

It's important to note that creating 3D models from CT scans requires advanced knowledge in medical image processing and 3D design. Additionally, the quality of CT images can affect the accuracy of the 3D model, so obtaining high-quality images is crucial.

Acquisition of CT images: The first step in creating a 3D model of suturable skin involves obtaining high-quality images through computed tomography (CT) scans of the skin. CT scans with a slice thickness of 0.5 to 1 mm are used to ensure the accuracy of the 3D model. The images are then processed and segmented to separate the skin from other tissues and structures.

3D model: Once the images have been obtained, a 3D model is created using MIS software. This model can be adjusted as needed to accommodate specific features or requirements of the final product. The creation of the 3D model is a crucial step in the development of suturable skin, as it allows for visualisation and modification of the skin structure prior to physical production.

Printing: Once the 3D model has been created, it can be printed using a 3D printer capable of printing flexible materials such as silicone. Proper printing settings must be used to ensure the accuracy and detail of the model.

2.2 PRINTER AND SILICONE MATERIAL SELECTION

The Delta Tower Fluid ST is a fluid 3D printer that offers precise dosing for additive manufacturing with fluids and pastes of different viscosities. It is suitable for working with one- or two-component materials such as silicones, LSR, resins, PU, ceramics, and other substances.

Unlike other dosing systems, extrusion with ViscoTec dosing pumps can also be reversed (retracted), allowing for controlled material breakage without dripping. The minimum possible extrusion amount is 0.0208 µl. Due to the delta kinematics, the printing platform is stationary, and only the printing head moves in all three axes. Therefore, the workpiece is not exposed to vibrations and cannot be deformed.

2.3 POST-PROCESSING

Common 3D printing processes for polymers, such as FDM, SLA, and SLS, offer various materials in this hardness range, with varying degrees of similarity in other important properties of silicone, such as durability, thermal stability, UV resistance, food safety, biocompatibility, and colour and translucency options.

After the 3D printing process is complete, additional adjustments can be made to improve the appearance and functionality of the model. These adjustments may include cutting and shaping the model to better fit its intended application. Silicones typically have a SHORE hardness in the range of 10A to 80A.

2.4 VALIDATION

The validation of the skin was gradually evaluated, having tested different skins until reaching a suitable texture that could be applied to the general prototype of the inguinal hernia. In this phase, we evaluated the usability of the prototype. It was evaluated by the three professionals (surgeon, biomedical engineer, and product/materials engineer) using the SUS scale.

The scale provides a result from 0 to 100, where a score of 0–25 indicates the worst imaginable, 25–50 represents poor, 50–70 signifies OK, 70–80 stands for good, 80–85 represents excellent, and 85–100 indicates the best imaginable. The minimum score required for the product to be considered useful is 50 points. Each discipline will objectively evaluate the prototype using this scale from their perspective.

OBJECTIVE 3: USABILITY AND APPLICABILITY OF PROTOTYPE SKIN SUTURABLE

Study design

The study is a randomised, crossover clinical trial conducted among third-year medical students at UVic and UCC.

The study was approved by the Research Ethics Committee of the University of Valencia, Central University of Catalonia, under the code 248/2023. The study fully adhered to all applicable local legal and regulatory requirements as well as the principles outlined in the Declaration of Helsinki.

Study subjects and recruitment

The study was conducted in the classrooms of the Teaching Unit of the Faculty of Medicine at Vic-UCC in Manresa. Students over 18 years old enrolled in the course *"Provision, Processing, and Elimination Systems IV. Digestion, Metabolism, and Detoxification"* during the academic year 2022-2023 were included.

Students who did not attend the practical class on suturing technique were excluded from the study.

Randomization

An online service (http://www.pinetools.com/es/generador-numeros-aleatorios) was used to generate randomization sequences in blocks of 5 patients, in order to ensure a balanced distribution between the two study groups. The allocation sequence was kept concealed internally. During the class, the researchers recruited the students and assigned them to the groups according to the randomised list. The allocation ratio was 1:1.

Study arms

The theoretical class was delivered simultaneously in both Group 1 and Group 2. The duration of the theoretical part was 30 minutes. During this part, a brief explanation was provided on the suturing technique, the necessary materials, and the different types of sutures, with a special emphasis on the simple stitch.

In Group 1, students performed a suturing practise using half of a pig's face cadaver. In this practise, they first practised the simple stitch, followed by the continuous stitch, and finally the subcuticular stitch. The duration of the activity was 30 minutes. Subsequently, they practised the same technique and types of sutures using the 3D prototype. This practise also lasted for 30 minutes.

In Group 2, the order of the techniques was reversed, starting with suturing using the 3D prototype and then with the pig's face cadaver.

Finally, in both groups, a test was conducted to evaluate various aspects, such as the applicability of 3D prototypes in medical classes, the comparison between suturing on animals and on 3D prototypes, and the usability of the 3D prototype.

Primary outcomes measures

During the test carried out in the final part of the class, various aspects were evaluated. Firstly, the applicability of 3D prototypes in medical classes was assessed. Four questions were formulated, requiring a yes or no response.

Furthermore, a comparison of techniques was conducted using a Likert scale. Finally, the utility of the prototypes was evaluated using the System Usability Scale (SUS).

Statistical Analysis

Sample size

All students from the third year of the teaching unit in Manresa have been selected ($n = 40$). This sample size provides a statistical power of 80%, assuming a type I error of 5% and a difference between groups ≥ 0.89 units of the common standard deviation.

Statistical analysis

Continuous variables were analysed using means and standard deviations for normally distributed data and medians and 25th and 75th percentiles for non-normally distributed data. Categorical variables were summarised using absolute values and relative frequencies. Significance tests were conducted to detect significant differences between the baseline characteristics of Group 1 and Group 2 and between outcomes. A student's t-test was used for continuous variables. Fisher's exact test was used to compare categorical variables. A bilateral α level of 0.05 will be considered statistically significant. The data were analysed using version 29 of the IBM SPSS Statistics programme.

The researcher who analysed the data was blind to the study group.

RESULTS

OBJECTIVE 1 & 2 PROTOTYPE DESIGN AND VALIDATION

1. BETA PROTOTYPE OF HERNIA INGUINAL / SUTURABLE SKIN

1.1 PROTOTYPE DESIGN

Rectangular samples with different densities (measured in SHORES) were obtained. Experts selected samples that closely resembled each type of tissue of interest, such as skin, aponeurosis, fat, muscle, peritoneum, and hernia. This selection process took a couple of months until the optimal density was found.

Next, the different tissues were printed using a silicone printer. The results are shown in Table 1. However, since the results were not satisfactory according to the experts, the 3D printing technique using inverse modelling was chosen.

The results obtained with this technique were more satisfactory compared to the other technique, although some changes were necessary, as shown in *Tables 1 and 2*.

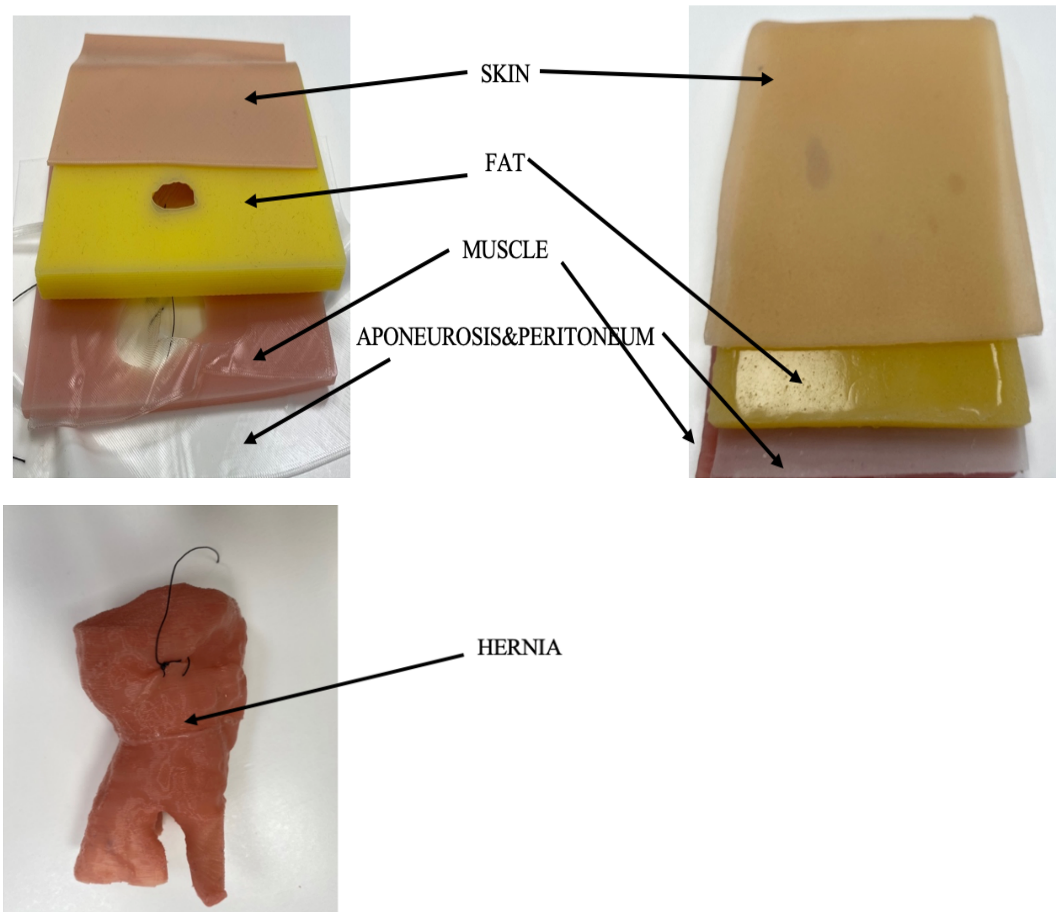
Skin was the tissue that had the greatest similarity and ability to be sutured. Therefore, a suturing workshop was organised in the digestive subject for third-year medicine students at the University of Vic, using a 3D-printed suturable skin prototype.

***Table 1*: Validation of tissues in both 3D printing methods.**

PROTOTYPE INGUINAL HERNIA *(02/2023)*	**Silicone printer**	**Reverse silicone printing**
SKIN	Yes	Yes
FAT	No	Yes
MUSCLE	No	Yes
APONEUROSIS & PERITONEUM	Yes	Yes
HERNIA	Yes	No

Table 2: Printing result.

Silicone printer	Reverse silicone printing



1.2 VALIDATION

To validate the final model printed using inverse modelling, a Likert-type scale was applied, and the results obtained are shown in *Table 3.* Both the skin and the aponeurosis and peritoneum achieved the best results, as all three evaluated dimensions (similarity, texture, and resistance) scored above 3, indicating that the product is valid. The characteristics of the muscle were not well evaluated by the professionals due to different deficits since it was not similar to human musculature, the density was very high, the resistance to cutting was null, and the appearance was awful.

***Table 3*: Final validation of 3D models**

PROTOTYPE INGUINAL HERNIA (*02/23)*	**Similarity**	**Texture/Density**	**Resistance to tall / tear**
Skin	4	3	4
Fat	2	1	1
Muscle	1	1	1
Aponeurosis & Peritoneum	4	4	4
Hernia	3	4	4

2. SUTURABLE SKIN

The doctor rated the prototype at 47.5, indicating that it is not useful for daily practise. The biomedical engineer, on the other hand, rated it 60, considering it to be quite useful. Finally, the materials engineer rated the prototype at 65.5, suggesting that it is useful. *(Table 4)*

Table 4: System Usability Scale (SUS) Professionals.

	DOCTOR	**BIOMEDICAL ENGINEER**	**MATERIALS ENGINEER**
SUS SCORE	47,5	60,0	65,5

OBJECTIVE 3: USABILITY AND APPLICABILITY OF PROTOTYPE SKIN SUTURABLE

All students enrolled in the Digestive and General Surgery course (n = 51) were selected in their entirety for the suturing class. Only 10 students attended, who were randomised into two groups of five individuals each. Group 1 began the activity with suturing on a pig cadaver, while the second group started with 3D printing. The questionnaires they completed were subsequently analysed. *(Figure 4)*.

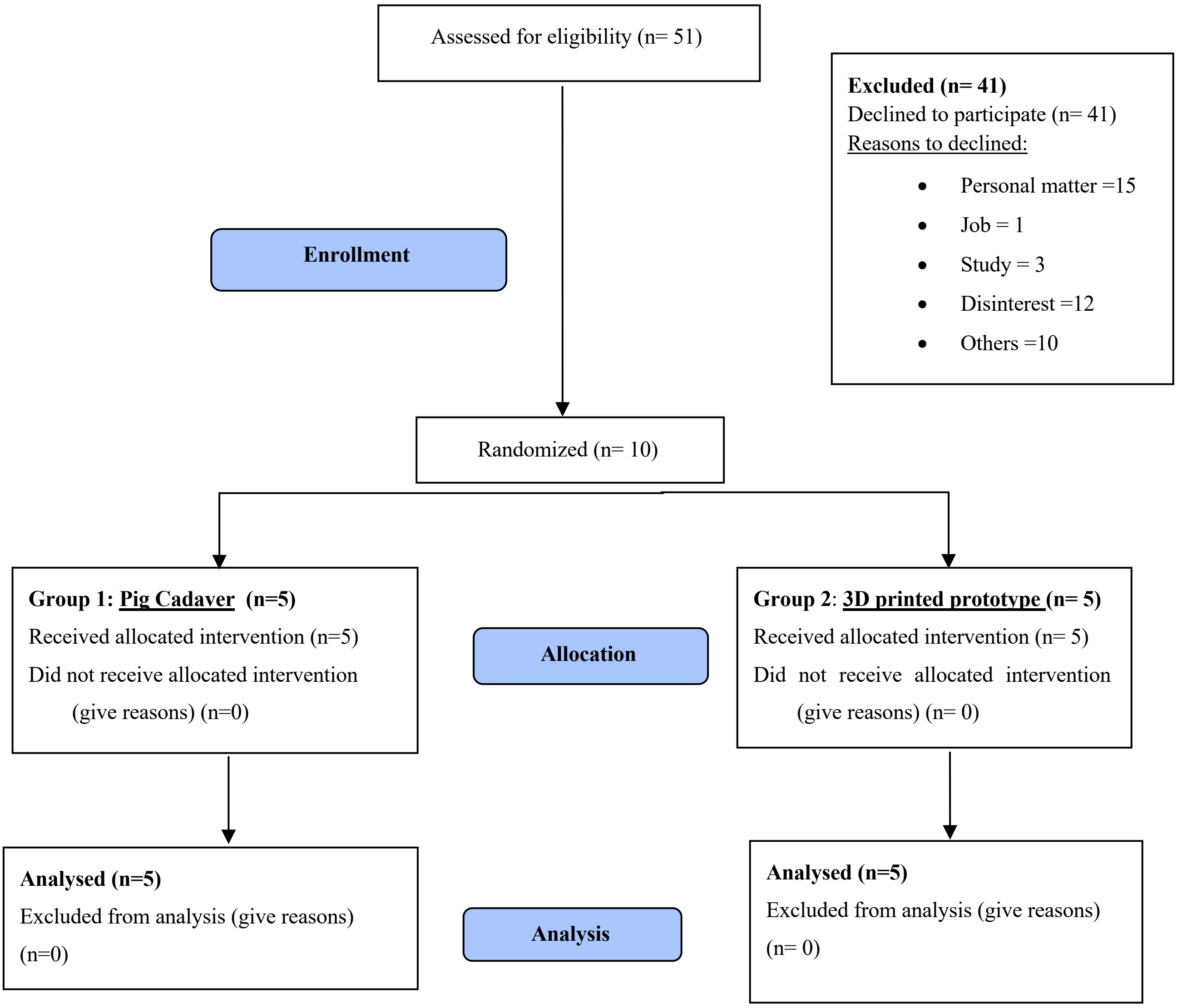


Figure 4: Flow-chart of the screening and selection of patients.

The groups were comparable in terms of sex and age. Most of the students were in their third year of medicine, but 40% of them were in their fourth year. Generally, students didn't have any other studies except for the two who had studied nursing and were distributed in both groups. When asked about previous experience with sutures, there was no difference between the groups. Regarding the material used by the students before, most of them had practised using animals. *(Table 5)*

Table 5: Baseline characteristics. Comparison between Group 1 and Group 2.

	GROUP 1 n=5	GROUP 2 n=5	p-value
Sex			0,527
Male	2 (40%)	3 (60%)	
Female	3 (60%)	2 (40%)	
Age (years)	22,60 (2,5)	22,40 (1,5)	0,883
Course			0,114
Tirth course	3 (60%)	5 (100%)	
Fourth course	2 (40%)	0 (0%)	
Other studies			1,000
Yes (nursing)	1 (20%)	1 (20%)	
No	4 (80%)	4 (80%)	
Suture			0,766
0	2 (40%)	3 (60%)	
1 to 5	2 (40%)	1 (20%)	
5 to 9	0 (0%)	0 (0%)	
> 9	1 (20%)	1 (20%)	
Material			0,37
Animal	4 (80%)	3 (60%)	
Artificial	0 (0%)	1 (20%)	
Animal + Human	0 (0%)	1 (20%)	
Animal + Artificial + Human	1 (20%)	0 (0%)	

n (%); mean (standard deviation); t student test; Fisher's exact test

When discussing the overall experience with the 3D-printed prototype, the students pointed out that they were mostly satisfied with the product. Additionally, the students expressed a desire to replace a theoretical workshop with a 3D-printed prototype for the suturing class. The students' opinions about replacing conventional workshops with 3D workshops for complex anatomy pathologies vary, but it indicates a shift towards adopting 3D workshops. When we asked if students would like to use 3D prototypes as a learning method, the answer was clearly "yes" *(Table 6)*.

Table 6: Utility of 3D prototypes in medical classes.

	GROUP 1	GROUP 2	p-value
	n=5	n=5	
Has your overall experience with the 3D printed prototype been satisfactory?			1,000
Yes	5 (100%)	4 (80%)	
No	0 (0%)	1 (20%)	
Would you replace a theoretical workshop with this type of suturing class?			-
Yes	5 (100%)	5 (100%)	
- No	0 (0%)	0 (0%)	
Would you replace conventional (theoretical) workshops with workshops that use 3D technology, especially in complex anatomy pathologies?			1,000
Yes	4 (80%)	3 (60%)	
No	1 (20%)	2 (40%)	
Would you use 3D prototypes as a learning method alongside theoretical classes?			-
Yes	5 (100%)	5 (100%)	
No	0 (0%)	0 (0%)	

n (%); Fisher's exact test; -: not applicable

In general, students think that the colours are not well represented in 3D prototypes and that the texture is not similar to that of humans. Additionally, they find it difficult to identify the individual layers in the prototypes. However, it should be noted that their preference for performing sutures on 3D prototypes instead of on animals is not statistically significant. *(Table 7)*

Table 7: Comparison of the suturing technique using a 3D prototype vs. a pig cadaver. Comparison of the texture, colour, identification of the structures, and suturing between both groups.

	GROUP 1 n=5	GROUP 2 n=5	p-value
Is the texture similar between the technique using pig cadavers and the 3D printed prototype?			0,714
None	0 (0%)	1 (20%)	
Little	1 (20%)	1 (20%)	
Neutral	3 (60%)	1 (20%)	
Somewhat	1 (20%)	2 (40%)	
Very	0 (0%)	0 (0%)	
Is the color similar between the technique using pig cadavers and the 3D printed prototype?			1,000
None	1 (20%)	1 (20%)	
Little	0 (0%)	1 (20%)	
Neutral	1 (20%)	0 (0%)	
Somewhat	1 (20%)	2 (40%)	
Very	2 (40%)	1 (20%)	
Can you identify the different structures (layers) in the pig cadaver and the 3D printed prototype?			0,286
None	0 (0%)	1 (20%)	
Little	4 (80%)	1 (20%)	
Neutral	0 (0%)	0 (0%)	
Somewhat	1 (20%)	2 (40%)	
Very	0 (0%)	1 (20%)	
Can you perform suturing on the pig cadaver and the 3D printed prototype?			0,524
None	0 (0%)	0 (0%)	
Little	0 (0%)	0 (0%)	
Neutral	2 (40%)	1 (20%)	
Somewhat	0 (0%)	2 (40%)	
Very	3 (60%)	2 (40%)	

n (%); Fisher's exact test

As we can observe, students rated the prototype as 62-65 (this means that this 3D prototype is useful because it is rated >50).

Table 8: System Usability Scale (SUS) Students.

	GROUP 1 n=5	GROUP 2 n=5	p-value
SUS	65,5 (9,906)	62,5 (15,909)	0,286

mean (standard deviation); t-student

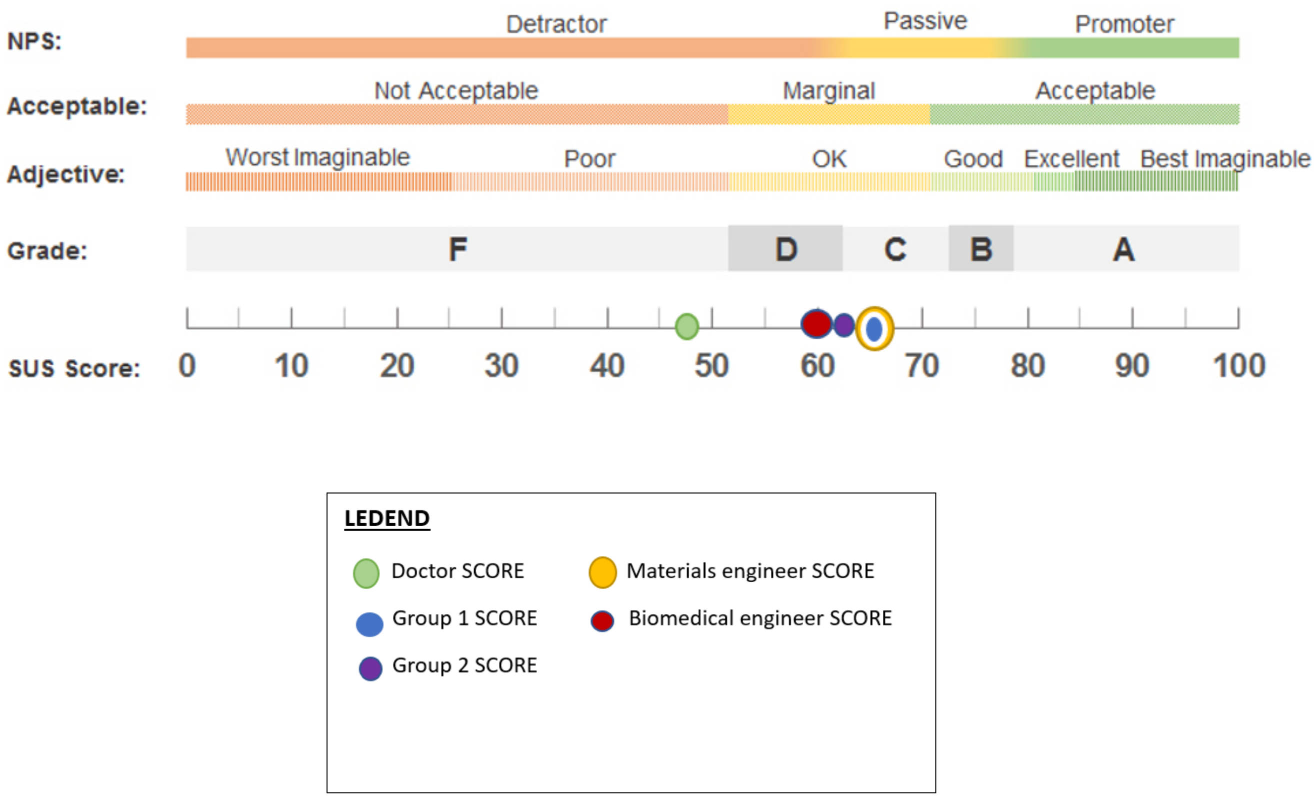


Figure 5: Summary of usability test results (System Usability Scale).

DISCUSSION

In the field of medicine, 3D-printed models have proven to be a promising tool in various specialties, including traumatology [2, 6], ophthalmology [7], maxillofacial surgery [4], and cardiac surgery [1]. These models have enormous potential to improve diagnosis and surgical planning, reduce surgery time, and provide personalised and safe treatments. Despite the evident benefits, there is a lack of studies on the utilisation of 3D printing in medical universities.

Previous studies have compared the effectiveness of 3D-printed anatomical models with cadavers. These studies have revealed significantly positive results, where students show a more satisfying experience and increased knowledge of anatomy when using 3D-printed models. Faculty members also emphasise that 3D printing of anatomical models provides variability in structures, including pathological organs, further enriching the learning experience. [8] In this study, we aimed to go beyond by seeking the possibility of creating 3D-printed models that accurately mimic cadaveric human tissues in terms of texture, colour, strength, tear resistance, and suturability. We successfully replicated 3D-printed tissues such as skin and aponeurosis, and to a lesser extent, the inguinal hernia. These structures were validated by medical professionals, 3D printing materials engineers, and biomedical engineers, who confirmed that the tear and strength of the models were optimal for conducting suture workshops. Students were able to easily identify these models as skin and realistically perform the suturing technique as if they were practising on a human cadaver. This provided them with an opportunity to acquire suturing skills in an optimal, realistic, and safe environment. These findings are especially relevant as no previous studies [9] have focused on the 3D printing of prototypes that accurately mimic human tissues.

Additionally, there were structures such as fat, muscle, and hernia that could not be validated due to their difficulty in being accurately reproduced. These limitations were a result of financial constraints and tight study deadlines, which prevented further revisions at this stage. Although we invited third-year medical students to participate in practical sessions, only a limited number of them attended to perform sutures, which limited our ability to comprehensively evaluate the model. Despite this, the participating students who completed the questionnaire expressed satisfaction with the prototype and showed great interest in participating in future workshops that utilise 3D-printed models.

However, it is important to mention the limitations of our study. The sample size to evaluate usability was small, which affected the power determined in order to detect statistically significant differences between the groups. This limitation indicates the need to ensure the participation of the selected sample in future research to obtain more robust conclusions.

Comparing our results with the two aforementioned previous studies, a preference by students for practical classes with 3D-printed models, especially for learning complex pathologies, is observed [8]. During discussions about the model's characteristics, students noted that the colour, texture, and visible layers were not adequately comparable to those of pigs. Consequently, they expressed a preference for using 3D models instead of animals in future practise. This preference is intriguing from a sustainability and efficiency perspective since the use of animals requires resources for their feeding, housing, and ultimately, sacrifice. On the other hand, 3D models allow for practise sessions without unpleasant odours and in a more hygienic manner. Additionally, students can have their own models to practise techniques at home as frequently as needed, and the models can be customised to replicate specific diseases or techniques. Previous studies have also shown that students prefer to perform practises using 3D models rather than cadavers [9].

While there were hopes to arise with the inverse silicone printing technique, which shows great similarity to the texture of human fat and reasonable similarity to muscle texture, printing the hernia proved to be unviable at this stage of the study; therefore, new studies will be necessary to improve the prototype.

In our evaluation using a Likert-type scale, we found that 3D-printed skin presents some similarities in texture, density, and strength compared to human skin. The same can be said for the aponeurosis, while the hernia shows notable similarities to human hernias in terms of texture and tensile strength.

Participants' opinions in the study were divergent regarding the model's usefulness. Students found it quite useful (SUS 62–65), while doctors (SUS 47.5) considered the model not yet suitable for daily practise. On the other hand, biomedical and materials engineers had more positive opinions (60-62.5), considering the new model as the best they had encountered in terms of touch and overall quality. These divergent opinions highlight the importance of validation and contributions from both physicians and engineers in advancing this extraordinary technology.

In summary, our future efforts will require more time and financial resources to explore new materials and combinations in greater depth. Additionally, the validation and contributions of physicians and engineers will be crucial to advancing this remarkable technology. Despite the limitations of our study, the results obtained so far support the preference of students to use 3D-printed models in their practises, offering a more sustainable, efficient, and realistic way to acquire medical skills. With further research and improvements in the models, we will be able to further enhance the training of future physicians and maximise the potential of 3D printing in the field of medicine.

CONCLUSIONS

Despite the challenges encountered, we have made significant progress in the design and development of a three-dimensional prototype. However, we acknowledge that there is much more work to be done in the future to achieve perfection and enhance the applicability of this technology in the field of medicine. As the first study to achieve the reproduction of soft tissues using 3D technology, we have laid the foundation for future research and improvements.

Although the number of participants in our study was limited, those who did participate expressed their interest in and desire to work with 3D printed models. This demonstrates the potential and positive acceptance of this technology among students and medical professionals.

In conclusion, if we can engage people in the 3D printing process and achieve perfection in the reproduction of human tissues, the knowledge imparted to students will be significantly enhanced. Our work has contributed to the progress of 3D printing and set the stage for future research and improvements in this field. With further efforts and advancements in the technology, we are confident that 3D printing will play an increasingly important role in medical education and improve healthcare overall.

ACKNOWLEDGMENTS

The author would like to express sincere gratitude to the following individuals for their invaluable support and guidance throughout the completion of this article.

First and foremost, my heartfelt appreciation goes to my family for their unwavering encouragement and understanding during this journey. Their constant belief in my abilities and unconditional support have been a driving force behind my achievements.

I would like to extend my deepest gratitude to my mentors, Dra. Roser Farré and Dr. Bartomeu Ayala, for their exceptional expertise, invaluable insights, and unwavering commitment to my academic and professional growth. Their guidance and mentorship have played a pivotal role in shaping the direction of this research and enhancing its quality.

Additionally, I would like to acknowledge the remarkable contributions of Dra. Anna Arnau, the epidemiologist who provided valuable assistance in methodology, data analysis, and interpretation. Her expertise and attention to detail greatly strengthened the statistical aspects of this study.

Finally, I would like to thank all the individuals and institutions that provided financial support, resources, and technical assistance throughout the course of this research. Their contributions have been instrumental in the successful completion of this project.

Without the collective efforts and support of these individuals, this article would not have been possible. Their dedication and encouragement have had a lasting impact on both my personal and professional development.

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ANNEXES

1. Annexes 1: Type of product

***Annexes 1*: Type of product.**

PRODUCT	MEDICAL DEVICE	CLASS
Anatomical model	NO	
Surgical planning model	Yes	I
Radiotheraphy molds	Yes	I
Surgical guides	Yes	IIa
Splint short term use	Yes	I
Splint long term wear >30 days	Yes	IIa
Custom implants	Yes	IIa-IIb
Custom implants SCC and SNC	Yes	III
3D design software	No	IIa-IIb
Bioprinter	No	

2. Annexes 2: Characteristics of Delta tower Fluid ST

Annexes 2: **Characteristics of Delta tower Fluid ST.**

LIQUID DEPOSITION MODELING

Technology	Liquid Deposition Modelling
Tools	1
Printing area	420 mm diameter x 400 mm height, cylindrical
Printing bed	20 mm thick aluminium plate with 200-watt heating up to 85°C
Nozzle diameter	From 0.06 mm to 2 mm
Layer thickness	From 0.03 mm to 2 mm
Printing material	Almost any fluid or paste
Formats	STL, OBJ
Included	3D printer, measuring gauge, memory card, power cable
Interfaces	USB
Operating systems	Windows, Mac, Linux
Power requirements	350 watts, 110 - 220 volts
Dimensions	70 cm x 167 cm (diameter x height)
Weight	45 kg
Office-friendly	Yes - minimal noise emission.