Intramuscular Injection Simulator

MECHENG 450 - 003 Winter 2021

Final Report


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Executive Summary

Global health professionals and students have recognized that there is a lack of proper training for intramuscular injections. This lack of training comes from realistic models being too expensive for training facilities and students to purchase. There is a need for accessible training simulators for students that don't have the funds or access to the top of the line simulators. They have had to use a variety of materials such as meats, fruits or simple training pads. The current global pandemic has played a major role in making their training facilities less accessible than before. To continue education despite the closed facilities, instructors are trying to teach their students these skills virtually. As a result, students have had to find ways to learn these skills without having an instructor there to help them walk through the process, visually guide them to the correct injection site, and double check that they have performed the injection correctly. Without proper training, there are several things that could go wrong during intramuscular injections such as hitting the patient's bone or nerves with the needle, performing the procedure at the wrong injection site, injecting the fluid in the wrong layer of the arm, or hitting a vein.

The goal of our design is to produce a simulator that is easily accessible to students and can teach them the necessary skills for successful intramuscular injections. We are aiming for the product to resemble the deltoid by having a texture of human skin, is as thick and dense as human fat and muscle, and includes a material that can resemble a human bone.

The concept exploration phase began with brainstorming, going through an iterative process of diverging and converging, and using various methods such as morphological charts and design heuristics to build on ideas. Ultimately decision matrices were used to select a concept. The selected concept was the physical feedback model which breaks down the simulator concept into three main material layers. The first layer is a base with a feedback block and false bones made out of paper mache for use in simulating the acromion and humerus. The next layer is a dough subcutaneous and muscle layer wrapped in plastic to preserve consistency. The final, outer layer is a gelatin and glycerin flesh simulator.

During the Engineering Analysis stage of the design process the design drivers were determined, with the primary drivers being the properties of materials, the availability of materials, and the cost of materials.

Various verification methods were used to support the final design concept and determine if the stakeholder requirements and accompanying engineering specifications were met. Through the various processes detailed within this report it was determined that 16 out 18 specifications were met. These results inform the current quality of our solution and where future work needs to be completed should this project be reassigned in the future. Validation of this intramuscular injection simulator requires further research and is two-fold, the solution should meet the verified specifications regardless of who is creating the simulator and it must also fulfill its role as an effective learning tool for nursing students. Details discussing the potential future validations steps are discussed.

Problem Description and Background

What are parenteral injections?

Parenteral injections refers to a non-oral manner of administering drugs. There are three main types of parenteral injections; subcutaneous, intravenous and intramuscular. Subcutaneous injections are administered into the fat layer between the skin and muscle, while intravenous injections go straight into the vein. Intramuscular injections are delivered deep into a muscle such as the gluteus, vastus lateralis or the deltoid muscle. The gluteus muscle is the preferred site for adults and children over the age of 2, while the vastus lateralis muscle is the site of choice for infants [1, 2]. The deltoid is also a common injection site for adults and older toddlers especially for inactivated vaccines, due to it’s easy access and faster absorption rate than the gluteus [1, 3].

What is the Deltoid?

The deltoid muscle is a thick shoulder muscle that originates from the clavicle and acromion and inserts a third of the way down the lateral side of the humerus [4]. In order to make an intramuscular injection into the deltoid, a safe injection site needs to be identified in order to avoid injury to the axillary nerve, radial nerve or humerus bone. The National Immunization Technical Advisory Groups (NITAGs) recommends injection into the midpoint of an imaginary triangle on the deltoid [5]. This imaginary triangle is to be located by placing two or three fingers below the acromion to indicate the base of the imaginary triangle, while the apex of the triangle points directly down as shown in Figure 1. An imaginary lateral line drawn across the deltoid from the base through the apex of the triangle narrows down the injection site. The injection should be given right on this line, approximately one third to one half of the way down from the base of the triangle. The injection must be in the correct site as well as the correct depth. The deltoid muscle is located beneath the epidermis, dermis and subcutaneous tissue as shown in Figure 2. Depending on the patient's biological gender and body mass a 25 - 38 mm needle will reach the deltoid muscle, but can also hit the humerus bone if the injection is not performed correctly [3].

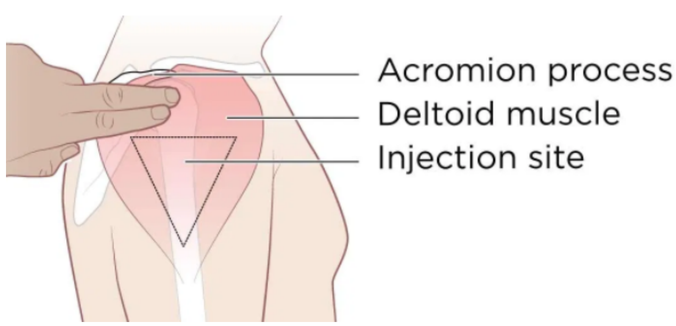

Figure 1. NITAGs recommended injection triangle site is depicted, correct location procedure reduces risk of nerve injury to the patient [5, 6].

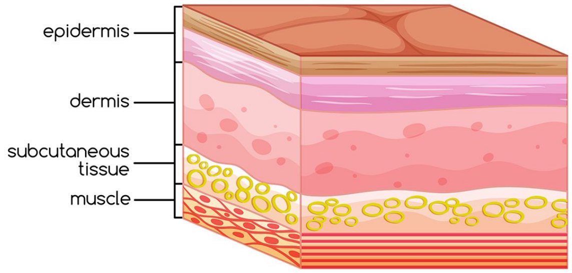

Figure 2. There are three layers of the skin, epidermis, dermis and subcutaneous tissue, before reaching the deltoid muscle [7].

What are Simulators?

From Schwartz's Principles of Surgery, "Simulation is the imitation of an actual or possible real-world condition or event" [8]. A simulator is a tool used to provide an experience that would otherwise be difficult or dangerous to encounter in a safe environment. Their use in the training of medical students has been introduced both to help with general skills training and to address the issues that arise from the technological advancement of medicine. As medical technology becomes more advanced it has become more difficult for doctors to follow the once standard apprenticeship system, instead relying on simulations to provide experience. This experience, however, is yet to be completely standardized.

Simulators can be described by their fidelity, which refers to how closely the simulators match the real world. This can range from pieces of rubber as low-fidelity to full body mannequins which are attached to sensor suites to replicate large portions of the human body as high-fidelity simulators. Every simulator brings out a different element of the body that is important to capture accurately to ensure that it is an effective learning and skills practice tool [8].

Efficacy of Training Simulators

Recent literature has taken a look at the efficacy of simulators as tools for training in the medical field. While the efficacy does vary based on the skill being trained and the level of fidelity simulators have been found to be an effective tool when used in training [9]. This is in addition to students responding positively to how simulators are used in conjunction with mentors with regards to their ability to learn skills and broaden their understanding [10].

Intramuscular injection simulators

Intramuscular injection simulators provide a way for trainees and students to learn and practice administering a vaccine. They remove the need for a human patient to receive the vaccine, thus reducing the risk of injury or harm. These simulators vary infidelity, which is closely related to the subsequent pricing. The following sections will be going over some of these simulators and simulators closely related to them. Table 1 demonstrates the differences between the spectrum of fidelity for intramuscular injection simulators for the deltoid. In Table 1, the high-cost simulators are the only ones that simulate skin and bone. In contrast, the lower-cost simulators have a trade-off between simulating bone or simulating the skin, not both. The simulators' fidelity is based on whether it has the shape of the body part, whether the texture is similar to that of the deltoid, and whether it simulates a bone and whether it has any other feedback mechanism, such as electronic sensors.

Table 1. Benchmarking of simulators with varying levels of fidelity

Product	Simulates Skin	Simulates Bone	Availability	Cost
Meat (Chicken Breast) [11]	No	No	High	$1-$3
Fruit [11]	Yes	No	High	<$1
VTurboWay Injection Pad [12]	No	Yes	Low to Mid	$10.99
Inject-Ed Injection Pad [13]	No	Yes	Low to Mid	$23.95
Wallcur Practi-Injecta Pad [14]	Yes	No	Low to Mid	$171.99
3B Scientific Intramuscular Injection Simulator - Upper Arm [15]	Yes	Yes	Low	$1475
Nasco Musclemate [16]	Yes	No	Low	$1849.95
Realityworks Upper Arm Intramuscular Injection Simulator [17]	Yes	Yes	Low	$1999

These simulators vary in fidelity, which make them suitable for different uses and meant for different levels of training. Figure 3 shows the highest fidelity simulator used for benchmarking, whereas Figure 4 shows the lowest fidelity manufactured simulator.

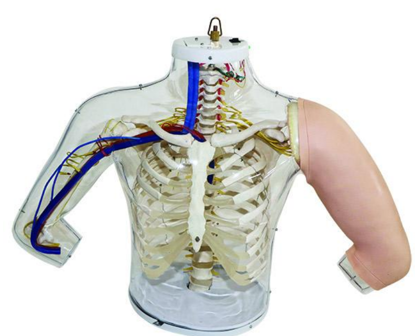

Figure 3. The Realityworks upper arm simulator provides a high fidelity simulation, capturing the shape of the arm, with sensors to determine correct needle placement and depth, as well as showing which nerve or bone (if any) was hit [17].

Figure 4. The Inject-ed injection pad provides a low-cost simulation that in turn is also low fidelity [13].

The high fidelity model has a user base targeted towards more experienced trainees, as they can benefit from the simulator the most to refine their skills, whereas the low fidelity model is more suitable for very beginner trainees, which can use this model to learn and practice proper vaccine procedures: disinfecting the area, preparing the syringe with fluid and administering the vaccine.

Although not yet developed, a smart needle from Havard is another simulator used for practicing intramuscular injection [18]. Harvard is creating a needle that will help users inject the medicine into the right layer of tissue or muscle. They made this needle to help aid in complicated injections, such as epidural injections; it will detect the changes in the tissues' densities by detecting the different pressures and resistances. However, these simulators do not help with landmarking, so the users must place the needle into the right site.

Other Simulators

There are other simulators used in the medical field that do not relate to intramuscular injections. Despite not having the same task, it is important to research what currently exists in low-resource settings, to better understand the materials that can be used to simulate different parts of the human body. They provide insight on low cost simulators, their level of fidelity and their efficacy for students in low-resource communities.

One such example is of a low cost kidney transplant simulator [19]. The low cost model, as shown in Figure 5, makes use of materials that would be accessible to medical students in a hospital or school.

The simulation model was tested by an experienced user base, namely medical residents of the hospital in which the model was created. It was determined to be an effective learning tool. Although it was successful in being a low-cost model for these particular medical students, it is important to consider that these materials may not be as easily accessible to those outside of school or hospital settings.

Another example is of a study focused on low-fidelity pediatric surgical simulations in low-resource settings [20]. The article describes four models of typical gastrointestinal pediatric surgeries. They were determined to be easily reproducible in a low-resource setting, as they were low cost and required only materials that could be locally sourced, such as sponges, thumbtacks, and animal tissue (sheep's intestines).

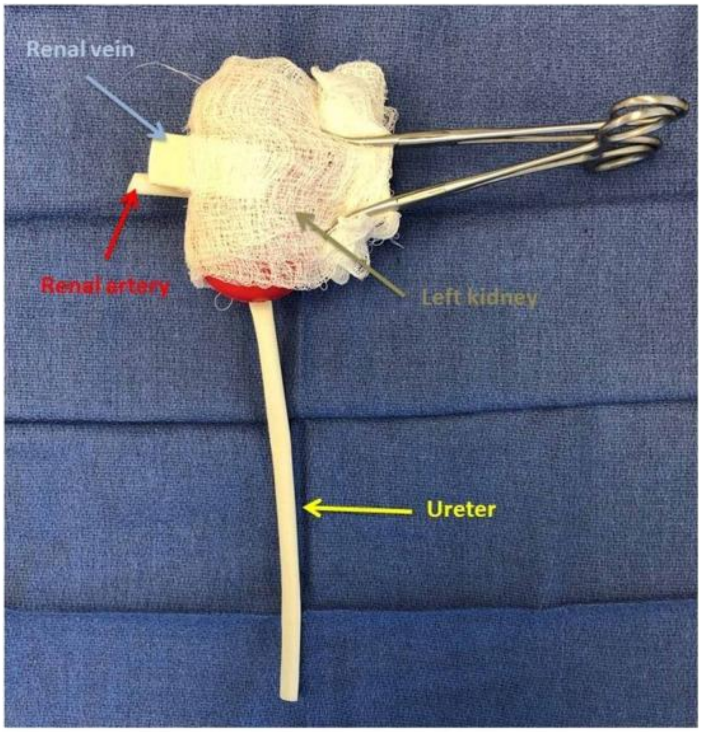

Figure 5. The kidney transplant simulator uses medical supplies to visually represent an actual kidney, which can be reproduced in a medical school or hospital for training [19].

Problem Statement

In Mexico, existing high fidelity simulators are not easily accessible to students and trainees, such as nurses and midwives, in low resource communities due to their price points. Due to the COVID-19 pandemic, there is a more significant gap in accessibility due to restrictions not allowing trainees to get skills practice in a school or hospital facility. Current inexpensive alternatives include raw meats and fruits, though they do not provide adequate feedback to the trainees regarding proper needle placement or depth. This leads to a need for a simulation-based training device to teach nurses and midwives basic injection skills that capture the deltoid's shape and provides a tactile response of hitting a bone. Furthermore, it is essential to ensure that the simulator is an open-source design to ensure students and trainees can afford and access the final product with the consideration of materials and cost. The team needs to create an affordable simulator for use in training intramuscular injections into the deltoid. It needs to be a homemade simulation-based training device to teach nurses and midwives basic injection skills.

Requirements and Specifications

The current requirements, shown in Table 2, were determined mostly from our sponsor Professor Meagan Eagle and stakeholder Juana Mercedes Gutiérrez Valverde. They were able to provide details on how the prototype should be made, the rough cost estimate and the bone requirement. The requirements can change after communicating more with sponsors and stakeholders in Mexico once we learn more about their expectations.

Table 2. Requirements and engineering specifications for design

Priority	Requirement	Specification	Source
High	Is low cost	< $1 USD ≈ $20 MXN per unit	Sponsor, CIA Factbook [21]
High	Is accessible	Open source design Can be built using local materials Requires 0 unique tools Includes assembly instructions Requires < 2 hours to construct and <3 days for drying, baking, etc	Sponsor
High	Simulates Skin	Nurses and instructors-based ratings - average rating above 4 using MiSSES survey	Sponsor , Journal of Healthcare Engineering [22,32]]
High	Has a bone	Provide tactile response to hitting a bone Provides landmark for shot placement Skin to bone thickness: 223 mm	Sponsor, Med J Armed Forces India [23]
High	Mimics skin tones	6 skintones following Fitzpatrick Scale	Sponsor, [24]
Med	Teaches procedural skills	Nurses and instructors-based ratings - average rating above 4 using MiSSES survey. Skills based on rubric provided by sponsor	Sponsor, Clinical Simulation Center [25]

Med	Feels like a shoulder	Nurses and instructors-based ratings - average rating above 4 using MiSSES survey	Sponsor, Journals of Gerontology, PubMed, JAMA [26, 27, 28, 32]
Med	Is in the shape of shoulder/upper arm	Max. Circumference: 332(M), 310(F) mm Length: 196.5(M), 180(F) mm	Sponsor, JAMA [26, 29]
Med	Feedback	Unit provides tactile, auditory, or visual feedback when an error occurs during use	Sponsor
Low	Is Durable	Can withstand 100 pokes without replacement Lasts 1 semester Can withstand 100 rubs of alcohol pads	Sponsor

Justifications

Is low cost:

The sponsor has requested that the price per unit be less than $1. Estimating the daily income of Mexico using the GDP per capita results in a value of around $28 per day [21]. Given that the team has been tasked with providing a tool that is accessible to students in these countries, it makes sense that a school supply be available for less than 3% of our estimated daily income. This is important because we currently do not have a reference for the durability of the final product and do not have estimates for how many a student may require. This low cost specification is also supported by student budget availability, which will be discussed in the engineering analysis section of this report. The minimum budget a student is able to spend on a simulator is 20 pesos.

Is accessible:

This prototype will be made at home by the students as requested by our sponsors. The reasoning behind it was to provide a more accessible simulator for the trainees. Especially due to the pandemic, it is becoming harder to participate in any social activities. The Solution will be an open source design, require zero unique tools and include assembly instructions. An Accessibility Survey (Appendix G) was sent out to 38 students in order to understand what technologies and materials were available to them. Budget and time constraints the student stakeholders face were also confirmed. The survey details will be discussed later in this report, but the time constraint defined is < 2 hours to construct and <3 days for drying, baking, etc.

Simulates Skin:

For our simulator, we need it to simulate skin. One problem with lower-cost simulators is that they do not feel like skin. Either the texture or resistance is off. For our simulator's skin, a needle must puncture the skin with force around 11.1 N when the needle is at a bevel angle of 90° [32].

Further exploration of the subject matter has revealed that the industry standard for evaluation of fidelity is to use surveys compiled from the responses of experts. The team has decided to evaluate the fidelity of the simulator with a goal of the final survey responses being above four points on a five point with the details of the survey being present in Appendix I.

Has a bone:

When performing an intramuscular injection, the injection provider must be conscious of how deep they insert the syringe. If the provider goes in too deep, they will hit the patient’s bone with the needle. This can cause pain and discomfort in the patient. This can also result in the fluid being injected into the bone instead of the muscle. To fulfill this requirement, our team is aiming to place this object in the location where the bone is located in a human arm [23]. After meeting with professionals at the Clinical Learning Center at Michigan, they suggested that the bone can be as complicated as a 3D printed bone or as simple as a stick. The material that will be used to imitate the bone will depend on what is accessible to the groups that will be using this device. Additionally, the bone needs to protrude out like the acromion bone [4]. The user will use the acromion bone to find their target zone based on the two-three finger method [5]. Having the bone protrude is necessary for finding a correct and safe injection site.

Mimics skin tones:

Throughout the 19th and 20th century there were many misconceptions about the anatomy of people of color, specifically about skin of color. Such misinformation was unfortunately published in notable medical journals and negatively influenced medical professionals, some biases are still present today [24]. Realistically medical professionals will be exposed to and must treat individuals of various backgrounds and skin tones. By designing a simulator with varying skin tones we can expose trainees to a more realistic training environment. To measure this requirement we decided to use the existing Fitzpatrick Scale, shown in Figure 6. This is an existing scale that classifies different skin types based on their reaction to sun exposure, although this was a scale that originated in dermatology it has been widely adopted in other fields [24]. Although this scale doesn't come close to including all of the various skin tones possible, it provides an inclusive range and obtainable number of skin tones that could be included in the final simulator design.

Figure 6. The Fitzpatrick scale is a skin type classification system developed by Thomas B. Fitzpatrick, a Harvard Medical School dermatologist, in 1988 [23, 31].

Teaches procedural skills:

In order to determine the effectiveness of the simulator as a learning and skills practice tool, there needs to be a method of evaluating this from the perspective of not only the user base, but also from the perspective of nurses that already have the skills, as well as instructors that will be teaching and evaluating the trainees. For this, the team will be using an existing template for simulator evaluation, the Michigan Standard Simulation Experience Scale (MiSSES). The MiSSES is an assessment tool based on existing simulation literature, which evaluates the effectiveness of a simulation for the following key domains: self-efficacy, fidelity, educational value, teaching quality, and includes an overall rating [25]. The Clinical Simulation Center also notes that this template is continually refined and is meant to be a framework, from which it can be adapted to specific use cases. Another template the team will be using is the intramuscular injection evaluation given to us by our sponsor Professor Megan Eagle. This checklist marks the required learning goals needed to provide safe intramuscular injections and is located in Appendix C. These templates will serve as an initial starting point, which will be updated as more information from sponsors and stakeholders in Mexico express their needs and their own metrics for evaluation.

Feels like shoulder:

The students that will be using this device will be practicing techniques that they will use when performing these injections on patients. The materials used in the simulator should follow the layers of the human arm: skin, fat, and muscle. The simulator will have a similar density and thickness to each of these layers. The skin density, fat, and muscle should be around 0.969 g/cm3, 0.9196 g/cm3, and 1.06 g/cm3, respectively. The skin density will be around 17.2 mm for men and 34.7 mm for women. The fat layer thickness will be around 8.3 mm for men and 11.7 mm for women. The muscle layer thickness will be around 15 mm for men and women [25, 26, 27]. .These values are averages for males and females in the United States. These values may change based on the averages for men and women in Mexico. Further research is required to ensure these values do not have significant deviations. One of the simulator's goals is that when the student has to perform this procedure on a person, they will feel comfortable doing so because the simulator they used mimicked a human arm. In addition, the team will also be looking at the puncture resistance of the skin, fat and muscle layers. The skin should have a puncture resistance below 11.1 N, while the fat and muscle layer should have a puncture resistance around 6.7 N [32]. These values are meant to be a way to evaluate the feel of the simulator empirically.

Further exploration of the subject matter has revealed that the industry standard for evaluation of fidelity is to use surveys compiled from the responses of experts. The team has decided to evaluate the fidelity of the simulator with a goal of the final survey responses being above four points on a five point with the details of the survey being present in Appendix I.

Is in the shape of a shoulder/upper arm:

In order for the trainee to be able to use the simulator to learn and practice proper placement of the vaccine on the deltoid, the simulator must be in the overall shape of the upper arm. For this requirement, the dimensions will vary depending on biological sex of a given person. For the specification, the maximum circumference around the arm was determined as an average of 332 mm for male and 310 mm for female adults in the United States [26]. This specification is determined by a study conducted in 1994 that determined averages for the United States, which the team is using as a starting point, but will likely change to better suit the needs of the target user base in Mexico. The length of the simulator was determined to be half the length of the upper arm such that the simulator includes the main component, the deltoid. This specification is determined by an average of 393 mm for male and 360 mm for female adults in the United States [29]. This was also determined by a study based in the United States, and it is important to consider and evaluate the possible differences in body dimensions between what was researched and the body measurements in the countries that will be using the simulators.

Feedback:
The sponsor has requested that the final design have some method of informing the user of error. Through discussion with our sponsor in Mexico the team decided on the possible options for feedback: visual, auditory, or tactile response to error. This specification is verifiable through usability testing, in which the proxy user is asked to place the injection in a correct spot and an incorrect spot, and then check for the feedback response for the simulator.

Is Durable:
The simulator should be able to be used multiple times before it needs to be replaced. The specifications for this requirement were given to us by our sponsor in Mexico. The simulator is to be made by the students which is why it must withstand at least four uses. Through discussion with the sponsor in Mexico the team has determined that both short term and long term durability needs to be considered. In the short term, the simulator should be capable of being used 100 times without losing all capabilities as a learning tool. This requires that it be capable of being poked 100 times and being swabbed 100 times. In the long run, as a learning tool it should be capable of lasting a semester or 4 months. This may require some maintenance but reflects the need for a tool which can be used during critical learning periods

Concept Generation - Generation

In order to fully explore the concept space the team went through an iterative process of diverging and converging ideas using several different methods to refine the space over time. This took the form of starting with a simple brainstorming session to generate either concepts or solutions to requirements. Next, we used the proposed solutions to form a morphological chart and had the team diverge to independently create concepts once again. Finally the team reconverged and selected four concepts for further exploration and selection. Several sketches and clarifying Figures can be seen in Appendix D.

Brainstorming
The team decided to begin with brainstorming as a way to rapidly propose ideas and build off of them without having the pressure of the group to find sensible solutions. Each team member was tasked with generating 15 ideas to ensure that there was a wide range of starting points for

further development. This also allowed for individual team members to explore interpretations of critical aspects to help prevent a narrowing of scope in the initial stages of generation.

Once these ideas were generated the team came together and placed them on a jamboard including additional ideas as they arose. A brief example of the jamboard can be seen in Figure 7, with the full scope being available in Appendix D. The ideas were then sent through a quick gut check to address whether they might be outside of the scope of the project or ill advised for feasibility reasons. The results of this jamboard brainstorming were then compiled into a morphological chart and the team dispersed again to independently explore 10 concepts using the jamboard as a starting point.

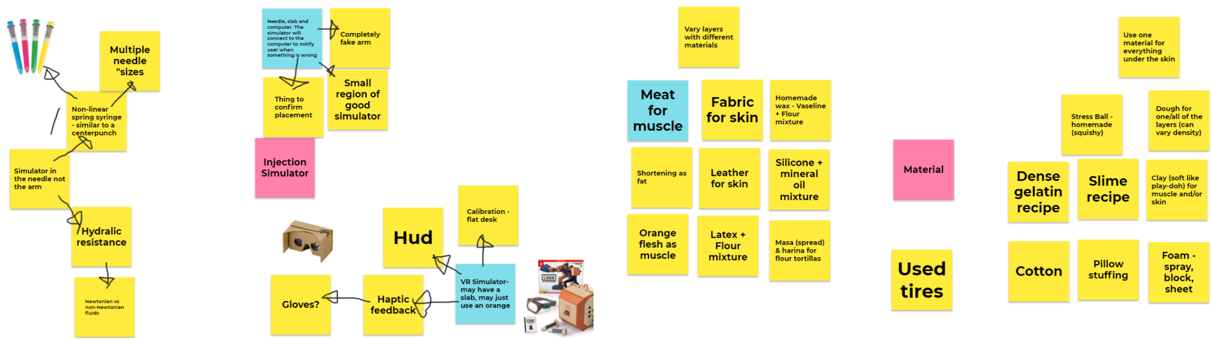

Figure 7. Jamboard Brainstorm Images

Morphological Chart

Having identified the range of concepts that the team wanted to explore further a morphological chart was used in conjunction with sketches to generate five more concepts. This was done to help generate full concepts rather than the requirements which were primarily addressed in the brainstorming session. In addition, sketches were used for clarification allowing team members to explain differences in interpretation of the components of the chart. These concepts in addition to the concepts explored through heuristics or other ideas were then compiled into a second morphological chart with the perceived best elements highlighted for use in the four selected concepts. An example of the morphological chart can be seen in Appendix D.

Other Methods

Concurrent to the exploration of the morphological chart, the team also used design heuristics and TRIZ to generate further concepts. This was done to add further detail to a concept proposed by the morphological chart or was seen in the initial brainstorm. This helped reduce the concept space by introducing similar concepts which could be evaluated once the team reconvened.

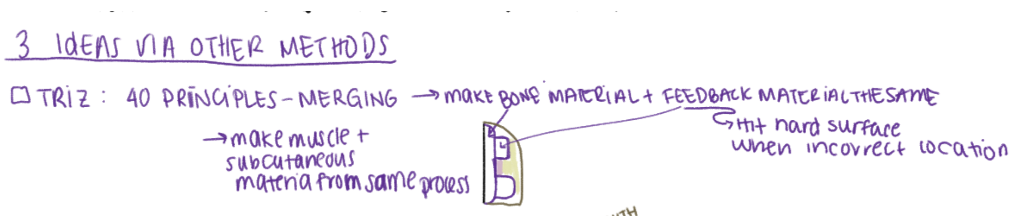

Figure 8. Example Use of TRIZ

Other Ideas

The final method of independent exploration used by the team was for each team member to propose two ideas that they liked but felt were not represented in the current set of concepts. This was to help address the random nature of exploration used by ensuring that if a concept might be good it could still be addressed even if missed by the dice. It also helped for introducing concepts beyond the scope of the morphological chart and other methods as any idea could be proposed. There was also the benefit of addressing the tendency to focus on a single concept at the cost of generating further ideas. By guaranteeing that the selected concept would be proposed there is less pressure to refine it allowing other ideas to blossom.

Concept Generation - Exploration

Having independently generated a total of 50 concepts the team then came together to explain their concepts and to reduce them into their most basic components. Using this reduction the team translated these components into a reduced morphological with the critical applications to propose four concepts for initial selection. These concepts were selected to represent the concept space as a whole and to highlight differences proposed during the exploration process.

Physical Feedback

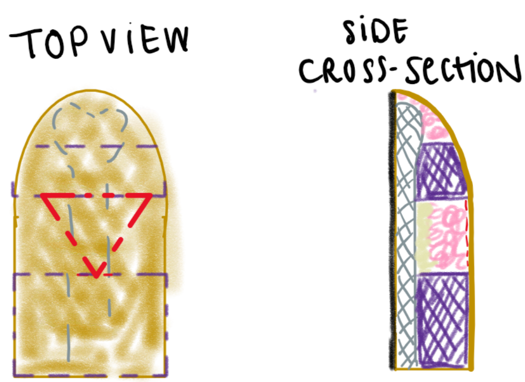

Figure 9. Sketch of Physical Feedback

The physical feedback concept is composed of several layers. The first layer is a base with a false bone made out of paper mache for use in simulating the acromion and humerus. The deltoid region is then wrapped in a flesh simulator to provide resistance to the needle. Remaining areas are then wrapped in a stiffer material as an early warning that the student is injecting into the wrong area. The entire device is then wrapped in an opaque skin simulator which can be marked on the upper or lower side where the deltoid is to help with training and verification of correct placement.

Advantages:
This design has a better underlying fidelity of the bone, which allows for training of procedural skills in addition to getting a feel for the actual injection. It is also small enough to be orientable to best fit the directions of an instructor. The current design also assumes construction on the part of the student which helps it to be accessible in other regions.

Disadvantages:
One disadvantage of the design is that it is only large enough to simulate the deltoid, which could cause problems for training a larger person or to get a feel for supporting an arm. Another problem is that the stiffer material could provide false landmarks for positioning, which effectively invalidates the effectiveness of the tool. Finally, due to the feedback mechanism the student needs to recreate the entire device and its components to simulate other body types.

Flat Plate

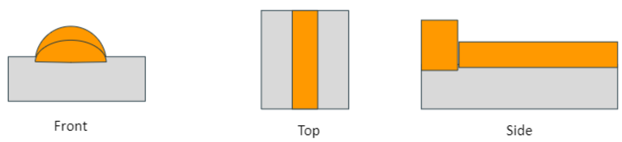

Figure 10. Basic Sketch of Flat Plate

The concept is to have a base which simply simulates the bone of an arm with a bump for landmarking. This base is then wrapped in flesh and skin simulators to provide the proper feel. The only feedback it provides is when the student injects too deep and hits the bone for tactile feedback.

Advantages:
The base is designed to be simple and easily manufactured. In addition, it relies on students to use materials available to them allowing for customization by each student. Finally, as a basic plate it can be oriented according to the students needs and is large enough to represent the upper half of the arm.

Disadvantages:
It requires that the base be manufactured, which introduces costs to the consideration. In addition, since the flesh is determined by the student there could be inconsistencies with the model which are hard for instructors to notice. Finally, this also places another financial burden on the student.

Strap

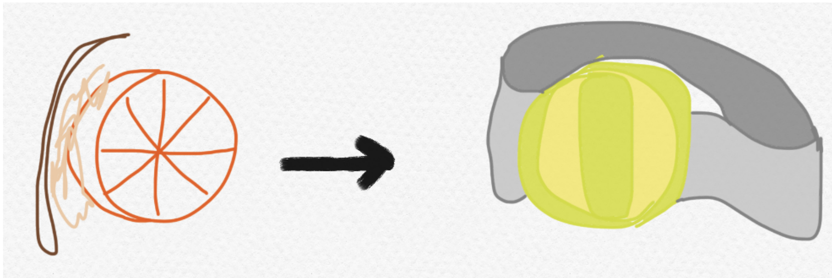

Figure 11. Sketch of Strap Concept

The concept is to have a small strap with a bone and base attached which can simulate flesh and bone once an injection sight has been located on a person. The base is 3D printed to attach a strap and have a bone stand in as a part of it. The flesh is substituted by a wrapped peeled orange which is then covered with leather to simulate skin.

Advantages:
The bone and base are the same part which is strapped to a person to train the skills. The simulator materials should be common to a household allowing for ease of creation by the student. Finally, the procedural skills can be trained on another person without fear of injury as the actual injection will go into the strap.

Disadvantages:
There is a possibility that the part is difficult to obtain in the desired setting as it is proposed to be 3D printed to shape. Another disadvantage is that procedural skill training requires another person, with the strap only allowing for texture training. Finally, the strap can block the view of the arm which might hinder efforts to learn placement through the strap.

Needle Resistance

Figure 12. Filler Image for Needle Concept

A concept that came from flipping the design space to have the simulation material be within the syringe rather than the arm. It would consist of a syringe that when depressed would provide resistance similar to the layers of the arm culminating in a hard stop to simulate bone

Advantages:
It is a fully enclosed simulator that can be used anywhere. As a result there is little material required outside of the syringe itself and its volume.

Disadvantages:
There were concerns by the team of how to manufacture the concept and how that would impact the cost of creating it. In addition, due to the flipped design space there is no way for the student to practice procedural skills instead focusing on the feel of the layers.

Concept Generation - Conclusions

The team employed a variety of methods to gradually refine the search space. First came the initial brainstorming session to begin the process of casting a wide net which could be slowly closed around the suggested concepts. This led to the use of morphological charts, TRIZ, and design heuristics to flesh out the early ideas and gave them substance. This process whittled down an initial 75 ideas down to 50 concepts before ending on four suggestions. Overall, the team did a good job of exploring the presented design space as we questioned what was necessary to the project and allowed the suggestions to form through group consensus. One possible issue with our concept generation was that we focused on simulating the arm for the majority of the process with only a few early ideas suggesting other possibilities. Otherwise, the team made a wide investigation of possible materials, feedback methods, size, orientation, coloration, and bone substitutes. Given more time, a wider range of ideas might have been found, but the existing group shows consideration for a variety of outcomes with significant discussion into the viability of each suggested concept.

Concept Selection

After generating a wide range of concepts and refining them, the concept selection stage allows for further refinement and evaluation. Moving into concept selection required methods of analyzing the concepts and evaluating their perceived functionality and efficacy. To better obtain individual assessments free of influence of others' opinions and suggestions, each team member was required to analyze and evaluate the refined generated concepts. Afterward, the team regrouped and shared their individual thoughts and discussed which concept would be selected.

Decision Matrix
Based on the need for analysis of functionality and efficacy, the design team determined the appropriate method to evaluate these concepts would involve the requirements and engineering specifications. This led to the use of decision matrices to assess each of the refined concepts in terms of how well the team believed a particular concept would meet the requirements. The team also viewed the choice of using decision matrices as a positive in terms of evaluating each individual concept against the requirements based on their perceived merit than to each other, so as to avoid any biases toward a favored or preferred concept. Table 3 demonstrates a sample design matrix that was created by a team member.

This decision matrix in particular uses a scale of -2 to 2. Where -2 represents the belief that the concept would not meet a given requirement at all, 0 is neutral, and 2 would be satisfying the requirement well. The requirements are also weighted by priority level from 1 to 3, where 1 represents the low priority category, and 3 represents the high priority category. This was done in order to quantify the priority levels and show greater emphasis on the highest priority requirements that need to be met. Furthermore, the team member that made this decision matrix chose to produce priority level sums as well as a total sum to observe the differences between the refined concepts overall, as well as the differences at each priority level. To better show the divergent process of making individual decision matrices, Table 4 shows a decision matrix of another team member.

Table 3. Sample design matrix I

Weight	Priority	Requirement	Physical Feedback	Flat Base	Strap Around Arm	Needle Resistance
3	High	Is low cost	1	-1	1	-1
3	High	Is accessible	0	-1	1	-1
3	High	Simulates skin	2	2	2	2
3	High	Has a bone	2	2	1	-1
2	Med	Teaches procedural skills	2	1	0	-1
2	Med	Device Feedback	2	1	1	1
2	Med	Is in the shape of shoulder/upper arm	1	1	-1	-2
2	Med	Feels like a shoulder	2	2	2	2
2	Med	Is durable	0	0	0	2
2	Med	Is water resistant	2	2	2	2
1	Low	Mimics skin colors	2	2	2	-2
		High Priority Sum	15	6	15	-3
		Medium Priority Sum	18	14	8	8
		Low Priority Sum	2	2	2	-2
		Total	**35**	**22**	**25**	**3**

This decision matrix has differences in scaling, where this team member for example scaled the evaluations from 0 being unable to meet the requirement, to 3 being satisfying the requirement well , and evaluation. This process of multiple decision matrices that the team followed allowed for individual evaluations, as different team members assessed the concepts based on how well each member believed a concept might satisfy the requirements of the design. With individual evaluations, the design team was then able to compare and discuss opinions and views toward the concepts, taking note of any trends and key similarities and differences.

Table 4. Sample decision matrix II

Rank	Requirement	Physical feedback	Flat base	Strap Around Arm	Needle resistance
High-3	Is low cost	3	0	0	0
High-3	Is accessible	3	0	0	0
High-3	Simulates skin	3	0	3	0
High-3	Has a bone	3	3	3	0
Med-2	Mimics skin colors	2	2	2	0
Med-2	Teaches procedural skills	2	2	0	2
Med-2	Feedback	2	2	2	2
Med-2	Is in the shape of shoulder/upper arm	2	2	0	0
Med-2	Is durable	2	2	0	1
Low-1	Feels like a shoulder	2	2	1	0
Low-1	Is water resistant	1	0	1	1
Low-1	Has multiple materials for use	1	1	0	0
	Total	**26**	**16**	**12**	**6**

Discussion and Decision

Comparing decision matrices between the team members, there were some notable differences in how each member created thresholds for criteria to be met. For example, feasibility and manufacturing constraints were considered slightly differently when assessing the first requirement, “Is low cost”. Table 3 has its evaluation for the low cost requirement based on the cost of 3D-printed parts. This is because, at the time, the team had not been given a final decision from the sponsor in Mexico on such a manufacturing constraint. Table 4 has its evaluation for the low cost requirement based on the assumption that any 3D printing would be more costly than the alternative of finding and using local materials, thus any concept that would require a 3D-printed part would automatically get the lowest possible score.

In terms of similarity and trends, across all the individual matrices, the needle resistance concept scored the lowest, making it the least adequate to meet the requirements. It is important to note, however, that the requirements and specifications that were created based on the assumption by the sponsors, stakeholders, and the design team that the simulator would be the arm, for the process of administering a vaccine on the deltoid. The needle resistance on the other hand, was generated through the help of design heuristics; specifically, flipping the design space. This misalignment of design space and requirements can be interpreted as a factor that ultimately resulted in this concept consistently scoring low. The design team chooses to be charitable and will further investigate how this concept may be reevaluated considering the different design space, such that the team can do its due diligence in fully exploring and evaluating this concept.

Another strong trend that the team noticed was that the physical feedback concept scored highest among most of the decision matrices. In fact, in all but one of the matrices was this concept the highest scoring, where the other matrix resulted in the physical feedback concept having the second highest score. Each team member expresses their rationale behind the highest scoring concept. Afterward, the team came to a consensus, choosing the physical feedback concept as the selected concept. The selected concept is further elaborated on and illustrated in the following section.

Final Solution

The final solution will be described in detail below, any previous versions of the concept or alternative materials explored can be found in Appendix F. All materials used throughout the entire process can be found in Appendix J. The solution needs to be presented to the stakeholder students in a very clear and concise manner that will result in minimal errors for end users. Detailed instructions were created in english and in spanish with a supplementary video, all of which can be found in Appendix E. The final intramuscular deltoid injection simulator design is shown below in Figure 13.

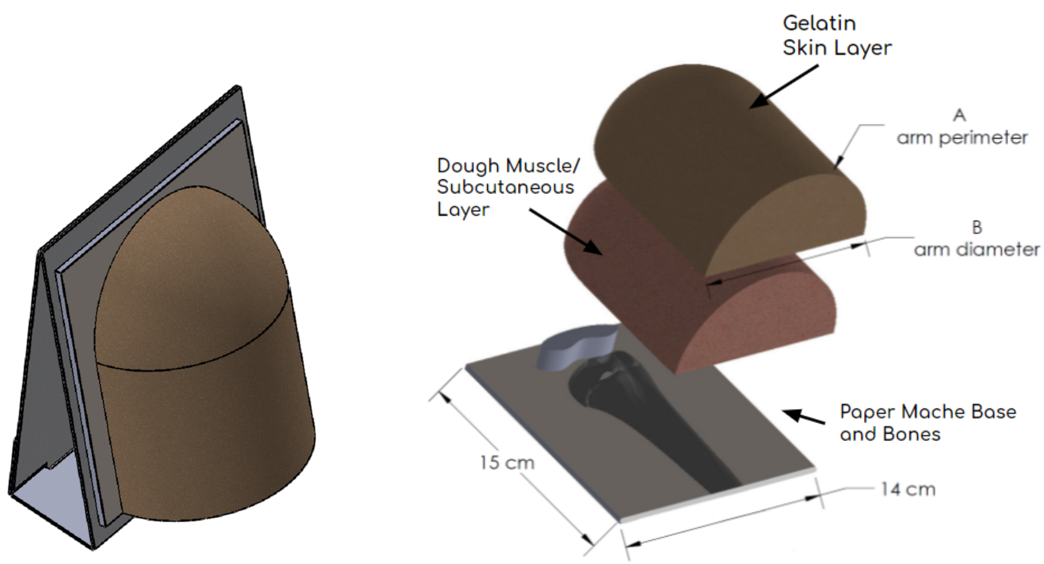

Figure 13. Left: CAD of the final simulator solution. **Right:** Exploded view of the solution (without the stand).

Design Breakdown

One of the main features of the design is the merging of parts. In this fashion the base and bones are created from the same material, being paper mache. This paper mache method was chosen because once dried the acromion and humerus model will be stable and hard as is required. Figure 14 shows a CAD drawing of the base and bones.

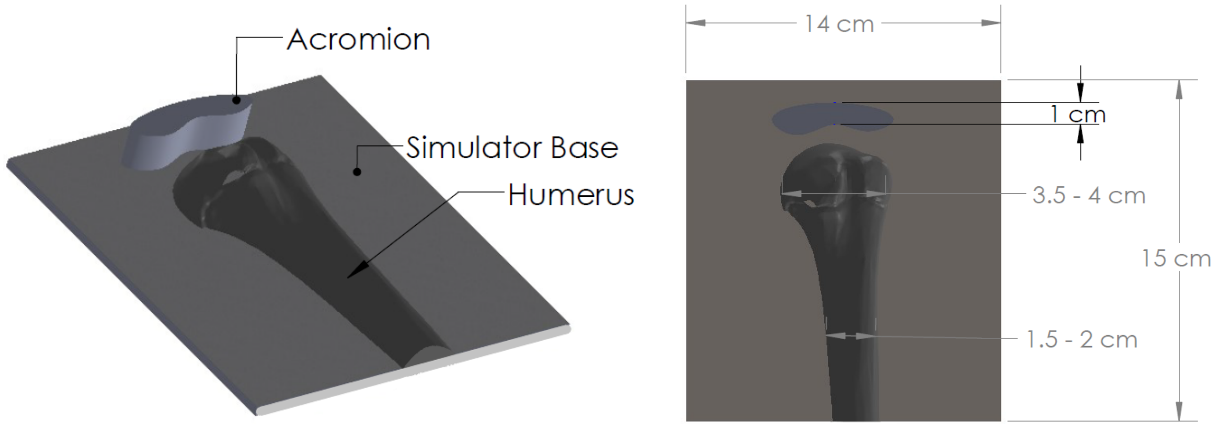

Figure 14. Left. CAD model showing the acromion, humerus and base which will be made out of paper mache **Right. CAD** image showing key dimensions.

The materials for this method are cheap and easily accessible to us, accessibility for stakeholders in Mexico will be discussed in the availability analysis section of this report. The process of creating the base and bones takes approximately 30 minutes, with a dry time of 3 days. The process will vary from stakeholder to stakeholder based on their location, materials and techniques. Dry time can be decreased to approximately 24 hours by baking the paper mache base about halfway through creation and at the end, at 175°F (80 °C) for 15 minutes.

To begin, rip a few sheets of old newspaper and create a "glue" from a 2:1 ratio of water and flour, which needs to be slightly heated until the dough consistency turns into a paste as show below in Figure 15

Figure 15. The ratio of water to flour is 2:1, starting with half a cup of flour and one cup of water is recommended. The Figure one the **left** is the initial doughy mixture before heating. Once the mixture is being heated feel free to add additional tablespoons of water until a paste like consistency is obtained as shown on the **right**, the mixture may be lumpy.

Once the glue mixture is ready the flat base of the simulator can be created. A smooth waterproof surface to work on will be needed, such as baking sheet, cutting board or simply plastic over your kitchen table. Begin applying the glue with a paintbrush to the newspaper strips and placing them on the flat surface, layering over a surface of approximately 14 cm X 15 cm and about 0.5-1 mm thick. The acromion and humerus can now be created using the provided measurements for reference. Layering should continue until the acromion height is approximately 2.5 cm and the humerus height is approximately 1 cm. The newspaper strips should be tightly packed to ensure the model is solid once dry and not overly soaked in glue as this will lengthen the dry time. Figure 16 shows the resulting paper mache base.

Figure 16. Paper Mache base and bones

The next layers include the muscle and fat layers which were made from dough created using a 2:1 ratio of flour to water by mass. Dough has a relatively short shelf-life so 2 teaspoons of cream of tartar, 1 tablespoon of oil and ¼ cup salt should be added to extend the shelflife by a few weeks to months. Red dye or paint can also be added to obtain a pink dough color. The dough should be dry to the touch and spring back when compressed. The dough option was selected because it is flexible, adapting the underlying bones and feedback block as well as taking the outer shape of the shoulder relatively easily. The creation of the dough layer takes approximately 30 minutes and is wrapped in plastic for containment. The plastic barrier also allows users to draw or add a placement triangle based on provided instructions. The triangle shows the target zone based on the two-three finger method to assist in correct injection site training. Figure 17 below shows the dough layer.

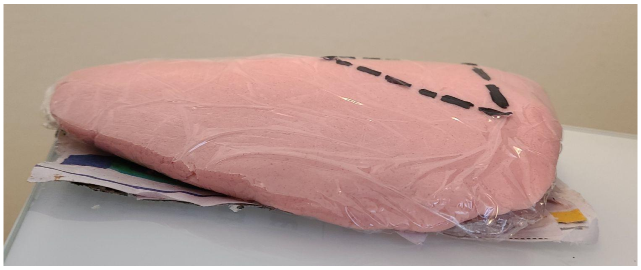

Figure 17. Muscle and fat dough prototype, wrapped in plastic with ideal injection location marked by the dashed triangle

A mixture of gelatine and water was used to create the skin layer. The downside of gelatin is it is an animal product and has a short shelf life, only a few days possibly 7 if refrigerated. To address the short shelf life, an equal part of glycerin with respect to gelatin was added to the mixture. The first gelatin and glycerin layer created is currently seven weeks old and does not show any signs of degradation or spoilage. The layer was created in a bowl using a ratio of 2:2:1 of gelatin, glycerin and water, mixed together with a few drops of make-up and microwaved for 8 seconds. The gelatin sets after about fifteen minutes. The initial texture is very shiny, almost sticky this is addressed by rubbing in a pinch of flour giving the layer a much more skin like texture. A perfect circle can be peeled out of the bowl and placed on the simulator. Figure 18 below shows this outer skin layer.

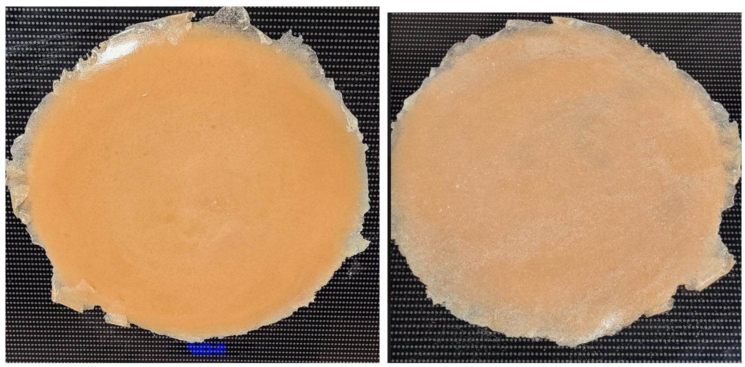

Figure 18. Left. CAD model showing outer skin layer on the paper mache base. **Center.** Gelatin and glycerin outer skin layer created, skin tone was obtained using L'oreal liquid foundation. Right. The same skin layer after being dusted with flour.

Intramuscular deltoid injections are usually performed on a patient who is sitting upright, this would mean the ideal orientation for the simulator would be vertically to imitate a real world scenario. To do this, an adjustable cardboard stand was designed to attach the simulator to. Any cardboard larger than 13 cm by 34 cm can be used. Students would be given cut and fold instructions and to create the stand shown in Figure 24.

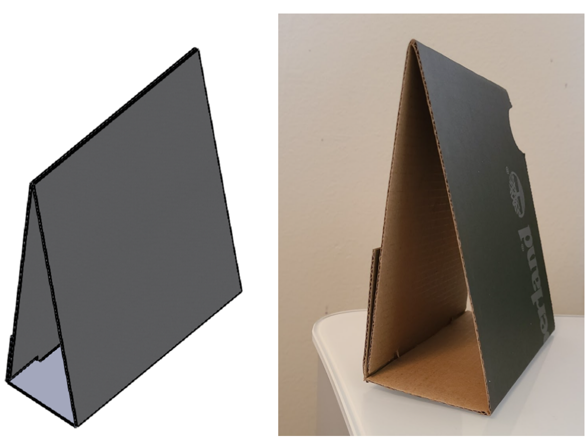

Figure 19. Left. CAD of cardboard stand. **Right.** First prototype of the cardboard stand.

The completely assembled simulator is shown below in Figure 20.

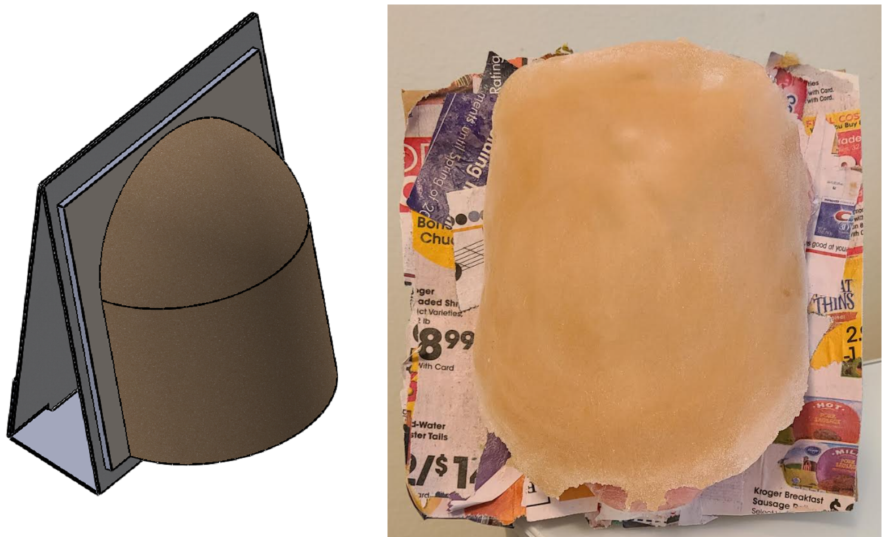

Figure 20. Left. CAD of the current selected concept, the physical feedback model. **Right.** Finalized simulator.

The design calls for a clean interface between all layers tape was used to not impact the overall texture of the prototype or interfere with the users ability to inject into it. This entire solution was created with materials available to the team, including some small purchases. The availability of materials for the team does not directly translate to availability for our stakeholders.

Engineering Analysis

The primary design drivers are the properties of materials, the availability of materials, and the cost of materials. The design drivers were determined by focusing on the accessibility aspect of the simulator and brainstorming the different roadblocks that would be faced by the student stakeholders. Other design drivers such as reusability of materials was considered, but was not a top priority. Experiments have been designed to determine that the selected concept and process is feasible and that the design decisions are valid and defensible. This relevant empirical testing of the properties and surveys conducted to validate the availability and cost concerns will be discussed below. In addition, usability analysis and failure method and effects analysis tests have been conducted.

Material Properties

Puncture Resistance:

To determine if our selected materials would be able to mimic a human arm, we are working to collect data on the force needed to penetrate our chosen materials. This mode of analysis is appropriate because we will be using the data collected to compare the forces applied on the simulator's layers to the force required to puncture the different layers of the human arm. The amount of force required to puncture a human arm is 11.1 N and 6.7 N for the muscle and fat layer. The assumption made is that the amount of force required to penetrate the different layers of the device should reflect the force required to puncture a human arm with a syringe. We had medium to high confidence in this method of analysis in theory, but the results discussed below have impacted this. We are currently overlooking the fact that the force gauge does not come with a syringe attachment and we will have to devise our own. To determine the amount of force required to puncture the different layer the Digital Force Gauge HF-200 series, shown in Figure 21, was used to record the force.

Figure 21. The HF-200 series Force Gauge with the attachment (left) that was used to record the force data for each of the layers. The attachment used to perform the tests (center). The attachment and syringe combination used to perform the second tests (right).

The forces were recorded using the attachment to determine the resistance. Thirty trials were conducted on each of the materials chosen for each of the layers. The material used for the bone was paper mache, a glycerin/gelatin mix for the skin and bread dough and play-doh for the fat/muscle layer. To test the resistive force of the paper mache, the force of the gauge making contact with the paper mache was used. A syringe was also used to record force. A syringe barrel with a 1'' needle was attached to the force gauge attachment and the trials were repeated for each material. The averages of the forces were calculated and are shown in Table 5 below.

Table 5. The average value of the force (N) for the following four materials: play-doh, bread dough, paper mache, and a glycerin/gelatin mix.

	Attachment				Attachment & Syringe			
Material	Play-Doh	Bread Dough	Glycerin/ Gelatin	Paper Mache	Play-Doh	Bread Dough	Glycerin/ Gelatin	Paper Mache
Avg. Force (N)	2.23	0	2.32	4.15	0	0	0	4.01

The digital force gauge that was used does not have a high sensitivity that can read the amount of force needed to puncture soft materials such as bread dough, play-doh, and the glycerin/gelatin mix especially when the syringe needle is attached. Other force gauges that are available can be used to try to find the force required to puncture these soft materials. These force gauges are mechanical and could provide data for these materials. Therefore, we will be focusing on the feedback given to us by medical professionals to improve our design instead of relying on data collected with the force gauge.

At this time, the force gauge presents significant limitations to the mode of analysis. While the test itself is appropriate and indicative of the materials the resource used was unable to provide interpretable data at this time.

User feedback:
Due to limitations of the force gauge, the team sent several iterations of our muscle layer to medical professionals. To test the muscle layer solely, we placed the different muscle layers into cups with a gelatin-glycerin skin layer on top shown in Figure 22. Afterwards, we had the medical professionals test our current design to obtain feedback.

Our conclusions from the current feedback were to proceed with using dough with yeasts and confirmed our bone requirement. Each medical professional could feel the acromion bone which is essential in finding the correct injection location.

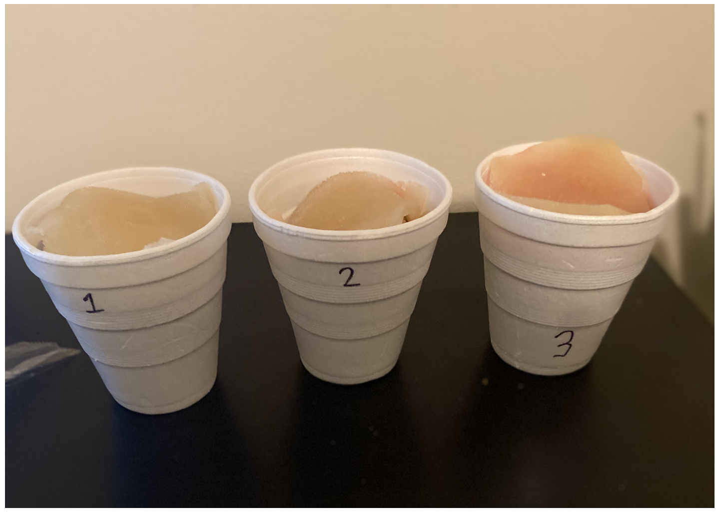

Figure 22. Muscle Cup Test: One is dough without yeast, two is dough with yeast and three is play doh. All three are covered with the glycerin/gelatin skin layer.

Have you given intramuscular injections before?

■ Yes
O No

Which cup felt most like a human arm?

O 1-Dough without yeast
■ 2-Dough with yeast
O 3-Playdoh

Which cup felt least like a human arm?

■ 1-Dough without yeast
O 2-Dough with yeast
O 3-Playdoh

Additional comments:
Needs more dough to be able to pinch the skin for injections.

How does our simulator feel compared to previous simulators you have used ?
Cannot remember

Could you feel the acromion bone?

■ Yes
O No

Do you have any additional comments ?
Stand needs more support and the skin is close but does not have the same surface texture.

Thank you for taking the time to complete this survey and participating in this research.

Figure 23. Completed Products Evaluation, an example of a filled-out product evaluation survey used to obtain feedback.

Durability:

The team has determined that in the short term the best tests of durability are poking the simulator and swabbing the simulator. These tests establish a baseline for use in individual sessions. At this time the final design is capable of withstanding 100 full uses with only minor harm which can be easily repaired.

Reusability:

The team has determined the gelatin/glycerin skin layer can be poked over 100 times without losing its integrity, although the injection site becomes visible before this. We have also determined the mixture can be completely re-melted, this can be done after each session or after every 25-50 pokes, as prefered by the student. The dough layer is re-usable for at least six weeks based on the earliest prototype we were able to create, although a longer lifetime is suspected. We recommend the dough layer be rewrapped after each session and mosited as needed. It is not anticipated that the paper mache base and bones would need to be remade.

Availability Assessment

The selected concept is an open source design to be created by the nursing students of the Autonomous University of Nuevo Leon. Some questions had to be answered in order to make sure the concept is fully accessible and available to these students. The questions include: "what materials might these students already have at their disposal," "what materials do they have access to purchasing," "can they purchase these materials based on their budget," and finally "what are the commitment constraints for creating the simulator." To answer these questions in a manner that directly gathered feedback from many student stakeholders in a short amount of time, a survey was created using $qualtrics^{XM}$, project creator, with advice from CSCAR (Consulting for Statistics, Computing and Analytics Research). The blank surveys in both english and spanish can be found in Appendix G. There is high confidence in this method of collecting data for analysis. The survey had to avoid assumptions and instilining biases while gathering a variety of information without being too long, risking uncompleted surveys. Professor Gutierrez fully supported the survey as a method of collected data from her students. She advised she had 38 first year students, which would be able to complete the survey. Currently a total of 34 responses have been completed. The small sample size is being overlooked. The data collected will be broken down and analyzed in the following sections and ultimately influence design decisions as iteration of the design process continues.

Material Availability:

The first section of data will show which materials students already had at home, could obtain and could not obtain. The purpose of this was to gauge students' physical access to materials and their familiarity with them. This section of data does not consider student budget limitations. Data was collected for the currently selected materials such as newspaper, gelatin and flour, but was also asked of other promising materials discussed when brainstorming such as silicone, and petroleum jelly. Collecting information on other materials will become useful if the currently selected materials did not perform well in material analysis or during use by a medical expert. This survey was created with the assumption that all students had access to water. The survey was also created before cream of tartar was used in a prototype, so no data was collected for this material. The data is shown below in Table 6.

From the data we can confirm that flour and newspaper are items at least half of our student group already has at home, with the exception of one student who states they cannot obtain newspaper. We will disregard this one outlier for now simply because any type of paper could be used and this was not stated in the survey. With flour and newspaper being deemed available a student should be able to create their own base and bone stimulator layer.

Table 6. Student responses to material availability.

Material	Available	Can Obtain	Cannot Obtain
Newspaper	12	21	1
Flour	19	15	0
Yeast	7	24	3
Gelatin	7	27	0
Glycerin	3	25	5
Petroleum Jelly	5	10	19
Play-Doh	9	25	0
Silicone	10	22	2
Latex	6	26	2

The most basic dough subcutaneous and muscle layer requires water and also flour, which we have established is an available material for the students. To adjust the texture and shelf-life of this mixture other ingredients will need to be added such as yeast, salt, cream of tart etc. This is something that may become problematic as 3 students have stated they cannot access yeast at all and no data was collected for salt and cream of tartar. One potential solution could be having students purchase play-doh as all students have confirmed this is a material they have access to. This layer will require further exploration, which we anticipate tackling with the puncture resistance results in mind as well.

The outer skin layer mainly requires gelatin and glycerin. From the data collected we can confirm all students have access to gelatin, but 5 have stated they cannot access glycerin at all. Although this is not ideal, it does not completely negate the gelatin skin layer. Not having access to glycerin means the shelf life of the gelatin skin layer will be very short, 3-7 days. The thought of having an alternative skin option has been often discussed due to the fact that gelatin is an animal product and would not be ideal for vegetarian and vegan students. This topic will be further explored now keeping in mind that it could just be an alternative for students who can't obtain glycerin.

Student Location and Store Access:

When discussing material access we wanted to gather information on where the students are located in order to verify they have access to purchase the materials needed. When discussing this with Professor Gutierrez we were informed that the UANL did not have any on campus housing, and due to covid most students who usually stayed near campus were at home, which could be anywhere in Mexico. To get a better understanding of our demographic group we collected information on student location and common shopping sites. The student location information can be seen below in Figure 24.

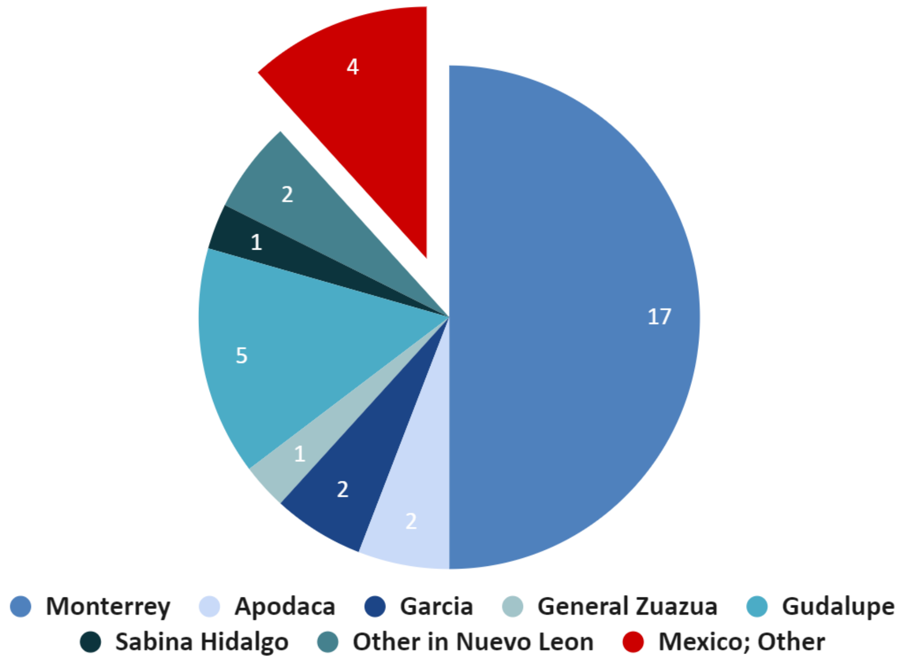

Figure 24. Demographic chart showing where the students surveyed are located. Most students are in the state of Nuevo Leon, as shown by all bluish colored slices.mHalf of all students are in Monterrey, the Capital of Nuevo Leon, where the UANL is located. The 4 students in other parts of Mexico did not provide a state or city.

This data actually shows most students are located in Nuevo Leon. This information allows us to confirm that our student base should have access to relatively similar resources and stores. This deduction was confirmed in our student shopping responses where the top shopping sites were Bodega Aurrera, H-E-B, Soriana and Walmart. This information will be used to guide the cost analysis in the following section. All, but one student had access to at least one of these shopping stores.

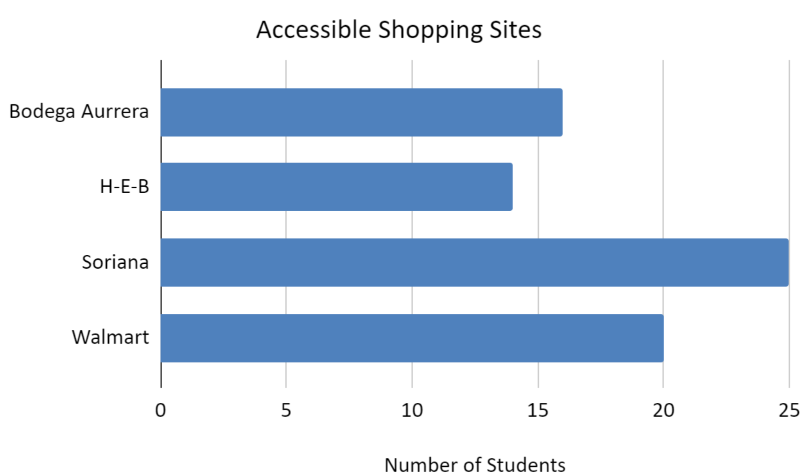

Figure 25. The graph shows the number of students who have access to the top four shopping sites. Students were able to list multiple stores, which is why there appears to be more than 34

students.

The one outlier listed costco and amazon as their source for shopping, meaning they should have access to the materials required, although our report will not cover cost analysis for this outlier. Figure 25 below shows a breakdown of the data collected for the four top shopping sites.

All, but one student has access to at least one of the stores listed above. Over 88% of the students have access to either Soriana or Walmart. This information will allow us to confirm new material availability and also guide how we determine pricing of the simulator in the cost analysis section of this report.

Student Budget Availability:

At the beginning of this project the price per simulator given by our sponsor Megan Eagle was less than $1. When discussing this topic with Professora Gutierrez, she advised she did not know if $1 was accurate and actually thought students might be able to commit to a higher budget. Knowing how limiting the $1 budget was on the potential solution it was necessary to determine if a bigger budget was possible. This survey question required student input, as recommended by CSCAR who advised that providing ranges via multiple choice options would limit student input and restrict the data. A summary of the budget data is shown below in Figure 26, before any outliers are removed.

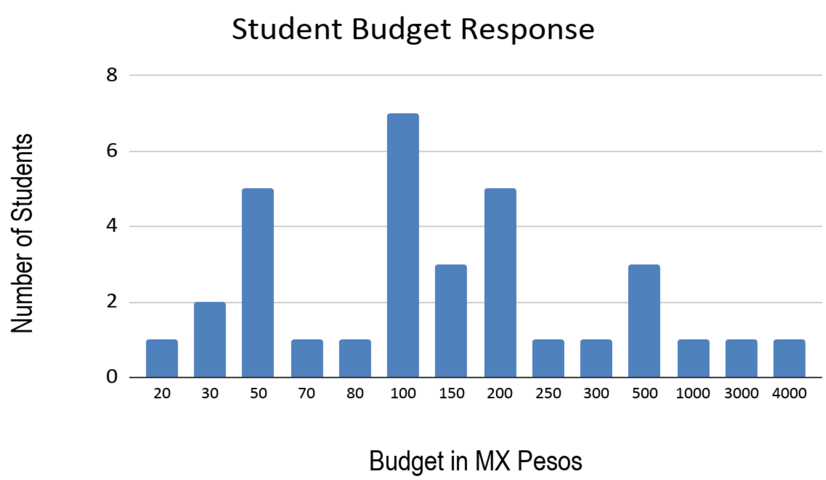

Figure 26. Budget information for the simulator was collected. The minimum budget is 20 pesos (1.00 USD), the maximum budget is 4000 pesos (200 USD). The mean is 384 pesos (19.2 USD) and the median is 100 pesos (5 USD). Price in USD is determined using a conversion rate of $1 USD ≈ $20 MXN.

Currently this budget data is not very useful due to the large variation in student responses. The goal of the project is to be accessible to the students, for this reason the high budget outliers were removed and a box and whisker plot of the updated data was created and is shown below in Figure 27.

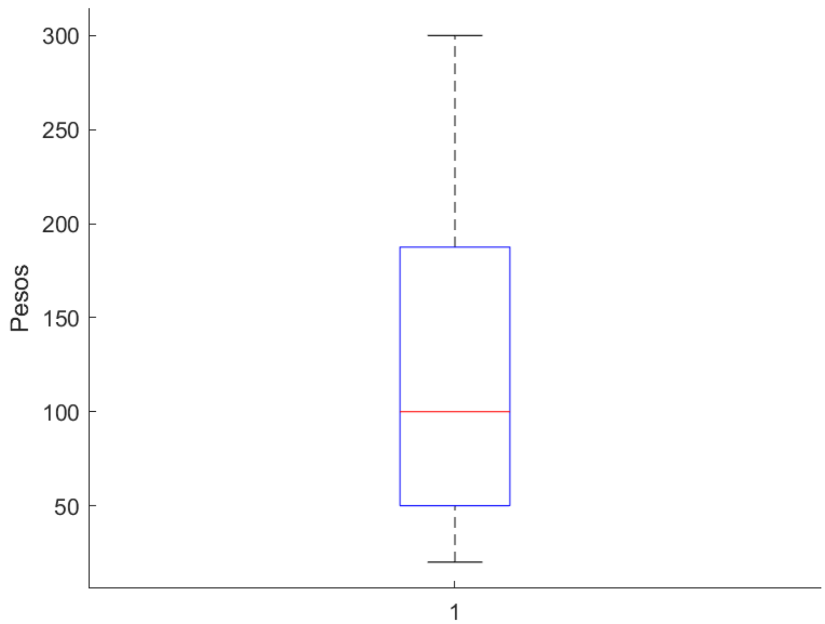

Figure 27: Updated Budget information. The minimum budget is 20 pesos (1.00 USD), the maximum budget is 300 pesos (15 USD). The mean is 118 pesos (5.90 USD) and the median is still 100 pesos (5 USD). Price in USD is determined using a conversion rate of $1 USD ≈ $20 MXN.

The data confirms most students can spend more on an intramuscular injection simulator than initially defined although the minimum budget is 20 pesos which supports the initial low cost requirement and specification of $1.00 USD The lower the total cost of the simulator the more accessible it is to more students, although quality should not be compromised. This topic will be further discussed under the cost analysis section of this report.

Student Time Commitment:

The selected simulator concept requires students to create the simulator according to instructions and dimensions provided. It is important to take into consideration students' limited time and busy schedules. The benefits of the simulator will need to exceed the work to create one in order for students to go through with all of the instructions. Information was gathered on how much time students would be willing and able to spend on creating the simulator, not including steps such as baking, curing, drying etc. These responses are shown in Figure 28 below.

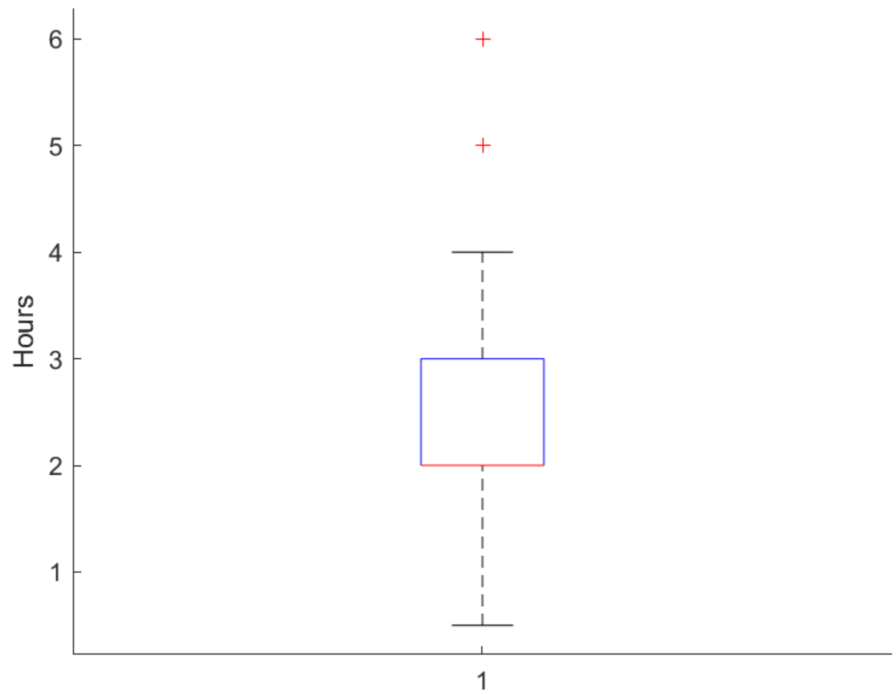

Figure 28. The minimum amount of time a student would be willing/able to spend on creating the simulator is 30 minutes, the maximum amount of time is 6 hours. The mean is 2.5 hours and the median is 2 hours. This time does not include baking, curing or drying times.

Information was also gathered on how much time students would be willing to allow for steps including baking, curing, drying etc. Those responses are listed below in Figure 29.

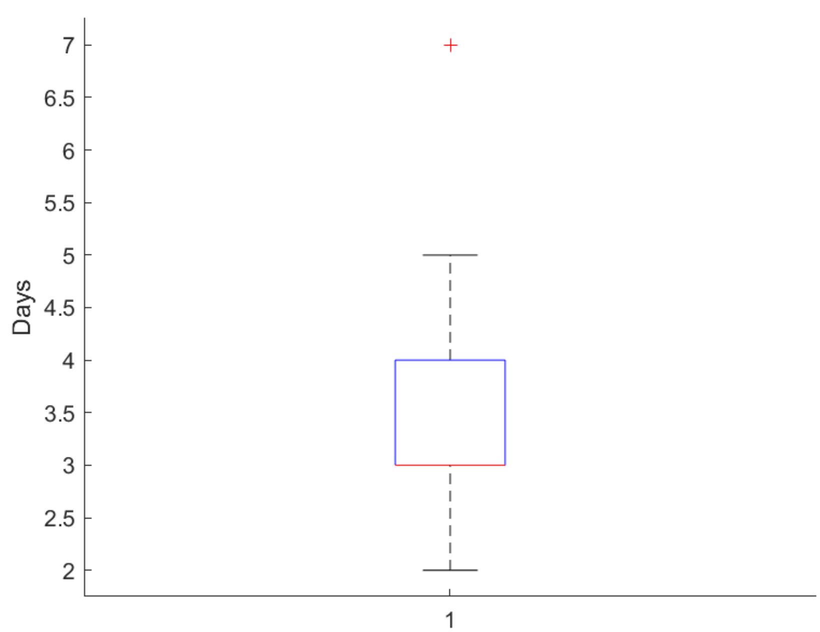

Figure 29. The minimum amount of time a student would be willing/able to allow for baking, curing or drying times is 2 days, the maximum amount of time is 7 days. The mean is 3.3 days and the median is 3 days.

This information will be essential as the design process progresses, the simulator needs to be tailored for student usability without compromising functionality.

Cost Analysis

For the selected concept, a cost analysis serves to calculate the cost of a particular simulator, given the price of the local materials available to the user-base. With this cost analysis, the team would like to know how much material would come in its packaging and how much it would cost, and compare it to how much is needed for the construction of the design. This is accomplished through researching unit prices of available materials in Mexico. For water, the unit price was determined to be \$13.48 MXN/m^3, as per 2019 data from the federal government of Mexico [33]. For the other materials, the team decided to use a weighted average unit price derived from the prices found on websites from the supermarkets reported by the availability analysis' survey, omitting the store Bodega Aurrera, as this store sells household items and clothes, but not pantry products or food, the primary materials needed for the designs. This is reflected in Table 7.

Table 7. Student response to accessible shopping sites

Store	Number of Students
Walmart	20
Soriana	25
HEB	14
TOTAL	**59**

Using the proportion of students that select a particular store as an accessible shopping site to all the responses, the team can calculate a weighted average for a unit price of a material. This calculation for the weighted average unit price is shown below:

$$Unit\ Price_{avg} = (unit\ price\ in\ W) \times 20/59 + (unit\ price\ in\ S) \times 25/59 + (unit\ price\ in\ H) \times 14/59$$

Afterward, the team listed out the materials and quantities needed for each layer or component of the simulator; base, bone, fat/muscle, and skin. With the materials organized in this manner, it is clearer to determine the cost of the simulator by breaking it down into costs per component, the sum of the product of the quantity of a material needed and the unit price of that material. To provide as an example, Table 8 shows this process, tabulated, for the selected concept the physical feedback model.

Table 8. Tabulated cost of selected concept ($1 USD ≈ $20 MXN)

Component/Layer	Material Used	Quantity Required	Unit Price (MXN)	Cost (MXN)
Bone	Flour	30 g	$0.01326 / g	$0.3979
	Water	30 mL	$13.48 / m^3	$0.0004
	Newspaper	N/A N/A	$0.00	$0.0000
			Total (MXN)	**$0.3983**
	Material Used	**Quantity Required**	**Unit Price (MXN)**	**Cost (MXN)**
Skin	Glycerin	30 mL	$0.26956 / mL	$8.0868
	Gelatin	7 g	$0.67721 / g	$4.7405
	Water	22 mL	$13.48 / m^3	$0.0003
		Total (MXN)		**$12.8276**
	Material Used	**Quantity Required**	**Unit Price (MXN)**	**Cost (MXN)**
Fat/Muscle	Flour	120 g	$0.01326 / g	$1.5915
	Water	240 mL	$13.48 / m^3	$0.0032
	Cream of Tartar	2 g	$0.59052 / g	$1.1810
		Total (MXN)		**$2.7758**
		Total for Simulator (MXN)		**$16.0017**

For the selected concept, the total cost of the simulator is $16.00 MXN, which is approximately $0.80 USD. There are costs associated with the materials that hold the different components together, in the form of a glue mixture composed of water and flour. These costs, as small as they are expected to be, will be updated in the cost analysis calculations and table, as that aspect of the design is explored and finalized.

From this table, the most expensive component of this design is the skin layer. This is due to the high cost of glycerin, with a cost of $7.97 MXN. The least expensive material in general is water, as the price is determined from the water consumption that a household in Mexico is charged for. It is important to note that the amount of material required was measured using a kitchen scale and measuring cups, allowing for a medium level of precision.

The actual price of a simulator that is constructed by a user will likely vary, as it is not expected that the user-base will have access to high-precision measuring tools, and the instructions for constructing the simulator will provide low-level precision measurements for a user to follow and construct to the best of their abilities.

The team also at this stage spoke with Prof. Gutierrez, and was informed that the students are expected to be evaluated with the simulator approximately five times throughout a semester. The results of the reusability and durability analysis inform us of which materials/components can be reused and, if so, how many times. With this information, the team could then calculate a cost per use for a given simulator design.

This analysis helps contextualize the materials used and the requirement, “Is low cost,” by presenting the cost of the design as a cost per use. The team is using averages to determine pricing for materials that can reflect actual prices that the user-base will encounter when attempting to gather materials to construct their own intramuscular injection simulator. This being said, it is very likely that the team is overlooking the financial situations of some or potentially many users, with currently only thirty four respondents providing information leading to a small sample size and only a handful of supermarkets from which we can extract data from.

One particular worry that the team had was the matter of the prices of materials varying throughout the country, as there are in-state students in the state of Nuevo Leon and out-of-state students throughout the country, due to virtual classes during the COVID-19 pandemic. After research through the pricing of the three prominent supermarket chains in Mexico, there was no price difference between stores of the same chain in different cities and states. This finding increases our confidence in using a weighted average of the unit prices of materials based on the prevalence of these big three chains as accessible shopping sites.

In general, the results of the cost analysis will be used to help inform material selection, along with material properties analyses. The lower the cost of a given combination of materials for a particular component, the higher it would rank in comparison to other combinations for the same component. Ultimately, the team aims to reach a specific combination of materials for the components that minimizes costs, that still achieves favorable fidelity for the simulator.

As more materials are explored, they will need to be included for assessment. Therefore, this cost analysis will be recurring.

Instructions and Usability Analysis

The post-instruction survey was created to get feedback on our instructions (Appendix E) and see if they are readable and easy to follow. Some concerns are the tolerances on the dimensions and the mixes being incorrect. For example, the dimensions could be too large making the end product an unrealistic simulator. Another concern is the instructions may be challenging to understand. All of these could lead to the student not making the device correctly. Our Instruction Evaluation's current design addresses the following: time of completion, readability of instructions, and if any additional skills are needed. The additional skills question was added because the student may not be an experienced cook and may need further explanation. We also asked questions to determine if the product is worth the effort put into making it. We also asked about the amount of time it took to complete it to ensure the end product will be more effective than the student's current injection simulator options.

The team created a specific instruction analysis survey for the students of Nuevo Leon to complete after initially reading the instructions which can be found in Appendix H. This survey was broken down into five sections, having at least two questions per section one to evaluate the written instructions and the other to give feedback on the usefulness of the pictures and diagrams provided for that section. The instructions and survey were directly emailed to the 32 students that had provided their email address during the accessibility survey sent out earlier in the term. Of those 32 students only 4 responses were received, a breakdown of those responses are shown below in Table 9.

Table 9. Student Responses to Instructions Survey Questions

Section of the Instructions	Average Response on a 5 point Likert Scale
Paper Mache Base and Bones Instructions	4.25
Paper Mache Base and Bones Images	4.75
Dough Muscle and Subcutaneous Layer Instructions	4
Dough Muscle and Subcutaneous Layer Images	4.25
Gelatin and Glycerin Skin Layer Instructions	4
Gelatin and Glycerin Skin Layer Images	4
Cardboard stand and Final Adhesion Steps Instructions	4
Cardboard stand and Final Adhesion Steps Images	4.25

Based on the survey responses every section of our instructions could be understandable with an overall average rating of 4.06 for all of the written instructions. The images and diagrams provided were considered helpful with an overall average rating of 4.31. These ratings are positive and don't show any immediate concerns, although the small sample size obtained is a source of concern for the team and something that would have been addressed if time had allowed. We had about medium confidence in this mode of analysis, due to our concern of getting a sufficient response from the students. Being that only 4 student responses were obtained to read the instructions, no students were actually able to perform them and create their own model, much less give feedback on the time investment and overall quality of the process of the solution.

Failure Method and Effects Analysis (FMEA)

The team used FMEA to evaluate possible modes of failure that the project might encounter. Of the failure methods evaluated, the impact of the environment on the simulator and concerns that the simulator would not be sufficient for instruction. In addition to these failure modes a few other factors that were considered are listed in Table 10 below.

The impact of the environment comes from concerns that the team will be unable to run a full spectrum of tests to simulate the local conditions that the simulators will encounter in use. As this has a high chance of rendering the simulators inoperable and a low chance of being detected prior to the completion of the project a more robust set of tests needs to be determined to address this failure mode.

The concern that the tool is of little use to instructors comes from concerns regarding the robustness of the instructions coupled with a lack of hard metrics to use for comparison beforehand. To address this the team is communicating with stakeholders to determine the best means to verify the fidelity of the simulators as a team, while also pursuing means to determine how robust our instructions are to minimize error on the part of the students during construction.

The analysis into failure modes was similar to brainstorming with attempts made to explore as many possible modes of failure as possible. Even with risks which were already acknowledged there were still several risks which were determined to be more severe than had been previously assumed. This will help to provide focus for further development and to highlight where the team has ignored possible considerations in the design. Based on the analysis done the team is reasonably confident that the analysis is representative but not conclusive, with additional focus and contingencies needing to be developed to refine the analysis over time.

Table 10. Failure Method and Effects Analysis

Item	Function	Failure mode	Effects of Failure	Severity	Causes of Failure	Occur within a year	Design Controls	Detection	RPN	Recommended Action
Bone	Provide feedback that needle is too deep	Does not provide feedback	Needle is injected too deep, simulator fails one of its primary tasks	8	Bone is not sufficiently stiff. Bone does not hold shape	2	Layers are separated to prevent leaks. Bone is chosen to be stiff	2	32	Find means to preserve desired stiffness
Skin	Skin can be pierced	Skin cannot be pierced	Simulator cannot be used	8	Skin layer cannot be pierced	2	Materials selected for consideratio n are not noted for their resistance to piercing	2	32	Find better materials to use in place of a skin layer.
Simulator Materials	Lasts for a semester in local condition	Loses integrity before semester is over	Component must be remade incurring financial burden	7	Environment causes spoilage which was not anticipated	3	Layers are separated and materials are selected for shelflife	8	168	Perform testing at extreme conditions to evaluate modes of failure early

Use	Injected with a needle	Student hurts themselves	First aid is required	3	Student is not careful with a needle	4		4	48	Highlight dangers of using syringe in instructions
	Used as a simulator	Insufficient Fidelity	Tool is of no use to students	9	Instructors inform the team that the tool is not useful as a teaching tool	4	Talking with stakeholders to determine acceptable bounds for fidelity	4	151	Re-evaluate materials selected for use in the simulator suggested kit.
Building	Material can be found locally	Material cannot be found locally	Simulator cannot be built by students	9	Lack of market research	2	Performing market research	2	36	Confirm all possible materials with stakeholders before final testing
	Instructions are safe to use	Student is injured during construction	Student is unable to use simulator	3	Heat during gelatin cooking. Blades to cut components	4	Assuming common sense	4	48	Add notes to instructions of where caution should be used,
	Stand is fully made	Insufficient support of structure	Simulator has to be leaned against a wall	3	Not enough material to make stand	7	Include required dimensions	10	210	Have students confirm that they have enough materials before

Engineering Analysis Discussion

The student survey responses provided minimum values for monetary and time commitments, coupled with the material availability assessment and cost analysis results we were able to confidently proceed with the simulator solution we had chosen. Prototyping was an important aspect of this project, having established our solution was viable we also created instructions and began evaluating them as this is how the final solution will be presented and created by the stakeholders.

Verification

Several different verification methods were used to support the final design concept and determine if the stakeholder requirements and accompanying engineering specifications were met. Through the various processes detailed below it was determined that 16 out 18 specifications were met.

Is Low Cost

< $1 USD ≈ $20 MXN per unit

We were able to test this based on the supermarket chains available to the student’s in Mexico, using their online websites to determine the price of materials, as well as information from the Mexican government on the cost of water for an average Mexican household [33]. With this information, the cost analysis introduced in the engineering analysis section was used to obtain a cost to make a single simulator and is shown in Table 11.

The resulting cost analysis comes out to $34.41 MXN, which is approximately $1.73 USD. This is for single use, and includes both required and suggested materials. From initial durability tests, we conclude that the simulator can be reused at 25 times per training/practice session, with the maximum number of sessions that the design can last for is unknown, due to time constraints.. However, given that the design can be reused at least for another session, this cost is halved. This alone has the design passing its verification at $17.21 MXN or $0.87 USD. Subsequently, if the stakeholder can use the simulator for more sessions, the cost per use can be determined as the cost of the simulator, divided by the number of sessions the simulator is used for.

Table 11. Tabulated cost of final design

Component/Layer	Material Used	Quantity Required		Unit Price (MXN)	Cost (MXN)
	Flour	60	g	$0.01326 / g	$0.7958
Bone	Water	1	fl oz	$13.48 / m^3	$0.0004
	Newspaper	N/A	N/A	$0.00	$0.0000
		Total (MXN)			**$0.7962**
	Material Used	**Quantity Required**		**Unit Price (MXN)**	**Cost (MXN)**
	Glycerin	30	mL	$0.26956 / mL	$8.0868
	Gelatin	7	g	$0.67721 / g	$4.7405
Skin	Water	15	mL	$13.48 / m^3	$0.0002
	Makeup	0.1	mL	$23.5333 / mL	$1.4000
		Total (MXN)			**$14.2275**
	Material Used	**Quantity Required**		**Unit Price (MXN)**	**Cost (MXN)**
	Flour	120	g	$0.01326 / g	$1.5915
	Water	120	mL	$13.48 / m^3	$0.0016
Fat/Muscle	Cream of Tartar	6	g	$0.59052 / g	$3.5431
	Oil	15	mL	$0.09054 / mL	$1.3582
	Salt	72	g	$.17915 / g	$12.8991
		Total (MXN)			**$19.3936**
		Total for Simulator (MXN)			**$34.4172**

Is Accessible
Open source design

For the design to be open source, the design information must be publicly available. The stakeholders have access to written instructions on how to build the design, as well as a supplemental video which visually explains the steps involved, both in Spanish. Anyone with access to the instructions can follow them to build the simulator.

Can be built using local materials

Local materials were verified via the inventory of the highest reported supermarket chains from the availability survey filled out by the students in Mexico.

Requires 0 unique tools

To verify unique tools, the instructions were reviewed, as they have a list of required tools and materials and an additional list of suggested tools and materials that can help the build but are not necessary. Unique tools are defined as any high-level tools that are not commonly found in a household, such as machining tools, power tools, etc. and we assume that the tools we list as required are considered common household items. From this confirmation, the design passes this verification.

Includes assembly instructions

The inclusion of assembly instructions is verified, as the team is delivering a set of written instructions as well as a supplemental video which visually explains the steps involved, both in Spanish.

Requires < 2 hours to construct and <3 days for drying, baking, etc

The availability survey filled out by students in Mexico includes questions targeted at gauging how much time they are willing to commit to the build. The results of our engineering analysis for availability allows us to define a maximum time for construction as well as drying/baking, which will be used as an upper bound for this verification, which was met when testing how long it takes to build a simulator.

Mimics Skin Tones
6 skintones following Fitzpatrick Scale

To verify this requirement, we created six different skin tones following the Fitzpatrick scale [23]. The picture below verifies, our skin layer can be used for different shades of skin. Students will be able to use a foundation that matches their skin tone, or any other skin tone they desire to obtain.

Figure 30. Fitzpatrick Scale Inspection

Teaches Procedural Skills
Nurses and instructors-based ratings - average rating above 4 using MiSSES survey/ Skills based on rubric provided by sponsor

We tested this using a survey which will be provided in the Appendix I, with accompanying results. When converted to a 5 point scale the responses to questions regarding improved skills and improved confidence fell above 4 points on average. This confirms that the design can be used to teach procedural skills.

Feels Like a Shoulder
Nurse students and instructors rate at or above a converted 4 point average when using a survey provided by the team.

This was assessed using a survey asking about the general fidelity of the prototype, the fidelity of the skin layer, and the fidelity of injection. From the 14 surveys collected the average scores on a 5 point scale were 4.6 for all three questions of feel and fidelity. In addition, when asked to compare our design against an injectable pad and an orange our design was rated the highest for puncture resistance and skin texture in 10 out of 12 responses. This confirms that the design sufficiently feels like a shoulder to be used in training. The results of the survey can be seen in Appendix I.

Has a Bone
Provide tactile response to hitting a bone/ Provides landmark for shot placement/ Skin to bone thickness: 223 mm

We used a survey asking about whether the bone could be felt and whether the bone provided adequate landmarking for shot placement. This yielded an adjusted average of 4 which meets our established threshold for fidelity. The instructions provide the measurements mentioned in specifications. These results are sufficient to pass the specification. The results of the survey can be seen in Appendix I.

In the Shape of an Arm
Max. Circumference: 332(M), 310(F) mm/ Length: 196.5(M), 180(F) mm maximum

Instructions regarding the dimensions of the design follow the standards set by the specification. A survey given to students at the Clinical Learning Center responded with an adjusted average of 3.5 when asked about the size and shape of the design. This is below the recommended threshold for success and does not pass specifications. While the instructions fulfill the requirements, there is still room for improvement as it does not pass tests of visual fidelity. The results of the survey can be seen in Appendix I.

FeedBack

Unit provides tactile, auditory, or visual feedback when an error occurs during use

At the Clinical Learning Center, we talked to staff, faculty, as well as nursing students while they tested our device to learn more about how they think it compares to a real arm. We asked through our surveys about the feedback block and if it was noticeable. We also asked about the drawn triangle that represents the injection site as a method of self evaluating the user's performance. Responses reported that the placement triangle was effective at checking to see if the injection was placed in the correct area. Most responses also reported that the feedback block was not noticeable. This test told us that we should make the feedback block more noticeable so that it can work the way it's meant to. Based on the survey responses we decided to omit the feedback block from our final design due to the large amount of time and effort it took to create the block, the excess weight it added to the simulator, and it's current lack of feedback.

Is Durable

Can withstand 100 pokes without replacement/ Lasts 1 semester/Can withstand 100 rubs of alcohol pads

We created a skin layer that was made up of glycerin, water, and gelatine and poked it with a syringe several times. The skin was divided into 5 different sections. In an increment of 25 pokes the amount of pokes for each section went from 0 to 100. The skin was then left to sit out for about 2 weeks. This test allowed us to determine the amount of possible pokes before needing to be remade. This test also allowed us to see if the skin was self-healing. Figure 31 below shows a skin layer broken up into five sections with different amounts of pokes.

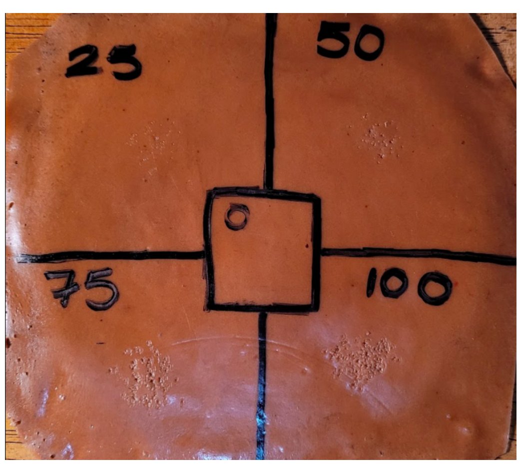

Figure 31: Skin layer with 0, 25, 50, 75, and 100 pokes with a syringe to test durability and self healing.

At 50 and up the pokes became more noticeable making it easier to give away the injection site. The skin was not self healing. The skin remains unchanged after the test was done. A skin layer was wiped repeatedly with alcohol wipes and the skin showed no change. The flour that covers the layer will be removed after each wipe but it can be reapplied for each use. This shows that the students will be able to practice the part of the procedure that has them clean the injection site. The specification of the device being able to last for 1 semester was not able to be tested because the duration of this project is one semester and the prototype was created about halfway through the semester. It is worth noting that both a sample of the skin and fat layer have lasted 6 weeks without noticeable degradation. This will have to be tested by future project teams.

Validation

Simulation based clinical education is a useful and successful teaching approach for nursing students without compromising patient well-being. Validation of this intramuscular injection simulator is two-fold. This simulator must meet all previously verified specifications regardless of who creates it and it must also fulfill its role as an effective learning tool for nursing students. Both of these aspects of the simulator were not the main focus of the design process and further research is recommended to fully validate this solution.

First the simulator should be able to demonstrate full compliance of all engineering specifications and stakeholder requirements for all students and medical professionals who will be creating their own simulator using the instructions and video provided. Steps were taken to validate instructions using surveys and as previously discussed many verification steps have been taken to control the outcomes of the simulators, but we must be conscious of the limitations such as limited sample sizes in surveys and the fact that we were unable to have someone outside of the team create a full simulator. Validation would need to be completed through large user participation while confirming the quality of the simulators created and addressing any vague or confusing instruction or ingredients that may lead to disparities between models.

The second aspect of the simulator which needs to be validated is its use as an effective learning tool. High fidelity simulators have been shown to be most effective in producing cognitive and affective outcomes. When aiming to achieve psychomotor learning outcomes, as we are with the intramuscular injection simulator, medium fidelity simulators were found to be the most helpful although learning task and context play a large role leading to varying educational outcomes [34]. Based on the shape, bone simulation, texture and visual feedback of our intramuscular injection simulator, it is considered medium fidelity which is ideal when trying to obtain effective learning outcomes. Aside from the level of fidelity of a simulator a recent study reported that debriefing was the most important factor in simulation, showing positive effects from self-debriefing and video-facilitated instructor debriefing [35]. The lesson plans and assessments associated with the use of the simulator was not the main focus of this project, but plays an essential role in its success as a learning tool. Some of the features and aspects of medical simulators that lead to effective learning are [36]:

1. Provide feedback during the learning experience with the simulator.
2. Learners should repetitively practice skills on the simulator.
3. Integrate simulators into the overall curriculum.
4. Learners should practice with increasing levels of difficulty (if available).
5. Adapt the simulator to complement multiple learning strategies.
6. Ensure the simulator provides for clinical variation (if available).
7. Learning on the simulator should occur in a controlled environment.
8. Provide individualized (in addition to team) learning on the simulator
9. Clearly define outcomes and benchmarks for the learners to achieve using the simulator.
10. Ensure the simulator is a valid (high degree of realism or fidelity) learning tool.

Using the listed features and a structure lesson plan we could take the validation process one step further by comparing learning outcomes from the simulator versus fruit, meat or family stand-ins currently in use. This would ultimately confirm and quantify the learning benefits of students creating their own simulator with the provided instructions and video.

Discussion and Recommendations

Critiques and Future Work

While the design met many of the design requirements, there were still areas for improvement that can be identified. They were identified and organized by function or component of the simulator.

Fat/Muscle Layer

Although feedback from usability testing suggests that the design is more favored than the simulators it was compared to, namely an orange and an injectable pad [14], the team also received comments about not being able to pinch the simulator like with a real arm. Upon consulting with one of our sponsors, we learned that this was more common practice for a subcutaneous injection; an injection into the fat layer rather than the muscle layer. Although this was not part of the design requirements, it may be useful to look into allowing for this form of interaction. The design could be expanded to simulate subcutaneous injections as well.

Shape of the Shoulder

Feedback from usability testing also indicates that there is better visual fidelity when compared to the other two simulators it was compared to. However, most feedback that was received also suggests improving on its overall shape to look more like a real shoulder and upper arm. Improvement of this visual fidelity would ultimately serve the stakeholders in getting a design that can better help learn and improve injection placement.

Bone Structure

Although the design meets the requirement of having a bone and it being hard enough to withstand needle punctures, the team noticed a variable when conducting usability testing.

Some needles were not long enough to reach the bone structure. For this reason, the design could be expanded by manipulating skin-to-bone thickness to mimic different use cases for the simulator, allowing it to simulate patients of different sizes.

Instructions
The design includes written instructions as well as supplemental video instructions to help clear any potential confusion when a user would attempt the build. Further user testing of the instructions would help improve overall clarity, as only 4 people have tested the instructions and provided feedback.

Material Properties
The team used surveys as part of the usability testing in order to understand the fidelity of the design. Although the primary mode of testing for simulator fidelity is based on these types of surveys, the team recommends more research into material properties to determine an additional form of verification for the "Feels like a shoulder" design requirement. This is something that the team attempted to find but through puncture force tests and comparing densities of materials, but did not lead to any verification methods.

Alternative Materials
The team aimed to find materials that would help the overall design in the form of substitutes or as additional recommendations to help lengthen the design's durability. The team recommends determining a larger list of viable materials, which would increase the design's accessibility by providing substitutions for different components of the simulator.

A large beneficial action that can be taken to help identify more improvements would be introducing formal usability testing at a larger scale and is therefore something that the team has determined to be a logical next step.

Engineering Standards

During engineering analysis the team considered using several different standards to evaluate the stiffness (ASTM D1388-18) and puncture resistance (ASTM F2878-19) of our design. However, for final verification we did not follow any standards for the development of our surveys, though the clinical simulation center was contacted for advice on what to include in a survey and initial designs of our cost and accessibility survey were presented to CSCAR for advice to minimize bias and maximize obtained information.

Engineering Inclusivity

The design team practiced engineering inclusivity throughout the design process and ensured aspects of inclusivity within the design itself as well. This section will discuss what steps were taken by the team to create and develop an inclusive design and inclusive space.

Stakeholder Engagement
The team focused on fostering engineering inclusivity initially by setting a point of connection via our sponsors. We were able to get in touch with a primary representative of the stakeholders in Mexico, Professor Juana Mercedes Gutiérrez Valverde. Professor Gutiérrez was our main point of contact to share ideas and have a conversation. Stakeholder engagement was the primary method through which a list of requirements was determined. Professor Gutierrez also helped us get in contact with her nursing students, who are the primary user base of the intramuscular injection simulator. The team interacted with the user base by sending them a survey to gauge what is accessible to them. During the verification stage of our design process, the team also interacted with students from The University of Michigan School of Nursing. They were critical to helping us gauge usability, using them as a proxy for our user base. We asked for feedback from their important unique perspectives as nursing students that have learned the skills, students that have interacted with other simulators as learning tools, and as students that have administered vaccines or real patients. The team also briefly interacted with subject-matter experts, such as representatives from the UM School of Nursing's Clinical Learning Center, to aid us in understanding the characteristics of simulators as a learning tool from the perspective of educators and simulation technicians.

Inclusivity in Design
The team also worked on making sure there were considerations of inclusivity in the design of the simulator. To incorporate aspects of inclusivity in the design itself, the team included inclusivity-focused elements within our high-priority requirements. This was accomplished by including a low cost requirement with an engineering specification of less than $1 USD per simulator. An accessibility requirement is also included, with engineering specifications of "open source design," "can be built using local materials," "requires 0 unique tools," "includes assembly instructions," and "requires < 2 hours to construct and < 3 days for drying, baking, etc." Through these requirements and specifications, the design is aimed to ensure that it can be affordable for low-resource communities by incorporating common household ingredients, materials, and tools, and can be built by anyone by being open source. Additionally, a skin tone requirement is also included with a specification of "6 skin tones following the Fitzpatrick Scale." This requirement allows the design to simulate the reality that in practice, the user base will likely interact with many types of people, of varying skin colors. The design team felt that it was important to reflect this by not limiting the design to one single skin tone, which is not representative of the population. Along the same line of thought, the team also realized that patients come in different shapes and sizes, and for that reason, the instructions also include different sets of dimensions, based on different use-cases representing different patient sizes.

Environmental Context Statement

We recommend disposing of the skin layer following procedures appropriate for glycerol to avoid issues with gelling, and that needles used for training be taken to a hospital for proper disposal. We recommend that the skin and fat layer be used and repaired for as long as possible, whether by reforming the skin layer to remove holes or by rehydrating the fat layer to provide the proper texture. As there is no large scale production planned there is no worry of additional impact due to manufacturing or factory pollution beyond what is required to initially manufacture the components. This does create an issue with a limited lifespan, but the expected lifespan is proposed to outlast the designs use at 6 months. This limited lifespan is after steps to extend it for as long as possible (taking steps to prevent spoilage and encourage reuse) and already considers recycling materials for use in its design. The design is biodegradable except for the skin layer.

Ethical Decision Making

Our team kept the school's Honor Code and ASME Code of Ethics in mind throughout the design process. First, we researched the different sizes of arms in Mexico to ensure our simulator accurately depicts what the students will be using. We were concerned if the size was not accurate. The students could potentially mess up the injection because they trained with a different size arm, leading to pain for the patients. When in the design stage, we ensured that our selected concept would not increase safety risk than other simulators by reducing the number of sharp objects needed to create the simulator. Another concern was using an animal product gelatin; we were concerned some may have an internal conflict of using an animal product. Tests were performed to determine a non-animal product substitute. However, due to time constraints, a suitable solution was not determined. Another concern was ensuring the simulator was environmentally friendly. Our final concept uses the minimum amount of plastic, tape, and most biodegradable material.

Social Context Statement

Engineers have to consider the impact their work will have on people and society. They should be working towards finding solutions that benefit people and not harm them. They must be mindful and respectful towards the community they will be impacting. When working on a project, engineers have to figure out who will be affected by their work and in what way. When creating our device, we took into consideration the costs and benefits of creating it. We gathered information to learn more about the level of accessibility the target audience has and how we can improve it. We did research on the stores in their area to find a location that has all of the required items at a reasonable price. We also took into consideration the environmental health and safety costs by using materials that can be used multiple times or can be disposed of in a way that does not negatively affect the environment. We also took into account the beliefs and values that the audience may have. We explored materials that were non animal based to make sure it is accessible to everyone.

Conclusion

Having gone through the process problem definition, concept expiration, engineering analysis and final verification the team is confident that we have created a design for an intramuscular injection simulator which can be used in low resource settings for training. The feel to both the hand and injection is reported to be similar to the experience of an actual injection. The resources to create the simulator have been verified to be available and within budget for the target group. The team hopes that it will be of use to students in Mexico for their education and continued skill training.

The feedback we have received from sponsors has been positive so far. There are still some design changes that we would like to explore though given the time. One is an exploration of other materials which could be used to create the simulator. This would allow for a wider range of availability and could continue to help with prospective costs of manufacture. Another remaining concern was increasing the visual fidelity of the design. This could help increase its use outside of landmarking training and allow for better transfer of skills.

The project has been a success and we hope to continue applying and refining the skills which we have developed over the course of this project.

Authors

This report was written through the combined efforts of Alexsis Salgado, Jack Carvill, Kevin Solorzano, Nallely Flores-Martinez and Vanessa Rojano. The team is sponsored by Caroline Soyars and Megan Eagle. The team is working under the direction of Dr. Kathleen Sienko.

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Appendix A: Project Timeline

Intramuscular Injection																
UofM																
Task	Start Date	End Date				F	e	b		M	a	r		A	p	r
		Date:	1/19	1/26	2/2	2/9	2/16	2/23	3/2	3/9	3/16	3/23	3/30	4/6	4/13	4/20
1.0 Problem Definition	21-01-19	21-02-08	Y	Y	Y											
1.1 Reach out to stakeholders	21-01-19	21-02-08	Y	Y	X											
1.2 Obtain initial requirements	21-01-19	21-02-08	Y	Y	Y											
1.3 Research Specifications	21-01-19	21-02-08	Y	Y	Y											
1.4 Design Review 1	21-01-30	21-02-08			Y											
2.0 Concept Generation	21-02-04	21-02-26				X	X	X								
2.1 Interview Stakeholders	21-02-04	21-02-24				X	X	X								
2.2 Identify Test procedures	21-02-09	21-02-22				Y	Y									
2.3 Identify possible Materials	21-02-11	21-02-17					X									
2.4 Begin Sketches of possible designs	21-02-09	21-02-15				X										
2.5 Begin Works-like prototyping	21-02-13	21-02-26					X	X								
2.6 Design Review 2	21-02-19	21-02-25						X								
3.0 Solution Development	21-02-23	21-03-17						X	X	X	X					
3.1 Begin Second Round of Prototyping	21-02-23	21-03-08						X	X							
3.2 Identify final materials	21-02-28	21-03-13							X	X						

3.3 Reach out to identify possible test locations	21-02-23	21-03-15						X	X	X						
3.4 Finalize test procedures	21-03-09	21-03-15								X						
3.1 Design Review 3	21-03-09	21-03-17								X	X					
4.0 Verification	21-03-18	21-04-19										X	X	X	X	
4.1 Finalize Design	21-03-18	21-03-31										X	X			
4.2 Begin Final round of testing	21-03-25	21-04-07											X	X		
4.3 Final polish/documentation	21-04-04	21-04-17												X	X	
4.2 Design Expo	21-04-08	21-04-19													X	

Figure A.1: Gantt Chart of Proposed Timeline

Appendix B: DR1 and DR2 Sections and DR3 Sections

Next Steps - Concept Exploration-DR 1

Concept Exploration

With the initial requirements and specifications established we can begin concept generation, by brainstorming a large variety of ideas. It is important to allow every team member the space to come up with their own ideas and concepts without skepticism or limitations while being conscious of biases towards certain ideas. We plan to individually brainstorm concepts for the simulator and then come together to expand and diverge on those concepts as a team. The focus of the brainstorming sessions should be on providing solutions to the existing requirements and specifications which can include thinking of different structures, materials, designs, processes etc. This ideation process should be short and cyclic in order to minimize potential blocks, pushing to create more ideas than originally planned.

Concept Development

Once many different potential solutions have been identified it is time to bring more focus to these ideas by iterating the ideas under more careful consideration. The ideas can be measured in terms of quantity, quality, diversity, and novelty. The purpose is to bring forward the high quality ideas that address the problem effectively and efficiently. There is some reduction in the number of ideas, but the focus should still be on expanding on the existing concepts. One method of further expanding on an existing idea is the repeated application of design heuristics. Some of the strategies that we may look to apply are the use of repurposed or recycled materials, provide sensory feedback, layer, and allow the user to assemble. Another method to further develop existing ideas would be to create a morphological chart. Due to the various layers of the human body and multiple specifications that must be met we will likely have different people coming up with the most effective way to address different components, thus a certain combination created by a morphological chart might be ideal.

Concept Evaluation

The high quality ideas must be criticized even further and reduced to a manageable set of potential solutions. It will be useful to screen the ideas by grouping related ideas together, identifying gaps in the groups of solutions and assessing the advantages or limitations of each idea. Constraints and barriers should also be identified, all while not being afraid to let go of an idea that is not within the team's capabilities. The process of reducing to one single idea should be very thorough and thoughtful by individually comparing each idea to the requirements and specifications. Based on the nature of the simulator we want to create we will likely group ideas in terms of affected stakeholders, anatomic location or funding required due to the low cost requirement of the simulator. The concept evaluation process can be very subjective, having individual team members narrow down the ideas individually before coming together will give everyone a chance to assess and measure each idea based on their individual thought process. Ideally the preferred concepts among team members should be similar, but if not an open discussion should be had where the concepts are reviewed critically against the requirements and specifications. Critical review should include the performance of prototypes, especially because the simulator has direct impact on the stakeholders training experience and performance in the medical field.

Project Plan, Status and Challenges - DR1

Challenges

The team foresees several challenges with this project going forwards. The first and most obvious is the global pandemic which makes doing any sort of in person testing difficult. Another is that two of the stakeholders that inspired this project do not live in the United States, and one of them lives at a 12 hour time difference. This makes communication difficult and may introduce language barriers while we try and determine what requirements they have. A third challenge is to assess possible methods of alerting the user that an error has occurred, given limited access to labs to test electronic solutions and not knowing the availability of resources in the desired end settings. There is also the issue of preserving the fidelity of the model, with multiple layers and a bone, while still having a low final cost to allow for construction by students who will make use of the model.

Stakeholder Engagement

At this point in the project, the team is reaching out to stakeholders to gain a basic understanding of what is required to design a medical training device, to source materials in another country, and test a medical device in a pandemic. As such, stakeholders are currently subject matter experts and will eventually be members of a focus group giving advice on how to further refine the teams prototype.

The team is currently reaching out to stakeholders to have an initial meeting over zoom. This is to establish a point of contact with the stakeholders. In addition this meeting can serve to highlight either other avenues of investigation or better people to contact going forwards. Once the team has an established set of prototypes the plan is to reach out to members of the Clinical Learning Center to see about having residents perform tests on the prototypes and gather feedback for another round of design. This might be difficult given the concerns of the pandemic, and if it cannot come to fruition then the team will need to seek other means of improving the designs iteratively.

There are several benefits to our team engaging with stakeholders throughout the design process. The first is that this is a biomedical project and the team is composed of mechanical engineers. By engaging with stakeholders, the team can gain knowledge common to the medical field that we might have ignored. Another related topic is the ease of gathering relevant feedback from stakeholders who have a better understanding of both the desired feel of a simulator and the pedagogical underpinning of why simulations are used in training. The stakeholders have connections and resources in the medical field that our team might not know about. They can connect our team with other individuals with different experiences and levels of expertise.

Despite the benefits, there are also several challenges associated with interacting with stakeholders. The first is that due to the pandemic in person interaction is limited, which may make it difficult to schedule testing and feedback sessions once the team enters the prototyping phase. Another is that due to the team's inexperience with the medical field at large we may not know the best questions to ask stakeholders to maximize our interactions or waste time asking questions that are common knowledge in the field. While this will likely be diminished as time goes on, it is still a concern in the early portions of the design process given our tight time constraints. A third difficulty might be differing standards between the team and our stakeholders. As we are tasked with a low-cost training tool there might be disagreements regarding the effectiveness of the tool and how to address those concerns from a cost perspective if our communication is flawed.

Thus far the team has reached out to experts on medical device design, with an initial meeting scheduled for February 12th at noon. We have also already had initial meetings with the Clinical Learning Center, Clinical Simulation Center, and Yvonne Wu, to gain a better understanding of the current state of simulators in medicine and how to account for differences in manufacturing in other countries. These meetings have provided a list of suggested materials to consider when designing a prototype, several other people to reach out to for further information, and some descriptions of the design process available in other countries. These conversations that we've had thus far have caused us to be more aware of information that we have found and how that might change because our design is meant to work in other countries instead of the United States.

The team met with Caroline Soyars and Professor Meagan Eagle, who instructed us to have a bone or something hard into the prototype. Also, they suggested making the prototype with materials at home. This is so the other students in other countries can also make these simulations at home. The team's next steps will be to establish communication with our foreign sponsors to better understand what materials will be available to their students. The team also met with stakeholders from the Clinical Learning Center, which then led the team to find a simulation evaluation survey. The other meetings with stakeholders were to establish a connection; the team will be utilizing them once further in the design process.

Team Organization
The team is currently meeting two times a week outside of class to discuss progress and determine if any issues have arisen that need to be addressed. Thus far, the meetings have been to tabulate the prior work done on the subject matter. Going forward, the time can be used to discuss possible concepts, or to critique proposed solutions.

There are not currently any sub-teams within the group as the primary focus has been on compiling prior work and defining the problem as defined by the sponsors and stakeholders. Going forward, each member of the team might work independently to develop several prototypes at once to take advantage of the low cost of the final solution to iterate through designs quickly.

The plan for meeting with sponsors is currently to meet with Caroline Soyars once every two weeks to provide updates on the progress of the team and otherwise gain clarification if necessary. Meeting plans involving our other sponsor Megan Eagle, have not been solidified at this time and will be scheduled according to her availability.

Timeline
Design Report 2 is due February 23rd. By that point the team should have identified the most promising candidates for works-like prototyping. This process will require communication with stakeholders that we have not met with yet. It will also require that the team identify promising materials that can either be procured easily or simulate the properties we desire well. In addition the team should be in communication with possible testing sites to develop methods of verification for later stages of development.

Design Report 3 is due March 17th. By that point the team should have gone through a first round of testing and have begun making iterative improvements on the selected designs. To accomplish this the team will need to have reached out to possible testing sites and identified the method used for testing and feedback on the designs. In addition, the selected designs will need to have been constructed with a look towards at home manufacturing.

The Final Report is due April 19th. By that time the team should have a finalized design in mind and have finished documentation and verification of said design. The final design should fulfill the most recent set of specifications and requirements. The design should also pass approval of our sponsors.

Incorporation of Presentation Feedback

One thing that changed in this report was ranking the requirements and specifications. This was done to give our readers a better understanding of what the team will be prioritizing.
Another thing that our stakeholders mentioned was to add requirements based on open-source design. Although the information that will be used is unknown yet, once the team meets with our sponsors in other countries, this requirement will then be complete. This requirement is

needed, so it is not forgotten, and potentially a product is made here but cannot be replicated in Mexico ~~or Indonesia.~~ Another suggestion was to add more benchmarking; in response, more prototypes were added to the benchmarking table. Also, another suggestion was made to change the Likert scale requirement. A questionnaire was obtained from Michigan Standard Simulation Experience Scale. This scale will evaluate several domains of the prototype. However, this is just a starting point.

Conclusion-DR1

The team has concluded the Problem Definition phase of the design project. We have identified the scope of the project to be the design of a low cost deltoid simulator for use in training of nurses, midwives, and doctors in Mexico ~~and Indonesia~~ in the practice of intramuscular injections. To address this problem we have compiled an early list of specifications to fit the requirements provided by the sponsors, with justifications from existing literature. In addition, the team has begun reaching out to other possible stakeholders to gain their insight going forward.

Going forward, the team plans to begin the Concept Generation phase of the design process. This will involve creating several possible designs to pursue into later stages. In addition, the team will continue researching possible materials and testing methods to help streamline later parts of the design process.

Project Plan, Status and Challenges-DR2

Challenges

As our team has progressed further with our project, we have come across new challenges on top of the ones we've been dealing with. The global pandemic continues to pose a challenge for our team. We are planning on meeting with faculty and students from the student learning center on campus. We want to present them with some of our prototypes to test and get some of their devices for us to look at. We have to work with them to find the best way to meet in person safely. Another challenge our team is facing is a lack of experience on our part with giving injections. We are going to be creating our prototypes but won't be able to adequately test it to the standards of medical professionals. We are planning to give our prototypes to nursing students and their teachers to test out and ask for any feedback such as what it does and doesn't do well.

We are also looking into communicating with students in Mexico. We would like for them to go through the process of creating the prototype's we designed to see how well they can be repeated. After talking to the students in Mexico, we hope to have a better idea of the materials and supplies that they have. One of our high priority requirements is making this device low cost. We want to give them the option to use materials that are cheap and easy to find. We need to work with them to determine if the materials we are currently using are accessible to them and are not expensive.

Stakeholder Engagement

We have started communicating with Mercedes who is a nursing professor at the Autonomous University of Nuevo León in Monterrey (UANL), Mexico. We met with her on zoom and are planning on scheduling another meeting with her when she is available. After our initial meeting with her, she told us that the simulator will be created by the students and they will be the ones to buy the materials. Mercedes will be sending us the rubric that they use to evaluate their students on intramuscular injunctions. We are working with her to learn more about the important things their students should be able to learn and practice.

We are continuing to meet with our sponsors Caroline and Megan. We have biweekly meetings with Caroline and try to meet with Megan when she is available. Caroline is helping connect us to people that can help us figure out the best way to find supplies in Mexico and the process we need to go through to learn more about what is available in Mexico. We are also going to work more closely with instructors and students at the learning center on campus. We would like to meet with them as soon as possible so that we can determine what is working and what is not with the materials we are considering for the device.

Team Organization

Our team is continuing to meet twice a week and adding additional meetings throughout the week if necessary. Some of our team members have started creating prototypes of the device. As a team, we are going to create different iterations of the design by using different materials to see which ones work best. Making the prototypes at home, allows us to determine if our design can actually be made at home and get a sense for how feasible it is. Each team member has chosen a part of the design to focus on. Jack is exploring a full dough device, Nallely is focusing in the drying process for the paper mache bone as well as the device's orientation, Kevin is investigating the way the materials interact with one another as well as the device's assembly, Alexsis is exploring using a four mix and plastic bottles for the bone, and Vanessa is looking into replicating skin color and different mixes for the muscle. While working on the prototypes, we will be aware of the process that we went through when creating them to provide clear instructions to the students in Mexico that will be trying to replicate the design.

Timeline

The next design review is in about two weeks by then we would like to have chosen the main materials that we will be working with and the overall set up of the device. Our time will be spent on finding the best combination of materials as well as any substitutes for each layer. To accomplish this the team will need to have reached out to possible testing sites and identified the method used for testing and feedback on the designs. In addition, the selected designs will need to have been constructed with a look towards at home manufacturing.

The Final Report is due April 19th. By that time the team should have a finalized design in mind and have finished documentation and verification of said design. The final design should fulfill the most recent set of specifications and requirements. The design should also pass approval of our sponsors.

Incorporation of Presentation Feedback-DR2

Per the feedback from the presentation the Concept Generation section was widened to include discussion of the design space and generally go through the methods used in more detail. It was suggested that we consider more specific challenges and how we plan on dealing with them. We have been finding challenges that we need to start taking into account even though they may not play a role now. It was also recommended that we included a timeline that shows our current and future plans for the device. This report includes details of where we plan to be at each of the future design reviews. We were also told to revisit our requirements and specifications to make sure that they cover all of the needs of our sponsors. We have updated some of our requirements and are changing the priority levels to make sure we focus on the main needs of our sponsors.

Conclusion-DR2

The team has concluded the Concept Exploration phase of the design project. We believe we almost fully explored the design space and have identified a wide range of concepts. We have selected one concept to measure against the current designs and specifications and began physical prototyping. Concept exploration will continue as we experiment with different materials and begin testing against requirements and specifications. Requirements and specifications have been updated based on feasibility and stakeholder needs and will continue to be updated as required.

Going forward, the team plans to identify the top design drivers and begin the Engineering Analysis phase of the design project. This will involve various analysis and assessments of material availability, material properties, costs, and user instructions. Analysis will be performed while being aware of assumptions made and the limitations of the analysis types. In addition, the team will continue to create prototypes and research possible materials and testing methods.

Selected Concept DR3

The selected concept was then individually assessed against the current requirements and specifications in a pass/fail fashion in order to determine immediate holes in the design. The selected concept met most currently defined requirements and specifications, while two needed further testing of the prototype. At least three of the requirements and specifications were under review, so it could not be determined if they would be met by this concept. The breakdown is shown in Table 5 below.

Table 5. The Feedback model measured against the requirements and specifications

Priority	Requirement	Meets
High	Low Cost	Yes

High	Accessible	Under Review
High	Simulates Skin Texture and Resistance	Needs Testing
High	Simulates Skintones	Yes
High	Has a Bone	Yes
Med	Teaches Procedural Skills	Needs Testing
Med	Feedback	Yes
Med	Feels Like a Shoulder	Under Review
Med	Shape of Upper Arm	Yes
Low	Durable	Under Review
Low	Water Resistant	Needs Testing

Requirements and Specifications -DR3

Is water resistant:

When performing an intramuscular injection it is essential to disinfect the area in order to avoid infection and contamination. It is crucial for the simulator to be alcohol resistant or at least waterproof so that the trainee can practice proper procedure. This requirement will need to be considered during concept exploration, specifically as we narrow down potential materials for the outer epidermis layer of the simulator. We are using the existing ingress protection scale published by the international Electrotechnical Commission (IEC), IP XX where the first digit is dust resistance and the second is water resistance [30]. We currently are not prioritizing dust resistance, but hope to obtain a water resistance score of IP X4-X7. Level 4 protection against water is tested by splashing water from an oscillating fixture for 10 minutes while a level 7 test immerses the product in water to a depth of one meter for 30 minutes [30]. This specification will be refined throughout the entire design process and tested multiple times to insure accuracy.

Project Plan, Status and Challenges-DR3

Challenges

As progress is made several challenges arise before the completion of the project. The first is that one of the primary stakeholders, the students, speak primarily spanish. This means that communication must be translated and written so it is clear in spanish as well as english. Another challenge is the continued challenge of verifying the final product in the pandemic and distributing the instructions and kits so that they can be evaluated. On the financial side, since each team member is constructing their own prototype, care must be taken to ensure that the budget is not surpassed and that there are means to reconcile and reimburse each team member for their purchases. A challenge that arose during testing was getting accurate data during the force test. The softer materials' puncture force was not being read by the force gauge. In order to use force to compare our device to an arm, we will have to explore using a mechanical force gauge over a digital one as well as looking for other methods to measure force.

Stakeholder Engagement
We have continued communicating with Mercedes who is a nursing professor at the Autonomous University of Nuevo León in Monterrey (UANL), Mexico. We have arranged to meet with her on zoom regularly to provide updates, and to ask clarifying questions. We are working with her to learn more about the important things their students should be able to learn and practice.

We are continuing to meet with our sponsors Caroline and Megan. We have biweekly meetings with Caroline and try to meet with Megan when she is available. Caroline is helping connect us to people that can help us Figure out the best way to find supplies in Mexico and the process we need to go through to learn more about what is available in Mexico. We are also going to work more closely with instructors and students at the learning center on campus. We would like to meet with them as soon as possible so that we can determine what is working and what is not with the materials we are considering for the device.

Team Organization
Our team is continuing to meet twice a week and adding additional meetings throughout the week if necessary. All of our team members have started creating prototypes of the device. As a team, we are going to create different iterations of the design by using different materials to see which ones work best. Making the prototypes at home, allows us to determine if our design can actually be made at home and get a sense for how feasible it is and allows us to refine instructions over time. Each team member has chosen a part of the design to focus on. Jack is exploring how to best describe the instructions for the muscle component. Nallely is focusing on the drying process for the paper mache bone as well as the device's orientation. Nallely is also focusing on compiling data from surveys to help justify specifications and verification. Kevin is investigating the way the materials interact with one another as well as the device's assembly. He is also doing work to justify our costs against what is available in Mexico. Alexsis is exploring using a flour mix and plastic bottles for the bone. She is also reaching out to stakeholders to get their opinions on the device and seeing how it can be improved. Vanessa is looking into replicating skin color and different mixes for the muscle. She is also doing work to verify our material properties. While working on the prototypes, we will be aware of the process that we went through when creating them to provide clear instructions to the students in Mexico that will be trying to replicate the design.

Timeline
The Final Report is due April 19th. By that time the team should have a finalized design in mind and have finished documentation and verification of said design. The final design should fulfill the most recent set of specifications and requirements. The design should also pass approval of our sponsors. A detailed project timeline can be seen in Appendix A.

Incorporation of Presentation Feedback

Per the feedback from our Engineering Analysis presentation a wider discussion of analysis methods and their impact has been included. This was to address the lack of explanation behind the methodology used to determine the results from the analysis. In addition, notes have been made of analysis that has not yet been completed, but would be of use in the final evaluation of concepts.

Conclusion

The team is in the midst of the Engineering Analysis phase of the design project. We have begun to find rigorous tests to validate our design decisions and continue to explore the space to justify the direction in which we have gone. While testing will continue, the team has established a baseline of methodology which can be refined and applied to further requirements as necessary to address our design drivers. Requirements and specifications have been updated based on feasibility and stakeholder needs and will continue to be updated as required.

Going forward, the team plans to verify the top design drivers and begin the verification and validation phase of the design project. This will involve various analysis and assessments of material availability, material properties, costs, and user instructions to determine our final specifications. Validation will be performed while being aware of assumptions made and the limitations of the verification types. In addition, the team will continue to create prototypes and research possible materials and testing methods until we converge on the final solution.

Appendix C: Adult Medication Administration Comp Sheet

Student Name/UMID#	Instructor Name:	Date:

ADULT MEDICATION ADMINISTRATION: INTRAMUSCULAR INJECTIONS

Medication Room:

Activity	Points	Comments	Concepts/ Learning points
1. Wash Hands.	**/1pt**		
2. Verbalizes and demonstrates the appropriate injection sites *(Deltoid, Ventrogluteal, Vastus Lateralus).*	**/1pt**		
3. Review MAR/eMAR for order and verify correct patient on eMAR and state the 6 rights of med administration (also check for patient allergies at this time).	**/1pt**		*Medication check (1 of 3) against eMar*
4. State drug information including drug action, recommended dosage, common side effects, any contraindications and nursing implications. *(Succinctly summarize above information without reading from drug book)*	**/1pt**		
5. Gather medication and check against the MAR *(giving the incorrect medication or dose will result in failure of the skill).*	**/1pt**		*Medication check (2 of 3) against eMar*
6. Calculate the proper dosage of medication and verbalize the volume of medication to be drawn into the syringe.	**/1pt**		*For pre-filled syringes, calculate and verify proper dosage and amount to be given*
7.. Select syringe and needle of appropriate size and gauge (can provide rationale for choice).	**/1pt**		
8. Remove the lid of vial (if appropriate *if previously unopened instead of "as appropriate"*) without contaminating the vial's diaphragm. Cleanse the top of vial for 15 seconds with an alcohol wipe.	**/1pt**		*Do not rely on manufacturer's process of sterilization for preparing capped vials; cleansing with alcohol should always be done*

1

Activity	**Points**	**Comments**	**Concepts/ Learning points**
9. Attach the needle to the syringe without contamination of either needle or syringe.	**/1pt**		
10. Inject air into the vial equal to the amount of medication to be drawn up.	**/1pt**		*Displaces volume of solution in a vacuum; will not create negative pressure.*
11. Draw the correct amount of medication into the syringe without contaminating the needle or the hub of the syringe. Remove air bubbles from the syringe-holding syringe at eye level.	**/1pt**		
12. Remove the needle used to draw up the medication and attach sterile needle of the appropriate size for administration. **** Critical step: Label syringe with the patient's name, drug and dosage prior leaving medication room.**	**/1pt**		*Outside surface of new needle is free of medication and will decrease irritation to the patient's skin.* *** Proper medication labels reduce medication error risk.*

Patient Room:

13. Collect or verify correct supplies have been gathered.	**/1pt**		
14. Wash hands on entering patient room.	**/1pt**		
15. Introduce self to patient and explain procedure.	**/1pt**		
16. Identify patient using 2 patient identifiers.	**/1pt**		*Name and birthdate against eMAR. Check for proper ID band on patient.*
17. Re-check MAR/eMAR and 6 rights of medication administration.	**/1pt**		*Medication check (3 of 3) against eMar*
18. States pre-administration assessments.	**/1pt**		*i.e. vital signs, sedation score, respiratory rate, date of prior immunization, consent form as needed*
Activity	**Points**	**Comments**	**Concepts/**

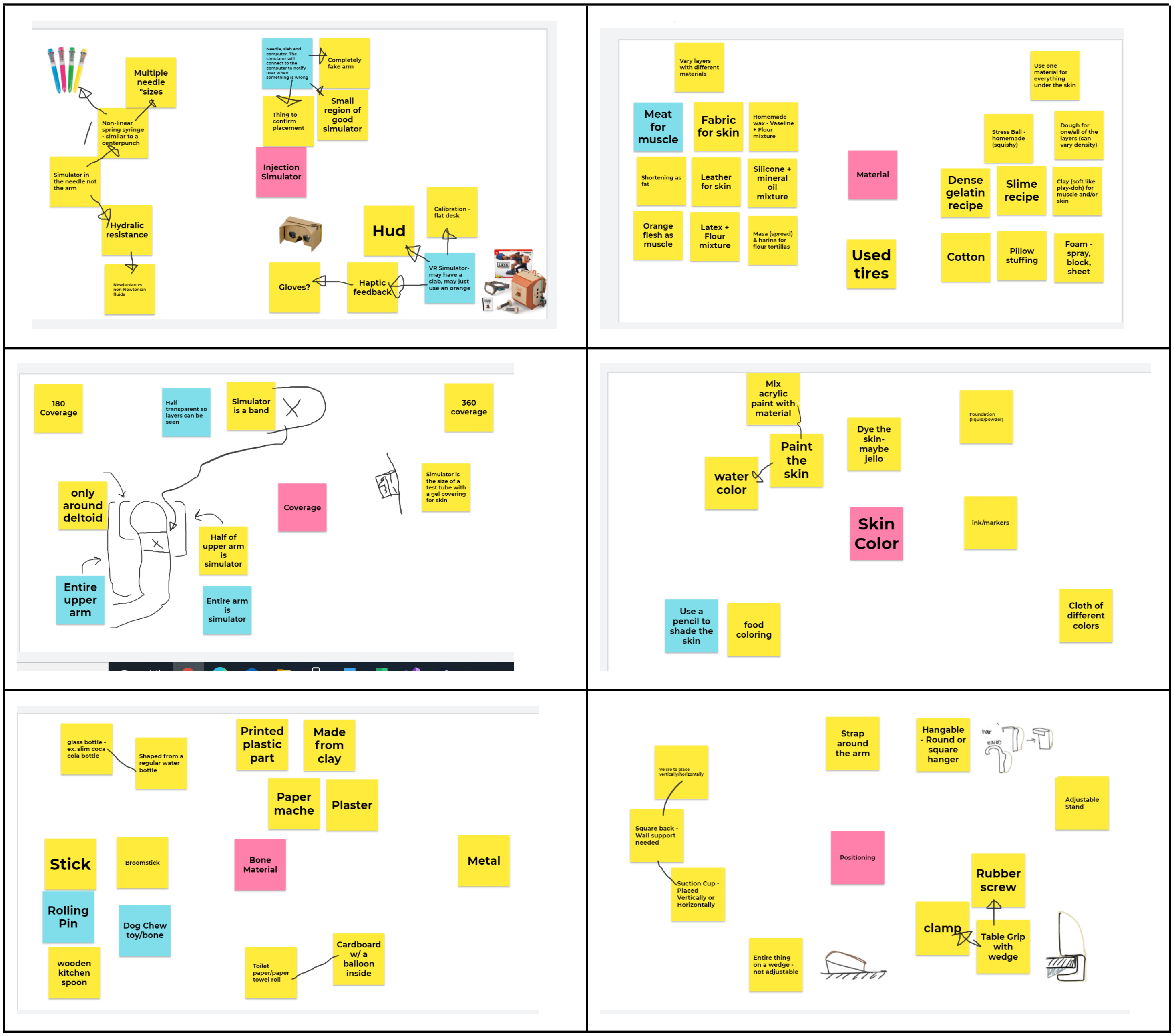
			Learning points
19. Provide patient education on medications patient is receiving. Discuss patient preference for injection site.	**/1pt**		*Know where last injection was given (per documentation on eMar)*
20. Provide privacy for patient. Position patient to properly visualize site.	**/1pt**		
21. Don non-sterile gloves.	**/1pt**		
22. Wipe the injection site with alcohol using circular motion, inside to outside.	**/1pt**		
23. Hold skin taut by spreading the skin between the thumb and index finger using the non-dominant hand.	**/1pt**		
24. Inject the needle at a 90 degree angle to the skin surface.	**/1pt**		
25. Stabilize the needle. Inject medication slowly without moving the needle.	**/1pt**		*Stabilizing the needle can be done by holding it near the hub with the non-dominant thumb and forefinger so your dominant hand is free to inject medication. Injecting slowly promotes comfort and allows tissue to expand.*
26. Place the syringe (activate the needle safety device) into the sharps container and remove gloves.	**/1pt**		
27. Document at the bedside.	**/1pt**		*Remember to document any pre-administration assessments, patient education and consider using teach-back methods to verify learner comprehension*
28. Verbalizes expected outcomes and when to reassess patient based on medication given.	**/1pt**		
Activity	**Points**	**Comments**	**Concepts/ Learning points**

29. Wash hands on the way out of the patient room.	**/1pt**		
****Violation in any of the 6 rights of medication administration will result in failure of the competency**.**			

______ /29 Passing score is 23/29 points

Updated 7/2020 LMP

Appendix D: Concept Generation Figures and Sketches:



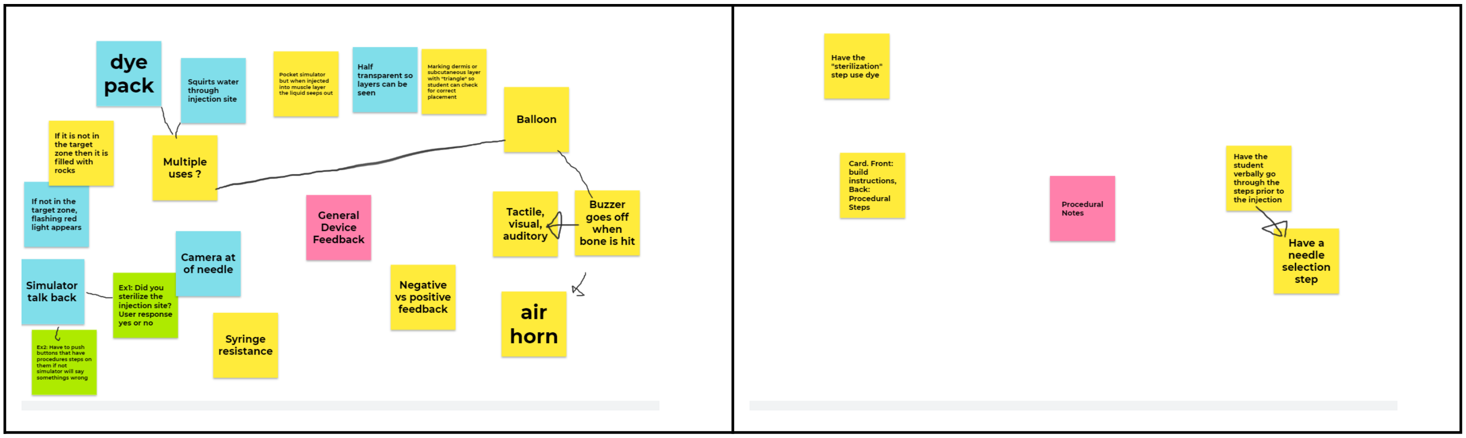


Figure D.1: Brainstorming Results

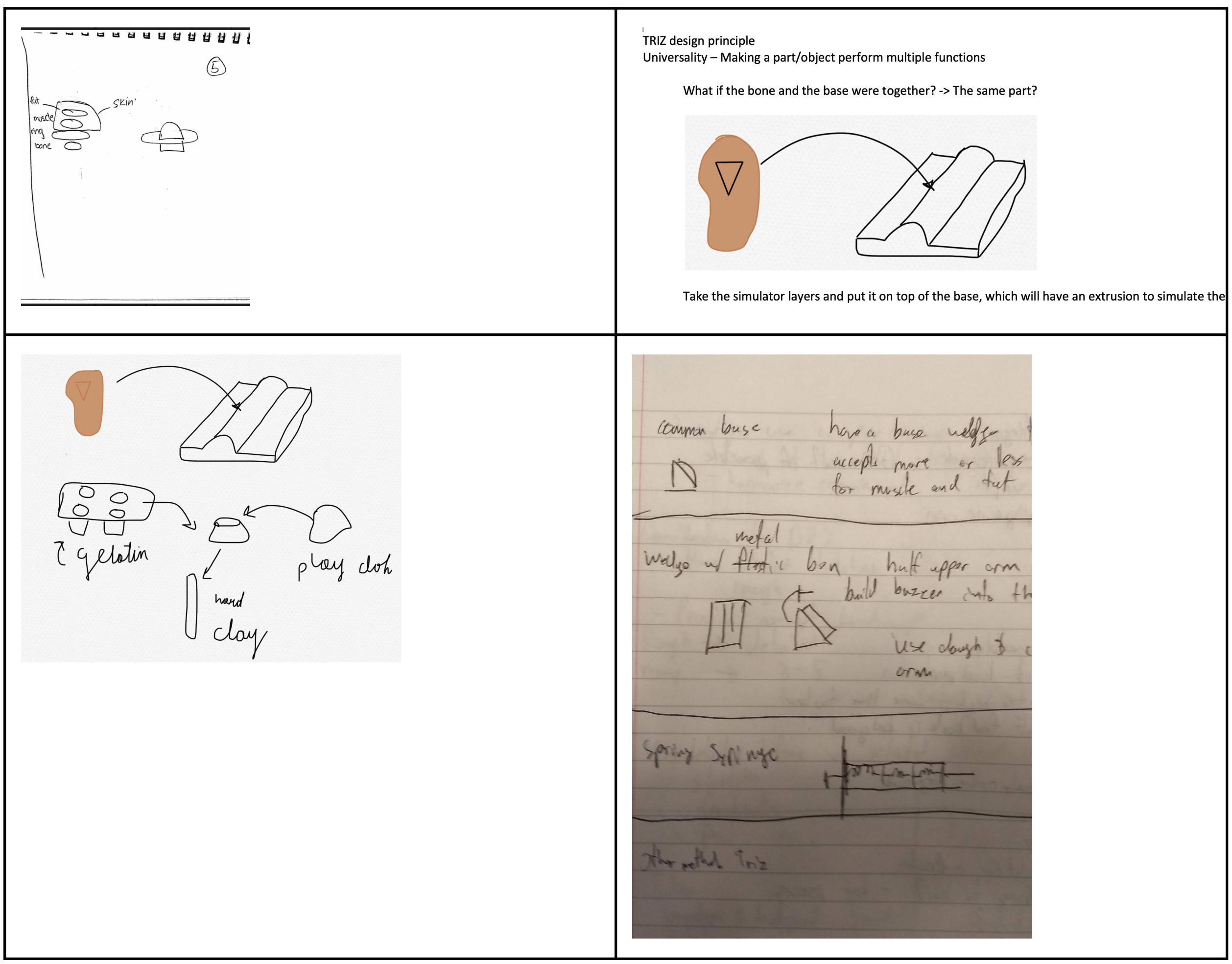
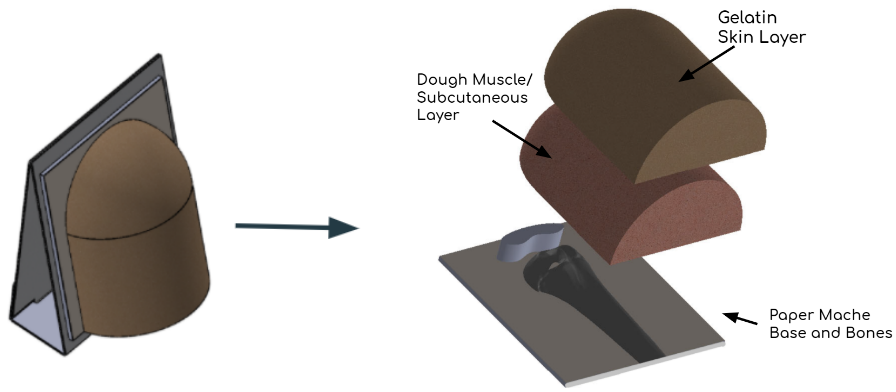


Figure D.2: Design Exploration Sketches

Appendix E: Selected Concept Design Instructions in English and Spanish

Intramuscular Injection Simulator Instructions

Supplementary Video



Tools Required:	Materials Required:
15-20 cm Ruler	1 ½ cups (360 ml) of water
Scissors	1 ½ cups (360 ml) of flour
Measuring cups	2 Tbsp (30 ml) of gelatin
Small Pan	2 Tbsp (30 ml) of glycerin
Small Flat Plate	Newspaper, or any other scrap paper
Plastic wrap	Tape
Spoon	Stovetop
13 by 34 cm cardboard	Permanent marker
Medium Mixing bowl	

Tools/Materials Suggested and Benefit

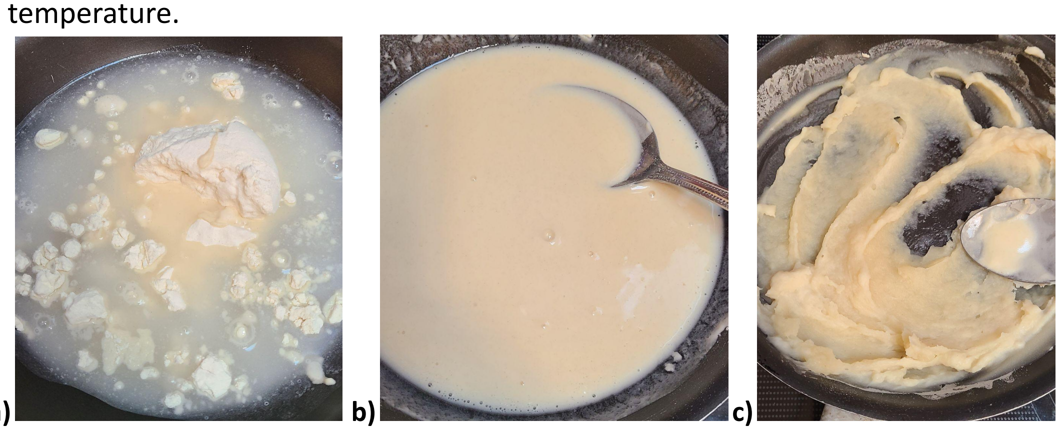
2 tsp (10 ml) of Cream of Tartar: Increases the shelf life of dough layer by a few months
1 tbsp (15 ml) of any oil: Softens the dough layer
¼ cup (60 ml) of salt: Increases the shelf life of dough layer by a few months
½ tsp (2.5 ml) Skin Tone liquid makeup: Visually creates a more realistic skin layer
A few drops of red dye or red paint: Visually creates a more realistic dough layer
Paint Brush (any size from 1.2 - 3 cm): Makes glue application during paper mache creation

easier
Conventional oven: Decreases paper mache dry time by a couple of days
Baking sheet: Used when baking paper mache model

1. Paper Mache Base and Bones

Tools and Material Required	Tools and Materials Suggested
15-20 cm Ruler	Paint Brush
Measuring cups	Conventional oven
Small	Baking Sheet
Spoon	Scissors
½ cup (120 ml) of water	
1 cup (240 ml) of flour	
Newspaper, or any other scrap paper	
Stovetop	

a. Place a small pan on your stove top and add ½ cup (120 ml) of flour and 1 cup (240 ml) of water as shown in Figure 1a. Fully mix with a spoon until all lumps are broken up as shown in Figure 1b. Then turn the stovetop on low to medium heat, stir until the mixture turns into a thick paste, approximately 5-7 minutes, as seen in Figure E.1c. Remove the mixture from the heat, this is your "glue." Allow it to cool to room temperature.



a) **b)** **c)**

Figure E.1: Flour and water mixture **a)** initially **b)** after mixing and breaking up all clumps **c)** after being heated for 5-7 minutes

b. Tear or cut up old newspapers or other scrap paper into 5 cm pieces or smaller as shown in Figure E.2.

Figure E.2: 5 cm newspaper strips, exact measurement not required.

c. On a flat baking sheet (or other protective surface if you cannot bake your model), use a paint brush or spoon to evenly coat both sides of the newspaper strips with glue as you place them down on the baking sheet creating a 14 cm x 15 cm base. Layer and overlap the newspaper strips until you obtain a flat 14 cm x 15 cm base with thickness of 0.5-1 mm.

> **Tips**
> A baking sheet is needed to bake the model and shorten dry time by a couple of days, if you will not be baking you can create your model over any sheet of paper or plastic.
>
> Use thin coats of glue between layers, too much glue will excessively lengthen drying time and lead to molding. A paint brush helps with thin and even coating.

d. Start creating the humerus and acromion model by continuing to layer paper strips and glue on the newly created base. Continue layering and overlapping newspapers using a ruler and referencing Figure E.3 to determine the general shape and dimensions you want to obtain. Continue layering until the acromion height is approximately 2.5 cm and the humerus height is approximately 1 cm. Refer to Figure E.4 as an example of how the base creation should progress. Discard any leftover glue. Leave the model out to dry for 2-3 days.

> **Tip**
> To shorten dry time to approximately 1 day bake at 175 °F (80 °C) for 15 minutes. Allow to cool. Repeat until the model is dry to the touch. Baking can also be done between layers, allow to cool before adding additional layers

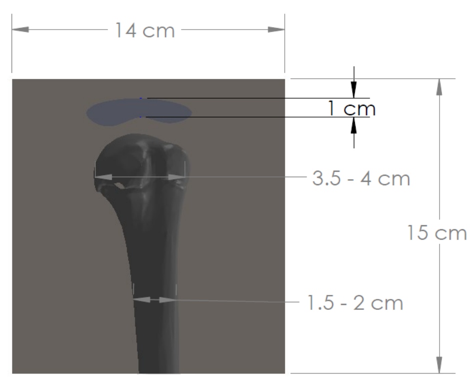


Figure E.3: CAD image of key

dimensions

Figure E.4: Pictures showing the progression of the paper mache bone models

2. Dough Muscle and Subcutaneous Layer

Tools and Material Required	Tools and Materials Suggested
Measuring cups	2 tsp (10 ml) of cream of tartar
1 cup (240 ml) of flour	¼ cup (60 ml) salt
1 Tbsp (15 ml) of oil ½ cup (120 ml) of water	A few drops of red dye or red paint
Plastic wrap	
Spoon	
Permanent marker	
Ruler	
Medium mixing bowl	

a. In a medium bowl mix together 1 cup (240 ml) of flour, 1 tbsp (15 ml) of oil and ½ cup (120 ml) of water. Knead flour into water until a cohesive mass is formed. The final texture should feel elastic and pliable, additional flour or water may be added slowly to obtain this.

> **Tips**
> Before mixing optionally add 2 teaspoons of cream of tartar and ¼ cup salt to increase shelf life by at least 1 month. Without these ingredients your dough will need to be fully replaced within a week due to spoiling.
>
> Also add a few drops of red dye, until a pink color is obtained to mimic inner muscle

b. Place dough on a 30 by 30 cm sheet of plastic wrap as shown in Figure E.5a. Create an upper shoulder shape by rounding out the top of the dough and flattening the sides as shown in Figure E.5b.

a) b)

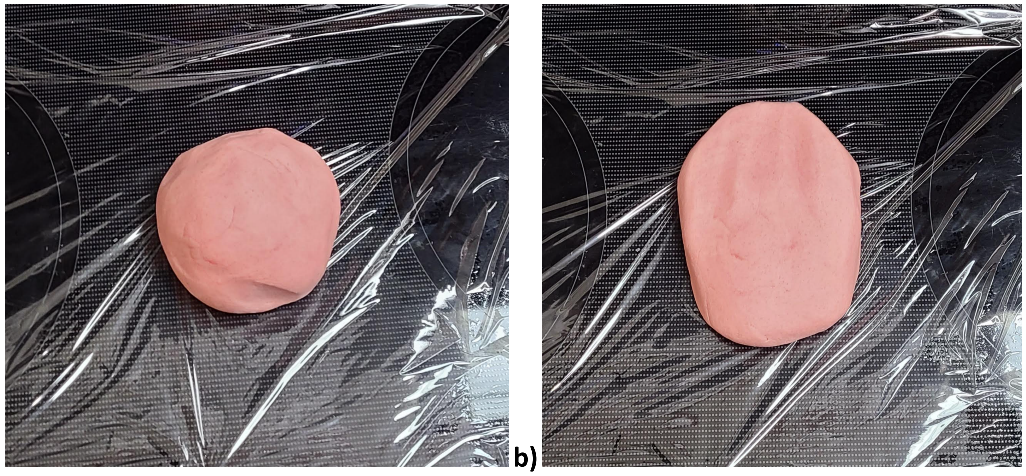


Figure E.5: a) Initial dough sphere on 30 x 30 cm plastic wrap **b)** General dough shape with rounded top and flattened sides

c. As someone in the medical field you will interact with many different people. Reference Table E.1 to determine which patient model you want to create. Once you have chosen, use your ruler and hands to shape and refine the dimensions given in Table E.1 as defined by Figure A.

Table 1: Average arm measurements

Dimension	Description	Average Male	Average Female	90th percentile Male and Female
A	Arm Perimeter	17.5 cm	16 cm	20 cm
B	Mid-upper Arm Diameter	11 cm	10 cm	13 cm

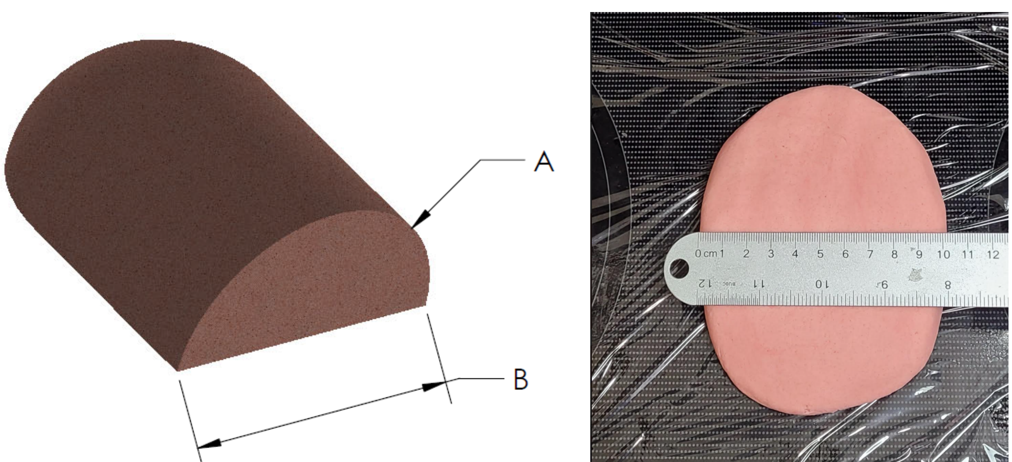


Figure E.6: a) CAD images of key dimensions. **b)** Final dough shape for an average female patient.

> **Tip**
> Different patient models will use less dough, remove excess dough and set aside. Any dough not used can be warped in plastic, placed in a sealable plastic bag or discarded.

d. Once you have obtained the desired shape and dimensions it is time to seal in the dough to keep it from drying. Bring the plastic corners in to the center of the dough, this will be the back of the layer as shown in Figure E.7

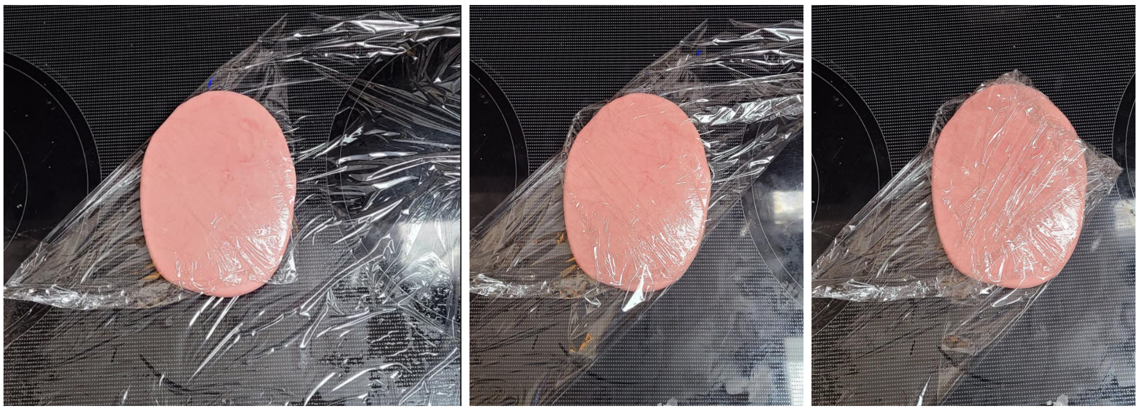


Figure E.7: Plastic wrap corners brought in to the center of the dough, this is the back of the layer.

e. To mark the proper injection site, place the dough over the paper mache base, press firmly without deforming. Measure 2-3 fingers from the top of the dough layer over the acromion and create a 5 cm line with a permanent marker, this is the base of your placement triangle and is shown in Figure E.8a. Next measure 6 cm directly below the top of the acromion, this is the point of the placement triangle and is shown in Figure E.8b. Connect the markings to complete the proper injection site triangle as shown in Figure E.8c.

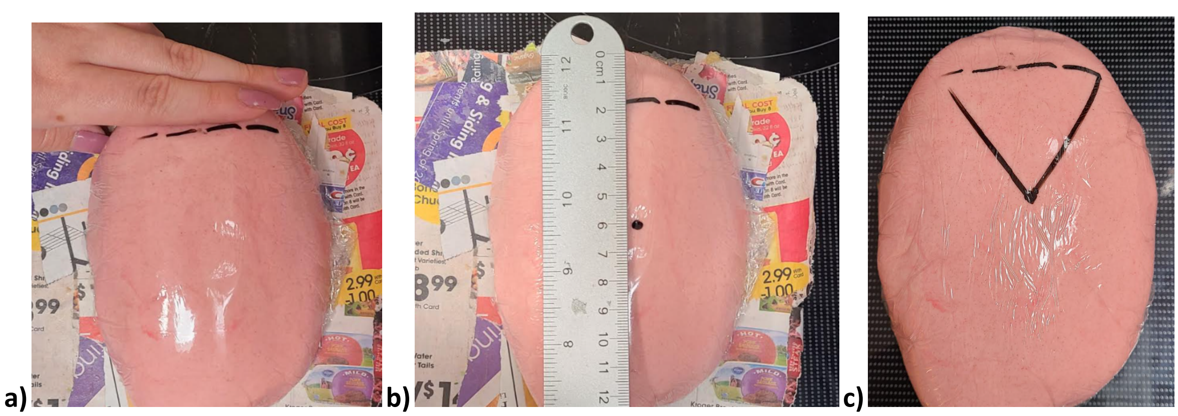


Figure E.8: a) 2-3 finger method used to locate the acromion and mark the base of the placement triangle **b)** The point of the placement triangle 6 cm directly below the acromion. **c)** proper injection site triangle.

3. Gelatin and Glycerin Skin Layer

Tools and Material Required	Tools and Materials Suggested
Measuring cups	Microwave

Small Flat Plate

Spoon

2 Tbsp (30 ml) of gelatin

2 Tbsp (30 ml) of glycerin

1 Tbsp (15) of water

Liquid Foundation makeup

a. Mix together 2 Tbsp (30 ml) of gelatin with 2 Tbsp (30 ml) of glycerin and 1 Tbsp of water on a small flat plate as shown in Figure E.9a. Microwave for 8 seconds, the mixture will be thin and evenly spread on the plate, it should not be lumpy. If the mixture is lumpy, microwave again for an additional 5 seconds. If a microwave is not accessible the mixture can be heated using a stovetop by creating a double boiler. Add a bit of water to a sauce pan and place a heat resistant bowl on top so it is resting on the edges of the pan, but not touching the water. Heat water on low. Until the mixture is completely melted.

a) b)

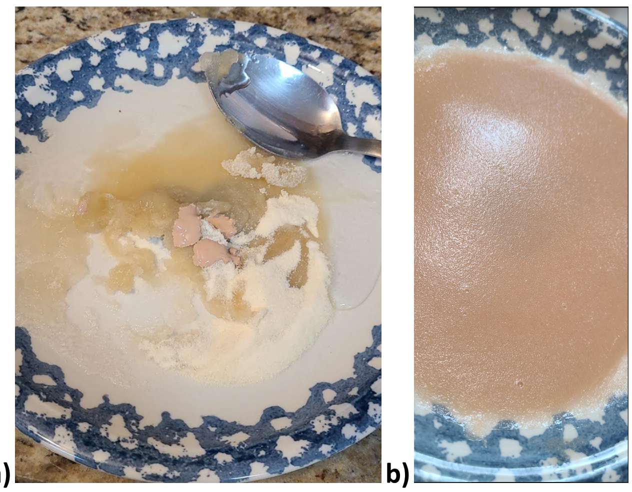


Figure E.9: Gelatin and Glycerin mixture **a)** before and **b)**after heating

> **Tip**
> Optionally, Add a few drops of any skin colored liquid makeup and mix in thoroughly. Add additional drops until desired saturation is obtained.

b. Leave out to dry and set for 10 - 15 minutes.

> **Tips**
> Place the plate with newly formed skin layer in the refrigerator for faster drying.
>
> Sprinkling a pinch of flour on the exposed side of the gelatin skin layer and rubbing it in while brushing off any excess flour will give your skin layer a more realistic texture.

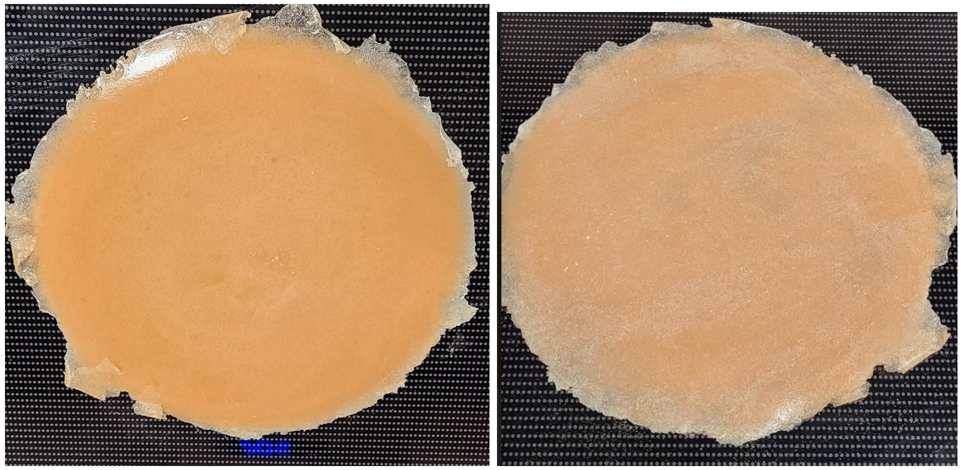


Figure E.10: Gelatin skin layer. **a)** No flour on top. **b)** Flour sprinkled and rubbed on top to give a more realistic texture

4. Cardboard stand and Final Adhesion Steps

Tools and Material Required	Tools and Materials Suggested
Scissors	
14 by 35 cm cardboard	
Ruler	
Tape	

a. The simulator will be mounted on a stand to obtain a more vertical orientation. To create this stand cut a large cardboard to be approximately 14 by 34+ cm. You will want to create a small flap and slits for adjustability. Reference Figure E.11 below for cutting dimensions and folding locations.

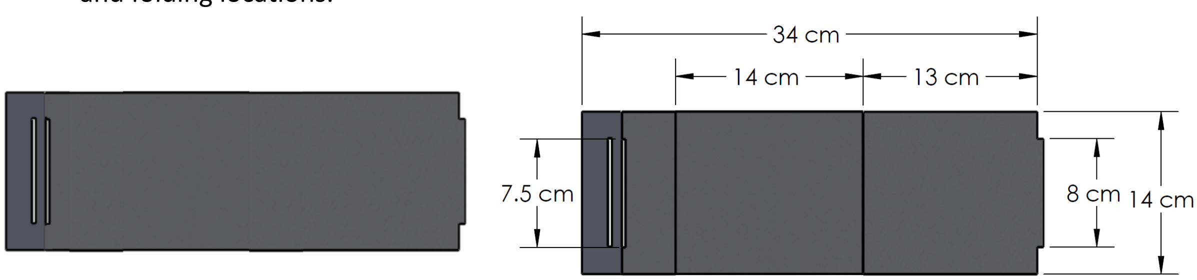


Figure E.11: a) Cut the cardboard along the outer solid lines. **b**)Fold along the vertical solid line using the above dimensions and ruler as a straight edge

b. The finished and assembled stand is shown below in Figure E.12a. Open up the stand and use tape to create tape circles with adhesive side facing out, place a few tape circles on the back of the paper mache base to the stand.

c. Next use the same tape method to place a few tape circles on the back of the dough layer plastic wrap. Carefully pick up the wrapped dough without deforming it and place the back of the layer directly on the fully dried paper mache base. Carefully press down so the dough fully covers the paper mache "bone" features.

d. Finally place the skin layer over the dough layer, no tape is needed as the skin layer is meant to be removable. The fully assembled injection simulator is shown below in Figure E.12b.

Figure E.12: a) Stand once it has been cut, folded and assembled. **b)** Fully assembled intramuscular injection simulator

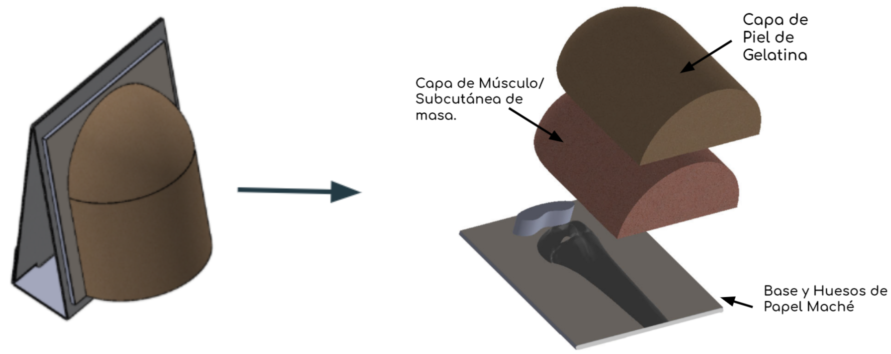
Reusability

a. Dough Muscle and Subcutaneous Layer
    i. After each practice session you will want to re-wrap the dough to avoid overdrying. Remember to mark the injection site as described in step 2e above.
        1. Moisten with water as needed
    ii. Completely remake the dough layer per step 2 when it has become too too hard/brittle or at any sign of spoilage.
b. Gelatin and Glycerin Skin Layer
    i. After each practice session or after 25-50 needle pokes, place the skin on a plat microwaveable plate. Microwave for 8 seconds. Mix with a spoon and microwave again for 5 more seconds. Let cool for 15 minutes.

Instrucciones del Simulador de Inyección Intramuscular

Creado por: Jack Carvill, Nallely Flores, Vanessa Rojano, Alexsis Salgado, Kevin Solorzano

[Video Complementario]



Herramientas Necesarias:	Materiales Necesarios:
Regla de 15-20 cm	1 ½ tazas (360 ml) de agua
Tijeras	1 ½ tazas (360 ml) de harina
Tazas medidoras	2 cucharadas (30 ml) de gelatina
Sartén pequeño	2 cucharadas (30 ml) de glicerina
Plato plano pequeño	Marcador permanente
Envoltura de plástico	Periódico o cualquier otro papel de desecho
Cuchara	Cinta
Cartón de 13 x 34 cm	Estufa
Tazón mediano para mezclar	

Herramientas/Materiales Sugeridos y Beneficio

2 cucharaditas (10 ml) de Cremor tártaro: aumenta la vida útil de la capa de masa unos meses

1 cucharada (15 ml) de cualquier aceite: suaviza la capa de masa

¼ de taza (60 ml) de sal: aumenta la vida útil de la capa de masa unos meses

½ cucharadita (2,5 ml) de maquillaje líquido Skin Tone: crea visualmente una capa de piel más realista

Unas gotas de tinte rojo: crea visualmente una capa de masa más realista
Brocha (tamaño de 1,2 a 3 cm): facilita la aplicación de pegamento durante la creación de papel maché
Horno convencional: Disminuye el tiempo de secado del papel maché un par de días.
Bandeja para hornear: se utiliza para hornear el modelo de papel maché.

1. Base y Huesos de Papel Maché

Herramientas y Materiales Necesarias	Herramientas y Materiales Sugeridos
Regla de 15-20 cm	Brocha
Tazas medidoras	Horno convencional
Sartén pequeño	Bandeja para hornear
Cuchara	Tijeras
½ taza (120 ml) de harina	
1 taza (240 ml) de harina	
Periodico, o cualquier otro papel de desecho	
Estufa	

a. Coloque el sartén pequeño sobre la estufa y agregue ½ taza (120 ml) de harina y 1 taza (240 ml) de agua como se muestra en la Figura E.1a. Mezcle completamente con una cuchara hasta homogeneizar como se muestra en la Figura E.1b. Luego encienda la estufa entre fuego bajo y medio, revuelva aproximadamente 5-7 minutos hasta que la mezcla se convierta en una pasta espesa, como se ve en la Figura E.1c. Retire la mezcla del fuego, esto es su "pegamento". Deje que se enfríe a temperatura ambiente.

a) b) c)

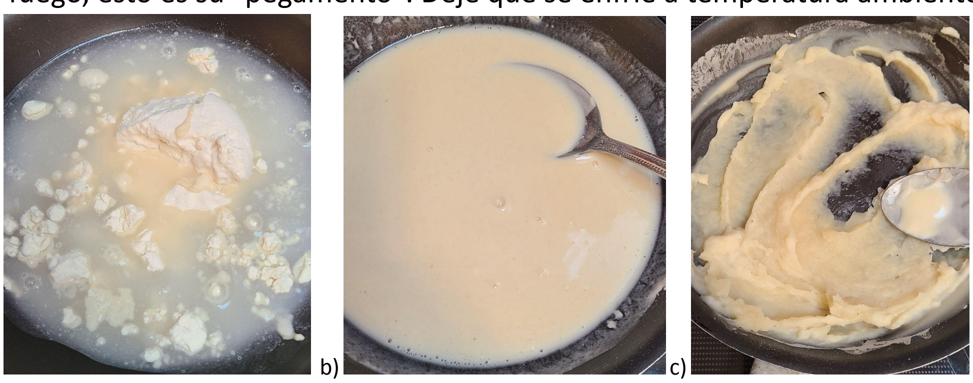


Figura E.1: Mezcla de harina y agua **a)** inicialmente **b)** después de mezclar y romper todos los bultos **c)** después de calentar durante 5-7 minutos

b. Rasgue o corte los periódicos viejos en trozos de 5 cm o más pequeños, como se muestra en la Figura E.2.

Figura E.2: Trozos/tiras de periodico (no se requiere una medida exacta)

c. En una bandeja para hornear plana (u otra superficie protectora si no puede hornear su modelo), use una brocha o una cuchara para cubrir uniformemente ambos lados de las tiras de periódico con pegamento mientras las coloca sobre la bandeja para hornear creando una base de 14 cm x 15 cm. Coloque y superponga las tiras de periódico hasta obtener una base plana de 14 cm x 15 cm con un grosor de 0,5-1 mm.

> **Consejos**
> Se necesita una bandeja para hornear para poder hornear el modelo y acortar el tiempo de secado, si no va a hornear puede crear su modelo sobre cualquier hoja de papel o plástico.
>
> Use capas delgadas de pegamento entre capas, demasiado pegamento alargará excesivamente el tiempo de secado y conducir al moho. Una brocha ayuda a crear capas finas y uniformes.

d. Comience a crear el modelo de húmero y acromion continuando colocando capas de tiras de papel y pegando a la base recién creada. Continúe colocando capas y superponiendo periódicos usando una regla y haciendo referencia a la Figura E.3 para determinar la forma general y las dimensiones que desea obtener. Continúe colocando capas hasta que la altura del acromion sea de aproximadamente 2,5 cm y la altura del húmero es de aproximadamente 1 cm. Consulte la Figura E.4 como un ejemplo de cómo debería progresar la creación de la base. Deseche los restos de pegamento. Deje que el modelo se seque durante 2-3 días.

> **Consejos**
> Para acortar el tiempo de secado a aproximadamente 1 día, hornee a 175 ° F (80 ° C) durante 15 minutos. Deje enfriar. Repita hasta que el modelo esté seco al tacto. El horneado también se puede hacer entre capas, deje enfriar antes de agregar capas adicionales

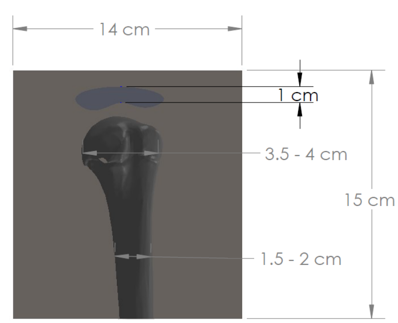


Figura E.3: Diseño del acromion y el húmero con dimensiones claves

Figura E.4: Imágenes que muestran la progresión de los modelos de hueso de papel maché

2. Capa Múscular/Subcutánea de Masa

Herramientas y Materiales Necesarias	Herramientas y Materiales Sugeridos
Tazas medidoras	2 cucharaditas (10 ml) cremor tártaro
1 taza (240 ml) de harina	¼ taza (60 ml) sal
1 cucharada (15 ml) de aceite ½ taza (120 ml) de agua	Un par de gotas de colorante rojo para alimentos
Envoltura de plástico	
Cuchara	
Marcador permanente	
Regla de 15-20 cm	
Tazón mediano para mezclar	

a. En un tazón mediano, mezcle 1 taza (240 ml) de harina, 1 cucharada (15 ml) de aceite, y ½ taza (120 ml) de agua. Amase la harina con el agua hasta formar una masa cohesiva. La textura final debería sentirse elástica y flexible.

> **Consejos**
> Antes de mezclar, opcionalmente agregue 2 cucharaditas de cremor tártaro y ¼ taza de sal para aumentar la vida útil de la masa por lo menos 1 mes. Sin estos ingredientes, la masa debe ser reemplazada después de una semana debido al deterioro.
>
> También puede agregar un par de gotas de colorante rojo para alimentos, hasta obtener un color rosado para imitar el músculo.

b. Coloque la masa en envoltura de plástico de 30 cm x 30 cm de medida, como se ve en la Figura E.5a. Forme el hombro redondeando la parte superior de la masa y aplanando los costados, como se ve en la Figura E.5b.

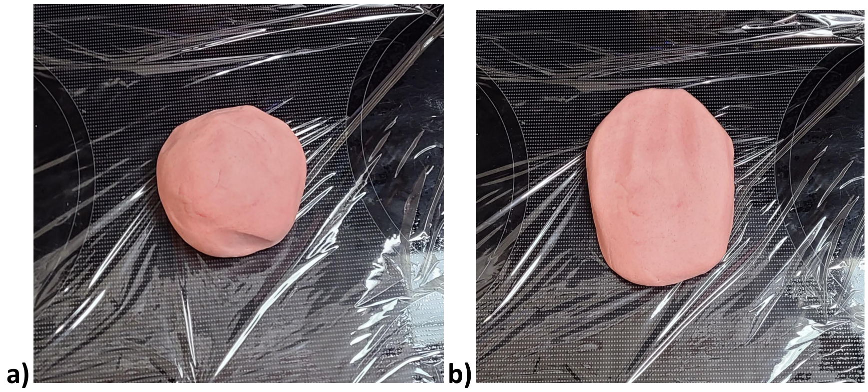


Figura E.5: a) Disco de masa inicial **b)** Forma general de la masa con tope redonda y costados aplanados.

c. Como alguien con una carrera médica, va a interactuar con diferentes tipos de personas. Use la tabla 1 como referencia para determinar el modelo de patinete que le gustaría crear. Después de elegir, use su regla y refine la forma del hombro usando las dimensiones de la tabla 1 y usando la Figura E.6.

Tabla E.1: Medidas promedio del brazo

Dimención	**Descripción**	**Hombre Promedio**	**Mujer Promedia**	**Hombre y Mujer Percentil 90**
A	Perímetro del brazo	17.5 cm	16 cm	20 cm
B	Diámetro de la parte superior del brazo	11 cm	10 cm	13 cm

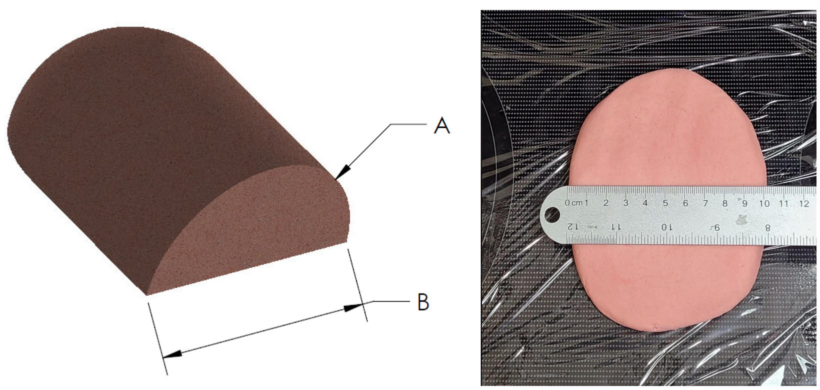


Figura E.6: a) CAD images of key dimensions. **b)** Forma de masa final para una paciente.

Consejo

Diferentes modelos de pacientes usarán menos masa. Remueva la masa de exceso y colóquela a un lado. La masa de exceso puede ser envuelta en plástico, puesta en una bolsa de plástico resellable, o descartada.

d. Después de obtener la forma deseada, es hora de sellar la masa para prevenir que se seque. Envuelva el plástico doblando las esquinas y los bordes hacia el centro de la masa. Esto será el lado trasero de la capa muscular como se muestra en la Figura E.7.

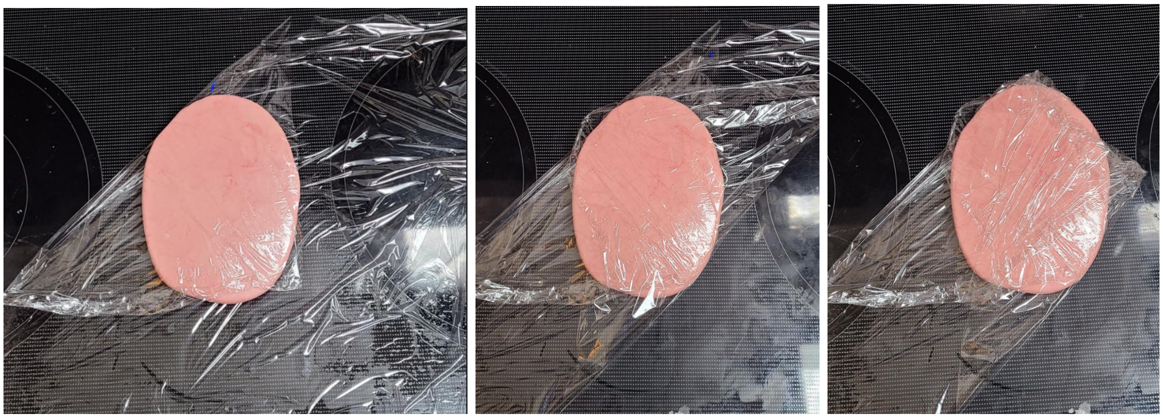


Figura E.7: Bordes de la envoltura plástica doblados hacia el centro de la masa. Esto es el lado trasero de la capa.

e. Para marcar el lugar de inyección adecuado, mida 2-3 dedos desde la parte superior de la capa de masa sobre el acromion y cree una línea de 5 cm con un marcador permanente, esta es la base de su triángulo de colocación y se muestra en la Figura E.8a. Luego mida 6 cm directamente debajo del acromion, este es el punto del triángulo de colocación y se muestra en la Figura E.8b. Conecte las marcas para completar el triángulo del lugar de inyección adecuado como se muestra en la Figura E.8c.

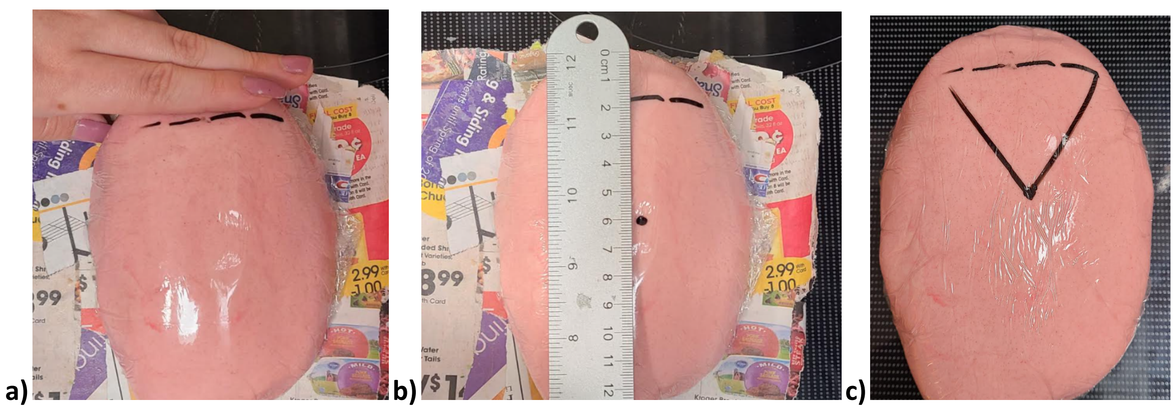
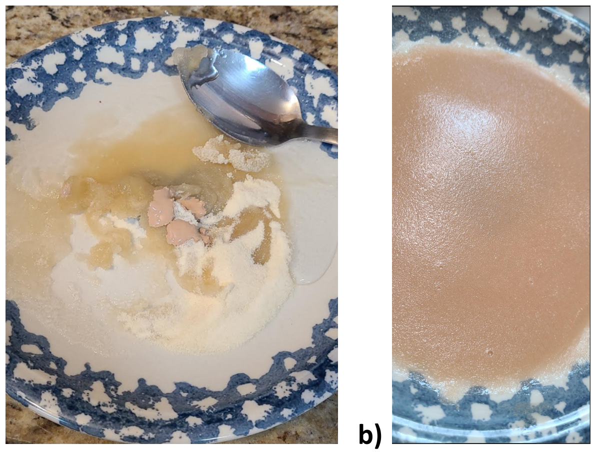


Figura E.8: a) 2-3 finger method used to locate the acromion and mark the base of the placement triangle **b)** The point of the placement triangle 6 cm directly below the acromion. **c)** proper injection site triangle

3. Capa de Piel de Gelatina y Glicerina

Herramientas y Materiales Necesarias	Herramientas y Materiales Sugeridos
Tazas medidoras	Microonda
Plato plano pequeño	
Cuchara	
2 cucharadas (30 ml) de gelatina	
2 cucharadas (30 ml) de glicerina	
1 cucharada (15) de agua	

a. Mezcle 2 cucharadas (30 ml) de gelatina con 2 cucharadas (30 ml) de glicerina y 1 cucharada de agua en un plato pequeño y plano como se muestra en la Figura E.8a. Microonda durante 8 segundos, la mezcla quedará fina y se esparcirá uniformemente en el plato, no debe quedar grumosa. Si la mezcla tiene grumos, vuelva a calentar en el microondas durante 5 segundos más. Si no se puede acceder a un microondas, la mezcla se puede calentar usando una estufa creando una caldera doble. Agregue un poco de agua a una cacerola y coloque un recipiente resistente al calor encima para que descanse sobre los bordes de la cacerola, pero sin tocar el agua. Calienta el agua a fuego lento. Hasta que la mezcla esté completamente derretida



a) **b)**

Figura E.9: Mezcla de gelatina y glicerina antes y después de calentar

> **Consejo**
> Opcionalmente, agregue unas gotas de cualquier maquillaje líquido del color de la piel y mezcle bien. Agregue gotas adicionales hasta obtener la saturación deseada.

b. Deje secar y deje reposar durante 10 a 15 minutos.

> **Consejos**
> Coloque el plato con la capa de piel recién formada en el refrigerador para un secado más rápido
>
> Espolvorear una pizca de harina en el lado expuesto de la capa de piel de gelatina y frotarla mientras quita el exceso de harina le dará a la capa de piel una textura más realista.

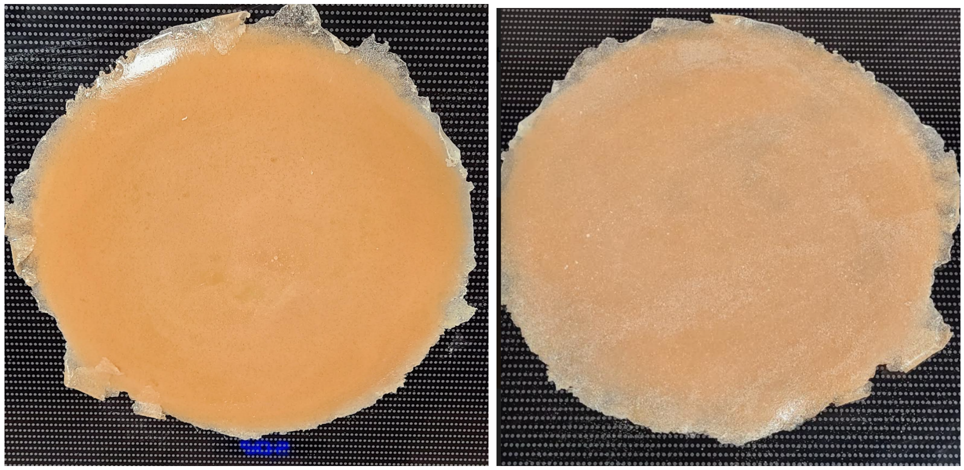


Figura E.10: Capa de piel de gelatina. **a)** Sin harina por encima. **b)** Harina espolvoreada y frotada encima para darle una textura más realista

4. Soporte de Cartón y Pasos Finales de Adhesión

Herramientas y Materiales Necesarias	Herramientas y Materiales Sugeridos
Regla de 15-20 cm	
Tijeras	
Cartón de 14 x 34 cm	
Cinta	

a. El simulador se montará sobre un soporte para obtener una orientación más vertical. Para crear este soporte, corte un cartón grande de aproximadamente 14 por 34+ cm. Querrá crear una pequeña solapa de 8 cm y hendiduras para ajustarse. Consulte la Figura E.11a continuación para conocer las dimensiones de corte y las ubicaciones de plegado.

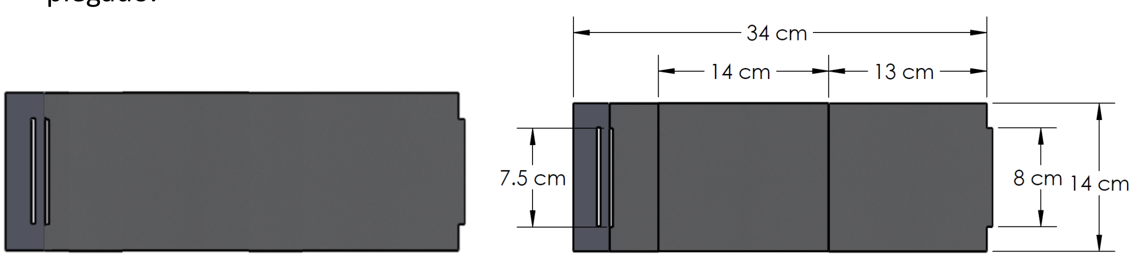


Figura E.11: a) Corta el cartón a lo largo de las líneas continuas exteriores. **b)** Dobla a lo largo de la línea sólida vertical usando las dimensiones anterior y la regla como un borde recto

b. El soporte terminado y ensamblado se muestra a continuación en la Figura E.12a. Abra el soporte y use cinta para crear círculos de cinta con el lado adhesivo hacia afuera, coloque algunos círculos de cinta en la parte posterior de la base de papel maché al soporte.

c. Luego use el mismo método de cinta para colocar algunos círculos de cinta en la parte posterior de la envoltura de plástico de la capa de masa. Recoge con cuidado la masa envuelta sin deformarla y coloca la parte posterior de la capa directamente sobre la base de papel maché completamente seca. Presione con cuidado para que la masa cubra completamente las características del "hueso" del papel maché.

d. Finalmente, coloque la capa de piel sobre la capa de masa, no se necesita cinta ya que la capa de piel está destinada a ser removible. El simulador de inyección completamente ensamblado se muestra a continuación en la Figura E.12b.

Figura E.12: a) Stand once it has been cut, folded and assembled. **b)** Fully assembled intramuscular injection simulator

Reutilización

a. Capa Muscular y Capa Subcutánea
    i. Después de cada sesión de práctica, querrá volver a envolver la masa para evitar que se seque demasiado. Recuerde marcar el lugar de la inyección como se describe en el paso 2e anterior.
        1. Humedezca con agua según sea necesario
    ii. Rehaga completamente la capa de masa según el paso 2 cuando se haya vuelto demasiado dura / quebradiza o ante cualquier signo de deterioro.
b. Capa de piel de gelatina y glicerina
    i. Después de cada sesión de práctica o después de 25-50 inyecciones, coloque la piel en un plato apto para microondas. Caliente en el microondas durante 8 segundos. Mezcle con una cuchara y caliente nuevamente en el microondas por 5 segundos más. Deje enfriar durante 15 minutos.

Appendix F Previous Concept Iterations and Alternative Materials

Selected Concept- D3

Once the physical feedback model was selected as the main concept the team began further refining the sketch and validating it against actual measurements from the requirements and specifications. This led to the addition of the acromion bone and removal of the dense feedback block above the injection site as it would not be physically feasible. The initial sketch updates are shown below in Figure 13.

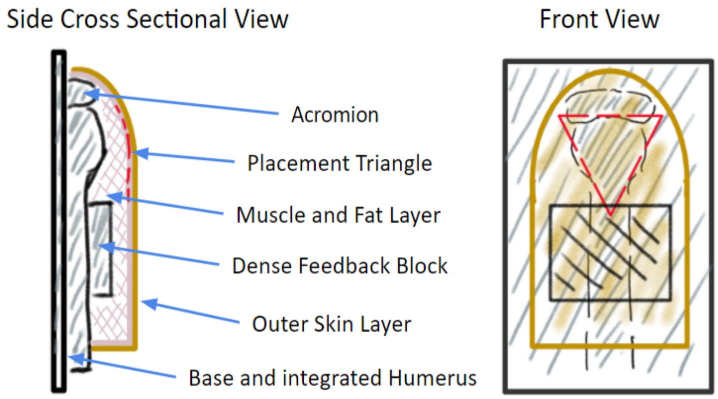


Figure 13. Updated Sketch of the selected concept after incorporation of realistic features and dimensions

A CAD model of the selected concept was also created to better depict the layers and relative scale between the layers as shown below in Figure 14.

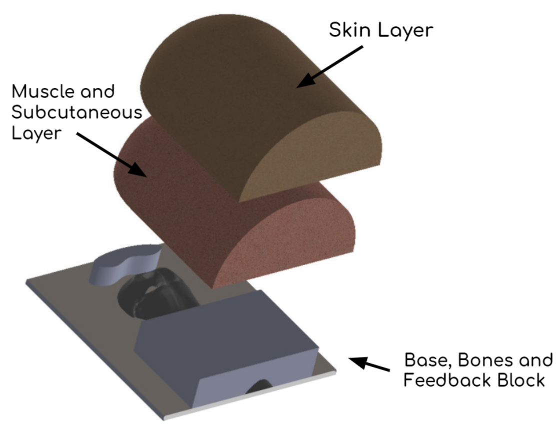
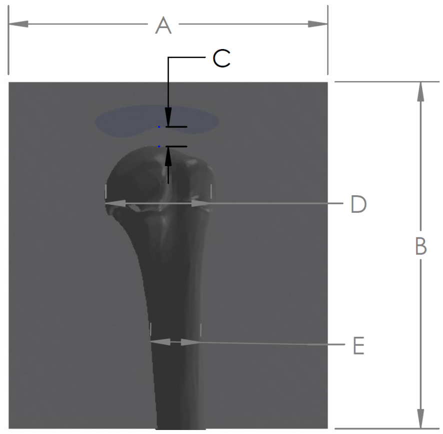


Figure 14. CAD of selected concept, showing three main sections.



Right. Front view of the CAD model showing general dimension markers.

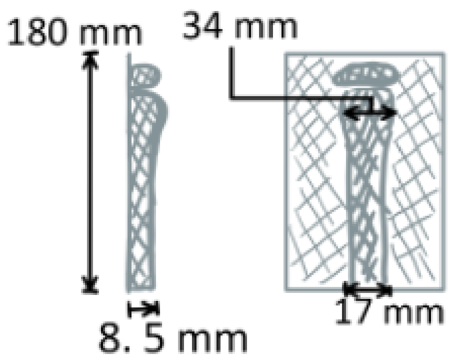


Figure 17. The average dimensions of a female humerus are shown on the **left** and were used to create the first based and bones prototype depicted on the **right**.

As previously stated the first base and bone prototype took over three days to dry, this was due to excessive use of glue. To address this problem a paintbrush is suggested to better control glue use as well as a bake time of 15 minutes at 175 °F (80 °C). Making these two adjustments allowed for a total dry time of less than 24 hours. One of the subsequent prototypes created following the new instructions is shown below in Figure 18.

The solid feedback block should be created in conjunction with the base and bones as it should be made directly on top of the humerus. The block should be made based on measurements and location provided. The feedback block is in place to notify a student when they are injecting into the danger zone, located 6 cm from the acromion bone[5]. The feedback block will not be visible from the outside of the simulator.

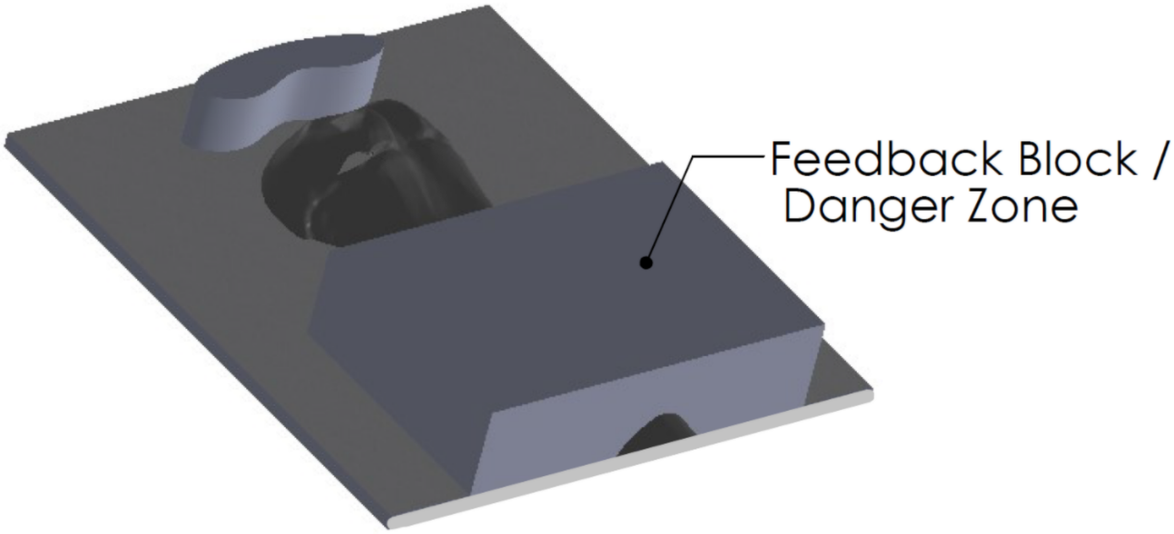


Figure 19. CAD model showing the base, acromion bone, humerus and feedback block, which will all be made from paper mache.

The final outer skin layer was initially created using 2mm foam paper. This material was chosen due to its smooth surface, better than a rough orange peel at mimicking skin texture. The flexibility of the outer layer is very important as it must take the shape of a shoulder and also allow the user to feel the underlying bones through it. The foam paper would require specific cutting and folding to obtain the correct shape. The first iteration of the cuts and folds is shown below in Figure 22, further exploration is needed to determine the most effective cuts and folding techniques.

Figure 20. The first muscle and fat dough prototype, wrapped in plastic and propped to show potential shape and flexibility.

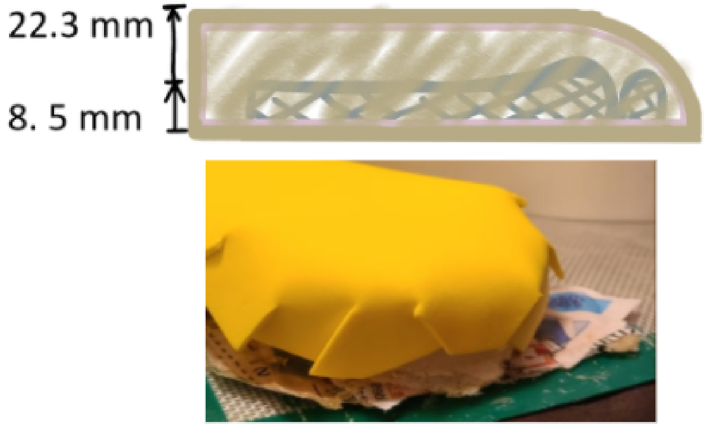


Figure 22. Top The average diameter of the female humerus as well as the average thickness from bone to epidermis, or outer skin layer. **Bottom** The first iteration of the outer skin layer using 2mm foam paper.

It was quickly determined that the foam paper was difficult to work with and shape. Although flexible, it could not keep a shoulder shape and once cut, lost it's slight likeness to skin.

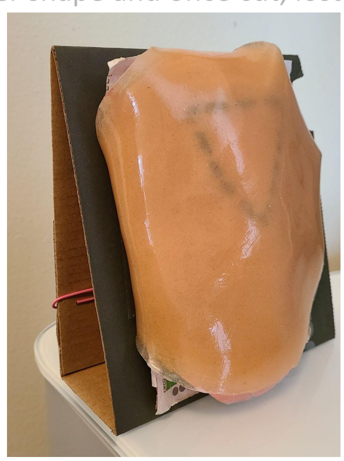


Figure 25. First finalized prototype of the selected concept. The outer skin layer is semi transparent, this unintentionally allowed visibility of the location triangle on the dough layer.

Alternative Materials

Below is a list of experiments conducted to find an animal-free alternative for gelatin. The team explored using a plant based product called pectin. At first the alternative seemed promising, however getting the mixture to harden was a frequent problem.

Mixture	**Fridge Duration**	**Notes**
1 part water 2 part pectin	15 min	Felt like gelatin skin mixtures at first, however, it harden overnight

2 part water 1 part pectin	Over 2 days	Mixture Mixture very slimy and breaks apart with little force
1 part water 2 part pectin 2 parts glycerin	15 min	Very slimy to the touch, and hard to puncture with a needle.
1 part water 2 part glycerin 1 part pectin 1 part flour	Over 2 days	Mixture very slimy and breaks apart with little force
1 part water 2 part glycerin 2 part pectin 1 part flour	Over 2 days	Mixture never harden
1 part water 2 part glycerin 3 part pectin 1 part flour	Over 2 days	Mixture never harden
1 part water 2 part glycerin 2 part pectin 2 part flour	N/A	Mixture burnt in the microwave. It was placed in the microwave for 8 seconds

From the above experiments, the closest solution was the 1 part pectin and water mixture. This mixture felt the least greasy and had similar resistance when being punctured by a needle. Unfortunately, the mixture completely hardens overnight. Next, the team tried several different combinations with flour to remove the slim; however, these mixtures barely set. The one that did harden was too tough to depict skin accurately.Further research is required to determine an animal-free alternative.

Appendix G: Accessibility Survey Questions

English

Where are you located? For example: Ann Arbor, Michigan

Please list one or more grocery shopping locations that you have access to below, include an online shopping site if possible.

For example: Target, Walmart, Amazon

How much would you be willing/able to spend on an a homemade intramuscular injection simulator?

Response is in dollars. For example: 3

How many hours would you be willing/able to spend on a homemade intramuscular injection simulator? (this does not include drying, baking or curing times). For example: 2

How many days are you willing/able to allow for drying, baking, curing etc.? For example: 3

Do you have newspaper?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have flour?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have gelatin?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have glycerin?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have yeast?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have petroleum jelly?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have play dough?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have silicone?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Do you have latex?

Yes	No, but I could obtain it	No, and I have no way of obtaining this

Would you be interested in continuing to collaborate with University of Michigan students on this project? If so please provide your email address below.

Please leave any additional comments or questions below.

Español (América Latina)

Donde esta ubicado/a? Por ejemplo: Zacatecas, Zacatecas

Enumere una o más tiendas de comestibles a las que tiene acceso. Incluya un sitio de compras en línea si es posible.

Por ejemplo: Walmart, Amazon

¿Cuántos pesos estaría dispuesto / podría gastar en un simulador de inyección intramuscular casero?

Por ejemplo: 50

¿Cuántas horas estaría dispuesto / podría dedicar a un simulador de inyección intramuscular casero? (esto no incluye los tiempos de secado, horneado o curado). Por ejemplo: 2

¿Cuántos dias está dispuesto / podría permitir para secar, hornear, curar, etc.? Por ejemplo: 3

¿Tienes periódico?

Sí	No, pero puede conseguirlo	No. Y no puedo conseguirlo

¿Tienes harina?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Tienes gelatina? (sin sabor)

Sí	No, pero puedo conseguirlo	No, Y no puedo conseguirlo

¿Tienes glicerina?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Tienes levadura?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Tienes jalea de petróleo?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Tienes plastilina?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Tienes silicona?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Tienes látex?

Sí	No, pero puedo conseguirlo	No. Y no puedo conseguirlo

¿Le interesaría seguir colaborando con los estudiantes de la Universidad de Michigan en este proyecto? Si es así, proporcione su dirección de correo electrónico a continuación.

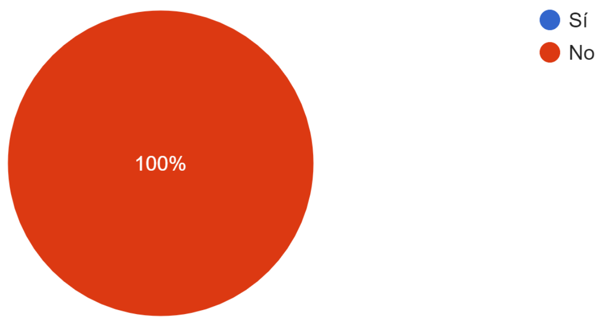
Deje cualquier comentario o pregunta adicional a continuación.

→

Appendix H: Instructions Survey Questions, Figures, and Raw Data:

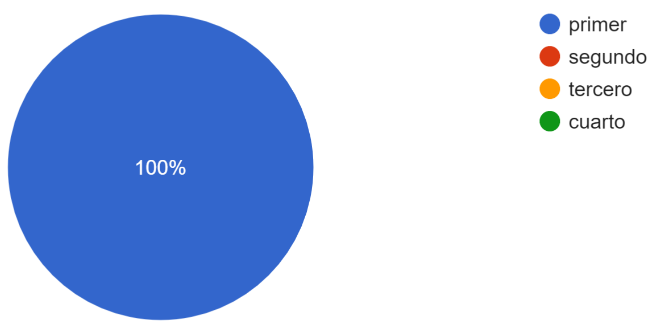
¿Ha dado inyecciones intramusculares antes?

4 responses



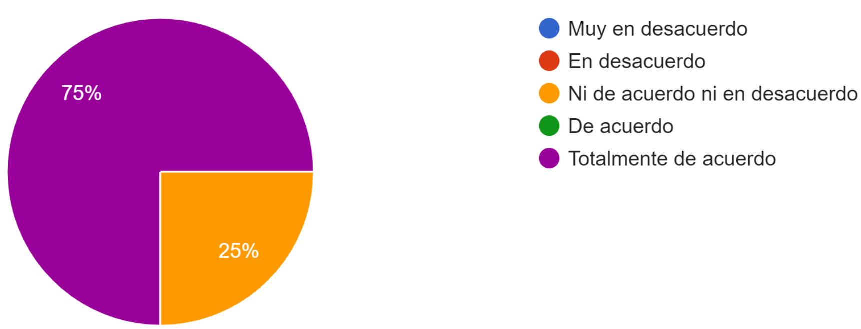
¿En qué año universitario estás?

4 responses



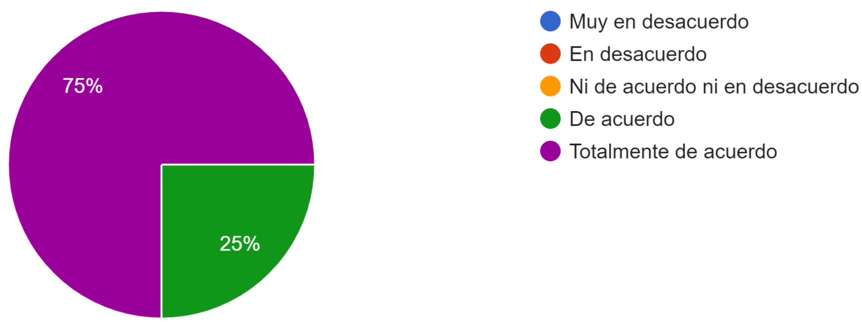
Las instrucciónes para el Base y Huesos de Papel Maché son faciles de entender.

4 responses



Las fotos/figuras en la sección para el Base y Huesos de Papel Maché ayudan a entender las instrucciónes

4 responses



Tienes algún comentario sobre la sección para el Base y Huesos de Papel Maché ?

3 responses

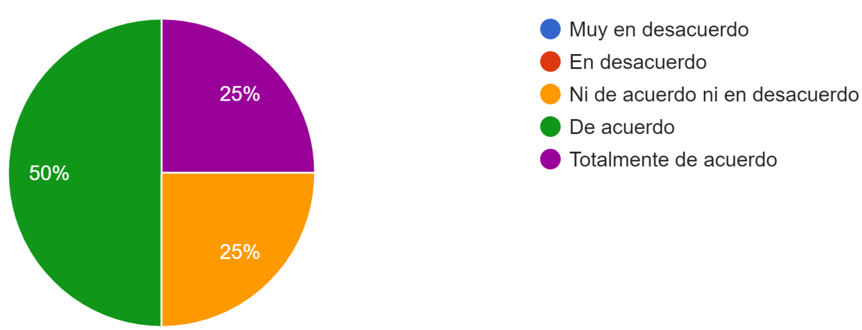
Ninguno

No

no

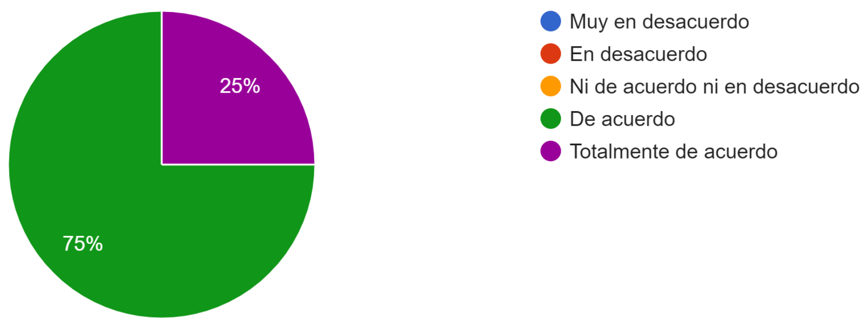
Las instrucciónes para la Capa Múscular/Subcutánea de Masa son faciles de entender.

4 responses



Las fotos/figuras en la sección para la Capa Múscular/Subcutánea de Masa ayudan a entender las instrucciónes

4 responses



Tienes algún comentario sobre la sección para la Capa Múscular/Subcutánea de Masa?

3 responses

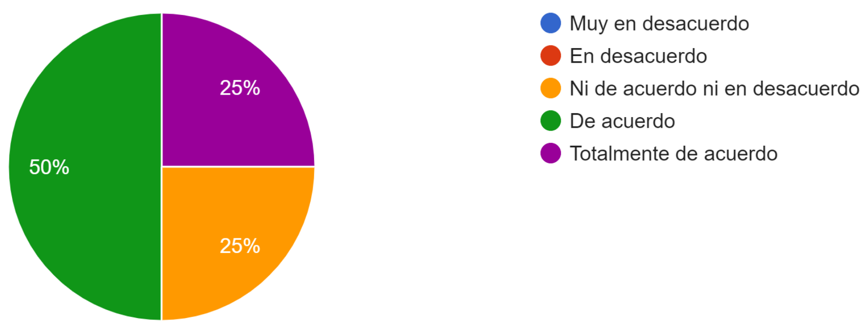
Ninguno

No

la medida de grosor de la masa de cuanto es? para que quede como las imágenes de la figura 8

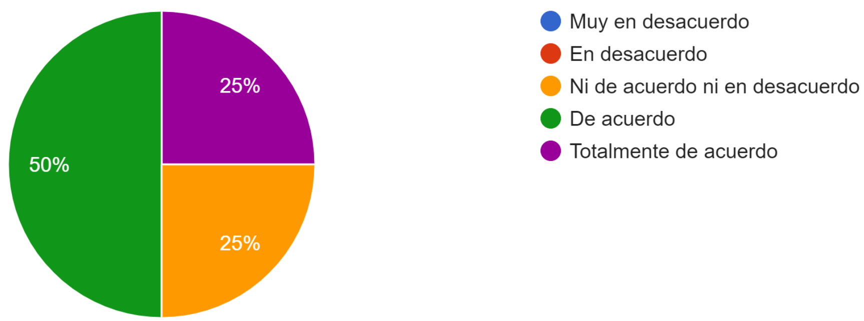
Las instrucciónes para la Capa de Piel de Gelatina y Glicerina son faciles de entender.

4 responses



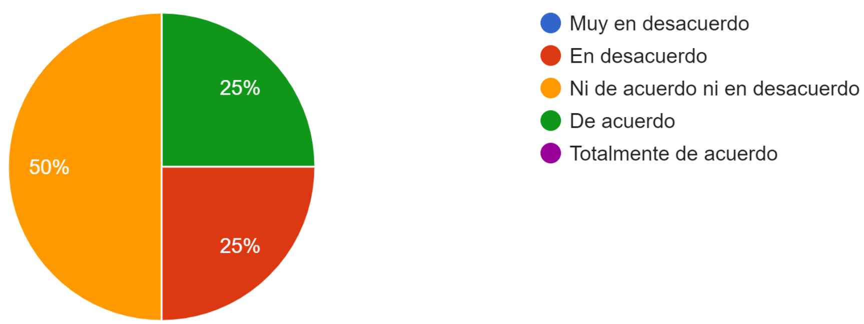
Las fotos/figuras en la sección para la Capa de Piel de Gelatina y Glicerina ayudan a entender las instrucciónes

4 responses



Me preocupa el producto de gelatina porque es un producto de origen animal.

4 responses



Tienes algún comentario sobre la sección para la Capa de Piel de Gelatina y Glicerina?

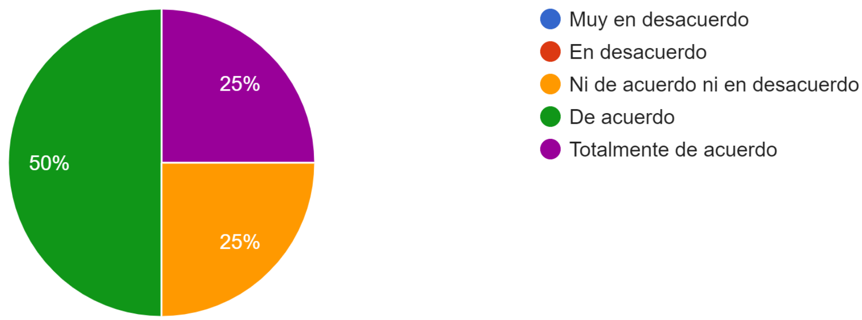
2 responses

Ninguno

no

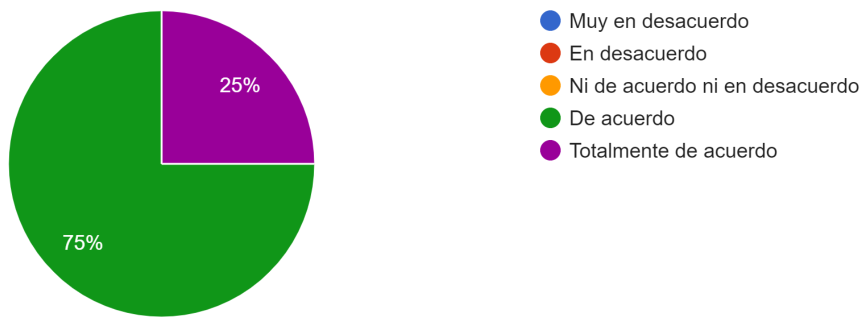
Las instrucciónes para el Soporte de Cartón y Pasos Finales de Adhesión son faciles de entender.

4 responses



Las fotos/figuras en la sección para el Soporte de Cartón y Pasos Finales de Adhesión ayudan a entender las instrucciónes

4 responses



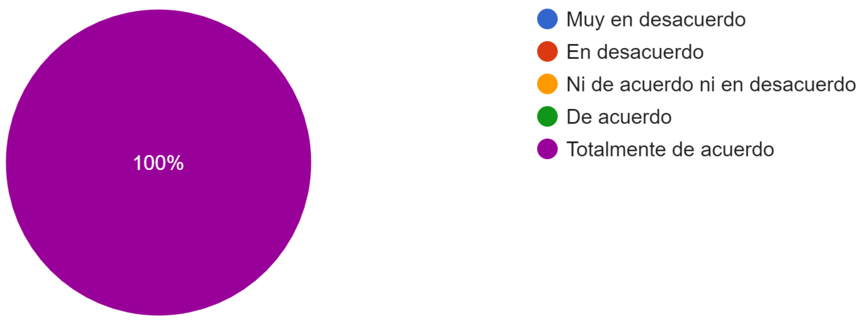
Tienes algún comentario sobre la sección para Soporte de Cartón y Pasos Finales de Adhesión?

2 responses

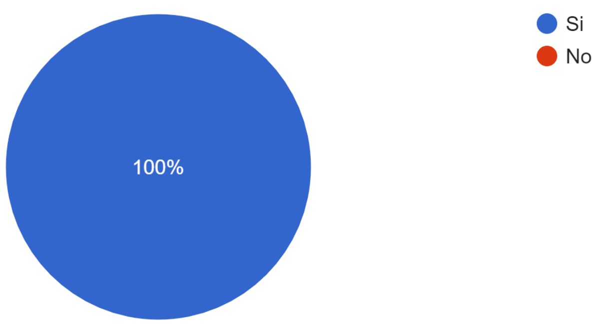
Ninguno

no

Estoy interesado/a en este simulador y creo que será útil en mi entrenamiento.
4 responses



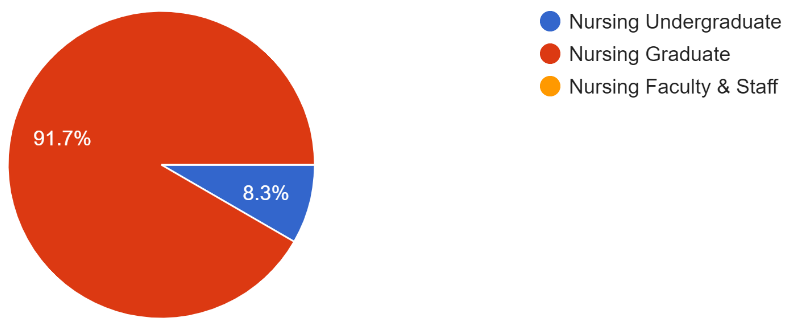
¿Estarías dispuesto/a a crear un simulador siguiendo nuestras instrucciones y despues completar otra encuesta?
4 responses



Appendix I: Survey Questions, Figures, and Raw Data:

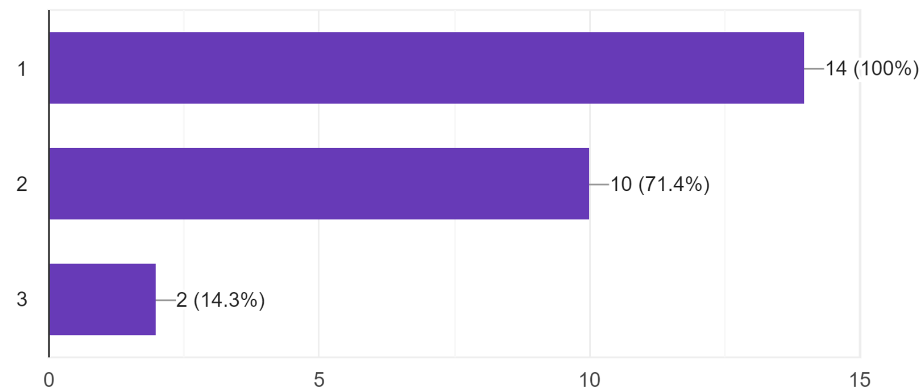
Occupation

12 responses



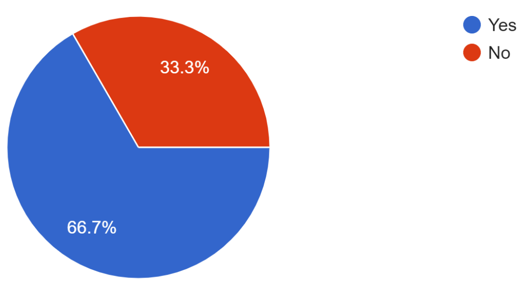
Which simulator did you interact with?

14 responses

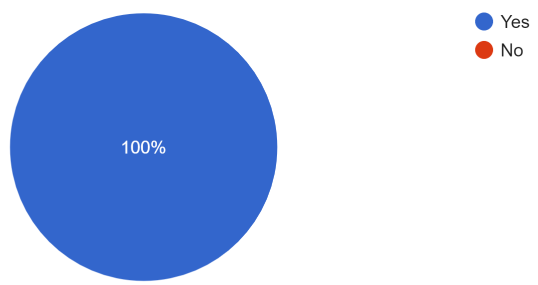


Were you able to locate the acromion?

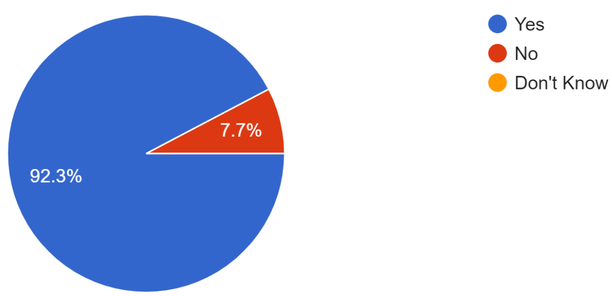
12 responses



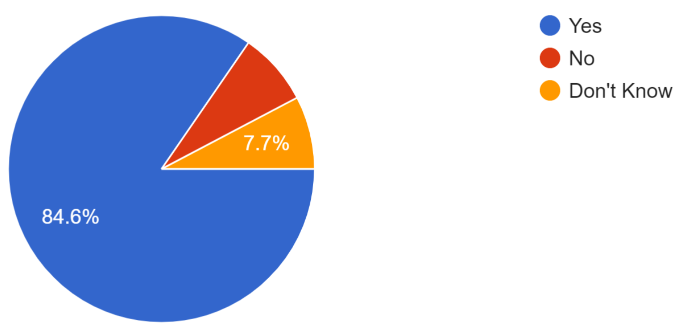
Were you able to identify the injection site?
14 responses



Was the location of the pre-marked injection placement triangle representative of the injection site?
13 responses

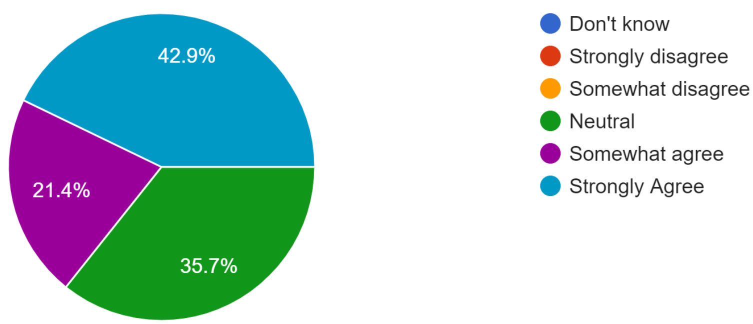


Was the size of the pre-marked injection placement triangle representative of the injection site?
13 responses



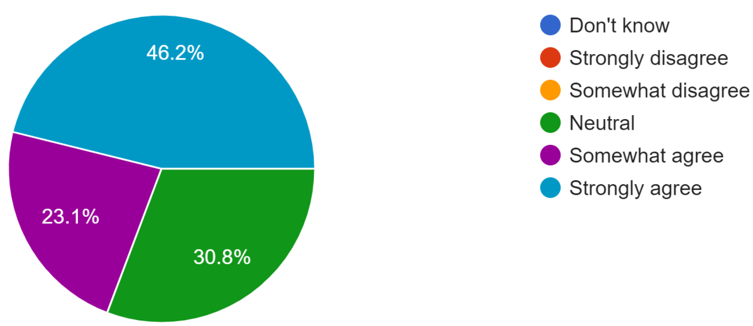
The simulator helped improve my skills

14 responses



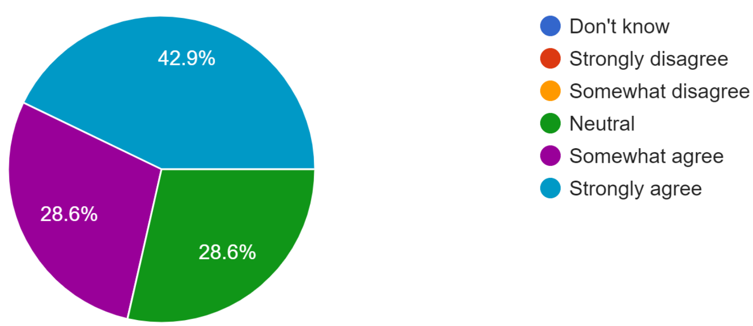
The simulator helped improve my confidence in locating injection site

13 responses



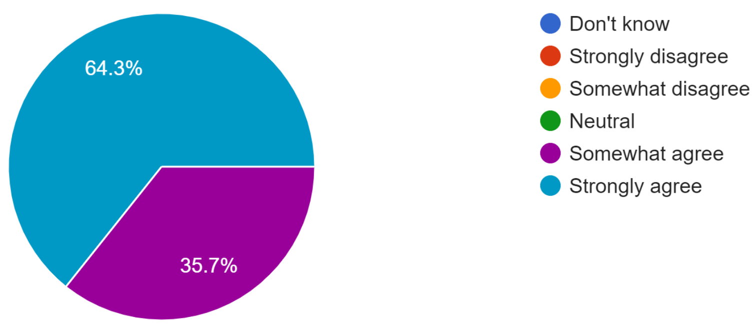
The simulator helped improve my ability to locate injection site

14 responses



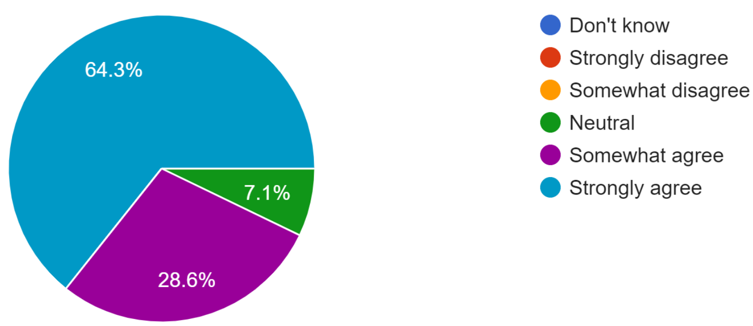
The simulator has adequately realistic characteristics/features for learning and practice

14 responses



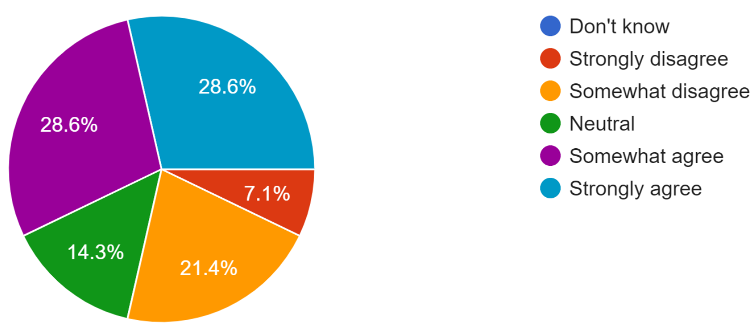
Realism of skin was adequate

14 responses



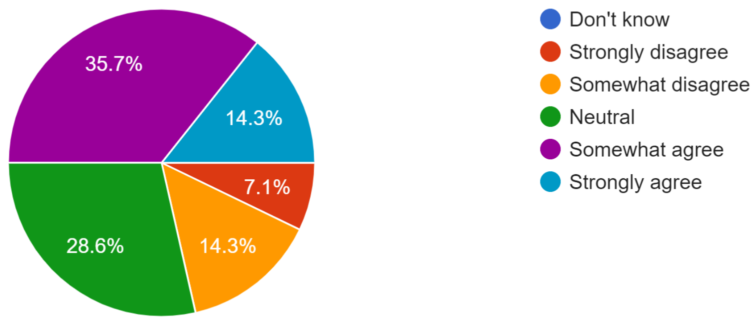
Realism of shoulder size was adequate

14 responses



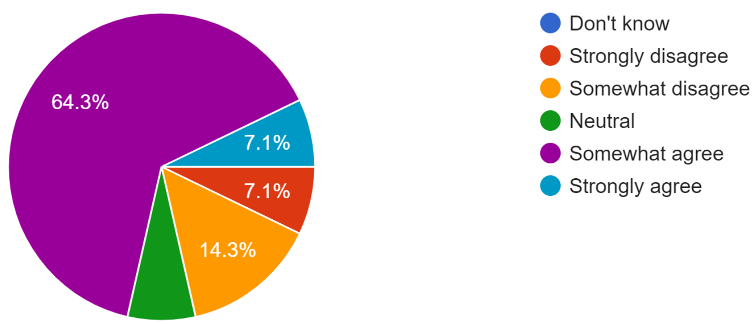
Realism of shoulder shape was adequate

14 responses



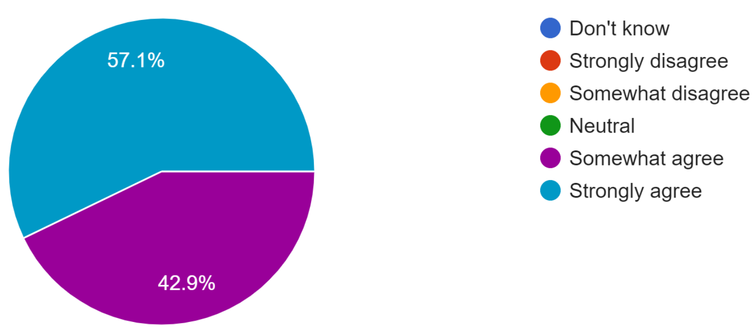
Realism of landmark (acromion) was adequate

14 responses

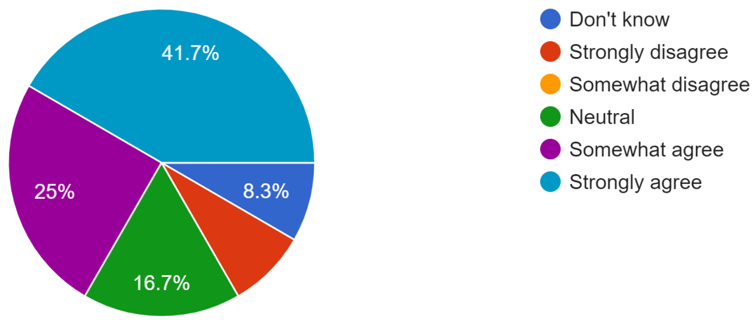


Realism of injecting was adequate

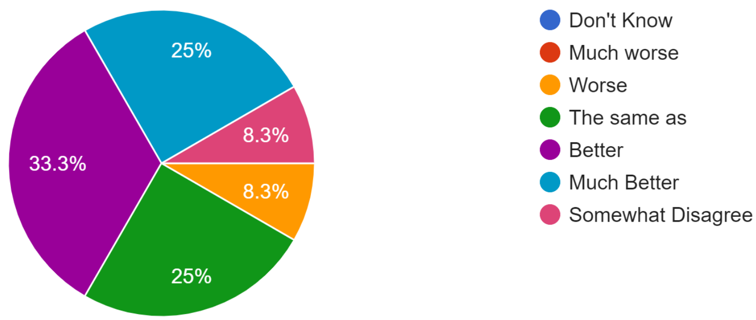
14 responses



The feedback block informs user of incorrect location
12 responses



The fidelity of the model is comparable to other tools I have used
12 responses



Appendix J: Bill of Materials

Note: prices vary depending on where the materials are purchased.

Name of Material	Description	Qty	Unit Cost
Balloons	15 number of balloons per pack	2	$1
Cream of Tartar	5 oz	1	$5.92
Flour	5 pounds	1	$1.19 - $1.42
Foundation	1 FL oz	5	$1 - $6
Gelatin	1.75 oz	11	$0.80 - $3.58
Glycerin	6 FL oz	10	$2.04 - $12.99
Isopropyl Alcohol	16 FL oz	1	$1.54
Plastic Wrap	200 sq ft	1	$2.29
Play doh	20 oz	1	$7.00
Super Glue	1 FL oz	1	$5.29
Wonder Foam	1 sheet	1	$0.79
Yeast	4.5 oz	1	$1.34