Design History Workbook The InnoDent	
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Contents

Section 0: How to Use this Document

This document is designed to guide you through BMEN 427 and 428. There will be portions that you work on this document individually and portions you submit as a group. When completing individual parts, each team member adds to the section starting with "Team member: (your name)" and "Date: (date work is complete)".

We have used italics to specify instructions for the various parts. Please remove instructions before submission. Non-italicized font, headers, and tables should be kept within the document. Modify tables and add figures as appropriate. If needed, speak to an instructional team member about the use of appendices.

Each member is to keep a lab notebook (physical or digital) notating each time the senior design team meets and include: the date, general reason for the meeting, all the people present (including clinicians/mentor/etc.), and notes from the meeting. To better manage the size and complexity of the DHF please keep the lab notebook separately from the DHF only referencing them in the DHF. Figure 1 describes the interconnectedness of various assignments.

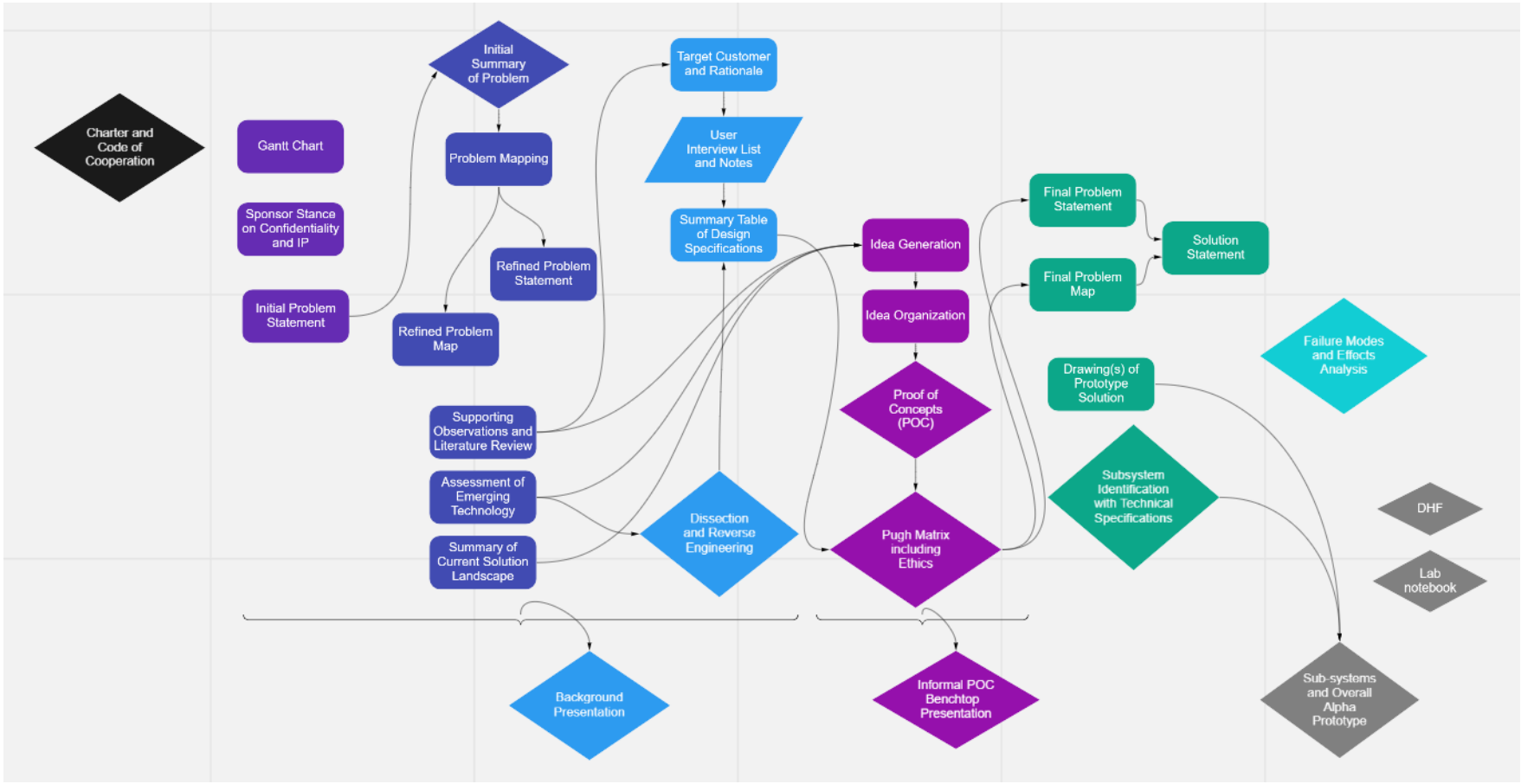


Figure 1. DHF Activities Flow Chart

Section 1: Charter and Code of Cooperation

1.1. Mission Statement

Our group aspires to improve the quality of life of patients through the research of a biotechnology field within the time frame of this semester and the allotted budget.

1.2. Expectations of Team Members

1. All members will contribute evenly to the workload of the group.
2. All members will complete their assignments on time unless otherwise communicated.
3. All members are expected to communicate in advance about any complications arising in their work.
4. All members will meet regularly to report the status of their respective works.
5. All members will remain professional relations with the group's respective mentor.

1.3. Decision-making Process

All decisions will be decided democratically through a group vote. Any ties or conflicts will be settled by the mentor or the instructional team if the mentor is unavailable.

1.4. Conflict-resolution Policy

The group will handle conflict internally in a respectful manner at first. After warnings have been administered by the group and the still problem persists, the group will report the instructional team.

1.5. What if someone contracts Covid-19

The group members infected with Covid-19 will contribute electronically to the group's efforts through Zoom or Facetime. If they are too sick to contribute, they will have their role within the group changed and, in the worst case scenario the other group members will temporarily take the sick members role in order to meet deadlines.

1.6. Communication Plan

The group will communicate through an IMessage group chat. The group intends to meet once a week minimally. Group members will effectively communicate and remind members of meetings before they occur. The group will use Google Drive to store and work collaboratively on documents.

1.7. Peer Evaluation Statement

Group members will be honest and fair in their evaluations of one another without being disrespectful. Constructive criticism will be highly valued within the group to ensure the best working environment.

1.8. Roles and Responsibilities

1. Meeting Coordinator: Emma Grace Pittard – Will communicate and remind members of weekly meetings as well as plan additional meetings as required due to workload.
2. Recorder: Anthony Gilles – Recorders will take meeting minutes when the group meets and upload them to google drive for documentation purposes.

3. Timekeeper: Anthony Gisolfi – Timekeeper will keep track of all deadlines in the group and notify members of upcoming due dates.
4. Encourager: Kollin Fillman – Encourager will reinforce positive feedback on group members' ideas and maintain high morale.
5. Devil's Advocate: Remy Bell – Devil's Advocate will respectfully find flaws in group members' ideas and kindly bring them to the group for acknowledgment.

These roles and responsibilities will be rotated every 2 weeks to ensure that everyone contributes equally in the group. The rotation will proceed down the list above.

I agree to adhere to these guidelines and do my part to ensure the success of the Team.

Anthony Gisolfi - Timekeeper **9/12/2023**
Team Member (Role, if defined) **Date**

Remy Bell - Devil's Advocate **9/12/2023**
Team Member (Role, if defined) **Date**

Emma Grace Pittard - Meeting Coordinator **9/12/2023**
Team Member (Role, if defined) **Date**

Anthony Gilles - Recorder **9/12/2023**
Team Member (Role, if defined) **Date**

Kollin Fillman-Encourager **9/12/2023**
Team Member (Role, if defined) **Date**

Section 2: Initial Problem Statement and Recording -

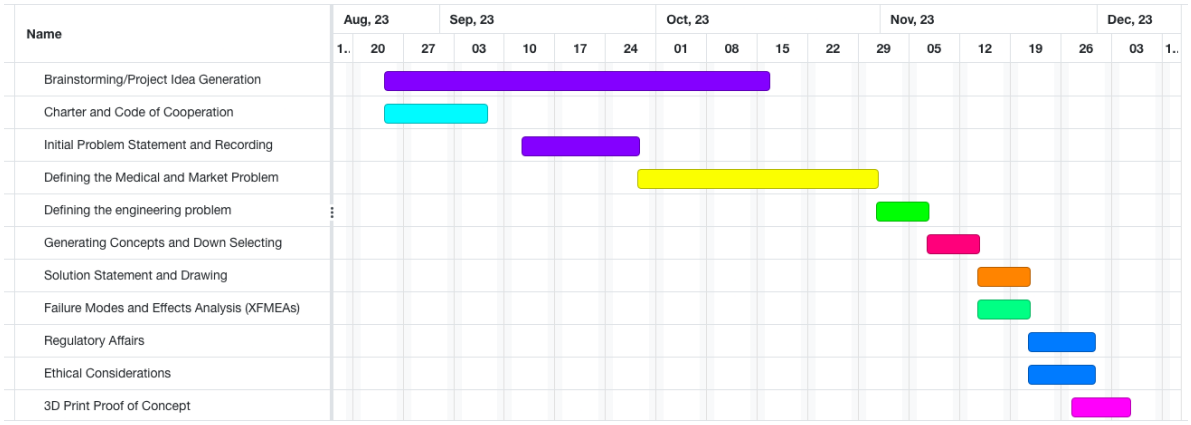
2.1. Initial Problem Statement

Approximately 28.3 million orthopedic procedures are performed every year around the globe, making them one of the most common surgeries[1]. Bone screws, the most commonly used orthopedic implant, are used for stabilizing bone fractures and fixating implants to bone[2]. In fact, billions of bone screws are implanted every year for stabilizing bone fractures and fixating implants to bone and 2.2 million orthopedic procedures involving solely bone grafting are performed around the globe annually [2-4]. The process of performing orthopedic surgery involves the sawing, drilling, or inserting of screws into the bone, often resulting in thermal osteonecrosis, which can result in further degeneration of bone tissue, functional impairment of joints, and failure of orthopedic screws. In fact, approximately 26% of bone screws are irreparably damaged and 13.5% of bone screws ultimately fail[2,5]. Failure of these orthopedic screws, generally caused by a low screw pullout strength, can exacerbate fractures and may require further surgery to replace the screws[6]. The biggest indicator for the success of a bone screw is the strength of the bone, which is largely dependent on the mineral bone density of the bone, although the geometry, microstructure, and materials properties of the bone are also contributing factors worth considering[7]. Specifically, the heat generated during drilling and the pullout strength of the screw are dependent on the bone mineral density of the bone[8]. Therefore, knowledge of the density of the bone can aid in the decision making of orthopedic surgeons when deciding different screws to use during surgery and the methods for installing the screws. However, the density of bone varies considerably within a bone, within different bones in the same patient, and across different patients[9,10]. Factors that influence bone density include age, sex, race, disease, previous medications, smoking, and even alcohol consumption[11-13]. Furthermore, due to the many methods of measuring bone density in the market, there is no standardized way to measure bone density, which makes comparison of results from cadaver to cadaver, experiment to experiment, and lab to lab extremely difficult. Creating a device that can easily measure localized bone density would improve clinical work and academic research by allowing easy comparison of research and experimental results in order to make a better informed decision of the type of bone screw to use during orthopedic surgery and to better understand the effects of diseases such as osteoporosis and bone cancers.

Currently, there exists no portable, simple, and sterilizable solution for determining the physical density of a bone at a specific point of interest. Existing technologies such as the DEXA scan uses X-Rays to determine the amount of energy absorbed by the bone, which can be correlated to its density. However, these scans require radiology equipment and highly specialized equipment, rendering them difficult to use in a surgical setting. Other methods, such as quantitative ultrasonography, offer promising possibilities to measure bone density, however they suffer from poor accuracy when compared to DEXA scans[14]. Furthermore, readings tend to vary considerably based on the model of the device and factors beyond control, often generating inaccurate data[15]. Other portable technologies, such as the OsteoProbe®, measure the strength of bone by micro-indenting the bone and quantifying the death of

microfractures generated[7]. However, technologies such as these struggle with sterilization and are often inaccurate due to their inability to be applied to different sized bones and bodies.

2.2. Gantt Chart-



2.3. Mentor Stance on Confidentiality and IP

Dr. Jackson has expressed his interest in confidentiality in our initial meeting. He has mentioned the idea of our group members signing non-disclosure agreements in order to protect the patentability of this design. However, Dr. Jackson understands that this design must be presented to faculty and students here at USC and accepts this breach of confidentiality. Dr. Jackson has also expressed the IP breakdown of any potential patent that may come from this design. 20% of the patent IP will be split among the group evenly, leaving each student with 4% IP of the total product. This, as Dr. Jackson stated, will only be an issue if the work completed in this class is deemed patentable.

Section 3: Defining the Medical and Market Problem

3.1. Supporting Observations and Literature Review

Team Member 1: Emma Grace Pittard

Product/Procedure/Service/etc 1: Universal Testing Machine

Activities	Environments	Interactions	Objects	Users
Testing of Mechanical Strength of Bone	Research Lab Does not need to be in a sterile environment	Will come into contact with the bone directly Researcher will load the bone between the metal clasps and tensile tests can be conducted on the bone and displayed onto a computer software	Holder for device Space for tensile/compressive object Moveable head Load accumulating software Cadaver bones will be used	Medical Researcher Biomedical Engineers Patients (cadaver)

Observations: There is large variability among each test and this device is very sensitive which makes it an inefficient model to measure bone density on its own.

Source: https://www.instron.com/en/products/testing-systems/universal-testing-systems[16].

Product/Procedure/Service/etc 2: Radiograph

Activities	Environments	Interactions	Objects	Users
Takes X-rays or gamma rays of bones within the human body	Imaging specializing office Hospitals Does not need to be in a sterile environment Specialized imaging room	Orthopedic specialists will locate the injury central location X-ray will be conducted by a nurse/ imaging specialist to determine state of bone at this location	Tube and tube housing Generator Beam filtration system Collimator	Doctors Surgeons Imaging Specialists Nurses Patients

Observations: Radiography does not allow for sufficient mathematical information about the biomechanical properties of the bone to serve as an effective method alone.

Source: https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/radiography[17].

Product/Procedure/Service/etc 3: Bone Density Scan

Activities	Environments	Interactions	Objects	Users
Uses low dose X-rays to check for signs of mineral loss and bone thinning Measures for osteoporosis, calcium levels and other bone minerals	Imaging specializing office Hospitals Does not need to be in a sterile environment Specialized imaging room	Orthopedic specialists will locate the injury central location X-ray will be conducted by a nurse/ imaging specialist to determine state of bone at this location	Scanning arm Low dose x ray beams Tube and tube housing Beam filtration system Generator	Doctors Surgeons Imaging specialists Nurses Patient

Observations: This is the most promising method currently however there are still large limitations among varying patients, experiments, and labs which makes it a difficult method to use holistically in the field of medicine.

Source: https://www.mayoclinic.org/tests-procedures/bone-density-test/about/pac-20385273[18].

Product/Procedure/Service/etc 4: Quantitative Ultrasound

Activities	Environments	Interactions	Objects	Users
Measures for osteoporosis using dual x ray absorptiometry (does not use ionizing radiation)	Imaging specializing office Hospitals Does not need to be in a sterile environment Specialized imaging room	Orthopedic specialists will locate the site that may be most susceptible to marking for osteoporosis Ultrasound will detect different bone properties at this spot and display in an image	Transducer and transducer probe Computer Conductive gel Monitor Imaging software	Doctors Orthopedic Surgeons Imaging specialists Nurses Patient

Observations: This does not provide sufficient mathematical information to adequately supply enough information to treat bone density problems alone.

Source: https://pubmed.ncbi.nlm.nih.gov/35508869/[19].

Team Member 2: Kollin Fillman

Product/Procedure/Service/etc 1: Bone Screws in Orthopedic Surgery

Activities	**Environments**	**Interactions**	**Objects**	**Users**
Orthopedic Surgery	Operating Room Sterile environment	Surgeon locates the fracture in the bone. Bone is drilled into to make room for screws. Screw is inserted into the bone to hold the fracture together.	Drill Bone Bone Screw	Surgeons Doctors Orthopedic Surgeons Nurses Patient

Observations: There are limitations in the surgeon's ability to assess the strength of the bone in the location they attempt to implant the screw, which can contribute to the chance of screw failure.

Product/Procedure/Service/etc 2: Sawing through Bone in Surgery

Activities	**Environments**	**Interactions**	**Objects**	**Users**
Orthopedic Surgery Osteotomy	Hospitals Operating Room Sterile environment	Surgeon observes the patient to determine the best location to cut into the bone. Surgeon uses a saw to cut into the bone at the designated location. Surgery process is continued until operation is complete	Patient Bone (dependent on patient condition) Bone Saw (type varies based on the operation being performed)	Doctors Orthopedic Surgeons Nurses Patient

Observations: Some sections of the bone are more difficult to saw through than others, and physicians don’t have the best way of knowing where the more dense sections of bones are.

Team Member 3: Anthony Gisolfi:

Product/Procedure/Service/etc 1: Bone Density Scan (DEXA or DXA)

Activities	Environments	Interactions	Objects	Users
Low dose radiation to measure bone loss	Performed in a hospital/Medical building Specialized imaging room	Uses ionizing radiation on patients	Utilizes dual-energy x-ray absorptiometry	Patients, nurses, and doctors, imaging specialists

Observation: There is a large limitation of this device due to its bulkiness.

Source: https://www.radiologyinfo.org/en/info/dexa[20]

Product/Procedure/Service/etc 2: Bone Mineral Density Test

Activities	Environments	Interactions	Objects	Users
Another low dose of radiation to measure bone loss	Performed in hospital Specialized imaging room	X-ray done on the lower spine	Uses DEXA methods	X-ray tech, doctor, nurse, patient

Observation: There is a limitation of this device due to its inability to be sterilized and admitted into an operating room.

Source: https://www.mountsinai.org/health-library/tests/bone-mineral-density-test[21]

Product/Procedure/Service/etc 3: Understanding bone densitometry

Activities	Environments	Interactions	Objects	Users
Interpretation of bone density scans can sometimes show other issues not related to bone density (gallbladder stones, etc.)	Performed in a hospital in a sterile enviroment	DEXA scans at hospital	Results of a DEXA scan and what they mean	Bone density is especially important for postmenopausal women Also relates to doctors, nurses, and all patient types

Observation: There is very little bone densitometry done outside a hospital environment.

Source: https://www.youtube.com/watch?v=KIciEsyHKYg[22]

Product/Procedure/Service/etc 4: Portable Bone Density Machine

Activities	Environments	Interactions	Objects	Users
Portable bone density machine that can be used in a patients house	Can be done almost anywhere due to portability	Ultrasound at the wrist	Need contact gel for device	Nurses and Patients

Observation: This is one of the few portable devices that can measure bone density but is limited to where on the body it can be used.

Source: https://www.youtube.com/watch?v=rpAnjbaj5ZU[23]

Team Member 4: Remy Bell

Product/Procedure/Service/etc 1: Dual Energy X-ray Absorptiometry (DEXA) Scan

Activities	Environments	Interactions	Objects	Users
Low radiation X-Ray Scan	Radiology office, Hospital, Clinic	Requires the patient to remain very still and remove all jewelry. The technician helps adjust the patient into position and interprets the transmitted data.	A scanning machine and a photon generator	Operated by a radiologist or technician Nurses Patients

Observations: DEXA scans appear to be the gold standard for determining bone density, however they require a lot of work and specialization.

Source:

"Bone density scan: Medlineplus medical test," MedlinePlus, https://medlineplus.gov/lab-tests/bone-density-scan/ (accessed Oct. 31, 2023)[24].

Product/Procedure/Service/etc 2: Quantitative Ultrasonography (QUS)

Activities	Environments	Interactions	Objects	Users

Ultrasonography	Portable, so testing may be done anywhere, including at home	Ultrasounds are quick and usually require patients to remain relatively still for short periods of time. Technicians help get the patient in place and apply any sort of gel or alcohol that may be required, although it depends on the model of the device.	Ultrasound machine	Requires little training, and therefore may be operated by nonspecialists, technicians, nurses, and even patients.

Observations: Ultrasonography seems like a promising solution for measuring bone density, however it is too new to verify its clinical usage.

Sources:

D. Hans, A. Métrailler, E. Gonzalez Rodriguez, O. Lamy, and E. Shevroja, "Quantitative Ultrasound (QUS) in the management of osteoporosis and assessment of fracture risk: An update," *Advances in Experimental Medicine and Biology*, pp. 7–34, May 2022. doi:10.1007/978-3-030-91979-5_2[19]

A. Sheu and T. Diamond, "Diagnostic tests: Bone Mineral Density: Testing for osteoporosis," *Australian Prescriber*, vol. 39, no. 2, pp. 35–39, 2016. doi:10.18773/austprescr.2016.020[25]

Team Member 5: Anthony Gilles

Product/Procedure/Service/etc 1: Dual-Energy X-ray Absorptiometry (DXA)

Activities	**Environments**	**Interactions**	**Objects**	**Users**
Method for measuring bone mineral density (BMD) Uses two distinct x-ray energy levels specific for soft	Radiology department of hospitals. Medical Research labs	Patient lies on table Procedure is performed, generating planar bone images. T score is calculated (standard deviations between patients	C arm with x-ray source (two distinct energy levels) Collimator Table to hold patient patient	Nuclear medicine technician Licensed physician Older patients (65 +) Patients at risk of having or

tissue and cortical bone		mean BMD and the reference population) Z score is calculated (standard deviations above or below age-matched controls)		developing bone diseases Doctors & Nurses

Observations: This technique does not directly measure the density of bones, it measures the levels of calcium and other minerals in bones (BMD), however, bones with higher levels of these minerals tend to be more dense and are stronger. Additionally, this method is not used on cadavers or cadaver bone samples.

Source:

M. Krugh and M. Langaker, "Dual-Energy X-Ray Absorptiometry," *StatPearls*, vol. 1, no. 1. Jun. 05, 2023. Accessed: Oct. 30, 2023. [Online]. https://www.ncbi.nlm.nih.gov/books/NBK519042/[26]

Product/Procedure/Service/etc 2: Compressive Resistance

Activities	Environments	Interactions	Objects	Users

Method for measuring bone compressive resistance (indirect measurement for bone density) Uses an indenter on parts of a cadaver bone sample to calculate the local elastic modulus	Medical research labs Cadaver labs	Bone samples of the appropriate dimensions were removed from cadavers Samples are inked to create a grid Samples are placed on the loading plate and the indentor compresses each grid of the bone at a constant speed until it reached a given compression distance (same distance for each grid) Data was imputed into the equation: E = **S(**1 - v2)/d To solve for the compressive resistance (elastic modulus)	Instron1125 Universal Testing machine 4 mm diameter indenter Cadaver bone sample/cross -section	Physicians Orthopedic doctors Research lab workers Patients (cadavers) with bone diseases

Observations: This technique is done on cadaver bone samples, which is in line with the medical problem that is trying to be solved (determining bone density in cadavers). A bone sample must be taken from the cadaver for this technique. Accessing and removing the bone from the cadaver could potentially eliminate the possibility to use the cadaver for other purposes in the future.

Source:

G. K. AITKEN,M.D. et al. " Indentation Stiffness of the Cancellous Bone in the Distal Human Tibia," Clinical Orthopaedics and Related Research, Dec. 1985. Accessed: Oct. 30, 2023. https://pubmed.ncbi.nlm.nih.gov/4064414/[27]

Product/Procedure/Service/etc 3: Quantitative Ultrasound (QUS)

Activities	**Environments**	**Interactions**	**Objects**	**Users**

Technique for measuring bone thickness Uses a mechanical wave to determine mechanical properties	Hospitals Medical research labs	Patient arranges relevant body part in the appropriate position in the QUS device, or to be probed Measurements are made based on attenuation, velocity or backscatter measurements, as surrogate markers for BMD Alternatively pulse-echo or axial transmission can be used to determine mechanical properties	QUS device (could be portable probing device or stationary device)	Patients with or at risk of bone fragility (secondary osteoporosis) Orthopedic doctors Nurses

Observations: This technique directly measures bone thickness, which is synonymous with bone density. It also has potential to be easily adapted into a technique used to measure the bone density in cadavers, without removing a bone sample.

Source:

Q. Grimal and P. Laugier, "Quantitative Ultrasound Assessment of Cortical Bone Properties Beyond Bone Mineral Density," *Innovation and Research in Biomedical Engineering* , vol. 40, no. 1. pp. 16–24, Feb. 2019. Accessed: Oct. 30, 2023.
https://www.sciencedirect.com/science/article/pii/S1959031818301982[28]

Product/Procedure/Service/etc 4: Quantitative Computed Tomography (QCT)

Activities	**Environments**	**Interactions**	**Objects**	**Users**

Technique for measuring volumetric BMD Rapid acquisition of 3D volume images and finite element analysis	Radiology department of hospital Medical research labs	Patient gets on table and CT scan is performed CT images are generated 2D CT images are used to reconstruct a 3D image of the bone Finite element analysis is used to determine the BMD throughout the volume image	CT scanners Peripheral CT scanners Analysis software patient	Radiologists Licensed physician Patients with or at risk of osteoporosis

Observations: The capability to produce 3D images is unique and provides a distinct advantage over previously discussed techniques. Has a relatively high ionizing radiation (compared to DXA).

Source:

J. E. Adams , "Quantitative computed tomography," *European Journal of Radiology* , vol. 71, no. 3. pp. 415–424, Sep. 2009. Accessed: Oct. 30, 2023. https://www.sciencedirect.com/science/article/pii/S0720048X09004343?via%3Dihub[29]

3.2. Initial Summary of Problem

Anthony Gilles

Healthcare Engineering Aspects

I. The healthcare system of interest is cadaver medical research. Samples are taken from cadavers and experimented on. The results are then compared to other cadavers (taking into account important differences in the cadavers themselves) in order to better understand the effects of different disease states.
II. In the current state of this healthcare system, the density of bones is an important variable when it comes to experimentation, and it varies significantly. This can make it hard to compare results between cadavers, experiments, and labs.
III. There are many devices or techniques that exist that measure bone density, such as DXA, QUS, and QCT. However, these techniques require equipment that is not accessible in cadaver labs, and additionally take more time for advanced analysis.
IV. The inefficiencies described in the healthcare system primarily impede research of diseases such as osteoporosis, which causes over 2 million fractures every year[30]. This issue causes researchers to take additional time during research working around not knowing the bone density, as well as not being able to cross reference or compare other experiments.

V. The cause of the problem is the lack of an easy to use device in the lab to measure bone density. This problem is distributed to a very specific group of people, that being cadaver medical researchers. The control of the problem is the missing bone density variable.

VI. This problem costs researchers a lot of time and money that is wasted doing additional experiments and work-arounds to account for not knowing the bone density.

Emma Grace Pittard

In order to improve the state of orthopedic surgery development, there needs to be a uniform method to determine and replicate bone properties including bone density, calcium concentration, and matrix stability. Bone density is important in determining the severity of osteoporosis, likelihood of bone fractures, and additional bone deficiencies. In the US, there are approximately 10 million cases of diagnosis of Osteoporosis and approximately 44 million Americans that suffer from a low bone density which can increase chances of bone fracture[30]. This property also is used as a predictor of bone screw failure which are frequently used in orthopedic surgeries. Approximately 26% of bone screws are irreparably damaged[2], and 13.5% of bone screws fail[5]. Currently, there is no model that can effectively measure bone density consistently among varying experiments, labs, and conditions. This makes it very difficult to effectively provide optimal treatment methods for such bone deficiencies. The current resolution to this issue is an accumulation of multiple biomedical tests on the same sample which can be very time consuming, expensive, and inaccurate. There needs to be a device that can more accurately measure bone density without the need for additional tests that can also act more uniformly among varying conditions and sample types. An effective preliminary study of a new bone density device can be effectively measured on cadavers to not only test the instrument but also improve the orthopedic surgical techniques simultaneously. This will allow for the most effective improvement in the development of orthopedic treatment and medicine.

Anthony Gisolfi:

Bone screws are one of the most common orthopedic procedures in the world used in stabilizing procedures. 2.2 million operations utilizing bone screws occur each year around the world [2]. As they are such a common procedure, there are complications and failures with these screws. Due to an existing problem with bone screw failure, there exists a need to characterize strength of a bone to determine if a screw will fail. One way to do this is with the material properties of a bone which correlate to material density value. Current devices determining bone density on the market such as DEXA scans are bulky, expensive, and non-sterilizable. A handheld device that is able to be sterilized is advantageous to orthopedic surgeons. This device would aid in determining which screw to use and how the screw would hold in a patient's bone. Furthermore it would allow for further testing on cadavers that could aid in the understanding of the relationship between material properties, bone density, and screw failure. The portability of such a device would be vital to research and surgical procedures as it would allow for the easy access of bone properties.

Kollin Fillman

The majority of procedures in orthopedic surgery involve osteotomy, or the act of cutting, drilling, or grinding bone tissue, and often make use of implants such as bone screws and suture anchors

for holding fractures together. Approximately 2 million bone fractures occur every year, requiring the use of screw implants to mediate these problems[31]. Two primary complications related to osteotomy are thermal osteonecrosis, or the death of bone tissue due to the high heat generated by friction, and screw pullout strength, or the amount of force the screw can take before being pulled out of place. Knowing the localized density of bone is important for minimizing these issues and determining the optimal location to cut into or drill into a bone. However, there are very few medical devices geared towards measuring the physical density of bone, and those that do are very large and difficult to use during a surgical procedure. In addition, the majority of studies related to bone density involve an assumed uniform density, rather than looking at the localized density of the bone at a specific point. A simple to use device that can measure the localized bone density for a patient would allow orthopedic surgeons to locate the best position to cut into a bone or insert a screw in order to minimize the risks of screw pullout or thermal osteonecrosis. Reducing these effects would similarly reduce the need for patients to return for treatment related to osteonecrosis or to have a screw/implant readjusted.

Remy Bell

Approximately 28.3 million orthopedic procedures are performed every year around the globe, making them one of the most common surgeries[32]. However, standardizing procedures are difficult because the properties of bone vary substantially between patients, betweens bones of the same patient, and within a singular bone itself. Therefore, when studying bones for academic research and for the training of medical students, it is difficult to maintain a standard that may be compared to. Although there exist methods for measuring the density of bone, they remain unaffordable and not easily accessible. For example, the current gold standard of bone density measurement, Dual Energy X-ray Absorptiometry (DEXA) Scanning, requires specialized training to operate, is costly, and needs to be done in specialized healthcare facilities, thus discouraging the widespread use of this technique in measuring the density of cadaver bones[24]. More convenient methods, such as quantitative ultrasonography (QUS), are more accessible, cheaper, and may be done “at home”, but provide highly variable and non-standardized results[9,25]. There therefore needs to exist a method to cheaply and readily measure the density of bone *ex vivo*. The inability to standardize the density of bone has many academic and educational consequences. For example, the variations seen in bone density may skew research data and add extraneous variables that are often unaccounted for when drawing conclusions in literature. These inconsistencies also translate to the medical field, as the training of medical students is highly variable and reliant on the bone that they are being trained on. Aside from the genetic differences that underlie the variability of bone properties seen between patients, the properties of bone do not remain constant throughout the life of an individual. Disease, age, and other physiologic factors such as weight will vary within a patient’s lifetime and must also be taken into account when attempting to standardize the properties of bone. Inadequate medical training and variations in literature due to a lack of standard for measuring bone density likely contribute a nontrivial cost in the healthcare system. It is therefore imperative that a method is devised to non-destructively measure bone density so that it may be used to standardize the properties of bone in literature and the medical field.

3.3. Target Customer and Rationale-

Stakeholder 1:

Hospitals or other medical facilities

The medical facilities are where the device will actually be bought and used, so they serve as a direct and imperative stakeholder for the implementation of this device competitively and successfully into the market. Hospitals invested in this device could provide novel additions to orthopedic surgeries which would increase their revenue and patient quantity.

Stakeholder 2:

Medical Researchers

Medical researchers will be involved in the clinical trials and initial experimentation of this device. Their role will be imperative in the implementation of the device into a medical setting. The researchers will have the opportunity to improve upon the design of the device which could allow for attraction to them to act as a stakeholder for the device.

Stakeholder 3:

Medical Professionals (Orthopedic Doctors/Surgeons)

The invention of this medical device can allow for improved options for patients needing certain bone density specific surgeries. This device is aimed to provide more universal accessibility to knowledge of bone density which can vastly help improve the accuracy of surgical techniques among many different conditions. Medical professionals that are stakeholders for this product would largely benefit from this device as they would have a novel addition to surgical procedures that can improve their surgical success and frequency of surgeries.

Stakeholder 4:

Biomedical Engineers

As with most medical device inventions, a biomedical engineer is crucial in the design and implementation of a device. A device with more uniform measurement capabilities would allow for increased ability to create bone stents and other devices that can spread over a wider range of treatments for patients which can increase the need for biomedical engineers. The biomedical engineers will also be able to directly improve and maintain the device created which would make them largely benefit from being a stakeholder for this device.

Incidence:

Billions of bone screws are implanted every year for stabilizing bone fractures and fixating implants to bone [2,4]. There are seen to be approximately 2.2 million orthopedic surgeries involving bone graft treatment globally annually with 600,000 of those being in the US specifically [3]. Approximately 26% of bone screws are irreparably damaged[2] and 13.5% of bone screws fail[5].

Prevalence:

An additional target user for this device would be the patients themselves suffering from osteoporosis or other bone density-based issues. Instances of osteoporosis have increased from 10.2 million people in

2010 to the projected value of 13.6 million per year by 2030[33]. A device that can more accurately measure bone material properties related to bone density could allow for a significant reduction in bone screw failures and improved treatment and understanding of osteoporosis.

3.4. User Interview List and Notes

Interview With:
J. Benjamin Jackson III, MD, MBA, CPE, FAOA
Professor of Orthopaedic Surgery
Foot and Ankle Division Chief
Chief of Staff - Prisma Baptist Parkridge Hospital
Director of Orthopaedic Research
Certified Physician Executive
University of South Carolina - Prisma Health

- **Can we take cross sections of the bone or does it need to be kept intact?**
  It needs to be kept intact.
- **Are we interested in the physical density or bone mineral density (measures the mineral concentration, more common result when googling "bone density")?**
  Physical density. You are completely correct that other techniques, such as DEXA scans, measure mineral concentration. We want to know how physically strong the bone is and essentially can it hold a screw (that is oversimplified but I think you understand).
- **Can you elaborate more on the purpose of the project?**
  - **For research purposes or for medical applications?** - Both
  - **What sort of results are being compared between cadavers/experiments?** - Many different things. Screw pullout. Suture anchor pull out. Heat generated while drilling bone or grinding bone or cutting through bone.
- **How can we compare our device's results to the real density of the bone? (accuracy)**
  I can work to see if we can get a microCT and/or DEXA scan on the cadaver bones that we measure. I'm also happy for you to suggest another form of 'ground truth' to measure.
- **How much variability in density is found within a single bone, and how does this vary between different bones in the body?**
  Unknown, but I would get 50% or more. I would believe that there would be significant variation even in different parts of the bone. The mid-shaft would have the strongest bone and near the ends the weaker because those same forces are being spread over a larger surface area.

3.5. Summary of Current Solution Landscape-

There are already a handful of solutions in the market that measure bone density. One such technology is outlined in this patent, which details the use of an impulse of energy to strike a patient's hard tissue, creating an induced vibration that is sensed and analyzed in order to determine the damping factor[34]. A transducer is coupled to the hard tissue and the output is amplified before being imputed into a computer that calculates the damping factor. The benefits of this method are that it is a handheld

device, making it easy to reorient compared to a stationary device. The risks of this device are that it requires direct contact with the bone, and removing tissue from a cadaver to access the bone could prevent it from being used again in the future.

Another technology is described by this patent, which outlines a probing device designed to measure bone density[35]. This device consists of at least one ultrasound source to provide ultrasonic pulses, multiple ultrasound detectors for measuring the arrival times of ultrasonic pulses, at least one data processing element to determine differences in arrival times of ultrasonic pulses, means to transfer data from the detector to the data processing element, and communication means adapted to transfer data from the data processing element to a non-dedicated computer. The benefits of this device are that it is a handheld device (easy to use and orient) and that the data analysis (differences in arrival times) is performed by the probe itself. The risks of this device are possible sources of interference of other tissue in the cadaver, since direct contact with the bone is not required.

The market that this need takes place in consists of medical (cadaver) lab researchers, orthopedic doctors, and people at risk of or with osteoporosis. The most important group within this market is people at risk of or with osteoporosis because this disease is associated with a loss of bone density, meaning a solution to the need will help better understand and diagnose this disease. Approximately 10 million people in the U.S. have been diagnosed with osteoporosis, and another 44 million have low bone density, meaning they are at risk[36]. Additionally, the number of osteoporosis cases is expected to rise to 13.6 million in 2030.

This means that the market is large enough and expanding enough to be commercially viable, however, it is important to note that the people with or at risk of osteoporosis are not the direct customers. This is because the need at its core comes from professionals within the medical field who need a better, more consistent way to measure bone density, meaning regular people without proper medical training will not be the customer or user. The number of people with or at risk of osteoporosis does influence the amount of doctors treating and researching the disease, and since this is a very common disease, there is a very large group of orthopedic doctors and medical researchers who would serve as customers and users of the solution to this need.

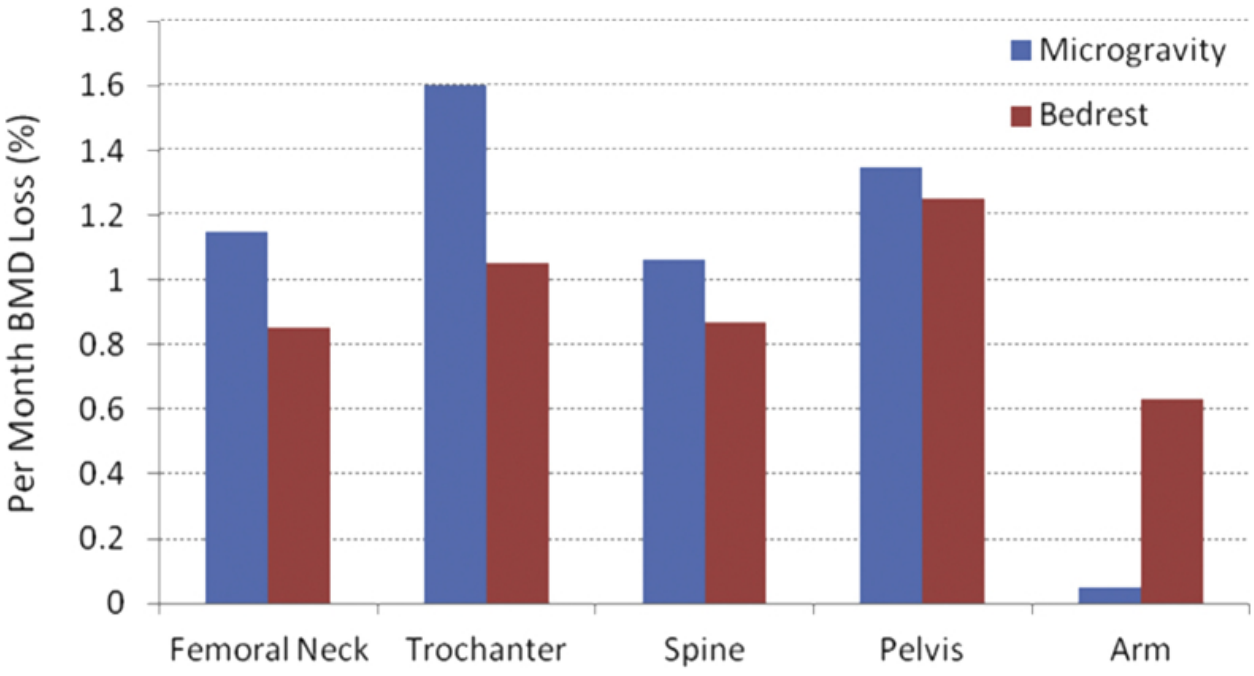
Osteoporosis is a costly disease; In the United States alone, $19 billion is spent annually treating osteoporosis-related diseases. By 2025, it is predicted that osteoporosis-related treatments will cost healthcare institutions $25.3 billion. As of 2002, the mean cost for a fracture caused by osteoporosis in the United States was $8,600, with approximately 5% of osteoporosis patients experiencing a bone fracture[37]. However, most costs are covered by health insurance[38]. It is also important to mention that out of these patients, 75% had to undergo rehabilitation services, which significantly increased the cost of treatment to approximately $30,000 . Due to the length of rehabilitation, patients are also losing tens of thousands in potential wages. Shockingly, the frequency of osteoporotic fractures in the United States is expected to grow by more than 48% between 2006 and 2025. Therefore, the ability to better research and treat osteoporosis is of great importance. However, as previously mentioned, the lack of standardization for the properties of bone in both academia and medicine has plagued this effort; The

ability to nondestructively measure the density of bone is a great step forward in this effort in slowing the growth of costly osteoporotic injuries.

3.6. Assessment of Emerging Technology

January 10th, 2018 - An application regarding a system and device to measure bone density is submitted to the patent office. This two-part application provided a device and accompanying system that can assess bone density through X-ray images of alveolar bone. The system ingeniously works by comparing an X-ray image of an unknown bone density to a reference image of a known density. The device and system then calculate and return the appropriate density of the bone sample. The application was submitted by Media Co.[39]

A common theme of bone density is how it constantly varies. This recent paper monitors the effects of mechanical loading on bone density in bed resting patients. Monitoring was performed with quantitative ultrasound imaging and dual X-ray absorptiometry in regions of interest. This graph from the paper demonstrates the density loss of microgravity and bedrest. It is of interest that different areas lose bone density at different rates. The paper determined that brief mechanical loading on bed resting patients can help to mitigate regional bone density loss[40].



Another recent paper uses the backscattering resonance phenomenon of ultrasound and photoacoustic signals to determine bone density. This process was proved to be a suitable method of detecting early osteoporosis and therefore bone density. The following image shows the schematic of their design which, while being too complex for our purposes, may help to contribute to a similar design that aids our purpose. This system used bone samples that were harvested from cattle and cannot be used in vivo. This system also involves many signals that could be disturbed in a non-lab environment[41].

3.7. Refined Problem Statement

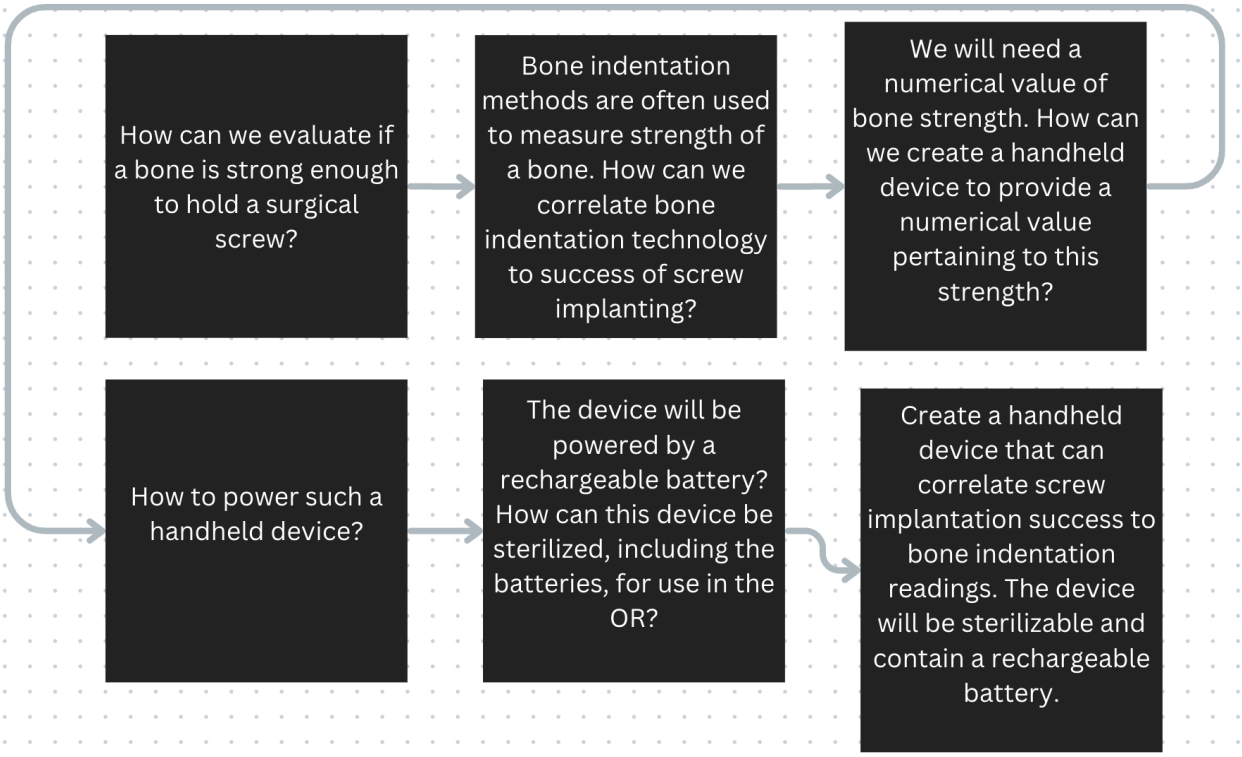
Approximately 28.3 million orthopedic procedures are performed every year around the globe, making them one of the most common surgeries[1]. Bone screws, the most commonly used orthopedic implant, are used for stabilizing bone fractures and fixating implants to bone[2]. In fact, billions of bone screws are implanted every year for stabilizing bone fractures and fixating implants to bone and 2.2 million orthopedic procedures involving solely bone grafting are performed around the globe annually [2-4]. The process of performing orthopedic surgery involves the sawing, drilling, or inserting of screws into the bone, often resulting in thermal osteonecrosis, which can result in further degeneration of bone tissue, functional impairment of joints, and failure of orthopedic screws. In fact, approximately 26% of bone screws are irreparably damaged and 13.5% of bone screws ultimately fail[2,5]. Failure of these orthopedic screws, generally caused by a low screw pullout strength, can exacerbate fractures and may require further surgery to replace the screws[6]. The biggest indicator for the success of a bone screw is the strength of the bone, which is largely dependent on the mineral bone density of the bone, although the geometry, microstructure, and materials properties of the bone are also contributing factors worth considering[7]. Specifically, the heat generated during drilling and the pullout strength of the screw are dependent on the bone mineral density of the bone [8]. Therefore, knowledge of the density of the bone can aid in the decision making of orthopedic surgeons when deciding different screws to use during surgery and the methods for installing the screws. However, the density of bone varies considerably within a bone, within different bones in the same patient, and across different patients[9,10]. Factors that influence bone density include age, sex, race, disease, previous medications, smoking, and even alcohol consumption[11-13]. Furthermore, due to the many methods of measuring bone density in the market, there is no standardized way to measure bone density, which makes comparison of results from cadaver to cadaver, experiment to experiment, and lab to lab extremely difficult. Creating a device that can easily measure localized bone density would improve clinical work and academic research by allowing easy comparison of research and experimental results in order to make a better informed decision of the type of bone screw to use during orthopedic surgery and to better understand the effects of diseases such as osteoporosis and bone cancers.

Currently, there exists no portable, simple, and sterilizable solution for determining the physical density of a bone at a specific point of interest. Existing technologies such as the DEXA scan use X-Rays to determine the amount of energy absorbed by the bone which can be correlated to its density. However,

these scans require radiology equipment and highly specialized equipment, rendering them difficult to use in a surgical setting. Other methods, such as quantitative ultrasonography, offer promising possibilities to measure bone density, however they suffer from poor accuracy when compared to DEXA scans[14]. Furthermore, readings tend to vary considerably based on the model of the device and factors beyond control, often generating inaccurate data[15]. Other portable technologies, such as the OsteoProbe®, measure the strength of bone by micro-indenting the bone and quantifying the death of microfractures generated[7]. However, technologies such as these struggle with sterilization and are often inaccurate due to their inability to be applied to different sized bones and bodies.

Section 4: Defining the Engineering Problem

4.1. Problem Mapping



4.2. Summary Table of Design Specifications

Customer or societal need (nonspecific, without numbers)	Engineering Design Specification (specific, testable, with numbers)
Sterilization for plastics with low melting temperatures	Must be admissible into an operating room. Components of devices, especially electrical ones, must be able to sustain sterilization processes. ISO 11135 describes the sterilization process. Because of the delicate internal circuitry of our device, we will likely use ethylene oxide sterilization. This means that the device must be able to survive temperatures of 37℃-63℃ in relative humidity (40% - 80%) for 1 to 6 hours[42]. Most hospitals already contain these machines, so there likely would be no extra charge for this, however, if one of these

	sterilization machines was needed, they cost around $10,000 for the size needed with this design[43,44]. Before being used, the device will undergo a test to ensure that full sterilization takes place. Many sterilization methods use a special tape/marker to denote full sterilization occurred which is a method that would be followed in this device sterilization confirmation as well. An example of this process would be autoclave tape.
Optimal Battery Type	Must be able to provide ample power to the device and be rechargeable. The device may also plug into the power sources available in an operating room. The batteries should last for up to 2 hours before recharge. The battery will need to be rated for 12V and 1.5A in order to meet the power consumption needs of the motor, PCB, and sensors. Our batteries would need to have a total capacity of 3 AH in order to Possible batteries that would sufficiently power the device and maintain sterile conditions would be nickel-cadmium batteries. Nickel-cadmium is commonly used in several hospital devices which makes it promising to be approved for use in this device as well.
Sensors with high degree of sensitivity	Due to the stiffness of bone, there will be very little displacement when compressed. Therefore, a sensor that can measure displacements in the order of tens of microns must be incorporated. Another sensor would be needed to measure the force being applied to the bone. The sensor would need to be able to measure loads in the order of a tenth of a Newton Due to the sensitive nature of this component, the sensors may be one of the most expensive components of the device. Capacitance plates from a cheap stud finder can also be used if the price is a deterrent but provides a lower degree of sensitivity.

Localized Density	Because we are delivering a known impulse and measuring the resulting displacement, we need a method to relate these parameters to the local density of the bone. Alternatively, the depth of indentation can be set constant and the force required to produce said indentation is measured instead. The device's output should be the force over total displacement, so either method would work. Bone indentation is commonly indented to 1/32nd of an inch for an appropriate reading. It should not be greater than 1/32nd of an inch[45].
Independent of bone size	Must be compatible with bones of varying sizes and maintain accuracy. For example, a femur bone has an average diameter of 2.34 cm while a thumb has one of 16 mm[46,47]. The device would need to be able to adapt to these bones without complication. A device with adjustable metal attachments could allow for a more universal and applicable device. To ensure the density calculations do not vary among different attachment types, bone density calculations can be measured and compared with different attachment sizes at the same location. A block of 316 Stainless Steel (Medical grade with Molybdenum for corrosion resistance) costs around $5 per kilogram. Only a few kilograms of stainless steel will likely be required. However, machining stainless steel is a costly process.
Handheld device	Must be a handheld device that can easily probe bones. For ease of use and comfort, the dimension of the handle will match that of the average grip, which is somewhere between 1.25 - 2 inches[48]. As it is handheld the grip must be able to withstand the average grip strength of the user over repeated uses of an estimated 2 minutes per usage. The average grip strength of a male is around 72 lbs[49]. The baseline model for the device will contain similar mechanical components as that of a universal testing machine, but downsized to fit into a handheld device. Some of these downsizes, such as

	using a shorter linear actuator, a less powerful motor, and a force sensor rated for less total force, will decrease the cost of these components compared to a universal testing machine.
Device applicable to both cadaver and living patients	The device must be able to be used in the operating room on a living patient but also must be used on cadaver bone. Devices such as collinear clamps have this desired diversity as they are often used in both scenarios.
A method of indenting bone	A motor will drive a linear actuator that will push an indenter forward into the bone. Alternative methods typically deliver 40 N of force during an interval of 1 ms[50]. The bone should not be indented greater than 1/32nd of an inch [45].

Section 5: Generating Concepts and Down Selecting

5.1. Idea Generation

Anthony Gisolfi:

Depuy Synthes Collinear Reduction Clamp

This fracture reduction device provides the simplicity of design that would be ideal for our device. It is simply a clamp that helps to reduce the severity of a fracture, but we could use this clamping technology to put pressure on the bone and measure the amount of pressure it takes to indent the bone slightly. This pressure reading could then be correlated to the density and strength of a bone through experimentation on sample bones. However, this method would only contact the surface of the bone and not the inside which is not ideal[51].

Zircon Stud Finder

This stud finder works by measuring the dielectric constant of the wall. When the constant changes, a stud is found. Since this is basically finding the density of the wall, we can apply this method to get a density reading of our bone. We can then compare this number to experimental testing on real

bone to find a correlation of this value to screw pull-out strength. This would be a more involved design than other designs and would require sufficient battery power[52].

DEXA Scan

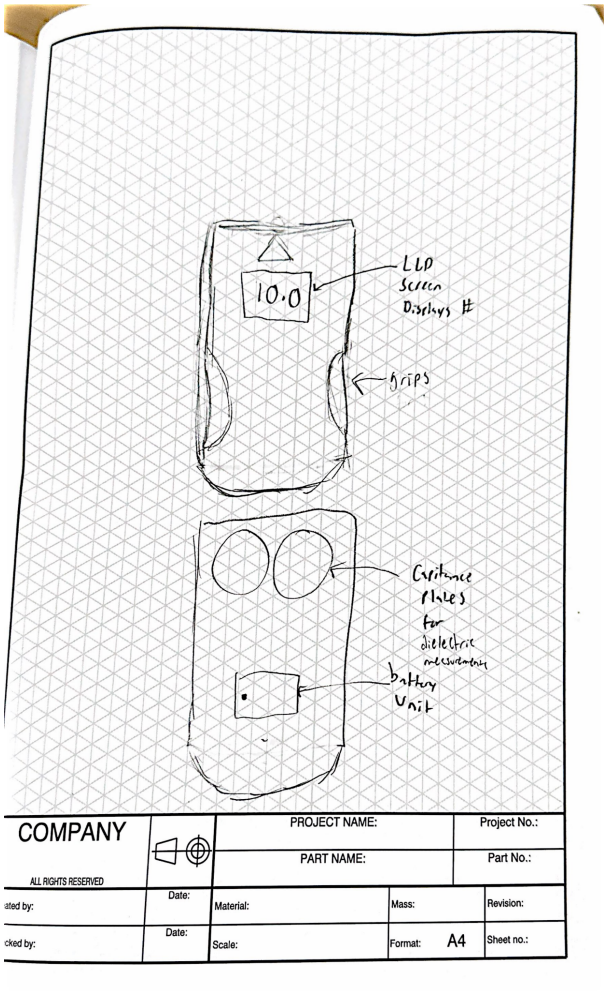
This dual X-ray absorptiometry device allows an accurate measurement of bone density through the use of X-ray techniques. The machine is bulky and expensive which is the opposite of our goal. This device could be helpful to compare the results of our device. Also, x-ray techniques would not be useful in the handheld device that we wish to design and could possibly be dangerous[53].

Duracell CR2 3 Volt Lithium Battery

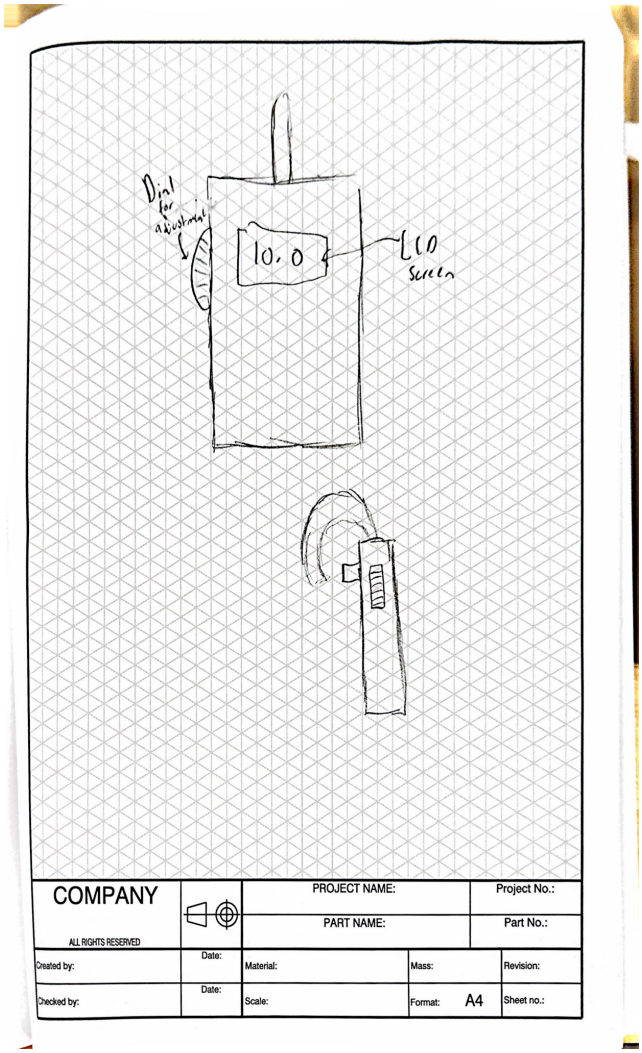
Although the specific power requirements of the device are unknown at the moment, we do know that our batteries have to be able to be sterilized. This battery, among others, is medical grade and is therefore sterile. Although this is useful, we may wish to use a rechargeable battery rather than one that needs to be discarded like this one[54].

1. The model represents a stud finder-like design. An LCD screen returns a numerical value of bone density. Grips for hands are on the side of the device. Battery housing unit on back of the device.

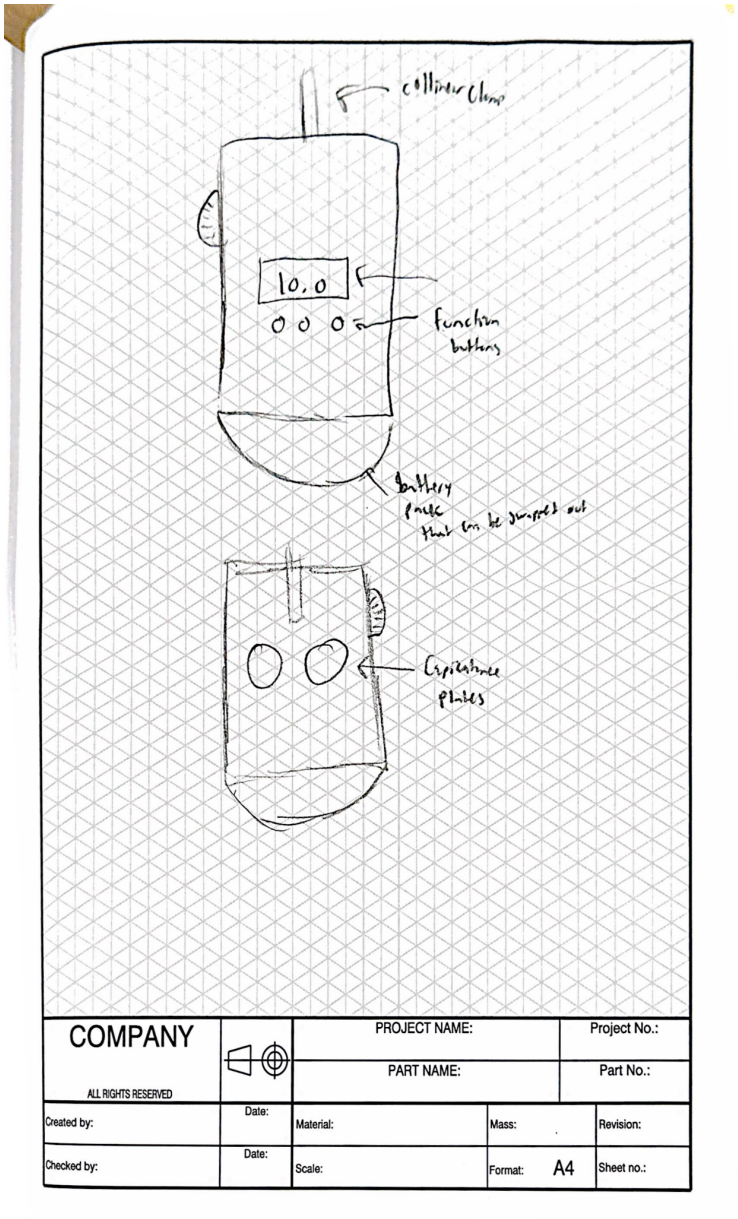
Capacitance plates in the device measure the dielectric constant.



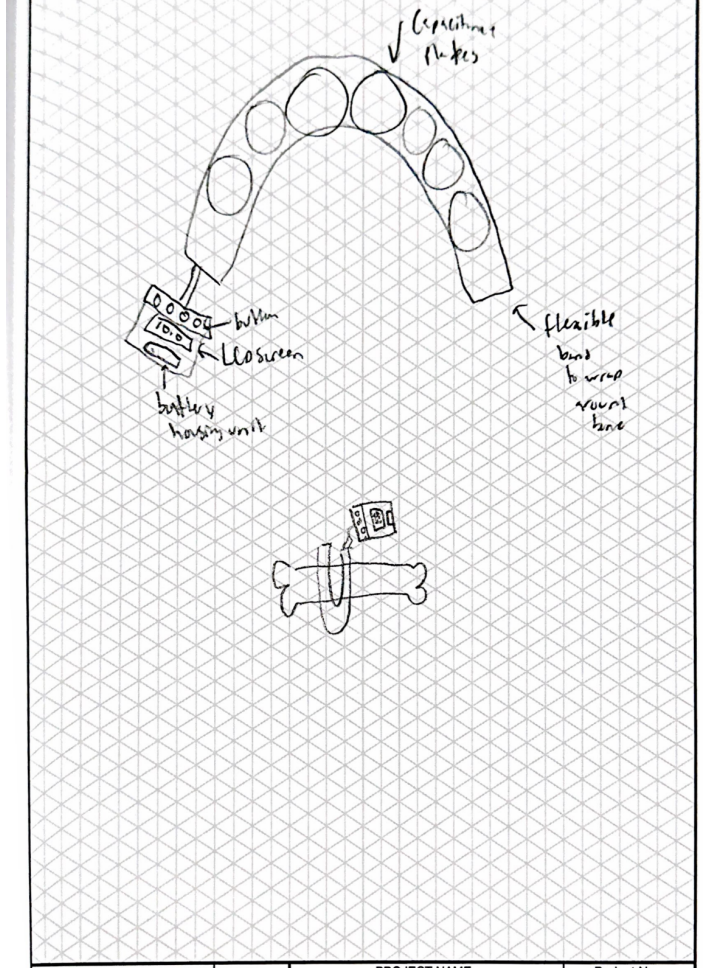
2. The model mimics a collinear clamp with a pressure gauge that displays on the LCD screen. There is a wheel for adjustments on the side of the device.



3. This model mimics both a collinear clamp and a stud finder for two methods of measurement. There are function buttons on the front side of the device to control methods of measurement and for powering the device on/off.



4. This model mimics a belt that would be wrapped around the bone. The capacitance plates inside the belt would measure the dielectric constant of the bone and display an LCD screen. This screen area would also have the batteries and function buttons.



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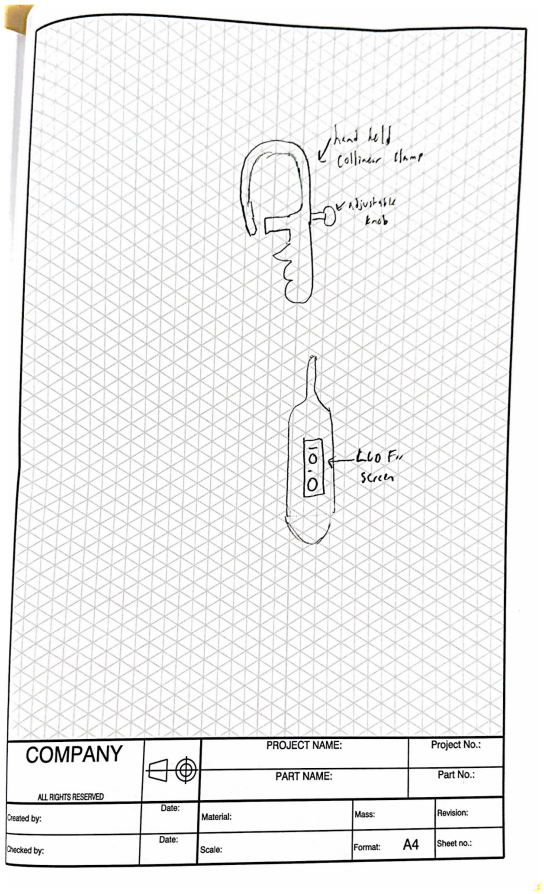
5. This model represents a small collinear clamp-like device with a pressure gauge to read the pressure the bone can sustain. There is an adjustment knob to control the device.



Emma Grace:

MiniOmni Bone Density Scanner

The Sunlight MiniOmni device is a handheld noninvasive light bone sonometer that resembles the DEXA scan on a smaller level. This device is lightweight, weighs 8 lbs, and is 12”x12”x13” which fits similar design goals of our device. The main limitation of this device is that it is not up to the sterilization standards to be used in a surgical setting. It also contains a large amount of noise due to passing through the skin which may also make this device not as efficient as needed to fulfill the need in a surgical environment[55].

Horizon DEXA System

The Horizon DEXA system is currently the most widely used bone density scanning device. The main advantages to this device are ultra-fast high output with low noise ceramic detectors, and high-frequency dual x-ray images with OnePass single sweep scanning to reduce errors and unclear imaging. The main problems with this device would be the size, imaging technique, and accessibility. These devices are very large and would only be able to be used in a special X-ray room which would be

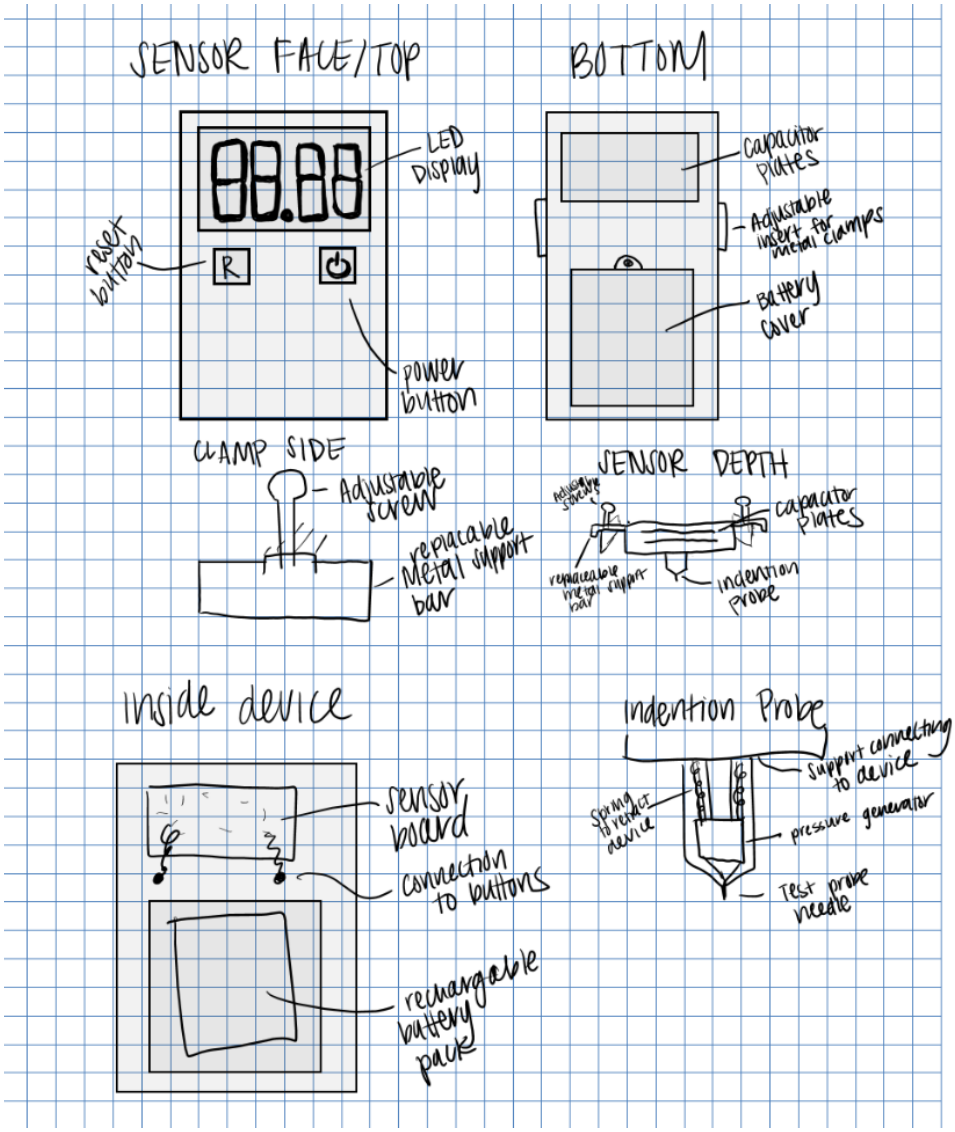
difficult to use in surgical applications. The X-ray also does not provide the most effective measurements for bone density. This is why our device is aimed at being hand-held with a pressure indention calculator to solve these current limitations with the DEXA system[56].

Bone Diagnostic Instrument (BDI)

The BDI is a reference point indentation (RPI) device that uses a microindentation technique to help test bone *in vivo*. This model uses a cyclic quasi-static indentation method containing a probe and a reference probe. There were issues found in this model in the accuracy of the experimental indentation test compared to the rheological computational testing at different bone locations which would make it an inefficient method to be used in a high-stakes environment such as a surgery room. Our model aims to make an indentation device that provides a higher amount of accuracy throughout the entire skeletal system with adjustable metal clamps and improved probing technique to prevent this from happening[57].

OsteoProbe®

The OsteoProbe® is an additional RFI device that focuses on micro indentation to measure the bone material strength index using an axisymmetric finite element model. This device utilizes a single dynamic indent which is similar to the model that we are trying to design. This device is the most similar model to our desired model, however, it specifically measures the cortical bone rather than the whole bone which is what our intended device plans to do. The OsteoProbe® also looks more on the friction coefficient between the tip of the indenter and the bone rather than looking at the specific density of the entirety of the bone which will be the main focus of our device [8].

6. 

The sensor face image displays the LED screen that will display the bone density indentation values calculated from the indentation probe. The two buttons needed are used to allow a reset option and power option for the user to easily use. The bottom face image contains the battery cover and capacitor plates which can measure bone density. An addition to this model would be the use of the indention probe as well to allow for more precise measurements. The clamp side image will contain adjustable screw attachments that can be replaced with the sized clamps to best suit the type of bone being measured. The sensor depth image displays the two capacitor plates that will be placed parallel to the face of the device. The inside device image displays the circuit board that will connect the buttons to the screen in addition to the wires that will cause the LED light to function. This model also includes the space for the battery pack. The indentation probe sketch includes the subcomponents of the probe and how it will connect to the device.

Anthony Gilles:

Quantitative Ultrasound (QUS)

The QUS device measures mechanical properties of bones, such as bone thickness, by emitting mechanical waves. This device can be stationary or probable, and Measurements are made based on attenuation, velocity or backscatter measurements, as surrogate markers for BMD. Alternatively pulse-echo or axial transmission can be used to determine mechanical properties. This device has potential in our design process because it measures properties throughout the whole bone (bone thickness), not just the surface properties[19].

Compression Force Sensor

McMaster-Carr is a hardware company that offers a variety of compression force sensors that measure applied loads. These sensors are thinner than a credit card and can be square or round. This device could potentially be combined with a collinear clamp to output a bone resistance force, which can be correlated to bone hardness. However, this device is very expensive (over $1100), so we could likely find another device or create our own force sensor based on this design[58].

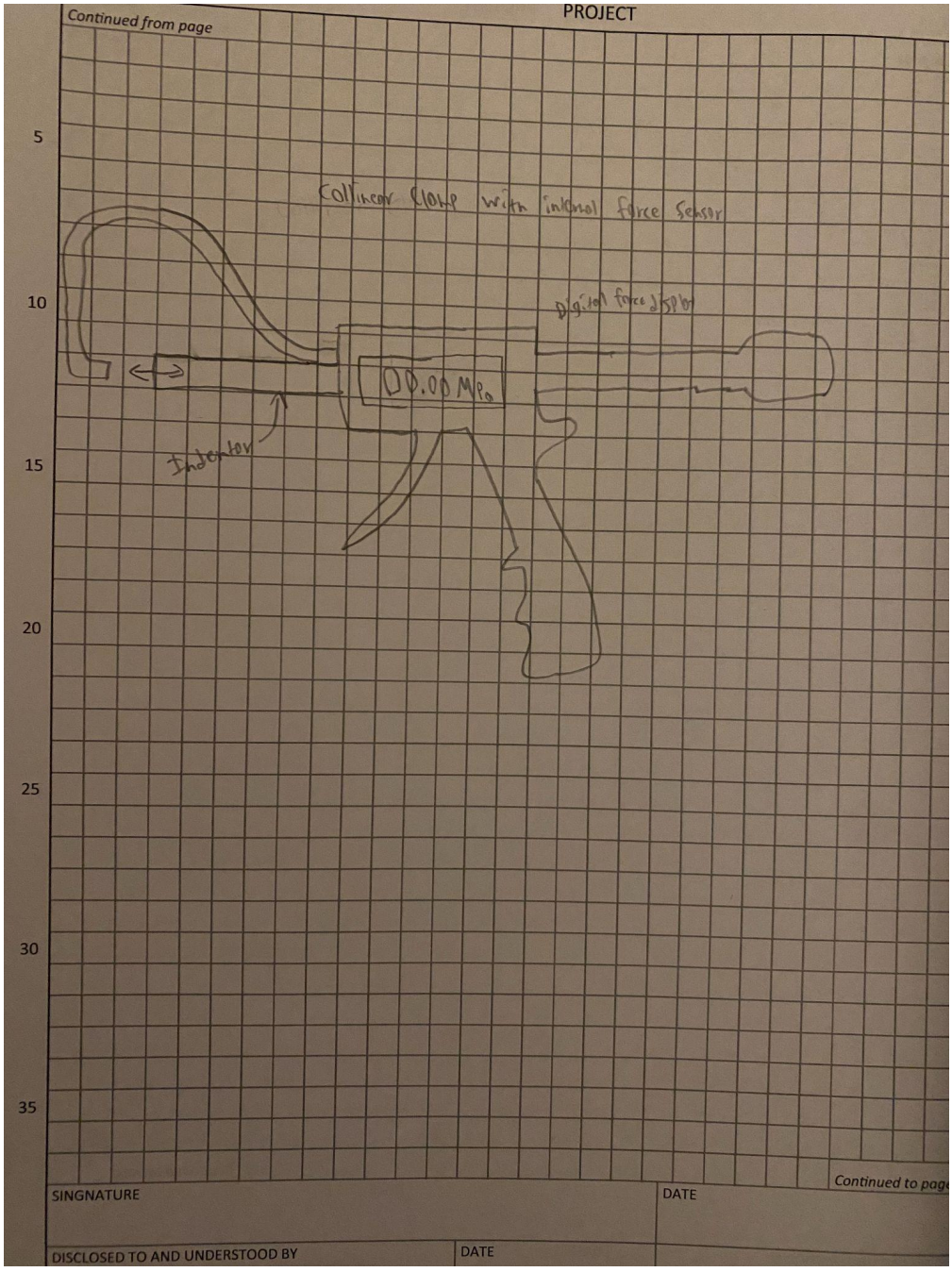
Stryker Linear Reduction Clamp

The Stryker reduction clamp is a device used to aid long bone, pelvic, and acetabular fractures. This device has a ratchet-based mechanism of action, with four hook sizes and a removable handle. The rod can also hold screws for precise screw placement. This device is a little more complicated than what we would ideally create, however, there are some key features that we could potentially incorporate into a collinear clamp design, such as the ratchet system[59].

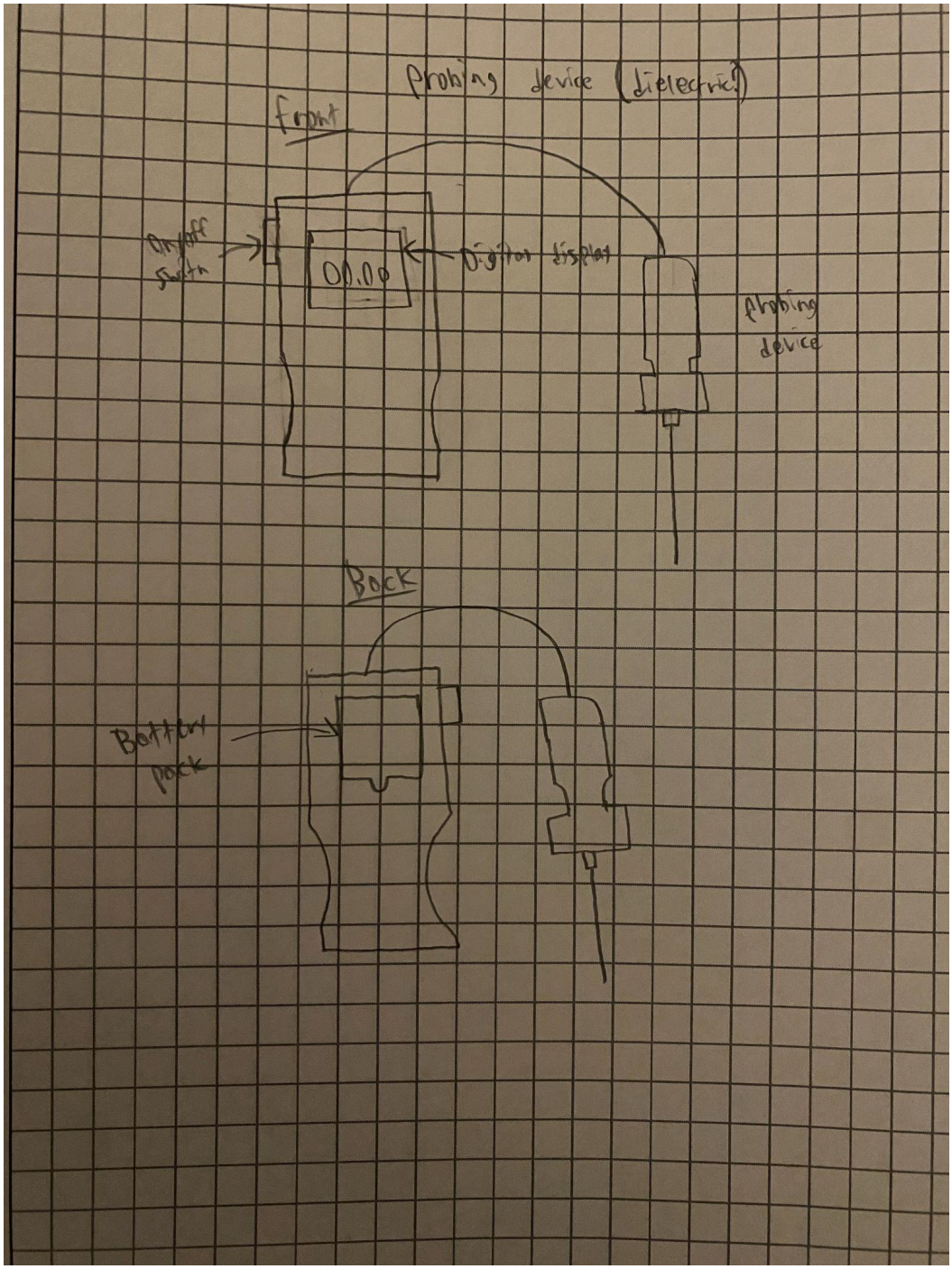
Sunlight MiniOmni

This device is a small, lightweight (<2 lbs) device that measures bone density for early assessments of osteoporosis. This device is a bone sonometer (uses mechanical/sound waves) that is placed and probes the skin and displays the results on a laptop/PC via USB. This device could aid us in creating a device that is easily probeable for its user. The ability to transfer data via USB could also be a potential feature to look into [12].

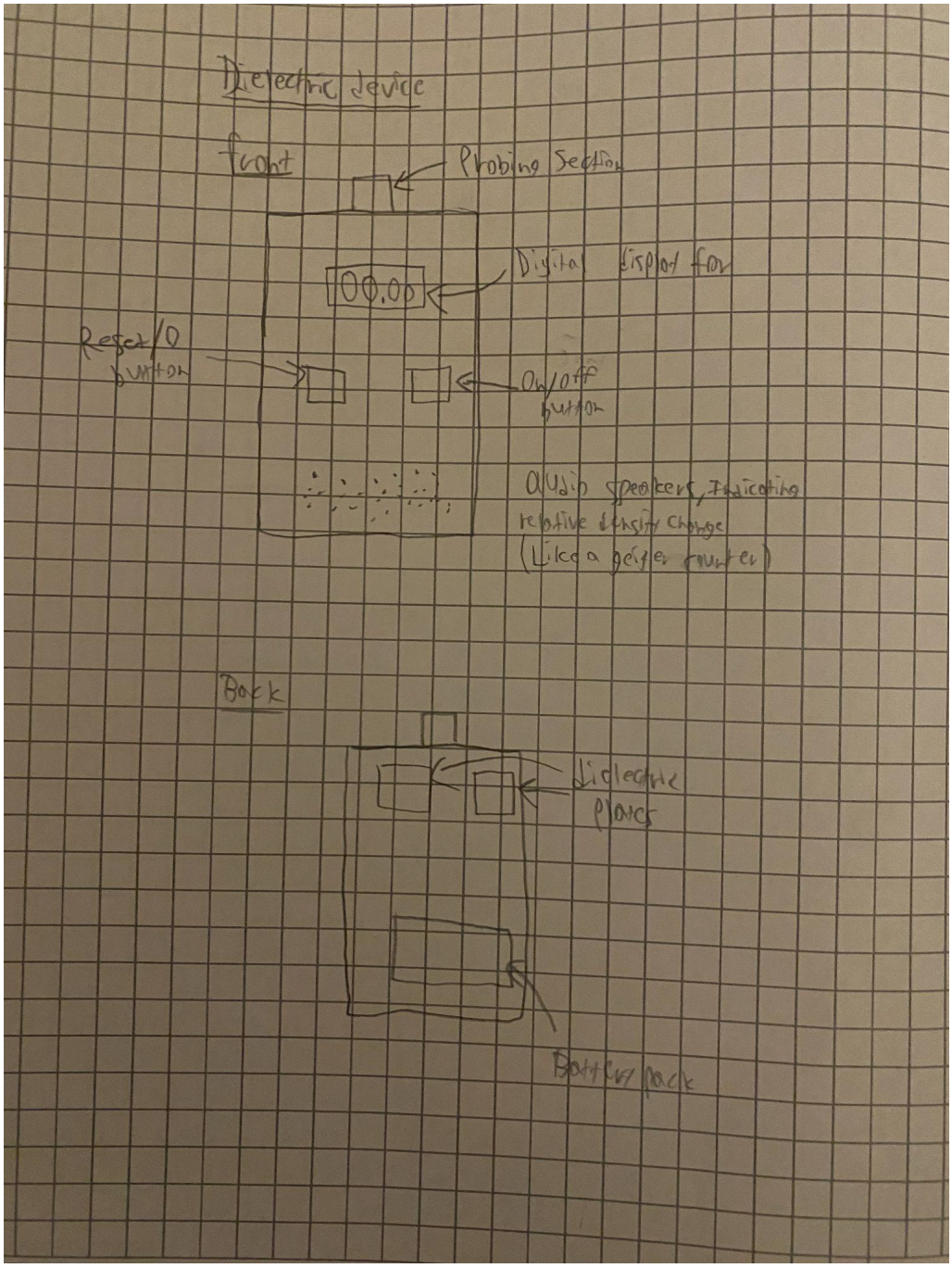
7.



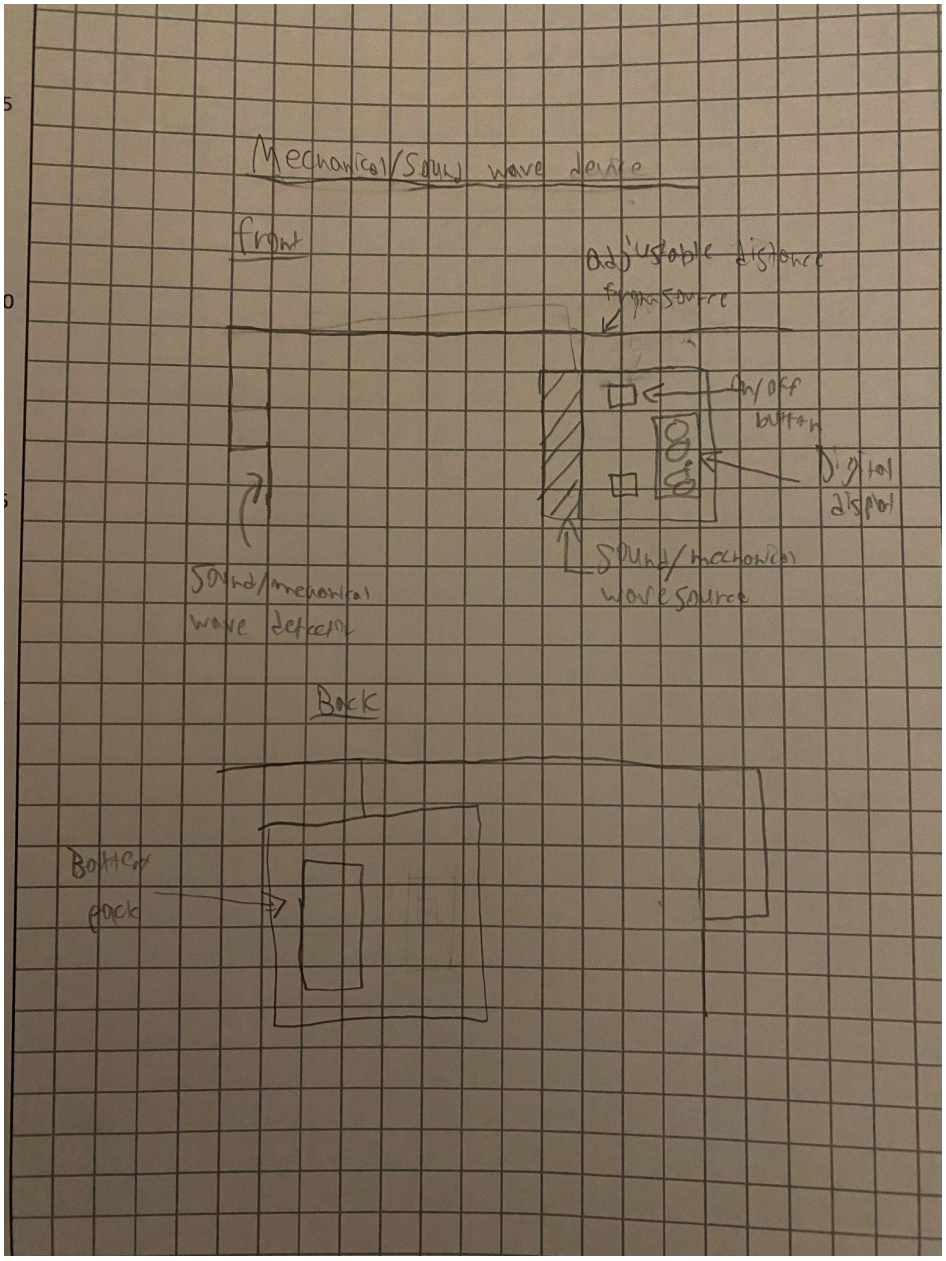
This model functions as a traditional collinear clamp, but incorporates a force sensor within the indenter. This force sensor (not visible) measures the compressive resistance of the bone, which is directly proportional to bone density. The force value is transmitted to and is displayed on the digital display.

8. 

This model represents a device that is optimized for probing. The probing needle provides measurements at very precise locations compared to other designs and is connected to the body of the device with a wire. This device could be a dielectric or possibly a mechanical wave device.

9. 

This model is a dielectric device that measures the capacitance (dielectric) plates to measure the dielectric constant of bone, which can be correlated with density. This value is displayed on the digital screen. It also has a speaker that can give audio signals for relative changes in the dielectric constant.

9. 

This model is a device that emits a mechanical wave through bone and can measure things like velocity and backscatter to determine mechanical properties of the bone. The distance between the emitter and detector is adjustable, and the values are displayed on the digital display.

Remy:

OsteoProbe®

The OsteoProbe® is a handheld reference point indentation device approximately the size of a highlighter that does not require the user to place a reference probe under the periosteum of the bone, thus removing the need for intensive training. The device operates by quickly retracting and indenting

the bone, then the force administered over a certain time and the displacement of the indentation is measured. However, this device measures the ability for a bone to resist cracking *in vivo* and not its density. I believe that the spring and impact mechanism of this device is an easy and simple solution to generate a specific impulse onto the bone and should be incorporated into the final design[60].

Indentation instrument for the measurement of cartilage stiffness under arthroscopic control

This indentation device is similar to the OsteoProbe®, except that it includes a reference probe and requires surgical training to operate. Using this method, the shear modulus and dynamic modulus of cartilage were correlated. A similar method could be used with our device, except by applying it to bone and correlating the physical moduli to the density of the bone[61].

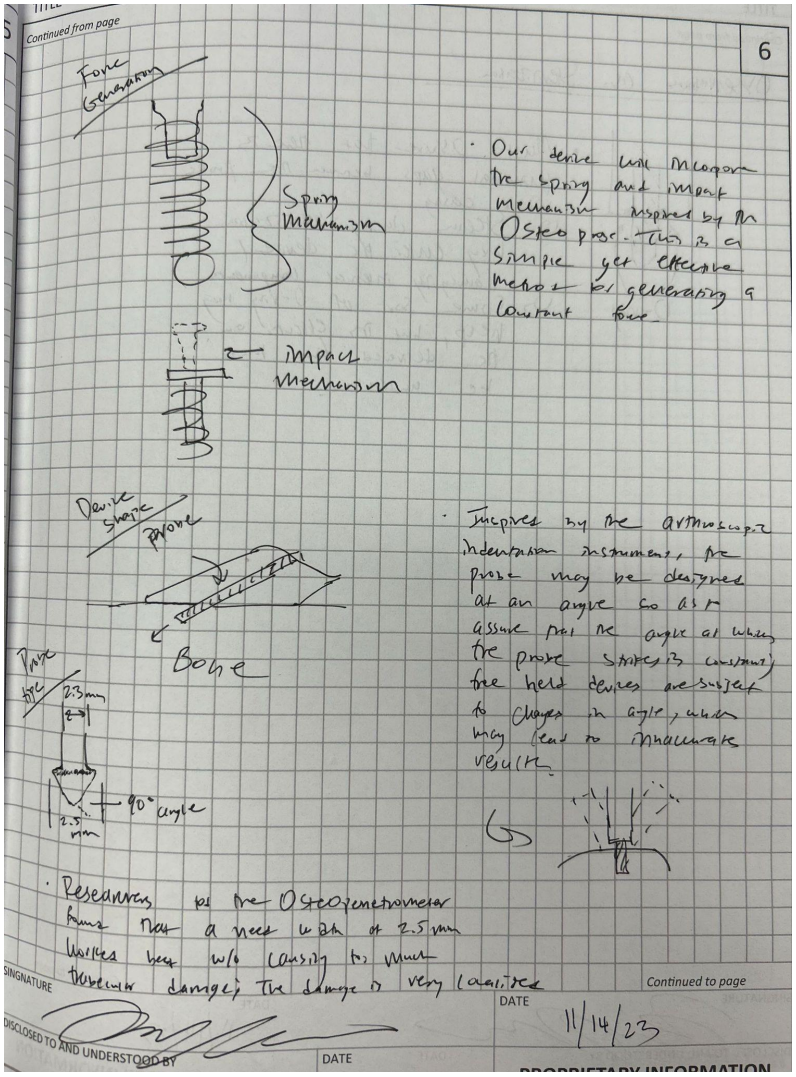
Osteopenetrometer

The Osteopenetrometer is a somewhat bulky attachment to a regular materials testing machine. Operates on hydraulics and therefore needs hydraulic fluid to be refilled after every few sterilizations. It was powered by a computer-controlled electromotor. By indenting a needle into the bone, a function of force of penetration versus depth of penetration is determined, Penetration strength was obtained, but was correlated to more relevant mechanical properties, such as yield strength, ultimate strength, Young's Modulus, and energy absorption. Like the previous two examples, this is an excellent example of the utility of bone indentation testing. This book was written in 1999; I believe with modern technology, the hydraulics and overall bulk of the device can be compacted down into a handheld device[62].

Nanoindentation device.

Nanoindentation is often used for small and thin materials, but may be used for bone to measure the properties of small microstructures such as osteons or trabeculae. This method operates by taking measuring submicron indentations, then correlating them to mechanical properties. The apparatus is not handheld but is relatively compact. Although I do believe that this device has some potential for our project, it is limited by its requirement to test only dried bone, which makes *in vivo* testing impractical. However, I think if we can scale this concept up to a micro-scale instead of a nano-scale, we can still obtain localized bone properties relevant for our project without being limited to using dried, *ex vivo* bone [62].

10.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6
Force Generation
Spring Mechanism
Impact Mechanism
Device Shape
Prong
Bone
Prong Tip
2.3mm
90° angle
2.5 mm
Our device will incorporate the spring and impact mechanism inspired by the Osteoprobe. This is a simple yet effective method for generating a constant force.
Inspired by the arthroscopic indentation instrument, the prong may be designed at an angle so as to assure that the angle at which the prong strikes is constant. Free held devices are subject to changes in angle, which may lead to inaccurate results.
Researchers at the Osteogenetrometer found that a need width of 2.5 mm worked best w/o causing too much threshold damage. The damage is very localized
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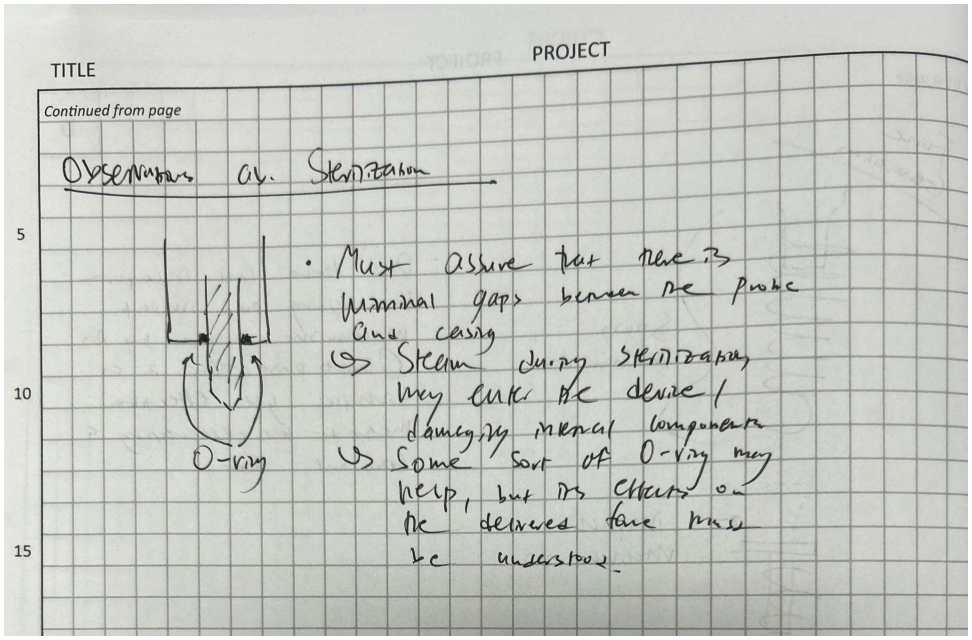
DATE
PROPRIETARY INFORMATION

11. 

<u>Kollin Fillman:</u>

Tinius Olsen Indention Tester

While not used for determining density, indentation tests are typically performed when trying to find the hardness of a material or the elastic modulus. While neither of these values can be mathematically related to density either, they may still be used to approximate the success of a screw being implanted into a bone. The major takeaway from this indentation device is that the applied load is being applied solely by the indenter, and that the section of the bone being tested will need to be fixed in place. The indenter portion of the device will need to be strong enough to indent bone while being light enough to still be handheld[63].

Stanley Stud Sensor

An internal capacitor edge sensor stud finder. These devices work by detecting a change in the dielectric constant / capacitance between two capacitor plates that are pressed against a wall. When there is a stud behind the wall, the dielectric constant or capacitance will change, which can be related to the density. While most stud finders are simply looking for a change in capacitance, our device would need to measure the exact capacitance in order to get a value for density[64].

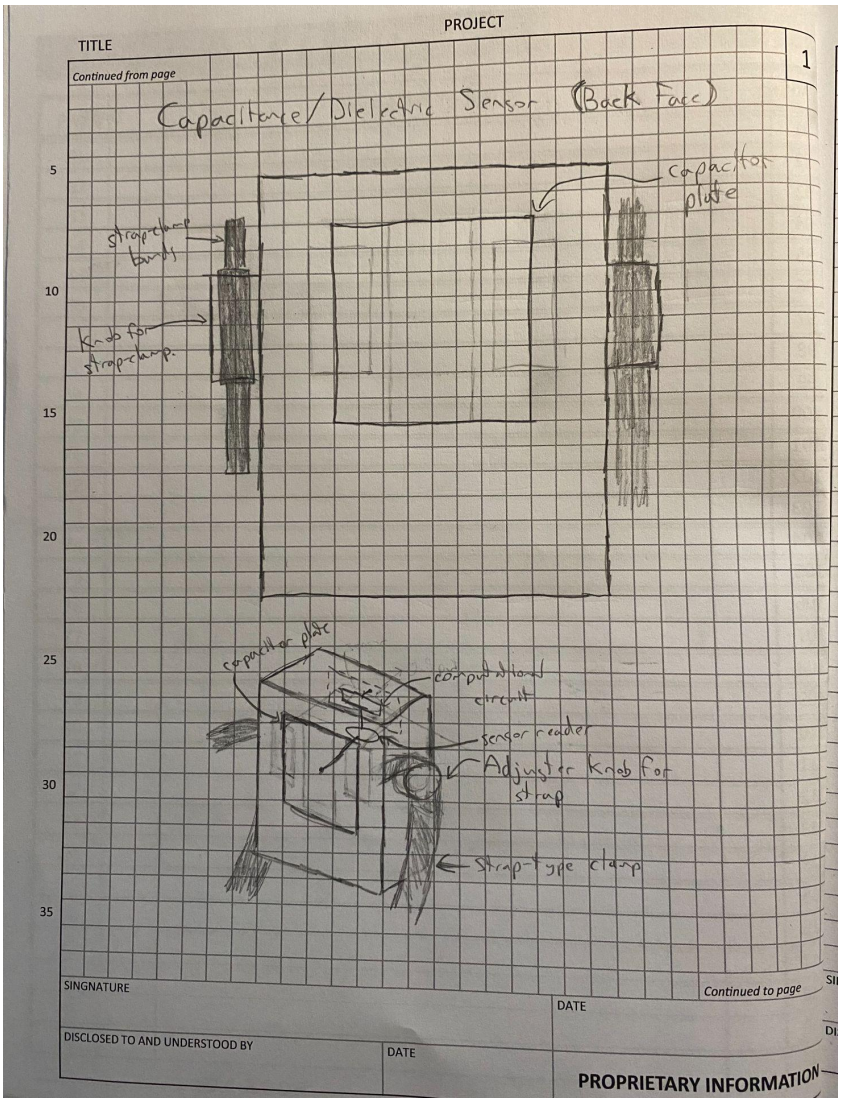
DePuy Synthes Collinear Clamp

Regardless of the method we choose for determining density, our device will need to be able to be fixed to the bone to get accurate measurements at locations of interest. The DePuy Synthes Collinear Reduction Clamp consists of a sliding rod mechanism attached to a trigger that supports multiple attachments for clamping onto a bone. By pulling the trigger, the sliding mechanism tightens the clamp

to grab the bone. We would like to incorporate a similar mechanism to our device to ensure good contact to the bone at a fixed location[65].

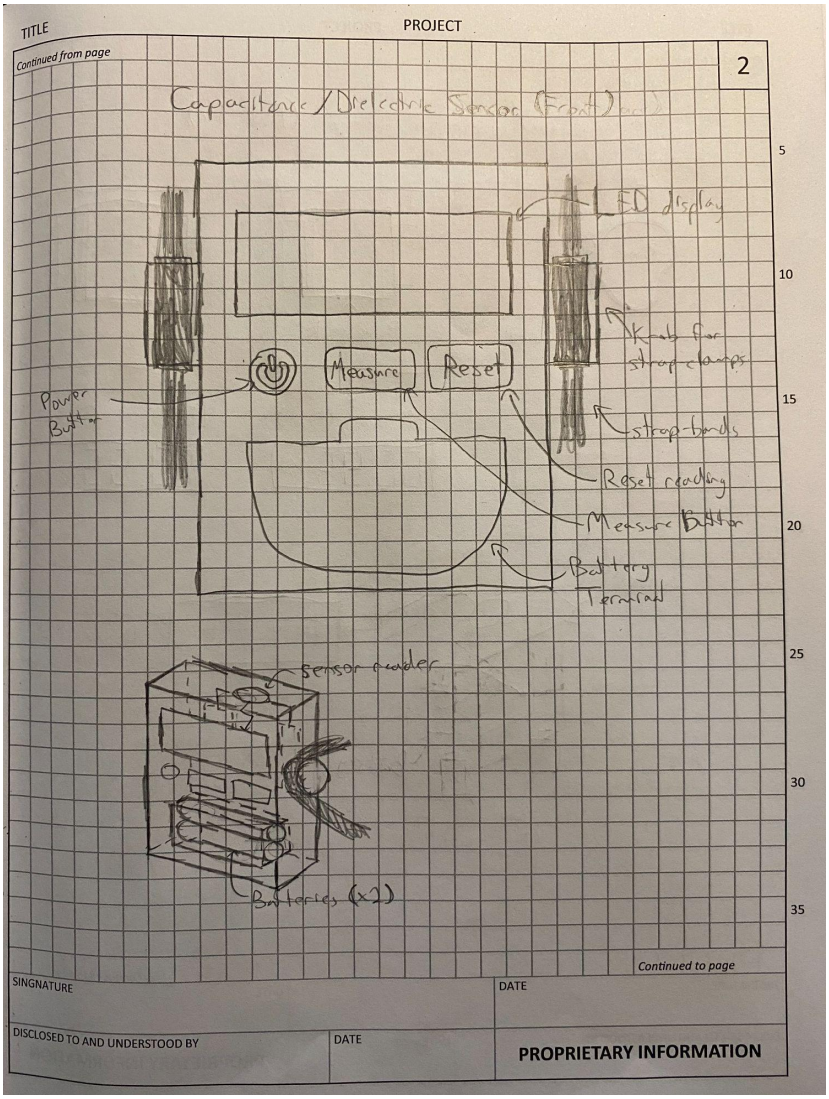
Butterfly iQ+ Ultrasound

Ultrasound imaging is another possible method that we could use for determining density of a specific point in the bone. Ultrasound could be used by taking internal images of the bone and using machine learning techniques to develop a methodology for determining bone density. The Butterfly iQ+ ultrasound device is of interest as it can be connected directly to the user's mobile device, and present the images using a mobile app. This idea may be applicable to our device as a way to make it more portable, and similarly the calculations for determining density could be done directly on the app and presented to the user while imaging[66].

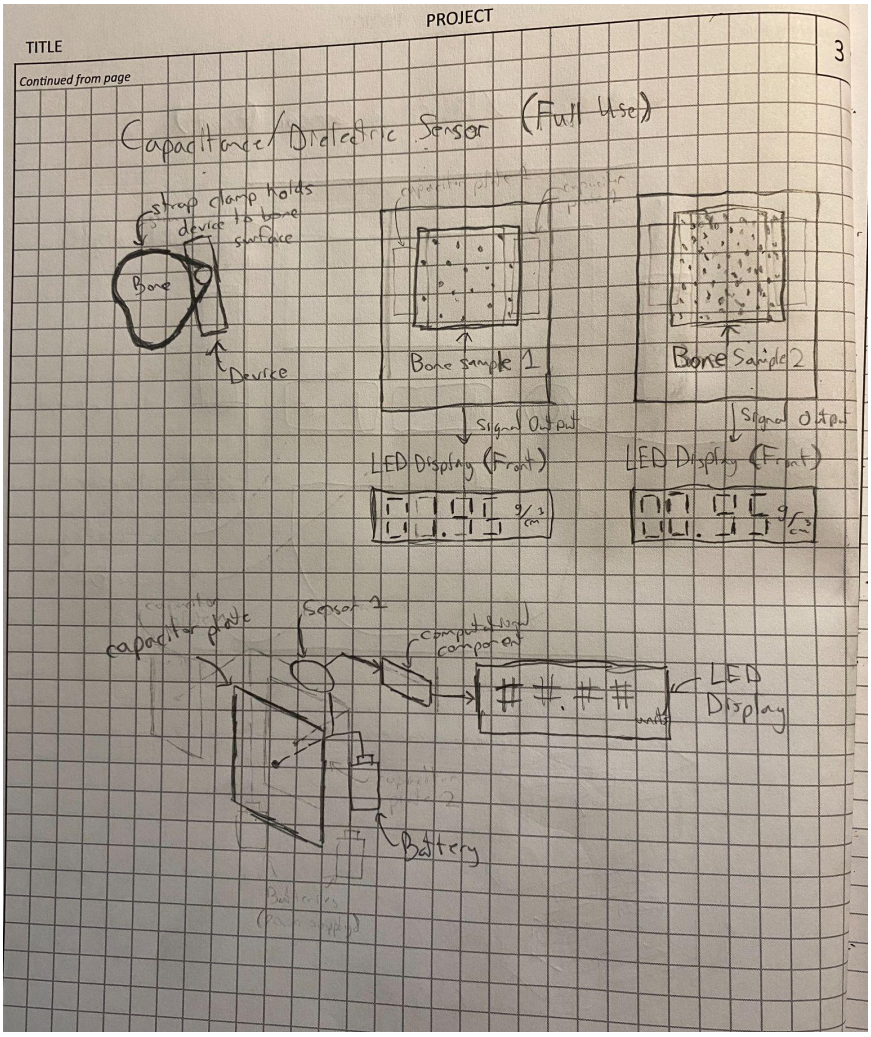
13. 

The first sketch depicts the back face of a device that uses dielectric or capacitance readings to determine bone density. The face features a capacitance plate that measures the capacitance of the

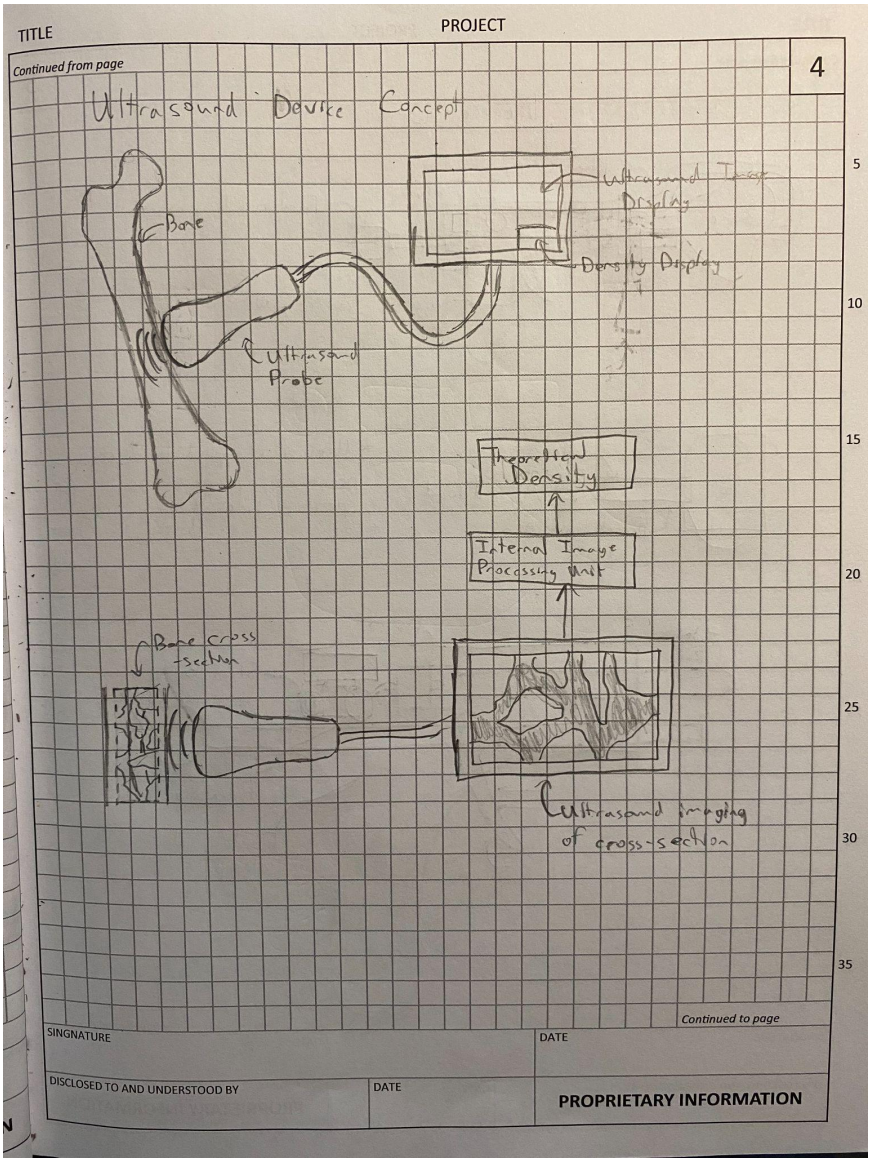
space directly in front of the plate, which in our case would be the bone. The device also features strap-like clamps that would wrap around the bone to ensure contact between the plate and the bone

14. 

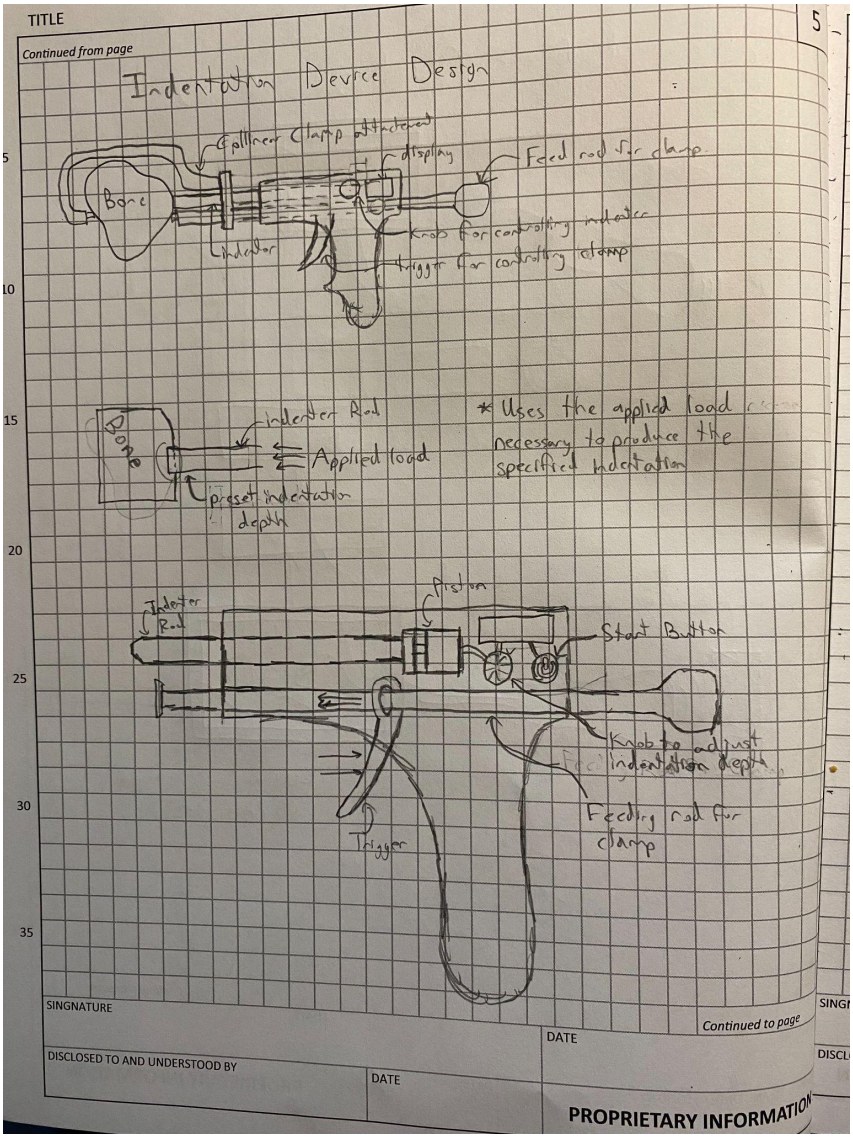
The second sketch depicts the front face of the same device shown in sketch 1. The front side of the device would feature the user interface for the device, including an LED Display, power button, and buttons to take and reset measurements made on the device. It also features a battery terminal to insert batteries that will power the device.

15. 

The third sketch provides a full depiction of the dielectric sensing device and how it would be used. The strap clamps are wrapped around the bone to bring the device in direct contact with the bone. The capacitor plate would then measure the localized capacitance value of the section of bone directly in front of the plate. This signal is sent to a sensor to convert the signal into an actual value of capacitance, which is then further transmitted to a computational component that would calculate the density based on the measured capacitance. Finally, this density value is displayed on the LED Display on the front side of the device.

16. 

The fourth sketch presents a possible design for a device that uses ultrasound to take images of the interior of the bone and send those images on a connected display, such as a mobile device or portable monitor. The device would then use image processing and machine learning to analyze the image and return an estimated density value based on that image. For example, the shaded portion of the display shown in the sketch may be considered “void” and would thus subtract from the total volume, and therefore density, of the imaged bone.

17. 

The fifth sketch is another possible device that performs an indentation test on the bone. The general structure follows that of a collinear clamp, where the user can attach clamp components to the device in order to stabilize it to the bone at the point of interest. On the interior of the device is a piston that is used to push the indenter rod into the bone to produce an indentation. The length that the rod can extend is set before operating the device using a small dial to determine how deep the indentation should be. The LED display is used to display the load required to produce the indentation at the desired depth.

5.2. Idea Organization

Stud Finder Sketches: 1, 3, 4, 8, 9, 10, 13, 14, 15,

Bone Indentation Sketches: 2, 3, 5, 6, 7, 8, 11, 12, 17

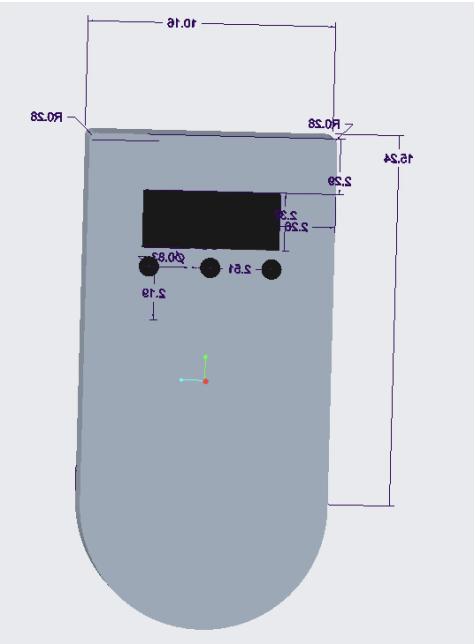
Ultrasound Sketches: 16

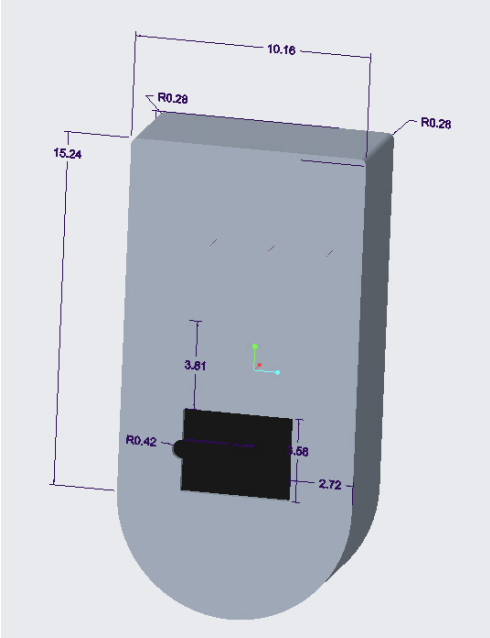
Almost all of our ideas utilized the theory that underline bone indentations devices and stud finders which utilize displacements in bone and capacitance respectively, to determine the properties of the bone. Many of our devices can be simplified or combined to create one stud finder option and one bone indentation method. The common themes in the stud finder models involve an LCD Screen, capacitance plates that measure the dielectric constant, function buttons to control the device, and a battery unit. Bone indentation devices share a common theme of a needle/probe that idents the bone, a method of indentation adjustment, an LCD screen, and a battery unit. However, most of our bone indentation sketches require a needle to be extended out of the device, which creates a gap between the outer casing and the needle. This may be a problem during steam sterilization, as steam may enter the internal components of the device. Possible solutions may include the use of an O-ring, which will create a better seal between the needle and casing but may disrupt needle use. Other solutions may include the use of a separate internal compartment housing the needle that is separate from the delicate internal components to prevent any damage. Possible issues with our stud finder devices would be dealing with the noise involved in reading the capacitance and finding a numerical value of the dielectric constant associated with these readings. Sketch 16 is unique and illustrates a probing ultrasound device. This device will use mechanical waves to determine physical properties by generating a cross-sectional image of the bone and using an internal image processing unit to calculate the density within that cross section. Possible issues with this ultrasound device include steam entering the device and damaging electronics, and the noise caused by other tissues. The possible solution to the sterilization issue would be O-rings, which was previously discussed, and the solution to the noise issue would be applying noise filters to negate noise caused by non-bone materials.

5.3. Proof of Concepts (POC)

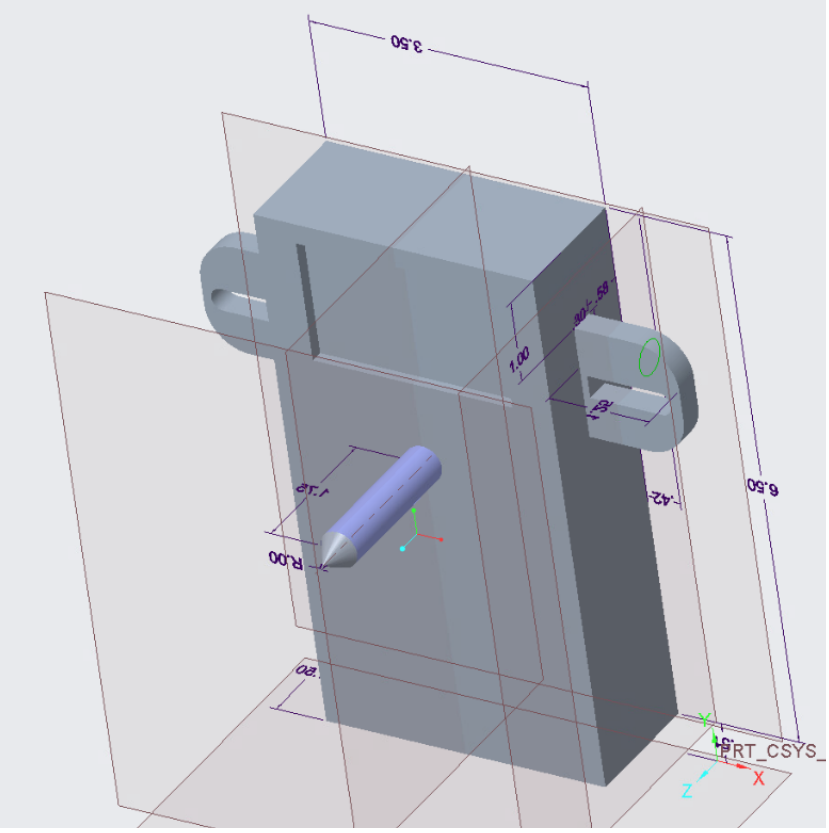
Anthony Gisolfi:

All dimensions are in centimeters. The view on the left is the front of the model while the view on the right is the back of the device.





Emma Grace Pittard:

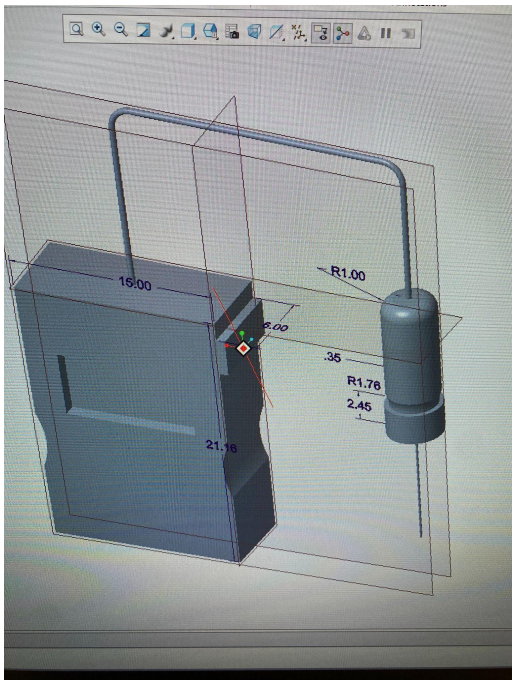


All dimensions are given in centimeters. The view is the bottom face of the device. The cutout displays where the capacitor plates will be found. The top face would include the LED screen and buttons.

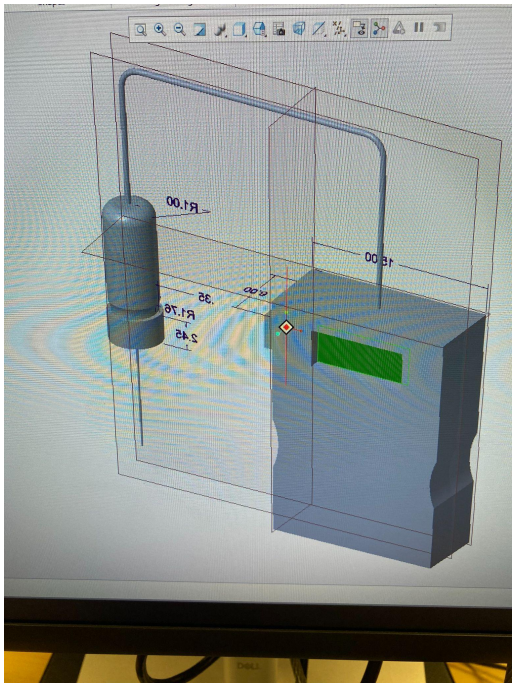
Anthony Gilles

All dimensions are in centimeters. The length of the probe handle, which is not listed, is 11 cm and the probe needle length is 9 cm. The chord length is not listed because it is a parameter that can vary.

Front

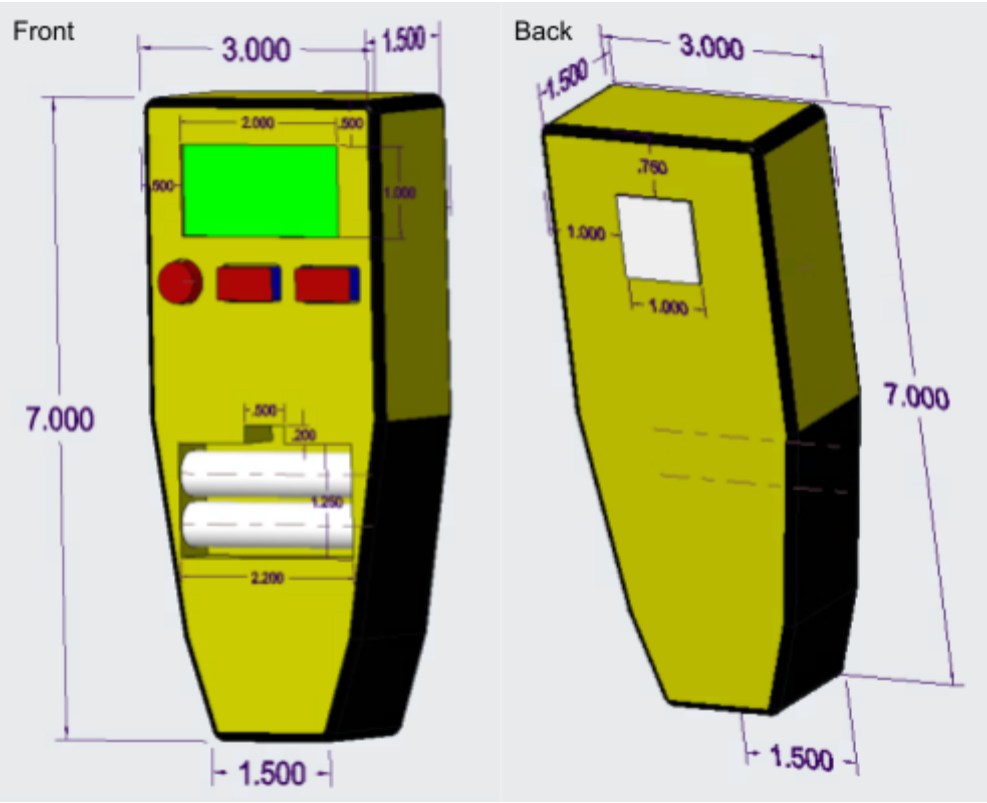


Back



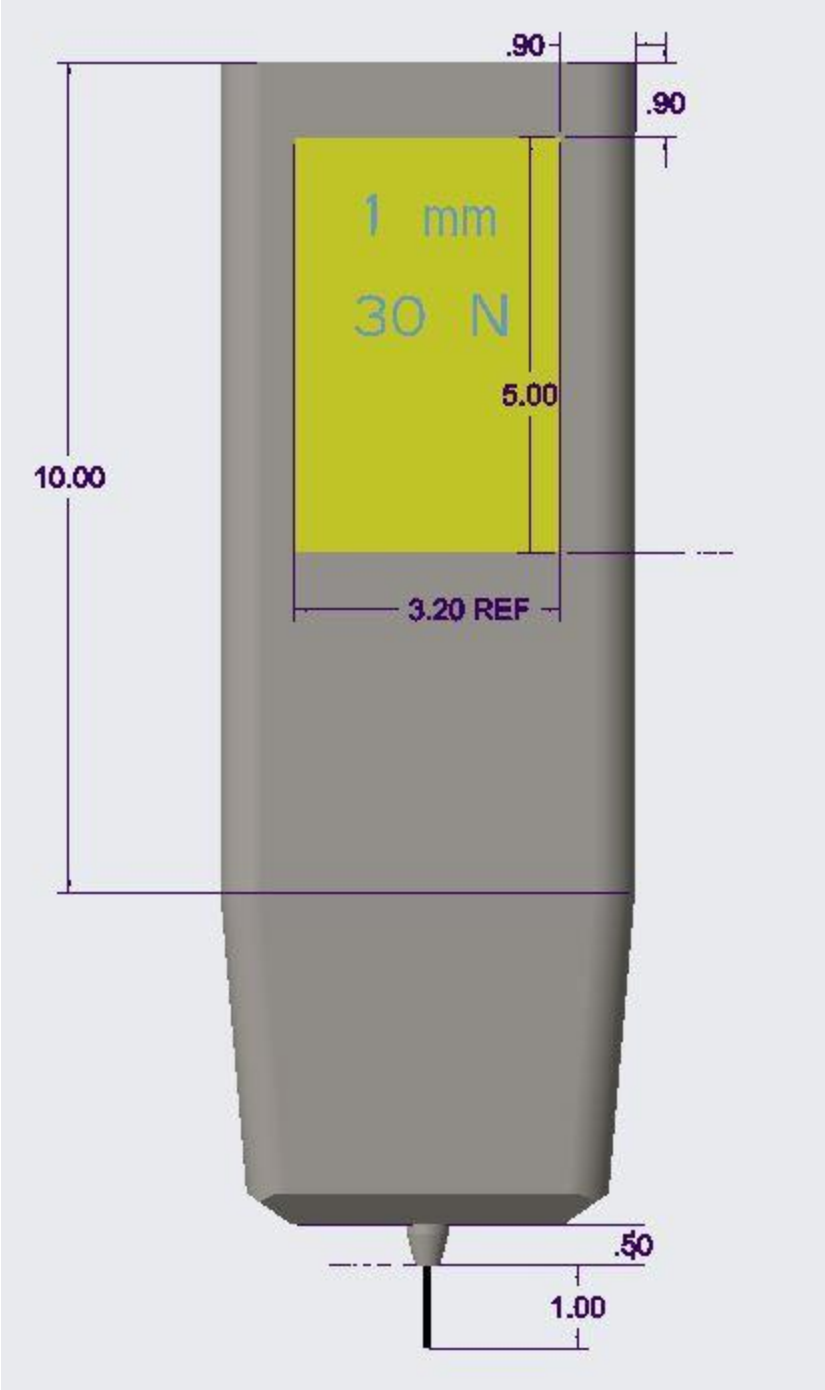
Kollin Fillman:

All dimensions are in inches. The front features the LED Display, the buttons to control the device, and the battery terminals. The back face features the 1 inch by 1 inch capacitor plate that will be used for measuring the capacitance/dielectric constant of the bone.



Remy Bell:

All dimensions are in inches. The front features a LED display that communicates information regarding the transmitted force and the measured displacement. The housing encloses an adjustable spring mechanism that generates the force needed to indent the bone. The needle protruding from the bottom of the device is the indentation needle (0.1 in. diameter) that is extended into the bone. A displacement sensor in the device measures the displacement of the bone after indentation.



5.4. Down selection

Specification	Weigh t	DEXA SCAN	Anthony Gilles'	Anthony Gisolfi's	Remy	Emma Grace's Bone Indentation	Kollin's Stud Finder

			Stud Finder	Stud Finder	Bone Indentation		
Sterilizable	**25**	**-1**	**1**	**1**	**1**	**1**	**1**
Optimal Battery	**10**	**-1**	**1**	**0**	**0**	**0**	**1**
High Sensitivity Sensor	**15**	**1**	**0**	**0**	**1**	**1**	**0**
Localized Density	**10**	**1**	**0**	**0**	**1**	**1**	**1**
Independent of Bone size	**15**	**1**	**1**	**1**	**1**	**0**	**1**
Handheld	**10**	**-1**	**1**	**1**	**1**	**1**	**1**
Applicable to Cadaver and Living Patients	**10**	**1**	**1**	**1**	**1**	**1**	**1**
Able to Indent Bone	**5**	**-1**	**-1**	**-1**	**1**	**1**	**-1**
Rank Score	**100**	**0**	**0.65**	**0.55**	**0.90**	**0.75**	**0.75**

Section 6: Solution Statement and Drawing

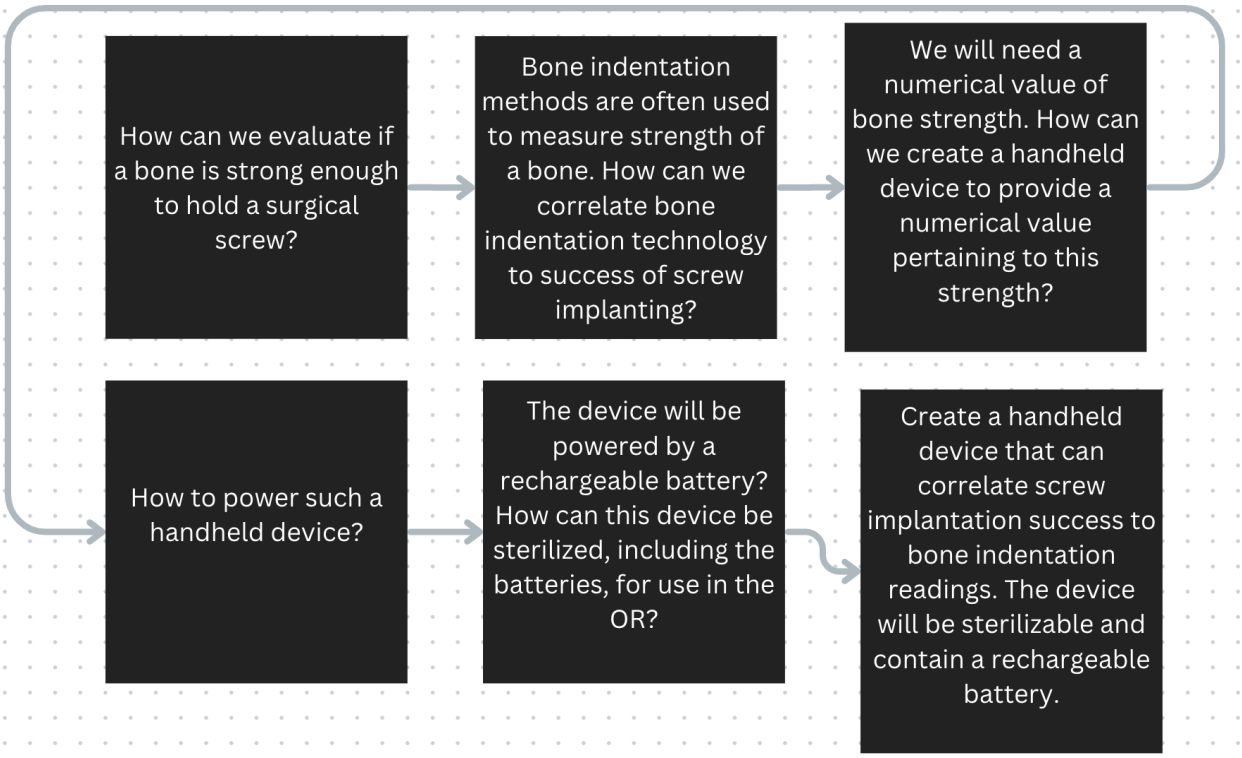
6.1. Final Problem Statement

Approximately 28.3 million orthopedic procedures are performed every year around the globe, making them one of the most common surgeries[1]. Bone screws, the most commonly used orthopedic implant, are used for stabilizing bone fractures and fixating implants to bone[2]. In fact, billions of bone screws are implanted every year for stabilizing bone fractures and fixating implants to bone and 2.2 million orthopedic procedures involving solely bone grafting are performed around the globe annually[2-4]. The process of performing orthopedic surgery involves the sawing, drilling, or inserting of screws into the bone, often resulting in thermal osteonecrosis, which can result in further degeneration of bone tissue, functional impairment of joints, and failure of orthopedic screws. In fact, approximately 26% of bone screws are irreparably damaged and 13.5% of bone screws ultimately fail[3,5]. Failure of these orthopedic screws, generally caused by a low screw pullout strength, can exacerbate fractures and may require further surgery to replace the screws[6]. The biggest indicator for the success of a bone screw is the strength of the bone, which is largely dependent on the mineral bone density of the bone, although the geometry, microstructure, and material properties of the bone are also contributing factors worth considering[7]. Specifically, the heat generated during drilling and the pullout strength of the screw are dependent on the bone mineral density of the bone[8]. Therefore, knowledge of the density of the bone can aid in the decision making of orthopedic surgeons when deciding different screws to use during surgery and the methods for installing the screws. However, the density of bone varies considerably within a bone, within different bones in the same patient, and across different patients[9,10]. Factors that influence bone density include age, sex, race, disease, previous medications, smoking, and even alcohol consumption[11-13]. Furthermore, due to the many methods of measuring bone density in the market, there is no standardized way to measure bone density, which makes comparison of results from cadaver to cadaver, experiment to experiment, and lab to lab extremely difficult. Creating a device that can easily measure localized bone density would improve clinical work and academic research by allowing easy comparison of research and experimental results in order to make a better informed decision of the type of bone screw to use during orthopedic surgery and to better understand the effects of diseases such as osteoporosis and bone cancers.

Currently, there exists no portable, simple, and sterilizable solution for determining the physical density of a bone at a specific point of interest. Existing technologies such as the DEXA scan uses X-Rays to determine the amount of energy absorbed by the bone, which can be correlated to its density. However, these scans require radiology equipment and highly specialized equipment, rendering them difficult to use in a surgical setting. Other methods, such as quantitative ultrasonography, offer promising possibilities to measure bone density, however they suffer from poor accuracy when compared to DEXA scans[14]. Furthermore, readings tend to vary considerably based on the model of the device and factors beyond control, often generating inaccurate data[15]. Other portable technologies, such as the OsteoProbe®, measure the strength of bone by micro-indenting the bone and quantifying the death of

microfractures generated[7]. However, technologies such as these struggle with sterilization and are often inaccurate due to their inability to be applied to different sized bones and bodies.

6.2. Final Problem Map



6.3. Solution Statement

The main limitations behind the current bone density measurement devices include large and expensive machines that are not easily portable, devices that do not meet sterilization requirements to be used in a surgical environment, and inaccurate readings among varying patients and/or varying types of bone[53,67]. To combat these issues, the device being made will consist of a lightweight and handheld bone indentation probe with adjustable clamps that contain equipment capable of undergoing proper surgical sterilization protocols to be used in many different medical applications[17]. This device will be about 6 inches long and 4 inches wide and weigh approximately 7.5 pounds. These sizes are estimates and may be subject to change depending on the size of the load-generating components of the device. There are three main subunits of the device: the base, the indentation probe, and the collinear adjustable clamps. Compared to a large DEXA scan or quantitative ultrasounds which are two of the most common forms of bone density measurement currently, this device will be able to accurately measure bone density without the need for a large imaging machine in an isolated room making it more intriguing to orthopedic surgeons and hospitals as a whole.

The base will contain the battery pack, circuit board, LED display screen, and attachment ports for the probe and clamps. To ensure proper hospital sterilization techniques can be performed on the device, the base will be largely composed of stainless steel 304 and ABS plastic. This plastic is lightweight

and is commonly used in hospitals already due to its ability to effectively undergo gamma radiation or ethylene oxide sterilization techniques[68]. To power the device, a rechargeable battery pack will be embedded within the base of the indentation device. Nickel Cadmium batteries are commonly used to power surgical tools and will be used in this device to coincide with devices already used in surgical settings for their high voltage, fast activation, and long storage life[69]. This will allow for an easy implementation of the device into surgical settings since the battery source will be largely consistent with those in devices already used.

The device will include an indentation probe made primarily of medical-grade stainless steel 304 and will consist of three components: The motor, the shaft, and the indenter holder. The indenter holder crucially holds the indenter tip that is used to form indentations in the bone. This small motor will have the capability to create a sustained load onto a fixed area of bone applied by the shaft and have a depth stop to assist in guaranteeing a bone indentation that is 1/32nd of an inch in depth. The depth of 1/32nd of an inch was chosen as it is slightly higher than what an OsteoProbe® uses and was recommended by Dr. Jackson[45]. To account for varying bone sizes among the body, the indenter holder will be detachable from the shaft and will come in multiple sizes. To maintain uniformity among measurements between the differing bones, however, the probe will maintain relatively the same ratio of indention: load applied: total surface area of the specified bone to scale the density calculations and use them holistically in the body. There will be three different indentation probes that can be used for groups of bones with similar sizes.

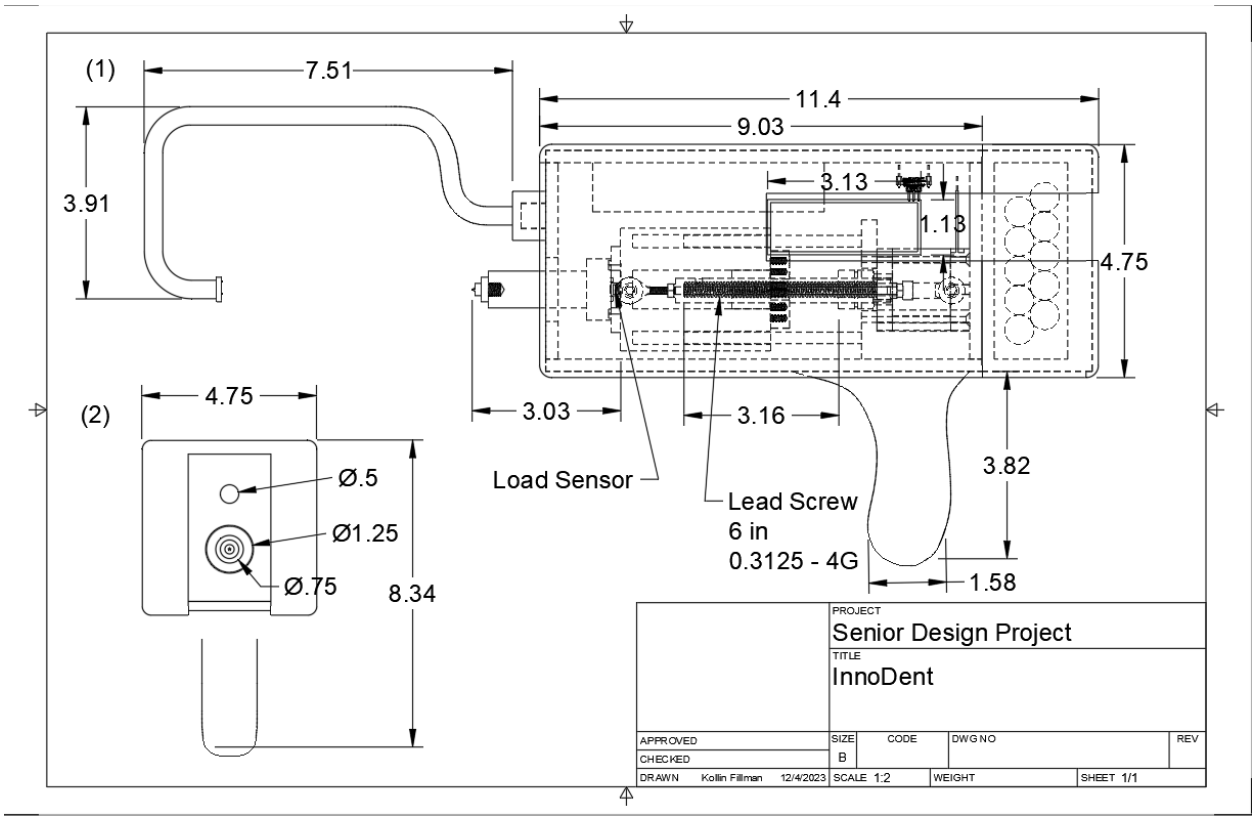
The final component of the device is the adjustable collinear clamps that allow for more extensive use among differing types of bone. The collinear clamps will also be made of medical-grade stainless steel 304 and will have four different sizes and shapes. Each clamp will contain a length range to allow for use in several different bone types with similar sizes instead of the alternative of making a specified clamp for every individual bone. The combination of the replaceable indentation probes in addition to the adjustable collinear clamps will allow for greater customizability among both multiple patients and multiple bone types which has not been accomplished so far. The materials used for all three components will also be capable of undergoing proper sterilization for surgical settings. With these benefits, this novel, portable, adjustable, and uniform bone indentation device used to determine bone density should become largely favored in surgical applications compared to devices already on the market.

6.4. Drawing(s) of Prototype Solutions:

Figure 6-1. Indentation Device: Full Model with attached clamping module

Standard view of our final CAD model of the indentation device. The clamping component can be removed and interchanged with clamps of different sizes to accommodate different bone sizes. The gray components are made of stainless steel, and the black components are made of ABS plastic.

Figure 6-2. Device CAD Drawing: Schematic with Right and Front Views of the Device

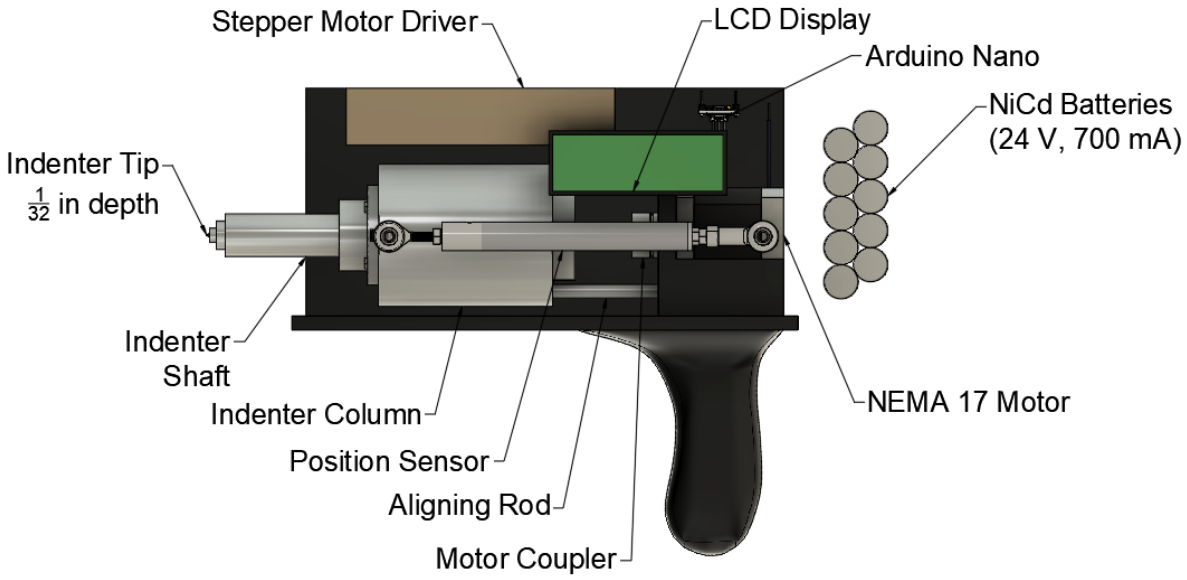


The schematic diagram of our device. All dimensions given are in inches. (1) View of our device from the right side with hidden edges shown to show the mechanical components on the interior of the device. The 3.16 inch dimension refers to the range of linear motion of the ball screw component, and thus the maximum displacement that can be produced by our linear actuator. The 3.03 inch dimension is the length of the indenter shaft, and correlates to how far from the front face that the indenter can actually extend. (2) View of the device from the front face with only visible edges shown. Note that certain dimensions, such as the device width and length, may be subject to change depending on the sizes of internal components that can be used.

Figure 6-3. Device CAD Drawing: Full body with internal components shown

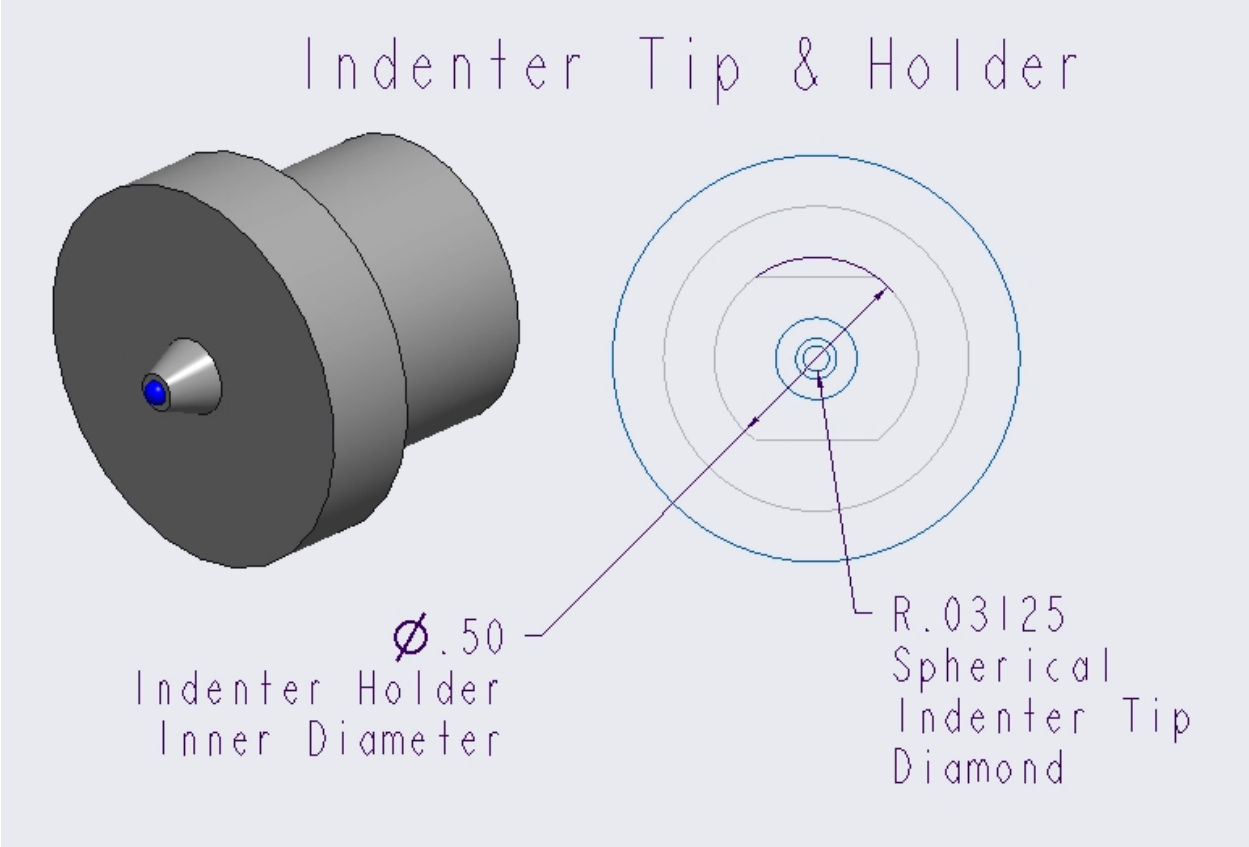
The CAD model drawn above displays the interior mechanism of our device from the right face. This consists of the linear actuator, the LCD Display, batteries, and electronics for controlling the stepper motor.

Figure 6-4. Device CAD Drawing: Right view of labeled internal components



All of the interior components of the device, with the exception of the lead screw and force sensor shown in Figure 6-2. The Arduino nano is a placeholder being used for the PCB component that will be used to control the NEMA 17 Stepper Motor in conjunction with the Stepper Motor Driver. The size of the stepper motor driver is subject to change depending on the available options that suit our needs. The motor, aligning rods, lead screw, motor coupler, and ball screw may be available together as an assembly rather than having to purchase/assemble them separately.

Figure 6-5. Device CAD Model & Drawing: Close up of Indenter Tip & Holder



An example of a possible indenter tip attachment for our device. This component would be threaded onto the end of the indenter shaft labeled in Fig 6-4. While the maximum depth of any given indenter tip has to be less than 0.03125 (1/32) of an inch, the exact sizes will be determined based on the products available.

6.5. Functional Block/Subcomponent Diagram or Flowchart

Subcomponent Title	Technical Description	Contributing discipline/ skill set	Design Specification Addressed
Casing / body	The outer body of the device is made of a combination of medical grade stainless steel and Acrylonitrile butadiene styrene (ABS). There will also be a grip below the trigger mechanism to make the device easier to hold and more comfortable. The ABS and stainless steel casing are resistant to high temperatures and	Machining	The stainless steel and ABS body of the device will allow the device to be safely autoclaved fulfilling the "sterilization" specification[70,71]. The device is also designed to be handheld and

	pressure, and therefore can easily be autoclaved.		ergonomic, fulfilling the "handheld" specification.
Collinear clamps	The collinear clamps are adjustable stainless steel clamps that allow the user to align the indenter with the location of the bone of choice and to create a tight seal with the bone. Importantly, the ability to adjust the collinear clamps allows the user to indent bones of varying sizes for universal measurement. The collinear clamp is removable from the device, allowing it to be autoclaved.	Machining	The collinear clamps address the "method of indenting bone" specification, as they align the indenter with the bone, allowing measurements to be made. The collinear clamp is fabricated from stainless steel and removable, allowing for it to be sterilized, fulfilling the "sterilization" specification. The use of collinear clamps also allows the device to be used in both living patients and cadavers, fulfilling "Device applicable to both cadaver and living patients" specification.
Indenter and shaft	The indenter is a cylindrical rod with a hemispherical tip made of medical grade stainless steel. This is the part of the device that actually indents the bone. The indenter will be exchangeable via a screw mechanism. The indenter will be screwed into a shaft that connects to the motor. The ability to remove the indenter allows it to be autoclaved.	Machining	The indenter is the part of the device that actually pushes against the bone and indents it, fulfilling the "method of indentation bone" specification. The indenter and shaft are fabricated from stainless steel and are removable, allowing them to be sterilized, fulfilling the "sterilization" specification.
Motor	A motor within the device will generate the force required to drive the indenter into the bone.	Electrical engineering, mechanical engineering, controls	The motor provides the power required to indent the bone, fulfilling the "method of indenting bone" specification.

Force Sensor	A force sensor will be connected to the motor to measure the force required to indent the bone a select amount.	Electrical engineering, controls	The force sensor measures the force required to indent the bone to a specific degree. This information is used to calculate the localized bone density, fulfilling the “localized bone density” specification. This also fulfills the “sensor with high degree of sensitivity” specification.
Displacement Sensor	A displacement sensor will be connected to the shaft of the motor to measure the degree of indentation that the bone will experience. After a predetermined amount of displacement occurs, the sensor will transmit a signal to the motor to stop driving the indenter and to retract the shaft.	Electrical engineering, controls	The displacement sensor measures the displacement of the bone to stop the indentation of the bone at a certain displacement to accurately calculate the localized bone density, fulfilling the “localized bone density” specification. This also fulfills the “sensor with high degree of sensitivity” specification.
Display Screen	The display screen will be an LED screen on the outside of the device that will display real-time data of the pressure exerted on the bone and the displacement of the indent.	Electrical engineering, controls	The display screen communicates the force applied to the bone and the indentation of the probe, which fulfills the “localized bone density” specification.
12V Batteries	The device will house 12V batteries to power the motor and LED display of the device. Ideally, the device should last for at least 8 hours so as to last for long surgeries. The exact number of batteries and their configuration will still need to be determined based on the power required to run the internal components.	Electrical engineering	The 12V battery will fulfill the “optimal battery” specification.

Internal wiring and printed circuit board (PCB)	The motor, force and displacement sensors, and LED display will all be wired to a printed circuit board. Here, the information from the force and displacement sensors will be integrated so that when a certain displacement is reached, a signal can be sent to the motor to remove the indenter from the bone. The information gathered from the sensors will then be transmitted via Bluetooth to a computer that will calculate the physical properties of the bone, then transmit the information back to the LED display.	Electrical engineering, programming, controls	The internal circuitry of the device allows the device to actually perform the desired and communicate information with the user, fulfilling the “method of indenting bone” specification.

Section 7: Failure Modes and Effects Analysis (XFMEAs)

FMEA Scope

With the adjustable bone indentation device provided, there are many possible points of failure. The largest failure point would be an inaccurate reading causing improper surgical diagnosis for screw implantation. One cause of inaccurate readings could be a result of improper collinear clamp size creating an unstable pressure during the indentation procedure. Improper indentation probe size can also result in inaccurate readings due to a nonuniform bone density scaling compared to the bone being tested. The mechanics of the indention probe could also fail resulting in an inaccurate load applied to the bone and an inaccurate reading. The subcomponents of the base of the indentation device (battery, circuit board, display) could also fail resulting in an inability to read and record the data collected from the test.

The device could also fail proper sterilization testing, rendering it unsafe for surgical applications. Alternatively, some exterior or interior components of the device may be affected during the autoclave process, thereby damaging an internal or external component needed for the device to function, rendering the device useless.

To address the failure of any sort of mechanical issue, the device will be designed with a tight tolerance and with mechanical redundancies that will prevent any sort of instability during the indentation process. Great care will also be placed when sealing the internal components from the external components through the use of O-rings for example, which will help minimize the chance of steam

entering the interior of the device and damaging any circuitry. This will also allow the device to be properly autoclaved, thus ensuring sterility in the operating room.

FMEA Table

Severity (S) ranges from 1-9 (negligible to critical) and Detectability (D) from 1-9 (easy to difficult). Occurrence (O) ranges from 0-0.5 (improbable to likely).

Process/Step/ Input/Output	Potential Failure Mode	Potential Failure Effect	S	Potential Causes	O	Current Controls	D	RPN	Recommended Mitigation
Sterilization	Failed Sterilization	Could infect the patient in an OR	7	Improper sterilization procedures	0.05	Materials that can handle proper sterilization	5	1.75	Step-by-step sterilization procedure must be completed before each use. The user will sign off that they performed the sterilization according to the guide and the signature will be approved, which also approves the device for use.
Battery	Batteries dying during use	Device unusable	3	Batteries were not charged	0.1	Non-Users responsibility to charge batteries	1	.3	Warn the user if battery levels are low in the device. Have long-lasting batteries and sell products with an additional battery, along with instructions on how to change the batteries.
Reading	The sensor board not properly functioning	This could lead to a false or inadequate diagnosis/ treatment plan	8	Wires could have become loose within the circuit board	0.03	Known experimental data	4	.96	The user could begin each use with a test bone that should return the same value each time to the user (calibration test). The user

									would then know if something is off.
Reading	Inconsistency among different bone locations	Inaccurate results	7	Inconsistent bone densities, especially with diseased patients	0 .4	Experimental testing data	8	22.4	Perform ample testing to understand how this inconsistency affects results.
Battery	Batteries failing due to not surviving sterilization	Device unusable and battery may be permanently damaged	6	Ruptures in the casing allowing the battery housing unit to be exposed	0.05	Resistant materials that would resist rupture	1	0.3	Ensure the casing is waterproof and steam proof through sterilization tests.
Reading	Bone indentation too deep	Improper reading	5	Indentation measurement compromised	0.09	Indentation should be 1/32nd inch each time	2	.9	Calibrate and test indentation before actually using it on patients.
Reading	Bone indentation too shallow	Improper reading	5	Indentation measurement compromised	0.09	Indentation should be 1/32nd inch each time	2	.9	Calibrate and test indentation before actually using it on the patient.
Stability	Adjustable clamp does not fully fit to the specified bone	Unstable area to perform indentation test	4	Indentation measurement compromised	.12	Create multiple clamps that can be adjusted to ensure	7	3.36	Perform checks to ensure the clamp is adequately secured to the bone being tested before performing the indentation test.

						proper fit			
Display	LED Screen malfunction /not displaying data	Inability to read data	6	Wires could have come loose, batteries may have malfunctio ned	.04	Screen with high lifespan	8	1.92	When powering on the device, perform a diagnostic check to ensure the screen is displaying accurate information.
Battery	Battery charge no longer lasting appropriate lengths	Device is unable to be used for full-length	2	Extended use of batteries could shorten their lifespan	0.2	Long battery life so this problem is minimize d	1	.4	Could sell the unit with additional batteries as backup, along with instructions on how to change the batteries.

S =severity; O=occurrence; D=Detectability; RPN=Risk Priority Number=S´O´D

Section 8: Testing Plan (V&V)

8.1. Design Verification Plans for Subcomponent - each component

Battery- The batteries will need to be capable of supplying enough voltage/current to the motor, Load sensor, and LCD screen to adequately power the device. The current and voltage will be verified by connecting the batteries in circuit with a voltmeter. The battery will be tested according to IEC 60623[72].

LCD Screen- The LCD display will need to be tested beforehand to verify that there is no distortion in the screen and that the display has enough resolution to clearly show the readings produced by the load sensor. This will be done by wiring the LCD screen to the load sensor or another device capable of outputting a digital signal and verifying that the output shown on the display is clearly legible to the user. The LCD screen will be tested according to IEC 63181[73].

Motor - The motor will need to be tested to ensure that it can produce enough torque needed for the linear actuator to produce a great enough load to indent into the bone. Additionally it will need adequate levels of controllability to be able to stop applying the load when the indentation is complete. To test if the motor is powerful enough, it will need to be attached to the rest of the indenter apparatus and run at its maximum rpm to determine what the maximum amount of force being generated is. The motor class of the motor will be determined at a later date and will be tested in accordance with NEMA standards[74].

Ball Screw Linear Actuator - The actuator will need to be sturdily attached to the motor to ensure that it doesn't break or disconnect while the motor is rotating the bolt. The ball screw itself will need to be properly threaded onto the bolt of the actuator to allow for smooth linear motion down the actuator. Verification procedures for the linear actuator include testing the actuator as it is attached to the motor running at its highest RPM to make sure that the central axis doesn't wobble, and to test the linear actuator multiple times after sterilization to see that any built up moisture or heat doesn't hinder the ball screw's efficiency. Standards of the linear actuator will be in accordance with NEMA standards[74].

Indenter Column / Indenter Holder - The indenter column will need a strong connection with the ball screw of the linear actuator so that the column can move downwards with the screw as the motor rotates the mechanism. This connection will be made with screws and will need to be observed while the apparatus is running to ensure that the two pieces are tightly attached. The indenter holder will also need to be tested to ensure that it moves smoothly to evenly transfer the load from the linear actuator to the indenter tip and eventually to the material. The indenter column and holder will be comprised of 304 stainless steel which will undergo testing according to ASTM A240 standard to ensure properly functioning[75].

Indenter Tip - The indenter tip will need to be tightly attachable and detachable from the indenter holder to ensure that the load is appropriately transferred to the bone while still allowing for the tip to be replaceable. The stability of this attachment can be verified by placing the indenter tip into the

indenter holder and applying a load transverse to the indenter tip and checking that the indenter tip doesn't move. The tip will also need to be tested while indenting an object to ensure that it can withstand being applied by it during a procedure. The indenter tip will be tested according to ASTM E384-17 and ISO 14577[76-77]. Because this is the component that makes human contact, it must be deemed biocompatible. The use of a diamond tip likely means that the tip will be biocompatible, but testing according to ISO 10993-1 must be performed[78].

Load Sensor - The load sensor will need to be appropriately placed within the device to make sure that the load from the indenter column is being applied correctly to the sensor. It will also need to be properly calibrated to make sure that the readings from the sensor are accurate. To calibrate the device, the maximum load generated by the device will need to be determined mathematically or experimentally, then that maximum load will be applied to the sensor and the sensor be adjusted to ensure accurate readings. The load sensor will be tested according to ISO 376[79].

Displacement Sensor - The displacement sensor will need to be appropriately positioned to measure the depth of the indentation produced by the device. The sensor will need to be calibrated to measure small displacements of 1/32 of an inch and smaller, and will be done through experimental trials on other materials. The displacement sensor will be tested according to ASTM F2537-06[80].

Sterilizable Materials - The device will need to undergo surgical grade sterilization safe for plastics with low melting temperatures. This device will undergo sterilization according to ISO 11135, ISO 22441, and FDA-2008-D-0060[81-83] to ensure sterilization occurred as desired and make it safe for contact with bone.

8.2. Design Verification Subcomponent Testing Results

N/A

8.3. Design Verification Plans for Final Prototype

When performing verification testing, two guidelines, the 21 CFR Part 820.3 and the 21 CFR 888.1600 should be consulted[84,85]. The first guideline outlines the FDA's definition of whole component verification testing, which it defines as the verification that the design outputs of the device meet the design inputs. Therefore, whole component verification involves verifying that our device is capable of measuring properties relating to the physical density of bone. The FDA further designs verification tests in their Design Control Guide[86]. Tests include a worst case analysis and thermal analysis of the assembly. The worst case scenario for our device would be a malfunction in the motor or sensors, causing the device to continue to indent the bone, harming the patient. Redundancies in design would prevent this from happening; The use of both a force and displacement sensor will prevent the motor from indenting excessively in case one sensor fails. In the event that both sensors fail or the motor fails to turn off, the collinear clamps of the device can be quickly unchastened to prevent further damage of the bone. A thermal analysis will be conducted on our finished prototype to ensure that none of the internal or external components reach above a temperature that can damage components or injure the patient. A

general rule of the temperature at which electronics become damaged is around 100℃, so all electronic components will be pushed to their limits and the internal and external temperature analyzed[87].

Under the code 21 CFR 888.1600, the device must demonstrate that it can determine the physical bone density *in vivo*. This test must evaluate the risk of bone fracture, soft tissue damage, pain discomfort, bruising, and bleeding. Preliminary testing may be conducted using cadavers and using animal models (ISO 10993-2)[88]. The device must also undergo non-clinical performance testing to evaluate the accuracy and precision of the device in measuring bone indentation. Human factors testing must verify that the product is intuitive and can be operated properly with instructions. The device must also be deemed biocompatible under ISO 10993-1[89]. The assembled device needs to undergo sterilization testing (ISO 11135) to ensure that the device can be properly sterilized without damaging any internal circuitry[90]. Here, we are using ethylene oxide sterilization due to the sensitive internal circuitry. Furthermore, any reusable components must have reprocessing instructions. The shelf life of the device must be determined based on the sterility and function of the device. Electrical safety verification testing (IEC 60601) should be performed to ensure that there is no electrical shorting or potential for electrical shock due to the circuitry of the device[91]. An electromagnetic compatibility test (ISO 14117) must also be performed[92]. Labeling must include instructions for use, instructions for reusable components, shelf life, information about the limitations of the safety of the device, and details on the accuracy and precision of the device.

8.4. Design Verification Final Prototype Testing Results

N/A

8.5. Design Validation Plans for Final Prototype

Under 21 CFR 820.30(F), the FDA defines product validation as the establishment of “evidence that all design requirements have been implemented correctly and are traceable to system requirements”[84]. Our greatest asset for an internal validation test will be our mentor, Dr. Jackson, an orthopedic surgeon who is very familiar with the processes involved in installing bone screws. An external validation test will be performed by providing orthopedic surgeons at Prisma Health with our device and hearing their feedback after using the prototype on cadavers. This is a form of human testing and will therefore require the approval of an institutional review board by both the University of South Carolina and Prisma Health. A proposal will need to be submitted, detailing how the risk to subjects will be minimized, how the selection of subjects is reasonable and equitable, how informed consent will be sought and documented, how data will be monitored, and how the privacy and rights of subjects will be protected[93]. After the surgeons are done using our device, they will be given a questionnaire detailing the usability of existing solutions, a comparison of our product compared to DEXA scans, changes in workflow as a result of our device, potential drawbacks of our device, potential strengths of our device, safety concerns with our device, barriers that may prevent other orthopedic surgeons from adopting our

device, and if our device serves as a portable and easy to use method of measuring physical bone density to make more informed decisions of screw insertion.

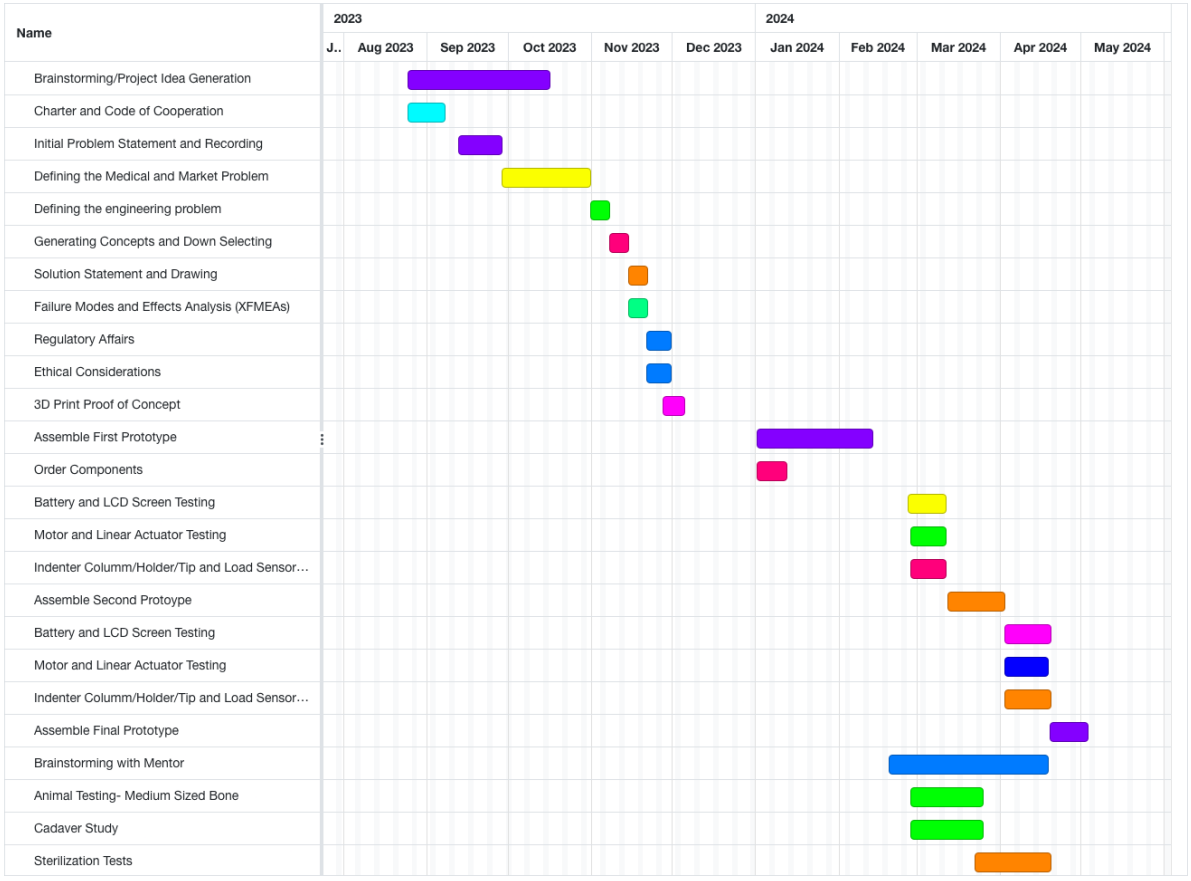
8.6. Testing Results for Final Prototype

N/A

8.7. Discussion Relating Final Prototype Results to Literature, Design Specifications, and Customer Needs

N/A

8.8. Project Planning and Scheduling



8.9. Budget and Bill of Materials

Item	Cost

Battery	$20.99[94]
LCD Screen	$10[95]
Linear Actuator w/ motor	$150[96]
Indenter Column/Handle/Collinear Clamp - SS	$110.83[97]
4 Indenter Tips – Diamond	$129.96[98]
Compression Load Sensor	$39.28[99]
Displacement Sensor	$189.00[100]
ABS Filament	$23.99[101]
PCB Board	$30.00[102]
3D Printing - CV2 Makerspace	$0.00
Total Cost	$704.05
Total Budget	$1000.00
Remaining	$295.95

Section 9: Regulatory Affairs

9.1. Intended Product Application-

The use of bone screws is largely used in the field of orthopedic surgery, specifically during implant surgery and stabilization of bone fractures/breaks. While these screws helped revolutionize modern orthopedic treatment, there are still large limitations with this device including failure as a result of low pullout strength which can cause large problems for the patient. It has been shown that the mass density of the specific bone can predict screw pullout strength, and therefore, the overall success of the bone screw as a whole. Unfortunately, there has not been a device that has been able to standardize bone material strength measurements among patients and differing bones enough to become widely used to predict bone screw success in surgical settings. The devices that are currently in the market have not been applied in surgical settings for bone screw implantation mainly due to them being large and expensive machines that require a specific imaging room to be used, they fail to meet proper surgical room sterilization requirements, and the readings are not accurate readings among varying conditions/samples as previously mentioned.

The device created will combat these limitations by being a lightweight handheld bone indentation device with adjustable clamps and indentation probes that contain materials suitable for proper surgical sterilization techniques to relate mass density to screw pullout strength ability in a surgical setting. The device will be used on the bone(s) of interest during a surgical procedure to help determine which type of screw will be most effective for the specified patient at the specified location. This device can rapidly produce readings associated with load and resistance after the indentation test which can be used to estimate the mass density of the patient's bone. Together, this device will provide a novel method of rapidly determining the effectiveness of surgical bone screws by relating the mechanical properties of the bone to the pull-out strength of the screw that will have capabilities to be used in surgical environments, unlike any current devices on the market.

Further applications of this device involve the possibility of relating the device's reading to potential signs of osteoporosis. Although this device will likely not fully diagnose osteoporosis, research on cadavers and live patient's bones could provide a relationship between this device's readings and the disease state, or the potential for developing this disease state. Other materials besides bone could also be investigated with this device. Although this is not very practical it is important to note that this device is not limited to bone studies only.

9.2. Summary of Similar and/or Comparable Products-

Comparable Product	Manufacturer	Classification	Similarities/Differences
DEXA Scan	DEXA Solutions	Class II Device	Similar to our device, the DEXA scan can quantify bone density and/or mass. There are many differences

			between our device and the DEXA scan, however. First, it uses low-dose X-rays as its primary measurement tool. It can use X-ray beams to measure minerals such as calcium in the bone. This test has large limitations because it is very large, expensive, time-consuming, requires a special imaging room making it incapable of use in surgical environments, and poorly predicts bone density at exact locations within the bone.
Quantitative Ultrasound	Telemed, Pinyuan Medical, Echolight, Canon, and others	Class II Device	Similar to our device, quantitative ultrasound devices are portable devices that have the capability of undergoing proper sterilization protocols to be used in a surgical environment. This device largely looks at the mechanical properties of bone including bone thickness, but is not as effective in bone density measurements. The main difference between this device and our device is that it uses mechanical waves to measure velocity, attenuation, and backscatter to calculate bone properties. It is susceptible to inaccurate readings however due to its use on the epithelial layer, rather than on the bone

			itself which can result in noise from soft tissues that would be avoided when using our device.
OsteoProbe®	Active Life Scientific Inc.	Class II Device	Similar to our device, the OsteoProbe® uses bone indentation to measure the material properties of bone. However, the OsteoProbe® focuses on the frictional coefficient of the bone and its resistance to cracking, instead of the density of the bone.
Osteo Penetrometer		Class II Device	The Osteo Penetrometer is another device that operates under the methodology of bone indentation. However, it is unique in that it measures a wide variety of mechanical properties including yield strength, ultimate strength, Young's Modulus, and energy absorption. However, this model is hindered by its encumbered design and use of hydraulics, which makes the device impractical for handheld use.
Bone Diagnostic Instrument (BDI)			Like the previous devices and our device, the BDI utilizes micro indentations of bone to calculate material properties. However, this device struggled with repeatability, often

			rendering inaccurate readings based on the location of the bone.

9.3. Regulatory Agency

The FDA will have jurisdiction over our device as it is considered a medical device. The FDA has jurisdiction over all medical devices, ranging from simple to complex in design, in all 50 states. The FDA is the only regulatory agency with jurisdiction over medical devices in the US and no other agency has power in this area[103].

9.4. Product Classification for FDA-regulated products

- ☐ Medical Device Class I
- ☑ ~~Medical Device Class II~~
- ☐ Medical Device Class III
- ☐ Biologic
- ☐ Drug
- ☐ Combination
- ☐ Not Applicable

This would be a class II medical device. There is an intermediate risk of this device because a load is being directly applied to the patient's bone, and the outputs are relevant in ensuring a surgical screw stays in place and doesn't cause further damage. This makes it too high of a risk to be a class I device, but not high enough of a risk to be class III, which are devices that sustain or support life.

9.5. Regulatory Pathway Description

- ☐ Orphan Drug
- ☐ Humanitarian Device
- ☑ ~~510k~~
- ☐ IDE and PMA (device)
- ☐ IND and NDA (drug)
- ☐ BLA (biologic)
- ☐ Not Applicable

This product would be a class ll medical device due to it making direct contact with bones, as well as applying a load (moderate risk), but does not sustain or support life like a class III device would. This device would require 510(k) premarket approval to prove safety and efficacy by showing substantial equivalence to another device on the market, which in this case is the Synthes Collinear Reduction Clamp, which was cleared through the FDA 510(k) pathway[104].

9.6. Overview of Research and Development (R&D) Strategy

Proposed Procedure/Methods	Reference
Bench	
Sterilization protocols- As per ISO11135 for Ethylene Oxide sterilization	Protocol[105]
Verification tests - compare to similar values in other studies	Similar Data[106]

Animal	
Medium-sized animal study (pig) - Tests to gain initial experimental data on bone sizes similar to small-medium sized bones in the human body.	Protocol[107]
Large-sized animal study (horse)- Test to see differences in larger bones that are similar in size to horse bones.	Protocol[108]
Human	
Cadaver bone indentation study - Can use device to gain human data and then determine actual bone density with an alternative method to assess accuracy with our device.	Protocol[45]
Clinical trials for class 2 devices - OsteoProbe®- (similar to ours)	Trials[109]

Section 10: Ethical Considerations

10.1. Identifying Ethical Considerations

One moderate ethical concern would be in the testing of this device on an animal. When doing tests on animals, the highest priority should be to minimize emotional distress of the animals during the testing of the device. Another ethical concern but of low significance is the testing of the device on cadavers, as it is important to respect those who have donated their bodies to science and use them sparingly for other research. Appropriate guidelines for testing on cadavers must be followed. It would be difficult to truly test the damage done to the bone without testing on a live patient during surgery which would pose high ethical issues if not fully FDA approved prior to testing. Even after full FDA approval, the privacy of the patients must be respected and a complete set of protocols to minimize patient harm will need to be stringently followed. An additional high-significance ethical concern would be inaccurate readings from the machine resulting in false data and diagnosis. This could result in implantation of a bone screw that fails and can cause additional complications for the patient.

Current devices on the market also contain some ethical concerns. The OsteoProbe® and DEXA scan both have concerns of possible inaccuracies in their readings. These readings are directly used for diagnoses which, if wrong, is a huge ethical dilemma. Similar to our device, an OsteoProbe® creates small damages to a bone, which on a live patient, is an ethical concern if the patient is unaware of the process. DEXA devices utilize low radiation dosages which need to be communicated to the patient. Our device does not have this same concern as it does not utilize ultrasound technology.

10.2. Recommended Solution

To minimize distress of animals, the institution's institutional animal care and use committee (IACUC) guidelines will be followed[110]. Briefly, the animals will be anesthetized before testing, then sacrificed according to proper protocol. Similar to the guidelines for animal testing, similar cadaver testing protocols will need to be followed[111]. Before FDA approval, a comprehensive understanding of the damage imposed on the bone due to the device will need to be fully documented. Before our device is approved, our device will need to undergo extensive testing on cadaver and animal bones to gain an understanding of the extent of the damage the bone takes. These cadaver and animal bones will be altered after this process and it is important that this alteration is understood if further research is being completed on these bones. In order to combat the concern of inaccurate readings, the device should be tested on a physically homogeneous material such as steel or polypropylene before use. These materials exhibit uniform properties at all locations, and therefore would have a constant stiffness and density. The accuracy of our device can then be tested by taking multiple readings of the indentation stiffness and making sure that they return values within 100 Pa of more established methods such as through the use of a Universal Test Machine. After ensuring that our device is yielding accurate readings, more tests will

need to be performed on bone samples. These sample bone tests will serve as further verification that our device is providing accurate results in comparison to previously determined experimental values, and to determine the upper limit of what loads we should be applying to bones in vivo. By determining how much force is needed to cause catastrophic failure in the sample bones, we can better avoid causing severe damage to a patient's bone, and potentially integrate a warning system to alert the user that they may be applying too much force on the bone.

Section 11: Intellectual Property (IP) and Technology Transfer

Dr. Jackson has expressed his interest in confidentiality in our initial meeting. He has mentioned the idea of our group members signing non-disclosure agreements in order to protect the patentability of this design. However, Dr. Jackson understands that this design must be presented to faculty and students here at USC and accepts this breach of confidentiality. Dr. Jackson has also expressed the IP breakdown of any potential patent that may come from this design. 20% of the patent IP will be split among the group evenly, leaving each student with 4% IP of the total product. This, as Dr. Jackson stated, will only be an issue if the work completed in this class is deemed patentable.

A final written agreement has not been reached between the group and Dr. Jackson regarding the IP of the project. The discussion above is based upon a Microsoft Teams meeting where the potential breakup of IP was investigated but is in no way final.

Section 12: Engineering Abstract

Title: The InnoDent: A surgical grade handheld bone indentation device capable of quantifying bone material properties

Authors: Remy Bell, Kollin Fillman, Anthony Gilles, Anthony Gisolfi, Emma Grace Pittard

Abstract:

Billions of bone screws are implanted every year for stabilizing bone fractures and fixating implants to bone[2]. The biggest indicator for the success of a bone screw is the strength of the bone, which is largely dependent on the mineral bone density of the bone[7]. The main limitations behind the current bone density measurement devices include large and expensive machines that are not easily portable, failure in meeting proper surgical sterilization requirements, and inaccurate readings among varying patients and/or varying types of bone[53,67]. To combat these issues, the InnoDent has been created. The InnoDent is a lightweight and handheld device capable of measuring bone material properties that can be related to overall bone density in the measured bone. There are three main subunits of the device: the base, the detachable indentation probes of different sizes, and the collinear adjustable clamps. The combination of the replaceable indentation probes in addition to the adjustable collinear clamps will allow for greater customizability among both multiple patients and multiple bone types which has not been accomplished so far. The materials used for all three components are lightweight and will also be capable of undergoing proper sterilization for surgical settings. With these benefits, this novel, portable, adjustable, and uniform bone indentation device used to determine properties relating to bone density should lead to improved bone screw success rates in orthopedic surgeries and should be more accessible in a surgical setting than devices currently on the market.

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