Designing and Testing a Novel Custom 3D-Modeled Post-Operative Knee Brace

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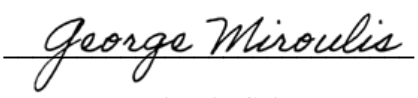

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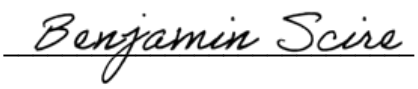

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Abstract

Combined, total knee arthroplasty (TKA) and ACL reconstruction surgeries constitute nearly one million surgeries performed annually in the U.S. alone[1]. With the demand for total knee replacement surgeries projected to grow by 673 percent to nearly 3.5 million operations by 2030, the need to properly rehabilitate patients after their operation is of high importance[2]. Typical rehabilitation works in stages, beginning with completely restricted movement and employing multiple braces throughout the recovery process that each allow different ranges of motion. Our adaptable post-operative brace design acts as a 'one-stop-shop'. This brace will be custom-fit to the patient and will have an adjustable range of motion throughout recovery and adaptable force redistribution intensity at the joint to unload forces on the tibia. Patients who have undergone TKA can lose up to 62% of their quadriceps strength due to the atrophy, and some patients have permanent physiological limitations to their knee's range of motion, a condition known as knee flexion contracture (KFC), as a result of the long-term immobilization of the joint[3,4]. Our brace hopes to address the shortcomings of current technology by allowing the patient to exercise their mobility at all stages with assistance from the brace, and foster better recovery of the knee joint following operation.

Keywords: Unloading brace, total knee arthroplasty (TKA), knee flexion contracture (KFC), flexion and extension, rehabilitation, Ascender brace

Introduction

Significance

Defining the Problem and Current Market Barriers

As awareness of knee-joint inflammation and osteoarthritis increases in younger populations, as does the prevalence of total knee replacement procedures. Total knee replacement surgeries are projected to reach 3.5 million in the year of 2030 alone[2]. The global knee replacement market size, currently valued at $9.45 B and projected to reach $12.48B by 2027, continues to increase as the market population expands and innovative surgical techniques are developed[5]. New methods of surgery have made the industry profitable, welcoming more players into the market. This growth extends itself into the realm of rehabilitation, most notably into the knee brace market. The post-operative knee brace market size was estimated at $1.5 B in 2018, and as key industry players expand their product line to fit the needs of new procedural tactics and develop groundbreaking medical devices it only continues to grow[6,7]. Key applications for braces include sport-related injuries, ligament ailments and arthritis indicating a wide range of customers. Ossur, a major player holding 6-8% of the orthopedic brace market, has multiple products for varying joint ailments and subsequent support needs: a device that combines stabilization and protection of the knee joint, unloader devices to relieve osteoarthritis pain, and the Rebound brace for functional ligament support[6]. The presence of both small and large companies, each with highly-accredited and diverse product lines, make market entry difficult.

Current knee-brace manufacturers produce multiple devices that are suited specifically for different needs throughout the recovery process. The market is lacking a standalone brace that helps facilitate the recovery process in a dynamic way, rather than static current brace options. The inadequate support and versatility from current braces often results in prolonged immobilization of the knee. This can lead to knee stiffness or the loss of muscle function,

which can develop into knee flexion contracture or arthritis in the joint[8]. Movement in the knee shortly after surgery is crucial for reducing chances of post-operative complications, and our brace aims to reduce pain in the anterior knee directly after surgery to increase early mobility and use.

Our Solution: A Novel Custom Modeled Adjustable Post-Operative Knee Brace

Our solution is to create a custom 3D modeled post-operative knee brace with an adjustable range of motion to be used over the entirety of a patient's recovery process and rehabilitation. This design builds on a current Icarus device– the Ascender– to develop a knee brace with the ability to adjust to meet the patient's needs at each stage of recovery. The custom 3D modeling will ensure that each patient will receive a brace best suited to their physiology, and the ability to continuously adjust the range of motion the brace permits ensures that this is the only brace that a patient will need to purchase over the duration of their recovery. Our design is aimed at achieving full joint-immobilization, an adjustable flexion range from 0 to 90º, and a system for dynamic tensioning commonly used in unloader braces. By integrating these features into one device, we intend to be the first knee brace in the market that is capable of supporting a patient through the entire recovery process while preventing common post-operative complications (e.g. knee flexion contracture). In doing so, this product will revolutionize the rehabilitation protocol post knee-operations.

Our project will serve to provide a novel joint support technology to improve upon the current post-operative treatment methodology and complication prevention capacity. As subsequently mentioned, there are many issues resulting from the traditional post-operative treatment plans, including lack of adjustability and individualized fit options, the necessity for multiple braces throughout the recovery process, and the common occurrence of complications, like knee flexion contracture and muscular atrophy[4]. In order to optimize patient care, our design will address such issues through the implementation of two key product features: brace individualization and multi-function integration.

Given the inherent physiological variability of the knee joint between patients, many current brace options fail to universally provide a perfect fit. Ill-fitting knee braces increase the potential for joint malalignment, skin irritation, excessive swelling, and inadequate support[9]. Our design will serve to combat such issues through knee brace individualization using a 3D scanning phone application, followed by CAD manipulation and powder bed fusion 3D printing. Additionally, our multi-functional integrative design will allow for joint-immobilization, flexion range adjustability, and dynamic tensioning unloading to provide a more cost-effective and efficient rehabilitation option compared to the widely-practiced sequential use of multiple non-functional and functional braces.

Innovation

Because our product intends to be used across the entire post operative recovery, it must cater to each stage of rehabilitation. Surgeon recommendations require total joint-immobilization directly following operation. Following immobilization, patients will shift into rehabilitative post-operative braces to gradually increase range of joint motion. Unloader braces are beneficial in mitigating complications including joint stiffness as they reduce harsh loads on the joint. Current devices target each stage of rehabilitation individually - there does not exist a standalone knee brace that can adjust its stiffness or angle of flexion to fulfill each stage of the recovery process. To best differentiate our novel brace design, relevant products on the market today are used as a reference.

Joint-Immobilization

Joint immobilization reduces pain post-operation, helps maintain full extension and facilitates proper range of motion during the rehabilitation process. Such devices are required by the surgeon to protect the joint and minimize joint flexion immediately following procedure[10]. These devices however are only utilized in the early stages of recovery as the patient begins increasing their range of motion. Ossur, a key player in the knee brace industry, holds numerous patents for their orthopedic devices ranging from knee to elbow braces[11]. The Ossur Rebound brace has multiple models under the product line, each providing a different range of motion and functional support depending on the device. Multiple immobilization braces exist on the market and Ossur's Rebound-immobilizer, the leading product sold at $50, provides adjustable medial and lateral stays with a rigid posterior to restrict motion of the knee following surgery[12].

Adjustable Range of Motion

Adjustable post-operative knee orthosis, filed under reimbursement codes L1832 and L1833, provide range of

motion to the knee joint throughout the recovery process. The Rebound Post-Operative model, manufactured by Ossur, provides a controlled range of motion for the knee. Their product is designed to limit flexion and extension with a OneTouch mechanism that enables adjustments to the angle of hinge[13]. Donjoy's X-Rom, another company's post-operative brace, utilizes Tele-Fit technology containing four sliders and a push-button control settings for brace placement and stability[14]. These unique hinge-mechanisms provide range of motion in a post-operative brace allowing the patient to adjust angles of flexion and extension as directed by the treating physician.

Dynamic Tensioning

The dynamic tensioning mechanism is designed to reduce the load on the ACL to facilitate ACL healing by transferring the load to the femur as the knee goes from flexion and extension. This technology allows for patient specific load adaptation so that the brace supports the patient's individual anatomy and rehabilitation needs[15]. Ossur's Unloader One® Plus is an example of this technology, featuring Ossur's patented 3-point Leverage System. Ossur combines a single hinge with dual Dynamic Force System straps to unload the knee joint. This product has been found to relieve knee pain and improve function of the joint as well as quality of life[12].

Our Improvements on Current Technology

Our novel brace aims to combine all three aspects of technology: joint-immobilization, an adjustable range of motion, and dynamic tensioning into one post-operative knee brace. We plan to expand upon ICARUS Medical's current Ascender brace to fully incorporate all three technologies and their capabilities into one product that is able to be used over the entire rehabilitation process[16]. Our brace will be the first to successfully incorporate all of these features and accommodate patients for their entire recovery while preventing common post-operative complications such as knee flexion contracture (KFC).

Materials and Methods

Conceptualization

Conceptualization of necessary brace design requirements was done through analysis of prior work and an initial literature review. Many problems became apparent and significant throughout this initial research period. Four user concerns were most prevalent and became guiding design parameters for the team. Adaptability to swelling, joint immobilization, range of motion, and reinjury avoidance. Past and current users of Icarus's current class of products were consulted in order to better understand what users valued before any empirical or technical investigations. This combined with the literature review allowed for an informed design to be crafted that could best fulfill important user value.

Prior Work and Materials

The Icarus Ascender brace was used as the base design for the project. This allowed the team to focus only on modifications of an existing product; this made design, manufacturing, and potentially FDA approval more streamlined. The brace is constructed of nylon pa 12 and is custom fitted to each patient using the aforementioned scanning technology on a user's smartphone. The brace is lightweight, consistently removes pain from a user's knee, and utilizes patented unloading technology that utilizes Boa dials that users can adjust. The modifications made by the team consist of the addition of a hinge cap system that integrates with the brace in order to adjust range of motion capabilities. The hinge cap is constructed of nylon pa 12 and steel pins that act as motion delimiters.

Printing and manufacturing are accomplished in house using an HP fusion jet industrial 3D printer. Icarus can receive a scan of a patient's knee and print their brace on the same day. Construction of any single brace can take up to a few hours for one skilled worker to execute, so in the future scaling of this process will have to be a major consideration.

Methods

Adaptability to Swelling

Other braces on the market lacked adequate space for a user's knee to grow as swelling set in after invasive surgeries; this caused massive discomfort among patients in their first days of recovery. The team adjusted the brace design to accommodate for this value. Brace framing was skewed outward away from the knee joint to allow for adequate room for the onset of swelling. With the addition of spacers that can be added once the swelling has subsided, the team designed a feature of the brace that facilitated an adaptability to swelling.

Joint Immobilization

An initial complete inhibition of movement is necessary at the knee joint immediately following invasive surgeries. Within the modifications that the team designed, the addition of a mechanism that could completely lock the user out of flexion or extension at the knee joint was necessary to achieve the previously mentioned need. To accomplish this, a hinge cap was created that could lock a user's knee in the appropriate position following their operation. The brace pivots around the central brace located at the knee. The hinge cap acts as a deadbolt on this hinge, completely inhibiting movement by inserting pins into the main hinge gear housing.

Figure 1. At the top we see the underside of the hinge cap that is then flipped over and guided into the gear housing which allows for complete inhibition of flexion and extension during initial stages of recovery of total knee replacements and ACL/MCL reconstructions.

Range of Motion

Knee braces have historically lacked any significant adaptability to range of motion allowances. Braces that provide assisted motion during the recovery process have the potential to elicit better patient outcomes than their counterparts that lack the ability. To facilitate this control over the allotted range of motion that each user is capable of, the team has designed a series of hinge caps that operate alongside the pins in the hinge. The hinge caps allow for varying degrees of extension. They are inserted into the outside of the hinge and are variable in size to allow for more or less extension depending on the dimensions of the cap.

Reinjury Avoidance

There is a high degree of reinjury among the millions of total knee replacements and ACL/MCL reconstructions. Reinjury can be attributed to atrophy in the quadriceps, tibialis anterior, and the connective tissue surrounding the knee joint. Atrophy in the knee can cause deformities such as KFC that result in permanent loss of quality of life in users. Atrophy is common during the forced sedentary period patients go through during recovery. To avoid this the brace will use the combination of the previously mentioned technologies and methods combined with an unloading technology that allows for assisted movement of the knee joint while redirecting forces that would normally burden the knee joint to the upper thigh and calf instead. This movement is aimed at allowing the knee and surrounding soft tissue to do some level of work in order to avoid atrophy and subsequent reinjury.

Results

Market Analysis

Analysis of the knee orthoses industry is beneficial in determining industry demand as well as the product's position and potential success in the market. The industry we are entering captures all orthopedic braces and support devices and equipment. The knee orthoses market has a projected compound annual growth rate of 4.3% reaching 1.9 B industry by 2025[17]. The rise in the market is primarily due to the increasing prevalence of knee conditions. There is an increase in osteoarthritis diagnosis, as well as ACL, PCL, and TKA injuries requiring operations[18]. Knee replacement procedures specifically are projected to grow 5.67% by 2030 reaching 16.1 Billion USD[19]. Furthermore, as more conditions and procedures

occur, surgeons and patients are seeking advanced recovery devices perpetuating the growth in the market.

The industry however is highly fragmented and competitive. North America holds the majority of the global market share as most key companies are founded in the U.S. Unlike ICARUS, these key players have diverse product portfolios with products ranging from knee to wrist-hand orthosis. Main consumers of orthopedic products are hospitals or clinics as they dominate the market in comparison to E-commerce sites (that allow consumers to buy the product directly)[20].

Despite being a small player in a fragmented market; our product ranges in capability allowing it to fit into multiple product segments. The most relevant knee orthoses products include prophylactic braces (primarily used to minimize rotational movement), functional braces (provide stability post-operation), rehabilitative (provide immobilization or controlled flexion and extension), and unloader braces (used to reduce forces on the knee joint). Functional knee braces held 32% of the market share in 2021 yet rehabilitative braces are expected to grow at a CAGR of 5.2% by 2029[20]. Furthermore, our device fits into multiple product segments because it effectively stabilizes the joint, minimizes forces, and promotes proper healing of the muscles - all capabilities medical professionals recommend to patients following procedures. That being said, it is important to remember our product is in direct competition with current products from reputable companies. Therefore, it is imperative to develop relationships with leading physicians during product development to gain credible reports of our product.

Product Classification

Regulatory Classification

We determined regulatory requirements and needs for our product. Knee braces are categorized based on intended usage. The FDA defines a brace as “a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, to prevent deformities, or to align body structures for functional improvement.” Based on this definition, knee braces are classified as class I devices and are exempt from premarket notification application typically required prior to bringing a device to market.

Icarus Medical Innovations has been a registered manufacturer with the FDA since 2020 and has launched many successful product lines since then. All of the products were exempt from FDA approval per FDA CFR 890.3475[21]. Our brace was a further improvement upon a current brace from Icarus and was exempt from this FDA approval as well, making it eligible to be brought to market immediately.

We understood that though we were exempt from the vast majority of premarket regulations, if we wanted to make any claims about medical effectiveness or validity, human trials would be necessary. Therefore, although FDA approval was unnecessary, clinical trials were still required for us to make specific medical claims prior to bringing the brace to market. Device good manufacturing practice (GMP) requirements are outlined to establish standards to promote the manufacture of safe, consistent, and effective products[21]. Therefore we must develop a plan for patient testing and determining efficacy of our product to fulfill the regulatory requirements prior to bringing our product to market.

Healthcare and Insurance Classification

We defined our product according to insurance and health standards. Healthcare Common Procedure Coding Systems (HCPCS) or Current Procedural Terminology (CPT) codes provide a uniform language for defining health services (DHS), as well as medical procedures and products for doctors and healthcare professionals. Similar to Icarus’s current Ascender R brace, the KRONOS post-operative brace will be classified as L1845 and L1846 under standard insurance or HCPCS. By definition, L1845 and L1846 refer to a knee orthosis, double upright, thigh and calf brace with adjustable flexion and extension joints, medial-lateral and rotational control, with or without varus/valgus adjustments[22]. This classification also refers to prefabricated items that have been bent, molded, assembled or otherwise custom fit to a patient. The main difference between L1845 and L1846 is that products defined as L1846 are custom fabricated[23]. This is possible via Icarus Medical’s 3D scanning application which allows for braces to be custom fit to the patient's knee.

It is important to define insurance classification to confirm our product is obtainable by patients and hospital networks for distribution. Typically, prefabricated knee orthoses classified as L1845 braces are more frequently covered due to their known efficacy with typical knee procedures and conditions. Custom-fabricated braces defined by L1846 are less likely to be approved by insurance providers because custom-fabrication is more costly.

Typically, coverage is granted to patients who display instances of leg or knee deformity, abnormal thigh or calf sizes, and conditions of low muscle mass[24]. This is relevant to inform future market entry and understand which products we will be directly competing with. Additionally, in defining which codes the brace will be classified as, we can ensure patient accessibility to our product as insurance companies will cover the price of the device. This will further inform methods for market entry and assist in defining which distribution channels Icarus should seek when launching the product.

Mechanical Testing

In lieu of a plausible study involving human trials, mechanical testing was completed to validate the efficacy and safety of the brace system. Equipment and cost limitations restricted the number of tests performed to five, all of which tested for the torque at which the hinge component of the brace failed. These torques were recorded, and the location and mode of failure was noted as well.

For each test, a single upright component of a brace was used, as opposed to an entire brace with two uprights, as shown in Figure 2. This reduced costs and space within each print cycle. The hinge on the upright was assembled, and the hinge pin cap was inserted into the hinge to mimic the "lockout" function of the brace. The hinge pin caps used were modified such that only one plug was used to lower the failure torque to more testable levels. Additionally, two hinge pin cap design conditions were tested: one with a metal dowel inserted into the pin, and one made entirely of the plastic material used by the 3D printer. After accounting for this change, we used a force meter to find the failure torques for each trial and found that our brace is able to withstand an average of 145 Newton-meters of torque in the metal dowel design and 119 Newton-meters in the entirely plastic design. Both are significantly greater than the physiological average torque of 70 Newton-meters produced by the flexor muscles in the knee[25].

Figure 2. Mechanical Testing Setup.

The most common mode of failure was the insert holes into which the hinge pin cap plugged on the main upright frame of the brace. Just under half of all failures (43 percent) included a failure of this type. Other failure modes included breakage of the upright gear (29 percent), failure of the upright body (14 percent), and failure at the pins on the hinge cap (14 percent).

Institutional Review Board (IRB) Approval Progress

To test the effect of our novel brace on promoting better patient outcomes, we intended to conduct a human study comparing our brace to braces used under the current standard of care following TKA and ligament repair surgeries. We hypothesized that our brace would facilitate a more rapid return to normal daily activities for patients that used it, and we developed a detailed protocol to outline the manner in which we planned to measure these results in a quantitative manner. The four tests included in the protocol are: a 30-second stair climb, a six-minute walk, quadricep activation evaluation using EEG, and tracking of Knee injury and Osteoarthritis Outcome Score (KOOS).

A lack of definitive relationships to surgeons willing to participate in the study within the University of Virginia Health System combined with our restricted timeline as graduating students ultimately paused our efforts to execute the protocol. However, the protocol, with minor alterations, could be used in a future study.

Discussion

Interpretation of Mechanical Testing Results

As previously stated, mechanical testing was limited in scope due to cost restrictions and business operation obligations of Icarus Medical Innovations. Additionally, given that our limited testing tools made only failure testing feasible, printed materials could not be reused for multiple tests because their structural integrity was compromised. Thus, only five total failure tests were completed, which vastly reduces the reliability of the results.

Still, the few tests that were conducted were promising. The hinge pin caps for the tests only had the volume equivalent of one pin, but a brace with a fully functioning hinge pin cap would have the equivalent volume of 10 pins. To be conservative in our estimations extending from 1 pin to 10, we chose a linear model. However, we expect that the increase in failure torque magnitude would behave more similarly to a positive exponential curve. This is because each additional pin not only provides extra support, but it also fills in negative space in the inserts, strengthening certain weak points in the testing uprights that would otherwise be absent in a normal brace. Thus, the failure torque of 145 with the metal dowel pin indicates with moderate confidence that our brace can withstand physiological flexion torques as well as additional environmental forces and maintain its structure and functionality.

Limitations

The proposed objectives of our project spanned across the entire medical device development process, from preliminary research through market entry. The broad project scope in conjunction with the 9-month timeline resulted in various inherent restrictions regarding time and resources. Additionally, There is a general lack of flexibility in terms of device materials and development and manufacturing procedure, which limits the potential design options and poses challenges in meeting the ideal values for all design specifications.

Despite being exempt from the vast majority of premarket FDA regulations, human trials are necessary to make substantial claims about medical effectiveness or validity. The intended experimental protocol for patient testing has yet to receive approval from the Institutional Review Board. Because of this, we have been unable to proceed as planned with patient testing and the subsequent market entry process. An alternative plan for data acquisition without patient testing had to be quickly developed and executed.

Additionally, the knee brace market is highly fragmented and competitive with potential top competitors being Donjoy's FullForce Brace, Donjoy's Armor Standard Hinge Brace, and Ossur's CTo OTS Sport Brace[20]. Successful entry to such a competitive market requires an innovative design with significant favorable data outlining superiority in terms of therapeutic benefit, recovery time, cost, and comfort. After market entry, there is a concern of scalability regarding the 3D modeled custom knee brace options. Although Icarus currently outsources 3D printers to print brace components, the complex and time-consuming nature of individualized brace design and manufacturing poses the question of whether the current process will be able to keep up with a growing demand.

Implications for Future Research and Considerations

In order to ensure sufficient mechanism strength and quantify the rehabilitative potential of the novel brace design, further mechanical testing should be conducted. More trials to evaluate the maximum torque the hinge mechanism can withstand will allow the confirmation of the results we achieved in our preliminary mechanical testing.

Additionally, extensive patient testing and further market analysis are crucial to ensure patient safety and device success upon official market entry.

Future Patient Testing

An experimental protocol was developed to evaluate the efficacy of the novel brace mechanism as a post-operative knee rehabilitation aid. Collaboration between Icarus and specialists in orthopedic surgery helped to inform the selection of necessary patient tests and facilitate the refinement of our experimental protocol design. A proposal outlining the intended patient study protocol was submitted to the Institutional Review Board for approval in January of 2023. When the patient testing protocol receives the necessary IRB approval, Icarus will be able to move forward with acquiring study participants and conducting the outlined procedure.

The intended experimental protocol consists of four tests of patient performance and progress: a 30-second stair

climb, a six-minute walk, quadricep activation evaluation, and tracking of Knee injury and Osteoarthritis Outcome Score (KOOS). The thirty-second stair climb and six-minute walk will be used to evaluate the patient's return to normal activity, quadricep activation will be measured using an EMG during various simple movements, and the KOOS score tracking will serve to quantify knee joint pain and swelling throughout recovery. As depicted in Figure 3, the patient testing will take place over the course of four visits: pre-operation, 2 weeks post-operation, 6 weeks post-operation, and 12 weeks post-operation.

The intended objectives regarding patient testing are to validate brace efficacy in supporting knee operation recovery and to obtain favorable quantitative data to improve future brace marketability. The patient test results would ideally reveal faster recovery times and superior therapeutic effectiveness in our brace over competing rehabilitation options.

	Visit 1 (Pre-Op)	Visit 2 (2 Weeks Post-Op)	Visit 3 (6 Weeks Post-Op)	Visit 4 (12 Weeks Post-Op)
Study Week	-1 or -2	2	6	12
Informed Consent	x			
EMG Sit-to-stand Test	x		x	x
6 Minute Walk Test	x		x	x
30 Second Stair Ascension Test	x		x	x
KOOS Questionnaire	x	x	x	x

Figure 3. Patient Testing Protocol Outline. An overview of the experimental protocol for patient testing, which will occur over the course of four visits. This table indicates when each patient study will be conducted.

Market Entry

After patient testing, the next step is to formulate a market launch strategy. Given hospitals and clinics hold 42% of the knee brace market, Icarus can leverage their current relationships with the department of orthopedic surgery at the University of Virginia to reach clinicians and surgeons that work with knee operation patients[20]. The support and expertise of medical professionals will improve company credibility and exponentially increase industry exposure.

In order to ensure success upon entering the highly fragmented knee brace market, further market research must be conducted to determine the most sought after characteristics of a rehabilitative brace as well as how to best present the mechanical and patient data to highlight such characteristics. It is important to utilize favorable patient test data and favorable user claims to advertise the benefits and efficacy of the design

Because there are countless knee braces currently on the market, it is essential to highlight the distinctive features of the novel design, including the following: the ability to serve as an immobilizing brace, the adjustable unloading component, and the capacity to serve as a functional brace after operation recovery. Further consultation with medical professionals will help to inform how to proceed in acquiring new patients and gaining distinguished recognition in the industry.

Ethical Considerations

In designing a post-operative knee brace designed to improve patients' quality of life, there are many ethical considerations that need to be made. One biomedical ethics issue that arises from our project is patient privacy. Because our project includes patient testing and collecting patient data, accessibility and gaining the rights to personal health information is necessary to determine our product's capabilities. The brace itself needs to be worn by multiple participants to adequately track how the brace assists in their post-operative rehabilitation. The ethical dilemma we encounter is maintaining privacy in the collected data and ensuring transparency in how we utilize the data in our analysis. Another ethical issue that arises with custom medical devices is ensuring inclusivity among all demographics. Medical devices are often made to fit certain body types, but such designs can marginalize certain individuals with unique characteristics. This means that we had to consider different treatments that require post-operative knee stabilization in our design plans as well as developing a product that could be custom modeled to each patient's physiological structure. Perhaps most obviously, swelling after a knee operation differs greatly among patients after surgery, so including features to account for changes in knee size over the recovery process were necessary.

These considerations also introduce the issue of accessibility to the product. Custom-modeled products are not always covered by insurance, so feasibility of cost must be considered when developing a product if we hope to reach and include all of the post-operative clientele. Our brace will be relatively inexpensive compared to many other post-operative knee braces, but for any patient that does not have insurance coverage, the cost of our brace might prevent them from accessing it. To address this issue, we designed our brace with the intention of

minimizing production costs as well as making it versatile enough so that the brace can be used across multiple steps of recovery, eliminating the need for subsequent knee brace purchases. The current standard of care after significant knee surgeries poses the risk for long term mobility reduction. The recurrence of knee pain, even after surgery, is common. Furthermore, patients who opt to forgo knee surgery after injury or development of osteoarthritis risk a rapid decline in knee health and mobility. Patients could experience abnormal healing and recovery patterns as a result of our brace, which would impact their overall wellbeing and health; however, we hope to limit the risks posed by the current standard of care and promote the long-term health and mobility of each patient to the best of our ability with this novel design.

End Matter

Author Contributions and Notes

S.F.A, M.J.C., T.S.B., L.K., and K.C.T. worked in conjunction to do background research and investigate prior art, aid in the development of the brace design, perform mechanical testing to the brace, develop an IRB protocol, and write this paper.

G.M., D.J., and B.C. worked as advisors and mentors and connected Icarus Medical Innovations to this project.

The authors declare no conflict of interest.

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