
# 2023

# ROTOGEAR

University of Illinois at Urbana-Champaign

## Final Report

**Authors**

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## ACKNOWLEDGEMENTS:

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## INTRODUCTION:

A ROTOGEAR is a knee brace that helps prevent several knee injuries, including osteoarthritis, ligament tears, and meniscus tears. It is designed for healthy adults, athletes, and those with recurrent mild knee pain, and can be worn during physical activity.

## KNEE ANATOMY:

It is important to have a basic understanding of the knee before diving into our report. The knee is a part of the body described by the connection of four bones: the femur, patella, tibia, and fibula. A joint is where cartilage on two different bones are in contact, and there are 3 pairs in the knee - femur/patella, femur/tibia, and tibia/fibula. Each joint has articular cartilage and meniscus - made from a fibrous type of cartilage - which acts as a shock absorber and adds some stabilization to the knee. Synovial fluid is in the empty space between the different types of cartilages, and allows for smooth flexion and extension of the knee. Tendons are tissues that bind muscle to bone, and ligaments bind bone to bone. The basic muscles around the knee are composed of the quadriceps muscles, hamstring muscles, gastrocnemius muscles, soleus, and tibialis anterior.

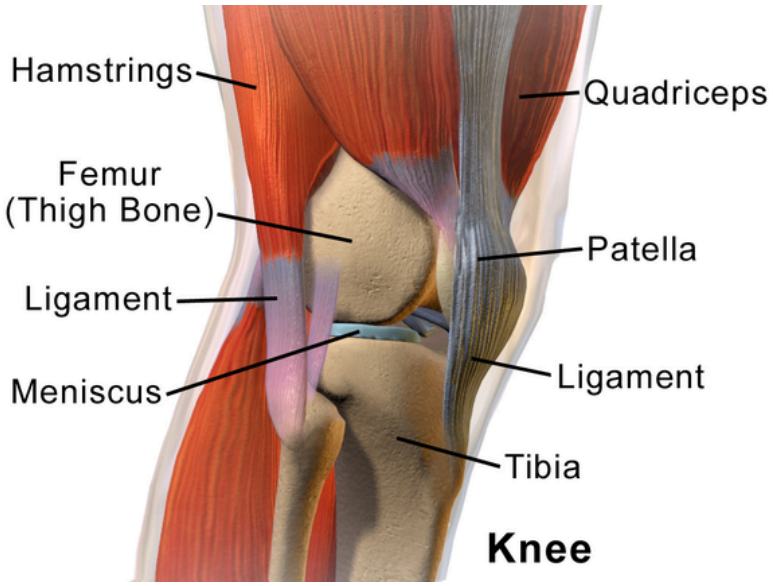
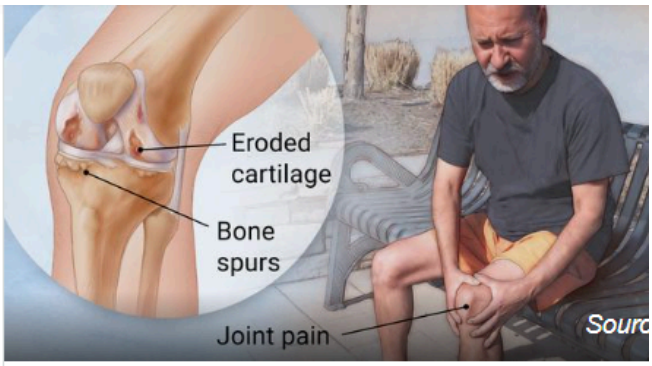



*Figure 1: Basic Knee Anatomy (Source: Wikipedia)*

## PROBLEM BACKGROUND:

The most important thing about a solution is its ability to solve a problem. If a solution does not effectively solve a pressing problem, the solution is not viable. If a solution solves a problem that does not exist, time is wasted. If a solution solves a problem but introduces several other problems with it, the solution is not ethical. Starting a successful business in today's age requires three cardinal prerequisites as criteria: viability, time, and ethics. Once those criteria are met, then we can worry about making money.




A type of arthritis that occurs when flexible tissue at the ends of bones wears down.

The wearing down of the protective tissue at the ends of bones (cartilage) occurs gradually and worsens over time.
Joint pain in the hands, neck, lower back, knees, or hips is the most common symptom.
Medications, physical therapy, and sometimes surgery can help reduce pain and maintain joint movement.

Very common

More than 3 million US cases per year

- Treatment can help, but this condition can't be cured
- Requires a medical diagnosis
- Lab tests or imaging often required
- Chronic: can last for years or be lifelong

*Figure 2: Osteoarthritis (Source: Google)*

The critical problem ROTOGEAR is solving is knee injury prevention. We stressed in our midterm report the severity, scope, and importance of knee injury prevention. For example, osteoarthritis is the most common joint disease in the world, affecting roughly 10% of adults in the U.S. (~33 million). It happens from slow articular cartilage degradation over time, due to a multitude of factors, including improper nutrition, genetics, age, gender (sorry women), obesity, overuse, and misuse. It is so common because there are so many factors that can cause it. It also happens to be most prevalent in the hands, hips, and knees. Osteoarthritis has no cure, since cartilage does not grow back naturally; that is why prevention is critical. Knee injuries are the most common type of injury (more than concussions) in the NFL, especially ACL/PCL tears and meniscus tears. NBA injuries are predominantly in the ankle, followed by knee injuries in second. Runner's knee affects nearly everyone, and can put a halt to your training schedule and aspirations for a personal best at track meets; I know for me it certainly did.

Clearly, the problem we are solving is extremely crucial. With all the types of knee braces that are on the market, you would think knee issues would have been solved by now. There are hundreds of brands out there, and it's no surprise knee braces are currently a hot research topic in the field of rehabilitation science and kinesiology. In this section, we are going to dive into the different types of knee braces on the market, their biomechanical interactions on the leg, and their abilities to prevent knee injury. We'll start with the worst product, and end with the best one currently on the market.

## COMPETITORS:

**Ankle weights:**

The worst kind of knee injury preventative device out there are ankle weights. What the designers of ankle weights had in mind was creating a simple, cost-effective, and affordable solution to improve the efficiency of muscle development around the knee during workouts or runs. Stronger muscles around the knee mean more load taken from the joints, which results in a more injury-resistant knee. However, ankle weights do not accomplish any of this. They have

been medically proven to cause a muscle imbalance, putting more force through the quadriceps muscles and less on the hamstrings. This occurs because there is extra resistance on the way up (quads do the work), but none on the way down (gravity does the work). So when you try to run with them, your feet awkwardly slam to the ground. A couple weeks of use will not do too much, but after a month your risk of knee injury will be increased due to muscle imbalance. Ankle weights are also designed to be mounted on top of the ankles, which puts stress and strain on the tendons and ligaments in that area, unnecessarily weakening them. Unlike cartilage, tendons and ligaments do grow back and repair themselves from microtears, but the recovery time takes much longer than muscles - 3 months vs several days for muscles. If a medical professional redesigned ankle weights, they would probably make it a weighted leg brace that redistributed the weight over the entire leg, rather than it being a point mass all at the ankle. This would remove the strain at the tendon and ligaments in the ankle, and would be a safer product. However, they would still cause a muscle imbalance in the leg due to the existence of gravity, and most uneducated people would still buy ankle weights instead of the leg vest because they're cheaper, smaller, and look less intimidating to wear. Ankle weights are just not the way to go.


*Figure 3: APEXUP, $25 for a pair (Source: Amazon)*

**Compressive knee sleeves:**

The next product that is a bit better than ankle weights is a compressive knee sleeve. There are hundreds of these types of products all on the market, due to their high demand, low profile, and low cost. People typically buy these if they have moderate joint soreness. They work by providing a slight compression around the knee, which stabilizes the knee by keeping the joints of the knee in place. This is good for people who have micro misalignments in their knee joints (the source of pain); the compressive brace will keep the joints from shifting and ensure contact in areas with the most amount of cartilage. However, this is the only benefit they have to offer. Firstly, they are made of compressive material, which means it limits the amount of blood flow going to muscles around the knee. This is dangerous because your muscles need essential vitamins, water, amino acids, oxygen, and glucose to function. Less blood flow results in less oxygen going to muscles. Less oxygen present for muscle cells means the preferred metabolic pathway for catabolism of glucose is through fermentation, rather than aerobic respiration. Just 2 ATP are produced per glucose molecule, compared to 38 ATP from aerobic respiration. Hence, your leg muscles are going to have significantly less energy with a compression placed on your knee, which can decrease your baseline of athletic performance if worn repeatedly for months. Also, there will be less amino acids going to your muscles, which means less protein synthesis, and a stunted muscle development. This lessened muscle activity will be a signal for your body to send the resources to other muscles that are not being suppressed. Ligaments and tendons also require water, collagen, and vitamin C, so compressing them is also a recipe for disaster. Although they are good for reducing mild pain temporarily, they do not reduce the risk of future knee injury. There are several angry and injured reviewers on these kinds of sleeves on Amazon who have worn sleeves for months, warning buyers not to sacrifice their joint health and money. One user complained of a weakened knee joint after prolonged use for months, taking him over 6 months to regain his knee strength back. The user, John, bought a copper fit compression knee sleeve, one of the most popular brands out there (Figure 4).


*Figure 4: Copper Fit Knee Sleeve, $20 (Source: Amazon)*

**Compressive hinged knee braces:**

Compressive hinged knee braces are like compressive knee sleeves, but with maxed out stats. Think of them as compression sleeves on steroids. They offer higher compression which is oftentimes adjustable with velcro, more stability with sturdy hinges, and have the added "benefit" of reducing force on joints. Unlike sleeves, they reduce forces because they are made of thicker nylon/neoprene, which acts as a shock absorber and takes some of the force every time your leg impacts the ground. These are good for people who have more serious joint pain and want a stronger remedy than sleeves. However, these are only a temporary solution, because prolonged lessened forces means muscles don't have to work as hard, which is dangerous in the long term. They do the same long term damage as knee sleeves, but on a bigger scale. They aim to temporarily reduce pain in the short term, but fail in the injury prevention department - just

like sleeves. The only reason I ranked them higher than sleeves is because most of them have patella stabilizing frames and adjustable compression straps, which are two great features to have despite the other consequences they bring.


*Figure 5: DR. BRACE ELITE, $30 (Source: Amazon)*

**Unloader braces (UC and TC):**

Unloader braces are worn by people with more severe knee pain, typically those who are coming off a ligament tear or surgery, as well as the elderly which disproportionately suffer from osteoarthritis (Affects 7% of world's population, according to the CDC). They work by adjusting a knob on the side of the brace which provides support to the patella either in the medial or lateral direction only, if it is a unidirectional unloader brace (UC). Some models have internal springs which significantly decrease the load on knee joints, an innovation that is very helpful for the elderly suffering from OA. They are designed to be worn only during the recovery period of injured athletes, and unfortunately those suffering from osteoarthritis must wear them for their lifetime, due to the immense aching they feel in their knee joints. Tricompartment unloader

braces (TC) can shift the patella to both the left and right, which is very helpful for those with pain in an unconventional side in their knee, or fluctuating pain on the left side or the right. The goal of these bulky braces is to redistribute and reduce loading on the joints in the knee: the patellofemoral, medial tibiofemoral, and lateral tibiofemoral joints. Studies have proven that they do indeed work, but they decrease forces in the quadriceps muscles and quadriceps tendons, measured via electromyography. According to a study published in March 2023 by Emily L. Bishop et al, they asked 8 participants with OA to perform basic chair raising and lowering exercises with a TC knee brace on and off. They found force reductions in the vastus medialis by 41% to 55%, and 30% to 39% in the vastus lateralis. We know that force reductions in muscles lead to a greater risk of knee injury, but the vast majority who require an unloader brace suffer from OA which is not curable anyways. Unloader braces are quite decent for OA management, but we all know prevention is better than cure. Ankle weights, knee sleeves, knee braces, and unloaders are all knee devices that still do not offer any sort of form of long-term injury prevention. That is until this next exercise/device is introduced.

*Figure 6: Komzer OA Unloader Knee Brace (UC), $123 (Source: Amazon)*

**Underwater running pods:**

This exercise is currently the best form of knee injury prevention on the market, and is used extensively by athletes to build muscle and endurance on recovery days. It's an especially prescribed exercise for rehabilitation athletes coming off a torn ligament or tendon. The continuity and fluidity of water is soft on the joints of the body, with no bad side effects. The higher viscosity of water significantly increases the rate of muscle synthesis, and more leg muscles equals less chance of knee injury. However, they are wildly inconvenient and expensive, taking up a huge amount of space. Only rich people can afford them; for the majority of people, they have to run in communal and shared pools. The inconvenience of going to a public pool to get benefits from this kind of exercise is a deal breaker to a lot of student-athletes like myself, as I rarely have enough time for a pool session at the ARC. If there was some sort of passive device like a knee brace that had similar benefits - but on a smaller scale - as an underwater training pod, I would totally buy it. Except that didn't exist. So I got to work.


*Figure 6: HYDROWORX 350, Price unknown (Source: HYDROWORX)*

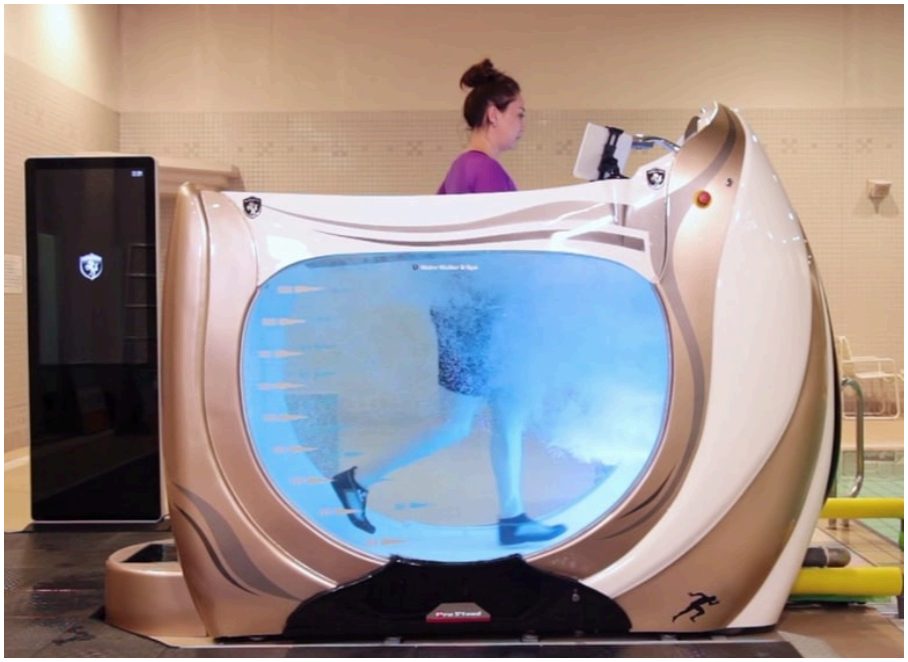


*Figure 7:Water Walker Spa, $89,000 (Source: Jacob Osborn)*

## OUR SOLUTION:

ROTOGEAR is a knee brace that works like an underwater training pod, except you wear it on your knee. It is the first ever knee brace to run off fluid resistance. Our working prototype is composed of natural rubber (75%), PLA (20%), brass (.3%), steel (.7%), polyester (3%), and neoprene (1%). It is designed to be worn during physical activity and is an injury-preventative device. It straps on with adjustable velcro, and with a breathable design for optimal oxygen diffusion and athletic performance. We recommend ROTOGEAR for athletes, those looking to put an end to their mild knee pain, and casual runners. ROTOGEAR is not for people who currently have osteoarthritis, rather it is a prevention against it. ROTOGEAR will be classified by the FDA next year as a medical device due to its preventative abilities.

## MANUFACTURING:

Building a ROTOGEAR is not difficult, but scaling our company and producing hundreds in the first phase of our startup is the tricky part. That is why we must streamline the manufacturing and assembly process and make a standardized design. We will try to partner with as many machining companies as possible to get the biggest bulk discount on injection molded parts. ShapeMaster is a facility in Ogden, IL that specializes in injection molding and vacuum forming, and they're usually fair on pricing. MPR also does injection molding and are based in Elgin, IL. We want to try to stay as local as possible to reduce shipping costs as much as we can. For the first phase of our business, however, we are going to run our shop with 15-20 3D printers. The parts in ROTOGEAR are small anyway, and throughput will be very fast. A sewing machine will be needed to sew the braces together, (which I already have!), thanks to the budget given to us by ISE. We also need one SLA printer to print the molds for the injection molding process itself. Using SLA instead of CNCing aluminum molds literally saves thousands of dollars, and the isotropic properties of SLA resin allow it to withstand the heat from the injection molding process. Once we gain a substantial amount of revenue to scale, we can afford to outsource plastics manufacturing to injection molding companies, generating high volumes of product at a much lower cost. An order for several thousand injection molded parts will cost roughly several cents per part, making it very cost-effective in the steady-state phase of our business.

**BUSINESS GOALS:**

1. **Company Overview:**

   ROTOFIT is a startup composed of three students who have a passion for innovation within the fitness industry for enhanced wellness. Our newest device is a knee brace called ROTOGEAR, which reduces the risk of knee injury in the future.

2. **Our Mission:**

   Our mission is to excel in osteoarthritis, ligament tear, and meniscus tear prevention. We want to improve the athletic ability of athletes while being as environmentally sustainable as possible.

3. **Unique Selling Point:**

**Ⅰ. Dual functionality:**

ROTOGEAR combines both the benefits of an ankle weight that enhances athletic performance and traditional braces, with better protection and injury prevention. The versatile tool can therefore be applied to a wide range of users that are appealed by such convenience.

**Ⅱ. Fluid resistance:**

Fluid resistance is a novel application for the design of brace knees. The fluid resistance statistically improved the protection that knee braces can bring to the users. Both the functionality and the novelty of the design improve the market expectation of the product.

**Ⅲ. Customized resistance:**

Compared to the traditional ways of switching to the weight desired in an ankle weight, ROTOGEAR offers an easier way to merely switch rotors. The improvement in user experience increases its competitive advantage in the market.

**Ⅳ. Exterior Design:**

The exterior design of ROTOGEAR distinguishes itself from its common competitors. The design is visionarily more drastic and thus more aesthetically appealing to the market.

4. **Target Consumers (people with recurring joint soreness/knee injuries, especially athletes):**

The advantages of ROTOGEAR over its main competitors guarantee a wide range of target customers appealed by both the protective and training functions of our product.

a. **Segment Overview**

**Ⅰ. Sports enthusiasts/ professional athletes**

Age range: 16 - 40 (the range captures most pro and semi-pro athletes)

Interests: participation in intensive sports whereas the bottom part, especially the knees, is highly demanded. Specific examples may include basketball, track and field, soccer, etc.

Demand: the group generally suffers from knee-related injuries and recurring joint soreness from the actions involved in the process of high-impact

activities. To reduce the chance of injuries while enhancing athletic performance, the group would require products with dual functions of both protection and training.

**Ⅱ. Patients in knee rehabilitation**

Age range: may include a broad spectrum, with the primary focus on adults over 30 years who have higher chances of knee injuries or surgeries.

Interests: interests may vary among individuals.

Demand: factors of knee injuries may include sports, daily activities, weather, etc. Knees are more prone to damage from the factors above with the increase in age. Therefore, the group shall demand a product that ensures the dual functions of both treatment and future damage prevention.

**Ⅲ. Fitness and health-conscious individuals**

Age range: adults between the range of 18 - 50 who regularly go to the gym or similar fitness routines.

Interests: continuous fitness capabilities, innovative methods that add efficiency and efficacy to their workout regimes

Demand: Multi-purpose supplemental devices that enhance the workout intensity while providing protection against common knee injuries caused by exercise

**b. Demographic Profile**

**Ⅰ. Gender**

There is a balanced focus on all genders since interests in sports and fitness vary widely across the range.

**Ⅱ. Income Level**

ROTOGEAR targets individuals from middle to higher-income groups who are more likely to invest in quality health and fitness equipment to enhance the safety and efficiency of training.

**Ⅲ. Educational Level**

ROTOGEAR targets individuals with higher education levels since the group statistically has higher health consciousness and are more willing to invest in our product.

**c. Psychographic Profile**

The group lives in active lifestyles with regular exercise routines to follow. In addition, the group is also technology pursuers who are fond of the benefits brought by

**5. Market Analysis:**

ROTOGEAR can be defined as a medical device and a sports accessory that provides protection and training for the users. Therefore, as compared to its two main competitors, both markets for knee braces and ankle weights can be considered potential markets for ROTOGEAR.

**Ⅰ. The market for knee braces**

Based on a four-year span of research report on the market size of knee braces from 2014-2017, the global market size is estimated at 1.5 billion in 2018 and a 4.3 percent growth in the next year. The major propellers that are responsible for the growth are the growth in osteoarthritis within the target consumers and the improvement in the wear-effectiveness of the knee braces compared to the past.

According to Stanford Children's Health, around 3.5 million children aged 14 and below are affected by some form of sport-related injuries every year, and 9 percent account for knee injuries. In addition, there has been a fivefold increase in ACL injuries in children with their rising interest in athletic activities. These factors are expected to drive the demand for prophylactic and functional knee braces. The market size is estimated to rise at a faster pace within twelve years from the beginning of the research and the market shares of the four types of common knee braces (Prophylactic, Functional, Rehabilitative, Unloader) are expected to remain around the same with a minor increase in the first two types.

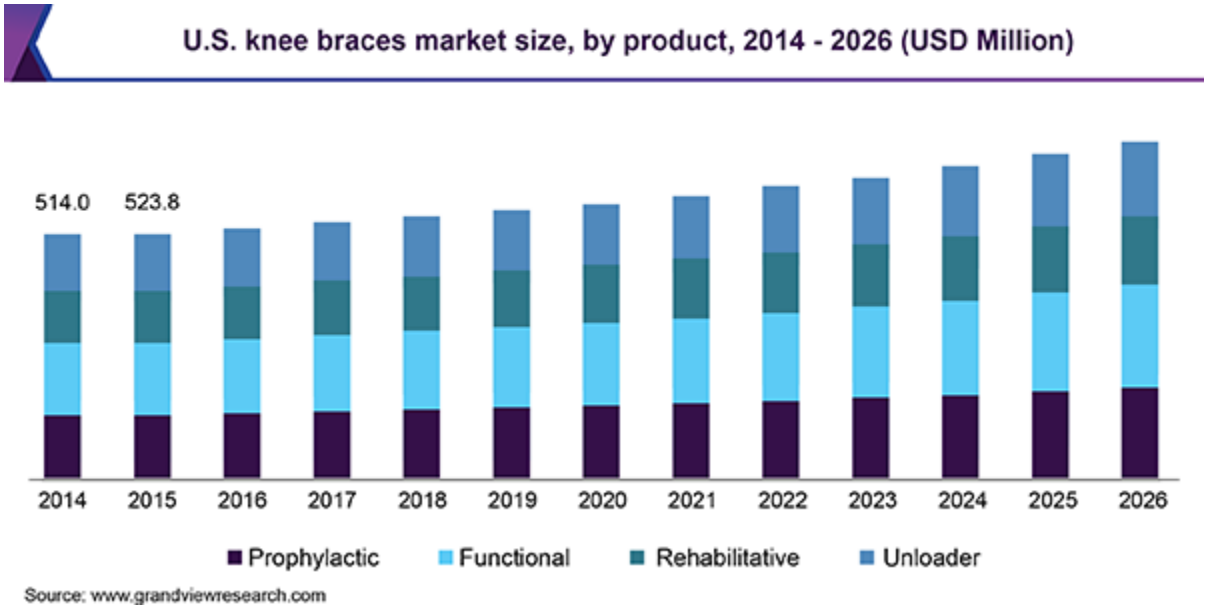



*Figure 8: U.S. knee braces market size, 2014-2026*


*Figure 9: Knee Braces Market*

**Ⅱ. The market for ankle weights**

Based on an exterior report "Global Ankle Weight Market By Type, By Application, By Geographic Scope, and Forecast", the market size of ankle weights is expected to develop revenue and exponential market growth at a remarkable CAGR during the forecast period from 2023 to 2030.

The growth of the market can be attributed to the increased need for ankle weights due to the increasing consciousness of health and the need for exercise. The trend will keep increasing within the period from observation on the report as the market size.


*Figure 10:Ankle Weight Market Size and Scope*

## 6. Marketing Entry Strategy:

As university students, we are faced with difficulties in promoting our products due to a lack of opportunities and money. In addition, since there have been many mature sports and medical brands in the market, customer loyalty to these brands may be another problem. The high competition in the market may narrow the sales of our product in the market.

### Ⅰ. Before Patent

Before the successful application of the patent, ROTOGEAR will be regulated by FDA legislation prior to market entry. In addition, without legal protection of our product, the design and technological competence of ROTOGEAR can potentially be violated by competitors in the market.

In order to attract external investment and hype in the market, we will start from the website Kickstarter. We have created a file for our product Kickstarter on which the investors who are interested in ROTOGEAR can have access to our goals and mission. More information about the product including the specifications, technical analysis, and business analysis will be made public in May, only after the patent application is applied. This platform provides a convenient way to connect with potential investors and interact with the community before it is released.

In addition, we will upload events to the website of our brand ROTOFIT so interested consumers and students can meet with us in person from our official website. In the past, we've done showcases at the ARC and set up a booth at EOH, where we had great interactions with the public and gathered information on customer discovery.

**Ⅱ. After patent**

After the successful application of the patent, ROTOGEAR will be eligible to enter the market, and will be only sold on our website. In future years, we will consider E-commerce platforms such as Amazon to promote and sell our product to attract a wider range of consumers. After gathering revenues from external investment and sales, we will further promote our product through online advertisements and contact large-scale dealers such Dick's, Walgreens, etc.

**7. Pricing Analysis:**

**Ⅰ. Competitor Pricing**

The prices of the knee braces differ greatly from each other. For common knee braces that aren't for medical uses, the average price lies within the range of $30 - $50. For medical use knee braces, the prices are usually higher and differ greatly from brand to brand, with most of them listed higher than $100.

**Ⅱ. Cost-Based Pricing**

We will set the initial selling price at $95. The price that we set is higher compared to most of the main competitors of ROTOGEAR . However, since the manufacturing price is higher for the fluid resistance mechanism than the traditional mechanism, which at the same time brings a much better effect, the

price is proper. In addition, marketing and advertising are likely to create extra fees for the product besides manufacturing, forcing us to set a higher price than the market.

**Ⅲ. Value-Based Pricing**

It is true that the price of ROTOGEAR is higher than many products in the market and higher than the average price of knee braces. However, ROTOGEAR has utilized a novel technology that brings better effects while combining the dual functionality of knee braces and ankle weights. The dual functionality will make the use of the product more convenient than having the functions separate. These features will increase the acceptability of the price to the consumers.

**8. Business graphs projections by quarter:**

**Ⅰ. Total revenue estimation by quarter**

We have estimated the quarterly revenue that we will gather after we have published our product into the market. The expected release date of ROTOGEAR is October 2024, and each quarter represents 3 months. We will consider the first five months to be the period in which our product is paid less attention due to it first being released in the market. However, after the successful application of the patent and our further promotion, we believe that our product will achieve success in the market and increase rapidly as shown in the graph. The raw data sheet is attached below.

| Rotofits Sold | Average Price | Estimated Revenue by Quarter |
|---|---|---|
| 1 | 95 | 95 |
| 5 | 95.665 | 478.325 |
| 25 | 96.33 | 2408.25 |
| 50 | 96.995 | 4849.75 |
| 100 | 97.66 | 9766 |
| 250 | 98.325 | 24581.25 |
| 500 | 98.99 | 49495 |
| 1000 | 99.655 | 99655 |
| 2500 | 100.32 | 250800 |
| 5000 | 100.985 | 504925 |
| 10000 | 101.65 | 1016500 |
| 20000 | 102.315 | 2046300 |

*Figure 11: Sales, Price, and Revenue, post October 2024*

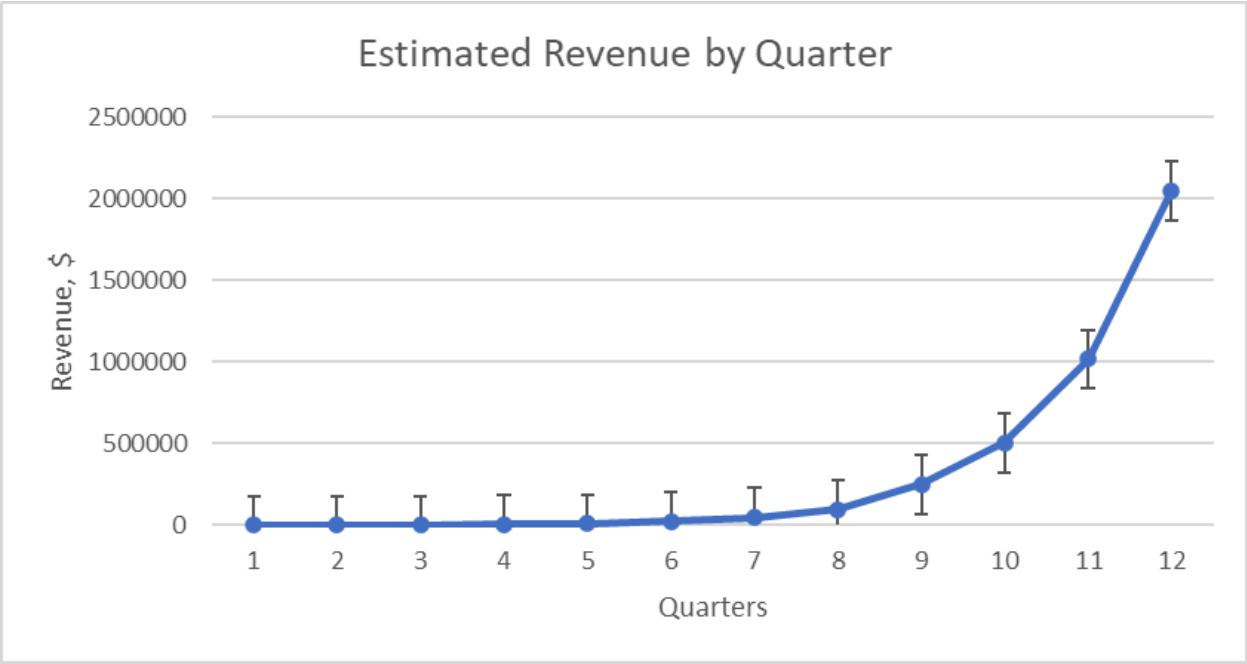



*Figure 12: Estimated Revenue by Quarter*

## Ⅱ. Gross Profit Estimation

By estimation and calculation, we have decided on the initial funds that we need to achieve profits and the profits projection by quarters. During estimation, we have assumed the average inflation rate per quarter of the price of ROTOGEAR to be 0.70 percent and the raw material inflation per quarter as 0.60 percent.

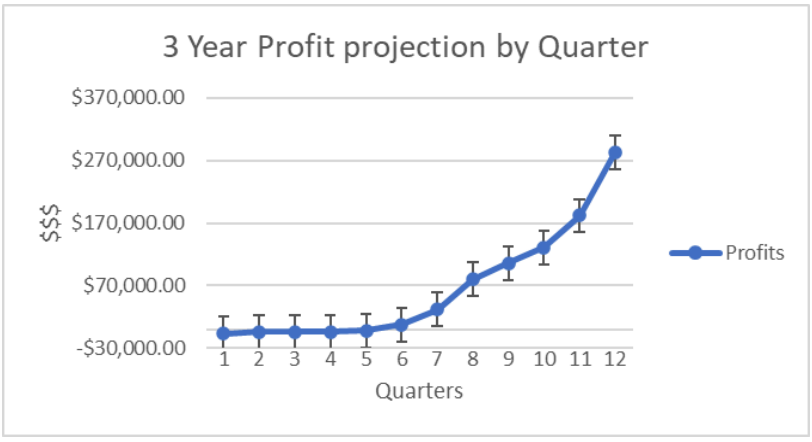



*Figure 13: Profit projection by quarter over 3 years*

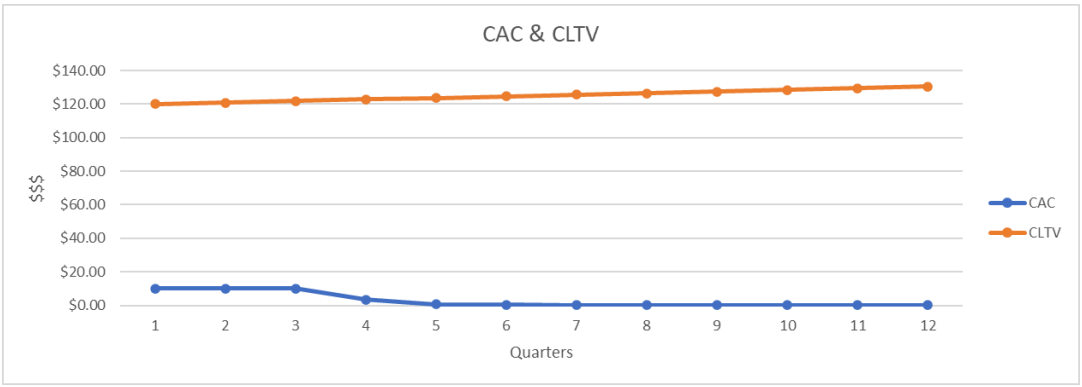
| Gross Profits by Quarter | Total cost to manufacture a Rotofit (includes everything) | Rotofits sold | Retail Price | Profits per quarter (cash flow) |
|---|---|---|---|---|
| 1 | $35.00 | 5 | $95.00 | -$6,881.25 |
| 2 | $35.21 | 10 | $95.67 | -$3,848.95 |
| 3 | $35.42 | 15 | $96.33 | -$3,613.05 |
| 4 | $35.63 | 30 | $97.01 | -$4,225.25 |
| 5 | $35.85 | 100 | $97.69 | -$2,111.24 |
| 6 | $36.06 | 300 | $98.37 | $7,411.06 |
| 7 | $36.28 | 800 | $99.06 | $31,482.91 |
| 8 | $36.50 | 1800 | $99.75 | $80,074.40 |
| 9 | $36.72 | 2500 | $100.45 | $105,616.65 |
| 10 | $36.94 | 3000 | $101.16 | $131,083.16 |
| 11 | $37.16 | 4000 | $101.86 | $181,650.24 |
| 12 | $37.38 | 6000 | $102.58 | $282,801.69 |

*Figure 14: Quarterly cash flows*

## Ⅲ. CLTV and CAC

CLTV(customer lifetime value cost) represents the extent of how well the product is connecting with the target customers and how they are responding to the products and services we are offering. CAC (customer acquisition cost) measures how much we need to spend to acquire a new customer. By plotting the graph, we found our strategy profitable since CLTV is much higher than CAC of ROTOGEAR.

| CAC | Avg transactions during customer lifetime | CLTV |
|---|---|---|
| $10.00 | 2 | $120.00 |
| $10.00 | 2 | $120.91 |
| $10.00 | 2 | $121.83 |
| $3.33 | 2 | $122.75 |
| $0.71 | 2 | $123.68 |
| $0.38 | 2 | $124.62 |
| $0.15 | 2 | $125.56 |
| $0.08 | 2 | $126.51 |
| $0.11 | 2 | $127.47 |
| $0.15 | 2 | $128.44 |
| $0.08 | 2 | $129.41 |
| $0.04 | 2 | $130.39 |




*Figures 15 and 16: CAC and CLTV*

## ENVIRONMENTAL IMPACT:

Neoprene and nylon are synthetic fabrics that do not biodegrade and are harmful for the environment, found in pretty much every knee brace nowadays. 380 tons of neoprene get disposed of per year, and petroleum is needed to manufacture it. These contaminants can seep into and contaminate our soil and groundwater supply, if not disposed of properly. While using cheaper, synthetic fabrics is way more economically beneficial to us, we choose to use more expensive natural rubber material - a healthier option for our planet. Our prototype is made up of less than 1% metal.

## FDA APPROVAL AND PATENT:

Next year in April will be when we submit the patent application to the USPTO. We were advised by Joe Barich not to reveal anything about the functionality of our brace even in innovation competitions like this, and I still don't know if I should present it on Friday. Even if we do show it, we still have a 1 year grace period to submit the patent application, so there is technically no harm in students and judges seeing it. It's not like anyone is going to steal our idea anyways; ISE students are pretty chill. In June 2024, we will then register our brace with the FDA. Registration is mandatory and just lets the FDA know that ROTOGEAR exists, and it does not mean it is free from FDA regulations. Along with registration, we must satisfy the premarket notification notification (Section 510k), which basically means "we must demonstrate to FDA's satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market" before we legally sell it to anyone (*Source:FDA)*. The good news is that most knee braces fall under Class 1 classification, which 95% are exempt from FDA regulation. The bad news is that our brace has a completely new feature that has never been implemented in a brace before, so it may take the FDA longer to get back to us and give us the green light to sell. Fortunately, if we get rejected by the FDA after submitting our PMN, they have an alternative route for medical approval, called De Novo. It involves a risk based assessment taken by the FDA for completely new products that enter the market which have no prerequisite. (This refers exactly to our device). FDA outlines the two options we have for getting De Novo approval:

## When and How to Prepare a De Novo Request

There are two options to submit a De Novo request for the FDA to make a risk-based evaluation for classification of the device into class I or II.

- Option 1: After receiving a high-level not substantially equivalent (NSE) determination (that is, no predicate, new intended use, or different technological characteristics that raise different questions of safety and effectiveness) in response to a 510(k) submission.
- Option 2: Upon the requester's determination that there is no legally marketed device upon which to base a determination of substantial equivalence (therefore without first submitting a 510(k) and receiving a high-level NSE determination).

*Figure 7:De Novo Request (Source: FDA)*

I'll discuss this again with my professor before making any formal decisions, whether to do option 2 directly or risk it and apply for the 510k. The good news again is that I met with professor Jan in the department of DRES and he assured me that getting FDA approval for our device shouldn't be too difficult. Before we submit anything, FDA recommends we submit a "Pre-Submission" form to gain early feedback on our device before the De Novo request submission. The FDA has everything on their website for all the criteria we need to submit in our request, so we will answer all their questions the best we can.

## HOPE FOR THE FUTURE:

We are really hopeful for the potential of ROTOFIT and especially our newest product, ROTOGEAR. I was hesitant to submit any patent last year for our adjustable dumbbell because I didn't have enough faith in myself to take that big leap, and I was torn in what direction I wanted to take my life in. This year, I have nothing to lose and am going all out with ROTOGEAR. It is my last year of college and I want to leave a positive impact on the fitness industry. I learned so much from last year's challenge and Cozad, and I'm optimistic for next year's competition. In the last 3 months, we pitched our idea at Socialfuse, participated in the BuildIllinois first ever hackathon, were amongst the four best pitches of the night at the POLSKY CNVC kickoff event

in Chicago, developed a heart rate monitor on a breadboard, developed a working prototype, and were awarded $250 from TEC to prototype our fitness products into reality. I'm grateful for anyone who has ever supported us or funded ROTOFIT this past year.

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