

## IntelliSleeve - Novel Monitoring of Knee Biomechanics for Rehabilitation

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### Problem Statement/Background

Amateur athletes and patients with musculoskeletal knee injuries lack a method to consistently monitor exercises and ensure they are using proper form while exercising. The lack of method is caused by user hesitancy to purchasing expensive or obtrusive devices that might accomplish this. However, proper monitoring of the knee mechanics, such as flexion and extension, is essential for prevention of recurrent and costly injuries that may occur due to improper exercise form. Therefore there is a need for a low-cost, simple, and individualized method of ensuring proper form over a wide variety of exercises for both injury prevention as well as injury rehabilitation. The flaw of current technologies attempting to solve the problem leave substantial room in the market to create an effective competitor. Therefore, the team has designed an innovative and cost effective wearable sleeve to monitoring of monitoring proper exercise dubbed the IntelliSleeve.

The market for this type of product is potentially large. ACL tears alone account for approximately 200,000 cases per year in the United States. The device would be targeted towards therapists and doctors, as well as athletes and casual exercisers. There are a few existing solutions, like the Breg Free Sport Knee Brace or the Omniforce Knee Brace. that attempt to tap this market by providing mechanical support to the knee in rehabilitation, however these devices restrict exercise and do not act as a good preventative measure for improper form. Emerging solutions, like the Lynxio Knee Brace, can help in rehabilitation and injury prevention, however they are often obtrusive and expensive.

### Approach/Solutions Considered

There are many diverse and innovative existing solutions that include, but are not limited to, monitoring, treating, and diagnosing musculoskeletal disorders and knee injuries. Table 1 summarizes some the existing products already in the market and provides a benefit-risk summary for each of them.

**Table 1.** Existing products in the market

Product	Benefits	Costs
Breg FreeSport Knee Brace [10]	<ul style="list-style-type: none"><li>• Designed for providing mechanical support for ACL/MCL tears, meniscal injuries, and a wide range of other conditions.</li><li>• Unobtrusive and does not seem to inhibit exercise motions</li></ul>	<ul style="list-style-type: none"><li>• Does not monitor physiological symptoms</li></ul>
Lynxio Knee Brace [11]	<ul style="list-style-type: none"><li>• Measures Knee angle and physiological symptoms</li></ul>	<ul style="list-style-type: none"><li>• Not actually implemented in the</li></ul>

	<ul style="list-style-type: none"> <li>Provides structural and mechanical support</li> </ul>	open market
Omniforce Knee Brace [12]	<ul style="list-style-type: none"> <li>Provides mechanical support to prevent injury and promote healing</li> <li>Athlete design oriented</li> </ul>	<ul style="list-style-type: none"> <li>Expensive (&gt;\$100)</li> <li>Convolved and bulky</li> <li>Somewhat restrictive in exercise motion</li> </ul>

None of the devices listed in Table 1 indicated they are designed to monitor and track fitness routines as well as rehabilitation exercises. Some devices restrict movement altogether, making rehabilitation exercises difficult and sometimes impossible.

An extensive search of the FDA database for keywords like “knee”, “knee rehabilitation”, “ACL”, and “meniscus” indicates no FDA regulated devices that support objective monitoring of knee conditions while simultaneously keeping track of exercises that are required to promote knee healing and effective rehabilitation.

### Design

The target customers are individuals performing particular exercises that involve knee motion and want to better monitor many of their exercises. After speaking with Purdue’s Associate Director of Sports Medicine, size, weight, and ease of application were key components in creating a device that is widely used. She particularly mentioned that ease of application and operation were major factors as to whether the athletes were inclined to use the different options. When attempting to transfer a potential product that better met these needs into private/individual use, cost became an important additional factor. Parameters were established for the determined needs that would make the solution an appealing option for the various potential customers.

Regardless of the customer, it has also been determined key factors that are vital in a final solution to avoid potential harm to the customers and create an ethically sound product. These specifications were made with the intention of developing a product that can be applied and used safely. To meet this the product will need to use materials that are biocompatible (will not irritate the skin), additionally the sleeve should not hinder the person’s ability to perform the exercises in a natural and safe manner. These required characteristics led to the establishment of the design specifications listed in Table 2 below.

**Table 2.** Summary table of design specifications, categorized by user needs.

#	User Needs	DI #	Design Specification
U1	Low Cost	DI 1.1	\$130 or less
U2	Comfort & Ease of Application	DI 2.1	Non-abrasive or irritating to most skins
		DI 2.2	Does not constrict natural leg motion. Adjustable for different patients.
		DI 2.3	Portable, easily removed/applied (time for new user to apply should be <30 sec.)

U3	Monitor knee motion	DI 3.1	Accurately measure knee angle flexion with error of +/- 5 %
		DI 3.2	Real time information is sent to the app (less than 0.5 second delay)
		DI 3.3	Record repetitions for specific exercise
		DI 3.4	Alert user when improper form occurs
		DI 3.5	Produce false positive and negative results at a rate of less than 1 in 40 exercise repetitions
U4	Aesthetic	DI 4.1	<250 grams
U5	Durable	DI 5.1	Impact Resistant: Housing is able to achieve an IK rating of 6
		DI 5.2	Water Resistant: IP value of 3 when housing is in and out of sleeve
		DI 5.3	Battery life: Lasts >2 hours
U6	User Interface	DI 6.1	Does not send user's information to third party sources
		DI 6.2	Application must be easy to navigate. User must be able to reach each function of application in less than three seconds.

### Final Approach

A solution to the problem is a wearable “smart” knee sleeve that would allow both athletes as well as knee injury rehabilitation patients to monitor their activity and ensure proper form over a wide variety of exercises. The sleeve would fit comfortably around the user’s knee and would not impede movement in any way. This would ensure that users are comfortable wearing the sleeve while performing. The predominant purpose of the sleeve would be to monitor the angles at which the knee is bending while performing exercises ranging from jump training, squats, and deadlifts to simpler rehabilitation exercises such as leg extensions. This is accomplished by using multiple motion monitoring integrated circuit devices connected to a central microprocessor to measure the knee angles. The angles would then be sent to a mobile application to interface with the user and provide useful feedback pertaining to the exercise. This sleeve would solve the problem by providing a low cost and effective method for users to ensure they are exercising with proper form, ultimately assisting in rehabilitation as well as injury prevention.

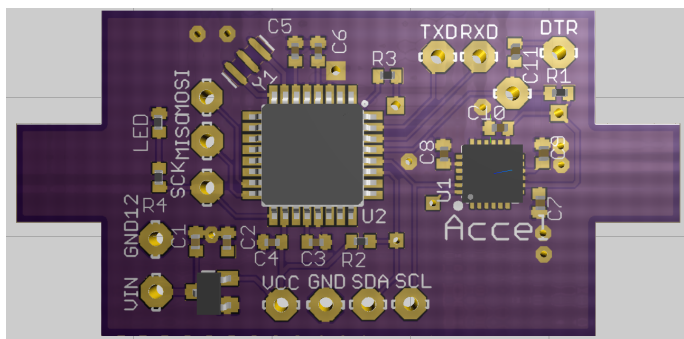


Figure 1. Final printed circuit board design

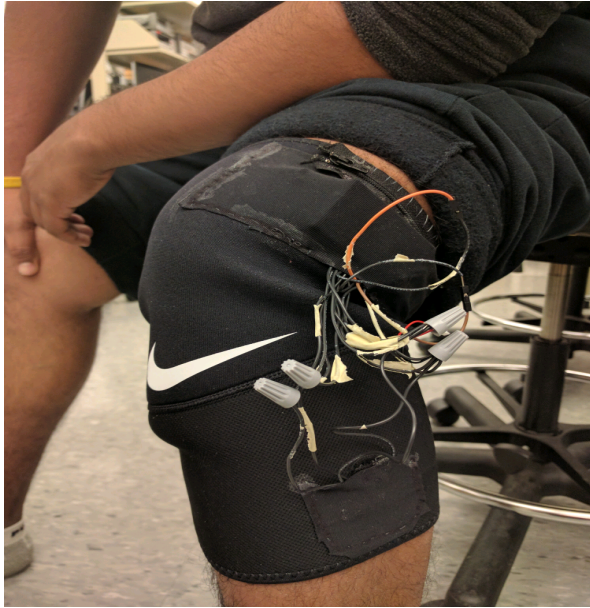


Figure 2. The IntelliSleeve in its final application.

The IntelliSleeve utilizes embedded system design applications to provide an optimal, low-cost way to quantitatively monitor knee and leg angles, ensure proper exercise, and not impede mobility. In order to accomplish this, a microprocessor, two small 6-axis motion monitoring devices, a custom printed circuit board, and a custom iOS application were integrated together to effectively collect data and communicate recommendations to the user. After initial prototype testing, knee angle measurements obtained from the preliminary prototype indicate consistent and accurate measurements for an extensive number of flexion and extension cycles on the knee. This device has also been proven to be nonrestrictive and yet durable enough for nearly any land based activity through rigorous water resistant, impact resistant, and user movement testing.

Ultimately, this device allows both athlete and knee injury rehabilitation patients to monitor their activity and ensure proper form over a wide variety of exercises. The IntelliSleeve is unique because it integrates innovative exercise technology into a sleeve that is comfortable for athletes to wear. However, in order to transition this device to the medical market its capabilities and features need to be expanded. This can be done by analyzing the user and market in greater detail and identifying additional potential needs. Afterwards, extensive research will be conducted in order to determine the feasibility of developing and deploying this altered product into the market. Subsequently, the IntelliSleeve will be sent through the anticipated FDA 510(k) regulatory pathway for controlled clinical testing in order to validate the altered device meets all the FDA's requirements. Once in the market, periodic randomized customer surveys would be administered to ensure the device continues to be safe, effective, and meet consumer needs. Successfully remaining competitive in the market will require taking customer feedback and translating it into product alterations.

### **Outcomes and Testing**

Two-sample t-tests were performed using MiniTab again for each set of leg angle replicates. The generated p-value (probability of deviation from normal) indicated that one subject did not generate consistent angle measurements while the other showed no significant differences in the average peak.

The test for the battery indicated the sample was able to last for more than 4 hours while the device was idle (not sending data to iphone application). While the device was sending data to the iphone, the battery lasted for 3.5 hours after a full charge.

From observing the raw data collected by the serial monitor on the PC and the IntelliSleeve iphone application for 10 minutes revealed the data from the device was able to send 100% of its data both wirelessly, indicating no data was lost along the line of transmission. A follow up observation indicated the system was unable to send all of its data after the sampling rate was switched to 200 Hz (200 samples per second) and completely non-functioning when the sampling rate was increased to 500 Hz.

This data indicates that the device is accurately detecting angle measurements and the hardware is operating as originally intended. In addition to the hardware however, the application functionality was also tested.

In order to validate the product with consumers, it was determined whether or not the average consumer would use the device, the extent they would use it, and the value they saw the product to have. A survey was created that attempted to answer these unknowns. This survey presented potential customers with three vital questions:

1. Would you use this? (No, Maybe, Yes)
2. How often would you use this during the time you exercise? (<25%, 25%-75%, >75%)
3. How much would you pay? (<\$30, \$30-\$50, >\$50)

The answers customers gave can be seen in the table below.

**Table 21.** Survey results as collected from potential customers.

Question			
1.	No: 0	Maybe: 2	Yes: 8
2.	<25%: 3	25%-75%: 4	>75%: 3
3.	<\$30: 4	\$30-\$50: 5	>\$50: 1

### Cost

Currently, the target cost for the product will be \$130. This price based on a survey done by the National Endowment for the Arts, which stated that the average American spends \$130 on exercise equipment per year [7]. Additionally, basic high quality knee compression sleeves without smart functionality range anywhere from \$50-\$200. \$130 is a fair price with the additional functions that this product can perform.

In terms of the financial strategy, working with schools' physical therapy programs, like Purdue's, will be stressed. Jessica Lipsett is an assistant athletic director for Purdue Athletics. If Purdue and other schools can be convinced to use the product, it would be possible to expand to the general public as well as hospitals and physical therapy centers.

**Significance**

Currently in the US there are approximately 200,000 new cases of ACL tears every year [2]. Each of these cases contributes to the total market size in addition to other similar knee injuries. Additionally, there are approximately 55 million gym memberships in the US [4]. If the assumption can be made that a conservative 10% of gym attendees perform exercises which put intense pressure on the knee, such as squatting and deadlifting, 5.5 million gym-goers could benefit from the product. Overall, these very conservative assumptions lead to possibly 5.7 million units in total being sold. This number multiplied by the \$130 price point for each knee sleeve creates a market size of 741 million dollars. This does not take into account many of the gym attendees requiring two sleeves, one for each knee. However, since it is best to use conservative assumptions and estimates, this will not be factored into the total market size.

**Table 3.** A brief summary of the current market.

	Approximate Population	Approximate Monetary Size (\$)
Amateur Athlete Sub-market	5,500,000	715,000,000
ACL Tear Sub-market	200,000	26,000,000
Total Market	5,700,000	741,000,000

The biggest deficiency in this market is that there is no widespread, low cost, effective way to train amateur athletes and patients to consistently exercise properly over extended periods of time. Trainers are very expensive and cannot be utilized at home. Knee injuries require frequent doctor visits as well as X-Rays, MRI's and other diagnosis tools that can quickly add up to a very expensive medical bill. Additionally, surgeries for an ACL tear can total about \$11,500 [5]. There is also a cost to being incapable of going to work for an extended period of time due to a knee injury. Depending on the profession and the benefits given to the employee the cost of this factor could waver significantly. According to UPMC Healthbeat, the average person will require 2-4 weeks after an ACL surgery before they can move around [6]. Using a conservative assumption that the person is working 40 hours a week for \$15 an hour and does not receive paid medical leave, the cost of such an incident would be between \$1,200 - \$2,400 due to being incapable of getting to work. This would total the cost of an injury to be around \$12,700 - \$13,900.

Ultimately, because the IntelliSleeve allows both athlete and knee injury rehabilitation patients to monitor their activity and ensure proper form over a wide variety of exercises, this device

will have a large impact on the way athletes train and patients rehabilitate. The IntelliSleeve is unique because it integrates innovative exercise technology in a sleeve that is not only comfortable for athletes to wear but also provides information in a quantitative, convenient, and objective manner.