Abstract—Knee orthotics play an important role in aiding in the recovery of those with knee injuries, especially athletes. However, structural knee orthotics is often very expensive, ranging between $300 and $800. The primary reason for this project was to answer the question: can 3D printed orthotics represent a viable and cost-effective alternative to present structural knee orthotics? The primary objective for this research project was to design a knee orthotic for athletes with knee injuries for a low-cost under $100 and evaluate its effectiveness. The initial design for the orthotic was done in SolidWorks, a computer-aided design (CAD) software available at Loyola Marymount University. After this design was completed, finite element analysis (FEA) was utilized to understand how normal stresses placed upon the knee affected the orthotic. The knee orthotic was then adjusted and redesigned to meet a specified factor-of-safety of 3.25 based on the data gathered during FEA and literature sources. Once the FEA was completed and the orthotic was redesigned based from the data gathered, the next step was to move on to 3D-printing the first design of the knee brace. Subsequently, physical therapy movement trials were used to evaluate physical performance. Using the data from these movement trials, the CAD design of the brace was refined to accommodate the design requirements. The final goal of this research means to explore the possibility of replacing high-cost, outsourced knee orthotics with a readily available low-cost alternative.

Keywords—Knee Orthotics, 3D printing, finite element analysis.

I. INTRODUCTION

The field of orthotic has developed over time to meet the needs of those who require additional support when performing everyday tasks. Specifically, orthotics in the world of sports have progressed to meet the specifications required to aid in post-injury recovery. One common injury for athletes is the knee joint injuries, which are rectified using knee orthotics. The best type of knee orthotic used for these injuries is structural knee orthotics. However, these braces can cost from $300 to $800 [1], making them an expensive product in terms of recovery. 3D printing represents a possible solution to this economic problem.

3D printing began in 1984 with the process of Stereolithography (SLA) developed by Charles Hull at 3D systems. In 1989, Fused Deposition Modelling (FDM) was created by Scott Crump, which led to the creation of the Stratasys company and rapidly expanded the field of 3D printing [2]. Today, 3D printing is used in hundreds of different applications and is useful in countless different fields. One specific industry that has begun to utilize 3D printing is the medical field, which makes up about 7% of all 3D printing [3]. Orthotics and prosthetics make up a large portion of these medical prints and have begun to offer less expensive and more personalized products.

The process for 3D printing an orthotic begins with a scan or concept measurements for the limb or joint that the orthotic is being designed for. These measurements are used to guide the CAD of the initial knee orthotic [4]. Following the end of design, the model is then tested and analyzed, allowing for the optimization of the design. When this is finished, the model can be 3D printed and ready for use. However, there are some issues with 3D printing orthotics. As noted by Rengier et al.: “The limitations of rapid prototyping include dynamic complexity and improper design, resulting in imprecise modelling” [5].

3D printing often cannot match the exact contours or shape of a joint, meaning that models can be flawed, not fit comfortably, or match up exactly with the forces acting on the joint. This can be an issue especially for the knee joint, as it includes many different forces as well as complex organic geometry [6]. However, with proper attention to details as well as repeated testing, this problem can be overcome. The goal of this project is to do just that and create a functioning, inexpensive knee orthotic.

II. THEORY

To create a stable structural knee orthotic, it is crucial to analyze the forces and stresses regarding the brace and the actual knee. Before jumping into the movement trials and stress testing of the knee brace, it is imperative to complete these theoretical calculations. A research group studying the biomechanics of a bilateral hinged knee brace, similar to ours, has developed a method to model the forces acting on the knee [7]. According to their model in Fig. 1, the knee experiences reaction forces and moments (rotational forces) at the joints of the knee and ankle. Different motions and static positions of the leg that an athlete exhibits during their sport will determine the range of magnitudes of the forces at these connecting points between the limbs of a human leg. A large portion of the design requirements for our knee brace will be based on the forces in this model and how the knee orthotic can establish a safe environment. This safe environment refers to a system of the knee where part of the forces at the knee is counteracted to a point where the athlete is safe from further injury. Additionally, as long as the forces at the knee are reduced enough from the orthotic, the knee can progress in the
The specific equations used to evaluate the safest possible system are:

\[
R_{\text{knee}} + m_{\text{shank}} a_{\text{shank}} = m_{\text{ankle}} a_{\text{ankle}} + R_{\text{ankle}} \quad (1a)
\]

\[
R_{\text{knee}} = m_{\text{ankle}} a_{\text{shank}} - m_{\text{shank}} a_{\text{shank}} + R_{\text{ankle}} \quad (1b)
\]

\[
M_{\text{knee}} - M_{\text{ankle}} = I_{\text{shank}} a_{\text{shank}} \quad (2a)
\]

\[
M_{\text{knee}} = I_{\text{shank}} a_{\text{shank}} + M_{\text{ankle}} \quad (2b)
\]

where \( R_{\text{knee}} \) is the reaction force at the knee joint, \( M_{\text{knee}} \) is the moment at the knee joint, \( m_{\text{shank}} \) is the center of mass of the shank (portion of leg between thigh and ankle), \( m_{\text{ankle}} \) is the center of mass of the ankle, \( a_{\text{shank}} \) is the acceleration of the center of mass of the shank, \( I_{\text{shank}} \) is the moment of inertia of the shank, and \( a_{\text{shank}} \) is the angular acceleration of the shank. Using (1) and (2), the specific forces placed on the knee can be found. These forces can be used for further analysis on the knee orthotic itself. Specifically, the forces can be used to find the normal and shear stress on the orthotic components. The equations to be used are:

\[
\sigma_{x,y} = k (F/A) \quad (3)
\]

where \( k \) is the stress concentration factor, \( F \) is the reaction force found in (1) and (2), and \( A \) is the area of the orthotic component and \( \sigma_{x,y} \) is the normal stress in \( x \) or \( y \):

\[
\tau_{xy} = E \sigma \quad (4)
\]

where \( \sigma \) is the normal stress, \( E \) is the Young’s Modulus of the material of the component, and \( \tau_{xy} \) is the shear stress.

These values can then be put into the Distortion Energy theory to find the factor of safety. The equation for the factor of safety is:

\[
n = S_y / (\sigma_x^2 - \sigma_x \sigma_y + \sigma_y^2 + 3(\tau_{xy}^2)) \quad (5)
\]

where \( n \) is the factor of safety, and \( S_y \) is the yield strength of the material. This factor of safety can then be compared to a selected factor of safety for the component. Following this, adjustments can be made to the component geometry to properly match the desired factor of safety.

Finally, after analyzing the stresses on the components, the overall yield stress for material must also be considered. The knee orthotic was printed using Polylactic Acid (PLA). PLA has a yield stress of 580.2 ksi [8], so any force must have a lower stress value of 580.2 ksi.

### III. PROCEDURE

To complete this project, the following procedure was used:

1. Designed brace components based on gathered average dimensions of model knee
2. Performed FEA to determine if the brace and material was able to handle typical knee and leg forces
3. Saved all part files as STL files
4. The STL files were sent to a 3D printer. The MakerBot Replicator was used for the 1st and 2nd iteration and the Stratasys F-270 was used for the 3rd iteration.
5. Assembled 3D printed parts and added padding with Velcro for comfort and fit.
6. Utilized physical testing to determine functionality.
7. Following physical testing, improvements and adjustments were made to the model components
8. Repeat and iterate steps 2-5 for higher quality
9. Analyzed the final design of components for determination of functionality

### IV. RESULTS

The following tables and figures display the results of testing, calculated cost, and changes made during the three iterations performed on the knee orthotic during this project.

#### TABLE I

<table>
<thead>
<tr>
<th>Part</th>
<th>Force applied</th>
<th>Von Mises stress</th>
<th>Displacement</th>
<th>Factor of safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pin</td>
<td>218 lbf</td>
<td>353.9 ksi</td>
<td>1.4x10⁻² in</td>
<td>3.32</td>
</tr>
<tr>
<td>Lower brace</td>
<td>218 lbf</td>
<td>197.3 ksi</td>
<td>1.6x10⁻² in</td>
<td>4.12</td>
</tr>
<tr>
<td>Upper brace</td>
<td>218 lbf</td>
<td>503.3 ksi</td>
<td>4.9x10⁻² in</td>
<td>7.43</td>
</tr>
</tbody>
</table>

#### TABLE II

<table>
<thead>
<tr>
<th>Part</th>
<th>Force applied</th>
<th>Von Mises stress</th>
<th>Displacement</th>
<th>Factor of safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pin</td>
<td>218 lbf</td>
<td>323.4 ksi</td>
<td>1.1x10⁻¹ in</td>
<td>3.41</td>
</tr>
<tr>
<td>Lower brace</td>
<td>218 lbf</td>
<td>171.1 ksi</td>
<td>1.2x10⁻² in</td>
<td>4.44</td>
</tr>
<tr>
<td>Upper brace</td>
<td>218 lbf</td>
<td>481.5 ksi</td>
<td>4.3x10⁻² in</td>
<td>7.79</td>
</tr>
</tbody>
</table>
TABLE III
FEA RESULTS OF ITERATION 3

<table>
<thead>
<tr>
<th>Part</th>
<th>Force applied</th>
<th>Von Mises stress</th>
<th>Displacement</th>
<th>Factor of safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pin</td>
<td>218 lbf</td>
<td>115.2 ksi</td>
<td>1.1x10^-4 in</td>
<td>5.03x10^2</td>
</tr>
<tr>
<td>Lower brace</td>
<td>218 lbf</td>
<td>165.3 ksi</td>
<td>0.9x10^-2 in</td>
<td>5.07x10^2</td>
</tr>
<tr>
<td>Upper brace</td>
<td>218 lbf</td>
<td>362.4 ksi</td>
<td>1.49x10^-2 in</td>
<td>2.53x10^2</td>
</tr>
</tbody>
</table>

TABLE IV
COMPONENT COSTS AND SUMMED TOTAL FOR ITERATIONS 1 AND 2

<table>
<thead>
<tr>
<th>Part</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pins</td>
<td>$6.25*2=$12.50</td>
</tr>
<tr>
<td>Connecting arms</td>
<td>$8.25*2=$16.50</td>
</tr>
<tr>
<td>Upper Brace</td>
<td>$14.11</td>
</tr>
<tr>
<td>Lower Brace</td>
<td>$12.13</td>
</tr>
<tr>
<td><strong>TOTAL COST</strong></td>
<td><strong>$55.24</strong></td>
</tr>
</tbody>
</table>

TABLE V
COMPONENT COSTS AND SUMMED TOTAL FOR ITERATION 3

<table>
<thead>
<tr>
<th>Part</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pins</td>
<td>$6.35*2=$12.70</td>
</tr>
<tr>
<td>Upper Brace</td>
<td>$21.11</td>
</tr>
<tr>
<td>Lower Brace</td>
<td>$16.42</td>
</tr>
<tr>
<td><strong>TOTAL COST</strong></td>
<td><strong>$50.23</strong></td>
</tr>
</tbody>
</table>

TABLE VI
SUMMARY OF DESIGN ITERATION CHANGES

<table>
<thead>
<tr>
<th>Part</th>
<th>Iteration 1</th>
<th>Iteration 2</th>
<th>Iteration 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pin</td>
<td>Initial Design</td>
<td>Extended pin depth</td>
<td>widened pin radius, decreased pin depth</td>
</tr>
<tr>
<td>Upper brace</td>
<td>Initial Design</td>
<td>Expanded width</td>
<td>Extended front arms</td>
</tr>
<tr>
<td>Lower brace</td>
<td>Initial Design</td>
<td>Extended back</td>
<td>Combined with connecting arms</td>
</tr>
<tr>
<td>Connecting arms</td>
<td>Initial Design</td>
<td>Added curve for better fit</td>
<td>Removed completely</td>
</tr>
</tbody>
</table>

Fig. 2 Factor of safety for pin (iterations 1 and 2)

Fig. 3 Factor of safety for lower brace (iterations 1 and 2)

Fig. 4 Factor of safety for pin (iteration 3)

V. DISCUSSION

The brace was expected to stabilize the knee and limit its movement to support all common knee injuries. With the intended structural knee brace design, a significant portion of the weight was relieved from the user's knee. This was actively observed in the variety of physical therapy exercises used to test the functionality of the knee orthotic, where the upper brace of the knee orthotic supported the weight of the patient’s leg and the overall brace restricted rotational movement and immobilized inward and outward movement of the knee.

The first iteration of the brace served as a useful model to observe its functionality and assembly; however, the brace was too tight to actually test on a patient. From the first design, it was discovered that the pins did not require a stopping mechanism, as the natural structure of the brace already immobilized the knee in hyperextension. The second design was rescaled to fit the patient’s leg, so the relevant
physical therapy exercises could be carried out.

Fig. 5 Factor of safety for lower brace (iteration 3)

Fig. 6 Factor of safety for upper brace (iterations 1 and 2)
After further analysis, a third iteration was developed for the MECH 510 class. This iteration was refined to provide additional comfort to the patient wearing the orthotic and simplify the design for mass production. First, the connecting arms and upper brace were combined, and the connecting arms were given straight edges. This was done to provide additional strength and normalize geometry for ease of production. Additionally, these changes were possible in terms of 3D printing the part as the new F-270 printer at Loyola Marymount University was used. This printer has a larger print volume, meaning a taller part with higher connecting arms could be produced.
A second change made to the parts was the expansion of the pin radius. This was done to increase strength, and a nominal radius was used to make production easier. For production of the orthotic on a large scale, this is highly desirable.

The third alteration made for the MECH 510 class was the straightening and thickening of the extensions of the lower brace. Again, this was done to increase strength and make it easier to produce the component on a large scale. When testing was completed for the first two iterations, it was determined that the 3D printed orthotic did not meet the expected standards for typical knee orthotics. This was based on the inability of the brace to restrict rotational movement and provide total support to the knee. However, it was capable of immobilizing the knee in lateral movement. This movement corresponds to the Lateral Cruciate Ligament, or LCL, on the outside of the knee. Injuries to the LCL typically come from contact to the inside of the knee, causing excessive stretching to the outside ligament, the LCL [9]. LCL injuries are common among athletes that play contact sports. Using this information, it was determined that the knee orthotic designed could function as an effective treatment for LCL injuries.

To improve the orthotic beyond being adequate for only LCL injuries, a third iteration was developed for the MECH 510 class. This iteration incorporated all the components from the original iterations to maintain its ability to aid LCL patients while also making alterations to aid other knee injury patients. Following these changes and additional testing, it was determined that the new orthotic would also function as a brace for Medial Cruciate Ligament, or MCL, injuries. The MCL runs on the inside of the knee and provides support when extending the knee [10]. MCL injuries occur when a knee is hyperextended, when is common when someone is jumping or lunging. The new design iteration provided additional support to the back of the knee and allowed for more support in extension movements. Also, the new brace was constructed out of ABS, which is much stronger than the initial PLA material. This indicates that MCL patients would have adequate aid from the orthotic to be functioning during rehabilitation. With this in mind, it was determined that the final design iteration from the MECH 510 class would be effective in treating MCL and LCL injuries.

Following the finalization of design for the knee orthotic, the results of the FEA performed were used to determine if the brace could function under the forces applied by a knee and leg. This consideration was important as the brace may provide support, but not handle higher forces that could be placed on the orthotic during physical therapy exercises. These forces were derived from previous research [6] and used as the normal forces in FEA. As seen in Tables I-III the main load bearing components were capable of experience the forces applied by the leg and knee. Additionally, the yield stress of PLA (580.2 ksi) was considered for the components. The von Mises stress of each part was compared to this value and after testing, no Von Mises stress exceeded 580.2 ksi. Finally, the set factor of safety of 3.25 was exceeded by all load bearing parts.

Once design and analysis were complete, cost was also considered. As seen in Tables IV and V, the total cost of each component is displayed. When these costs are summed, the total cost of the knee orthotic was $55.24 for iterations 1 and 2, and $50.23 for iteration 3. This meets the goal of designing the knee orthotic for under $100.

VI. CONCLUSION

In conclusion, the 3D printed knee orthotic represents a viable option for MCL and LCL injury patients. Because the original design required improvements to increase its functionality, there were three design iterations. The final iteration was stronger and had a dramatic increase in factor of safety. This was due to the increased thickness of parts and the usage of ABS material instead of weaker PLA. It also was more cost effective than the original design and previous two iterations. While the first two iterations each cost $55.24, the final one only costs $50.23. Although the final iteration is a viable design, improvements can still be made on future iterations. First, design changes can allow further immobilization of rotational motion, which is especially important for ACL injuries. Second, the orthotic can be designed to provide more support in order to reduce the risk of reinjury. Third, scanning and Mimics (medical CAD software) can be used to improve the accuracy of the design for different individuals. Finally, stronger materials can be utilized to reduce the necessary amount of material, thus reducing cost. Overall, this knee orthotic is functional for MCL and LCL injuries, but additional research is required to make a universal knee orthotic that can be used for all knee injuries.

REFERENCES
"Rapid Prototype Technique in Medical Field." Sree Siddaganganga College of Pharmacy, October 1, 2008.


