Finite Element Analysis of Icarus Knee Brace Under Tensile Stress to Investigate Structural Integrity

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Abstract

Patellofemoral knee osteoarthritis (PFJOA) is a prevalent degenerative disease-causing pain and mobility impairment worldwide. This study investigates the structural integrity of Icarus Medical's Ascender Knee Brace, a novel intervention for PFJOA management, through finite element analysis. PFJOA symptoms develop due to cartilage degradation along the trochlear groove and on the underside of the patella. PFJOA is exacerbated by factors like joint instability, obesity, and systemic inflammation. Current management and treatment options for patellofemoral knee osteoarthritis include non-operative approaches such as physical therapy, pharmacological interventions, and orthopedic devices like knee braces. Our analysis simulated daily activities like climbing stairs and running to evaluate the brace's performance and durability under varying mechanical stresses. Results seek to highlight the significance of extension stops in enhancing the brace's ability to withstand peak forces, thus reducing the risk of structural failure. This study offers valuable insights into the brace's durability and suggests areas for potential structural optimization to improve efficacy and pain relief for PFJOA patients. By advancing orthopedic device design standards, this research benefits both manufacturers and patients, enabling tailored solutions based on biomechanical analyses. Personalized knee braces can address individual patient needs, leading to improved satisfaction and rehabilitation outcomes. Overall, this study underscores the importance of advanced analytical techniques in orthopedic device design, aiming to enhance patient care and well-being in PFJOA management.

Keywords: patellofemoral knee osteoarthritis, finite element analysis, knee braces

Introduction

Background

Patellofemoral knee osteoarthritis (PFJOA) is a degenerative disease that damages the articular cartilage along the trochlear groove as well as the underside of the patella, leading to inflammation and pain (Sheth, 2022). This happens as the cartilage deteriorates, becoming rough and potentially exposing the bone beneath, which makes bone movement along this uneven surface painful (Sheth, 2022). Prior instances of instability, including dislocation, joint laxity, and malalignment within the joint are oftentimes symptoms identified with patients that exhibit patellofemoral arthritis (Kiel, 2023). These symptoms' emergence can be exacerbated by various risk factors, including age, obesity, prior interarticular or patellar fracture, previous dislocation or subluxation incidents, overuse from high impact running or weight training, and conditions of arthritis in other joints (Kiel, 2023). The risk profile is further amplified by systemic inflammatory conditions like rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, systemic lupus erythematosus, and more (Kiel, 2023). 10% to 24% of patients dealing with knee osteoarthritis have patellofemoral knee osteoarthritis (Jagadeesh, 2022). With 654 million people enduring the effects of knee osteoarthritis, PFJOA is a prevalent disease that hinders the mobility of millions worldwide (Cui, 2020).

Various non-operative management strategies have been explored, encompassing non-pharmacological approaches such as patient education, self-management techniques, physical therapy, and weight loss interventions. Additionally, treatments like Extracorporeal Shockwave Therapy (ESWT), cold therapy, taping, bracing, and orthotics have been considered. In terms of pharmacological management, options available include non-specific anti-inflammatory Drugs (NSAIDs), acetaminophen, oral narcotics, and duloxetine. Injection therapies, on the other hand, encompass glucocorticoids, hyaluronic acid, Platelet-Rich Plasma (PRP), as well as other regenerative therapies such as Bone Marrow Aspirate Concentrate (BMAC), adipose, or mesenchymal stem cells. Furthermore, alternative treatment modalities like radiofrequency ablation and botulinum toxin have been considered within the spectrum of available options (Kuwabara, 2022).

Orthopedic devices like knee braces are pivotal in providing support, stability, and protection to individuals with knee osteoarthritis and serve as a common non-invasive treatment option (Donvito, 2019). Icarus Medical's Ascender brace proves to be a promising innovation for patient treatment and management. The Ascender's notable characteristics include the patient custom 3D printed design, lightweight (less than 1lb) breathable Nylon 6 material, an adjustable tension dial, multi-compartment unloading (patellofemoral/tibiofemoral), and the ability to unload up to 40lb of force experience by the patient's knee (Icarus Medical, 2024).

Significance

This capstone project delves into an orthopedic framework by conducting a structural analysis of Icarus Medical's off-the-shelf Ascender Knee Brace utilizing finite-element analysis. This analysis and its results carry multifaceted and impactful significance across various areas of study. The primary goal was to enhance patient safety through a thorough examination of how integrated extension stops affected the knee brace's structural integrity. This distinction is pivotal as it directly relates to the brace's ability to offer dependable support under diverse mechanical stresses, ultimately ensuring enhanced protection for users. Furthermore, the insights garnered from this analysis can guide future optimization of the knee brace's design and functionality, thereby improving its durability and overall effectiveness in real-world applications. By aiding in establishing rigorous design standards and limitations for orthopedic devices, this research benefits Icarus Medical and informs the broader industry, fostering increased confidence among healthcare practitioners and patients alike. The insights gained from this project pave the way for more personalized orthopedic solutions. Knee injuries or conditions are non-uniform, and patients may have varying needs regarding support, range of motion, and comfort. By fine-tuning design parameters based on biomechanical analyses like finite-element modeling, manufacturers can tailor knee braces to better suit individual patient profiles. This personalized approach enhances user satisfaction and contributes to more effective and empathetic rehabilitation protocols tailored to each patient's unique requirements.

Crucially, the project's outcomes hold promise for enhanced rehabilitation outcomes, as a well-designed knee brace significantly contributes to recuperation from knee injuries or surgical procedures. The adoption of advanced analytical techniques like finite-element analysis also highlights a broader trend aimed at catalyzing innovation in orthopedic device design, aligning with the overarching objective of advancing healthcare technologies to positively impact patient care and well-being. By employing finite-element analysis, we can simulate various mechanical loads and stress conditions that the knee brace may encounter during typical use-case scenarios. This allows us to identify critical points of stress concentration, deformation patterns, and potential failure modes, providing valuable insights into areas where the brace's design may require optimization.

Limitations

The complexity of the CAD model proved to be problematic when attempting to implement the knee brace meshes into the most recent versions of finite element analysis software such as Autodesk Inventor and Fusion 360. This hindered our ability to complete the conditions necessary in order to run simulations under the study parameters. As a result of utilizing older software, we lacked the ability to access the Nylon 6 material that Icarus Medical uses in the development of their Ascender knee braces. Consequently, we determined that the Autodesk Inventor 2021 material Nylon 6/6 would be sufficient to supplement the absence of the Nylon 6 material when performing simulations. The results presented from using dated versions of the finite element analysis software possess limitations due to the fact that the simulation software may provide inaccuracies or issues no longer present in updated versions.

Materials and Methods

A single-point finite element analysis simulation using Autodesk was performed on the Icarus Ascender Knee Brace. Within the simulation, four pin joints were constrained within the gear holes created by the hinges of the brace. The Autodesk material Nylon 6/6 was applied to the entirety of the CAD model. A lateral force was applied and evenly distributed across four faces located on each side of the brace. These locations include: two faces on the hinge gears and two proximal faces above and below the hinge gears along the body of the brace as seen in Fig. 1. The two faces on the brace's body were created by constructing two, 2-inch offset planes, with respect to the origin's

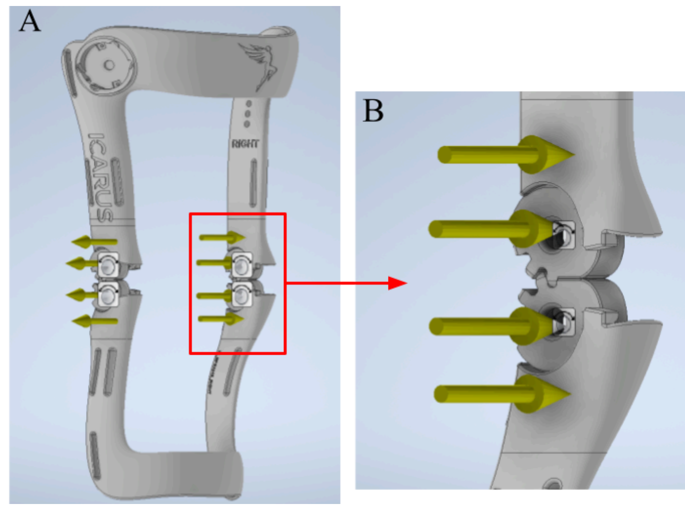


Fig. 1. (A) Full view of the brace depicting the four locations of the faces (yellow arrows) for applied forces and the pin joint constraints in the gear holes (white boxes). (B) Zoomed in view of the pin joint constraints in the gear holes (white boxes) and locations for applied force on the faces of the gears and the body of the brace (yellow arrows).

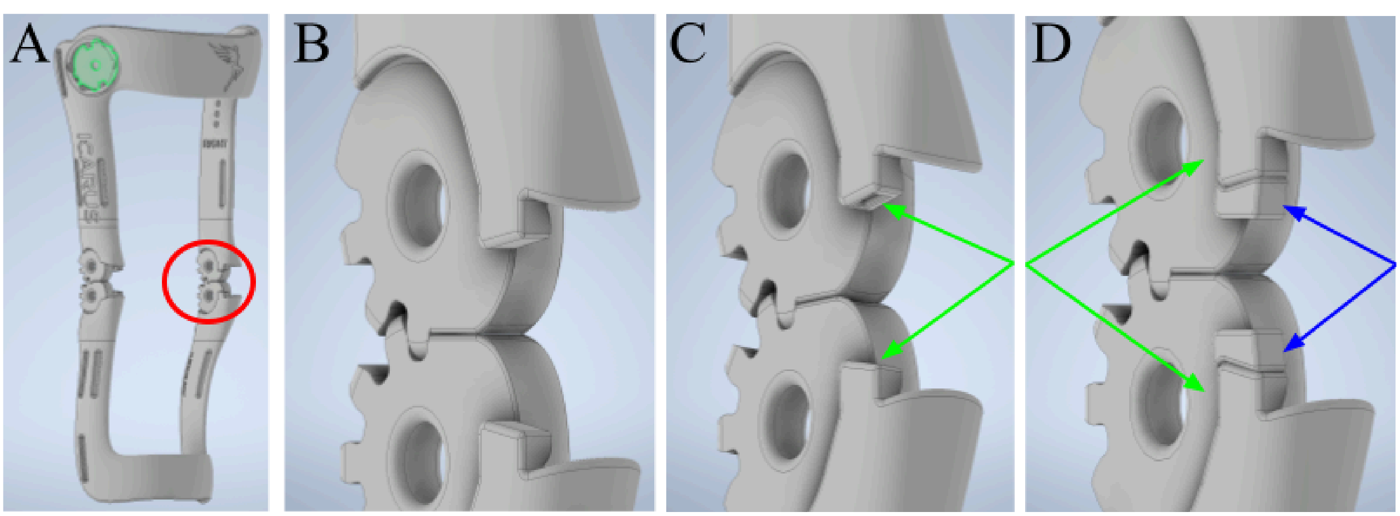
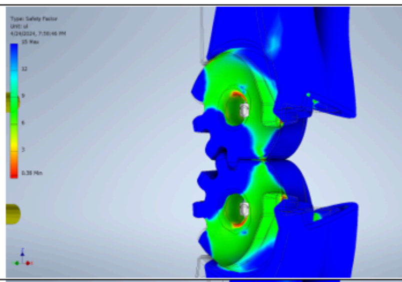
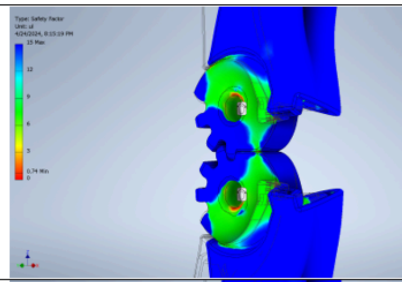
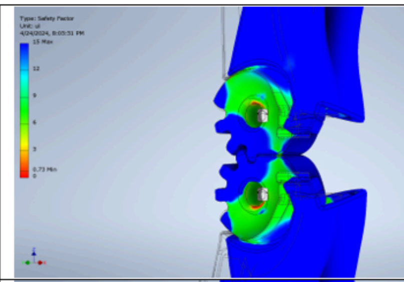
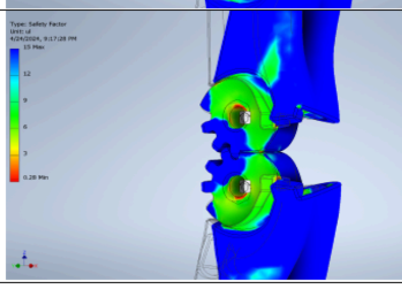
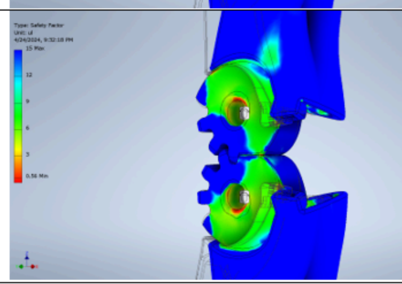
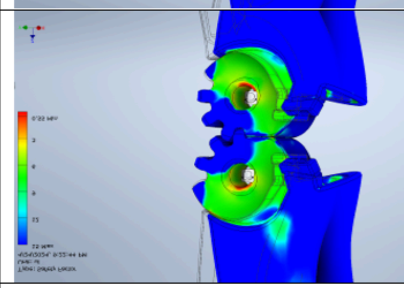


Fig 2. (A) Full view of the Off-The-Shelf Icarus Ascender Knee Brace with a red circle depicting the field of view shown in subfigures (B), (C), and (D). (B) Zoomed in view of the knee brace without extension stop holes or stops. (C) Zoomed in view of the knee brace with extension stop holes (green arrows) and without extension stops. (D) Zoomed in view of the knee brace with extension stop holes (green arrows) and extension stops (blue arrows).

XY plane. Subsequently, the split body tool was utilized to split the brace's top and bottom components to create the surfaces for the applied simulated loads. Additionally, automatic constraints created by Autodesk were applied to increase processing speeds.

Table 1. Safety Factor Simulation results depicted as color maps across the various knee brace scenario conditions.

Applied Force (lb-force)	**Finite Element Analysis – Safety Factor Simulation**		
580			
760			
Brace Conditions	Without Extension Stop Holes or Stops	With Extension Stop Holes without Extension Stops	With Extension Stop Holes and Stops

The meticulously chosen force-loading conditions were based on loads typically experienced by the patellofemoral knee joint during daily life. These forces equate to respectively three times the body weight to mimic the impact experienced walking up stairs and four times the body weight to mimic the impact during running scenarios (Hart, 2022). A baseline weight of 190 lb, representing an "overweight" scenario for an average male with a height of 5' 9", was used to calculate this force (CDC, 2022). The simulation design representing walking up the stairs involved applying a resultant force of 570 lb, or 285 lb to each side of the brace, distributed evenly across the four face locations on the knee brace as previously described. Similarly, the simulation representing running conditions was conducted in the same manner, and involved increasing the resultant force to 780 lb, or 390 lb evenly distributed on each side of the brace. The forces were applied laterally on both sides of the brace. The simulations were executed to assess the durability of the Icarus Ascender Knee Brace for instances of mechanical failure under different loading conditions representing everyday activities such as walking up the stairs and running. Under these loading conditions shown in Fig 2., the study compared three respective variations of the knee brace design including: without embedded extension stop holes or extension stops (Scenario 1), embedded extension stop holes without extension stops (Scenario 2), and embedded extension stop holes with equipped extension stops (Scenario 3).

Results

The safety factor simulation analysis shows specific areas located on the brace that are most likely to exhibit mechanical failure under the given loading conditions. Therefore, the safety factor simulations identified that critical areas with the highest likelihood of structural failure under applied loads were centered on the holes of the gears and hinges as seen in green in Table 1. As the applied loads were increased from 580 lb-force to 760 lb-force, the surface area of the critical safety factor subsequently increased towards the periphery of the gears and onto the frame of the knee brace. This observed effect is most notable in Scenario 1, where results indicate a larger surface area of non-blue coloration above and below the gears on the knee brace's frame. This shows that the hinge from the unmodified knee brace of Scenario 1 is therefore more susceptible to structural damage or failure when compared to the knee brace with the equipped extension holes and

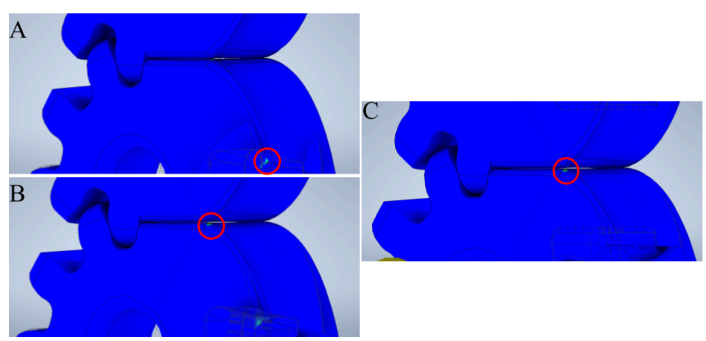


Fig. 3. A magnified image highlighting the localized area of highest stress for all three scenarios. (A) OTS Orthotic without Extension Stop Holes or Stops. (B) OTS Orthotic with Extension Stop Holes without Extension Stops. (C) OTS Orthotic with Extension Stop Holes and Stops.

extension stops of Scenario 3.

The stress analysis shown in Fig. 3 highlights the areas of highest stress experienced by the knee brace. In Scenario 1, the area of highest stress was located at the intersection between the knee brace frame and the gear's anterior-lateral position. However, the area of maximum experienced stress on the brace is notably different across Scenario 2 and Scenario 3. In Scenarios 2 and 3, the areas of highest experienced stress were located between the joints of the two gears. As shown in Fig. 4, the values of maximum experienced stress located in Scenario 1 were reported to be 13.02 ksi while Scenarios 2 and 3 experienced notably lower levels of stress that were reported to be 7.732 ksi and 7.551 ksi respectively. Scenarios 2 and 3 show an average 58% decrease in maximum stress values when compared to Scenario 1.

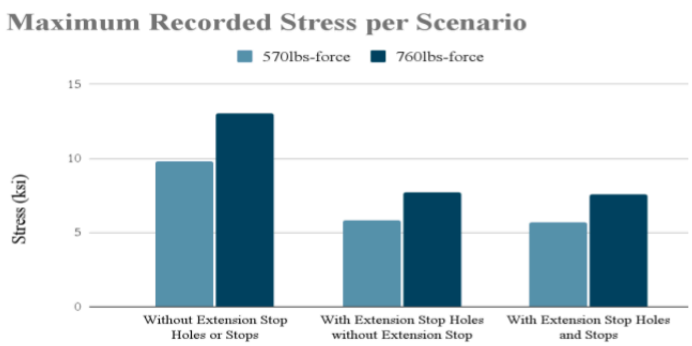


Fig. 4. The maximum recorded stress values (in ksi) for each scenario during the stress simulation.

Discussion

The safety factor analysis results indicated that all three scenarios display similar potential areas of failure, centered inside the holes within the hinge. However, since Scenarios 2 and 3 expressed smaller surface areas of non-blue coloration, the inclusion of extension stops enhances the brace's ability to absorb peak reaction forces exerted by the patellofemoral joint. This is further supported when considering the 58% approximate reduction in maximum experienced stress values by the knee brace with the extension stops as opposed to the unmodified knee brace studied in Scenario 1. The increased ability to absorb peak reaction forces decreases the likelihood of structural failure experienced by the knee brace when under heavy loading conditions. Notably, there were issues experienced when converting the knee brace's mesh into fatigue finite element analysis software. This limitation hindered our ability to develop a predictive model for long-term knee brace usage under force-loading conditions based on the structural differences observed in the three scenarios. We believe that the findings contribute valuable data towards confirming the durability of Icarus Medical's off-the-shelf Ascender Knee Brace. These findings inform future relevant studies and indicate areas for potential structural changes focused on increased efficacy and pain reduction in patient-centered knee braces for patients suffering from patellofemoral knee osteoarthritis.

Challenges and Learning

We faced many challenges within the duration of this capstone. Particularly, we experienced a shortened timeline to complete the project due to unforeseen complications during the preliminary phases of the project. There was also an issue regarding the incorporation of the complex CAD model meshes into the most recent version of Autodesk's finite-element software. To remedy this issue, we conducted various simulations on Autodesk Inventor's 2021 version of the software. However, this improved our ability to modify CAD models and sketches to incorporate them into compatible software that was viable to use.

Future Work

In order to continually and iteratively improve non-invasive treatment options for patellofemoral knee osteoarthritis, we believe the development of an IRB-approved experimental design of the Icarus Ascender Knee Brace focused on gait analysis would produce the most impactful results. The study will incorporate data collected and analyzed by motion sensors, motion tracking software, and pressure plate sensors. This experimental design reveals insights for a detailed investigation regarding how the three knee brace scenarios impact the patient's gait patterns, malalignment, as well as any user-reported improvements towards pain reduction within the patellofemoral joint. Upon completion of this protocol, data collected via motion tracking software should be collected and implemented into an OpenSim database. OpenSim is an open-source software system for biomechanical modeling, simulation and analysis (Delp, n.d). This would allow for the modelling and measurement of important joint angles and relevant muscle reaction forces to inform potential design decisions for future Icarus Medical orthotics.

End Matter

Author Contributions and Notes

H.M.C. and N.K. performed relevant research, H.M.C. conducted the simulations, N.K. assisted during simulation preparation and manipulation, H.M.C. analyzed data; H.M.C. and N.K. wrote the paper.
The authors declare no conflict of interest.

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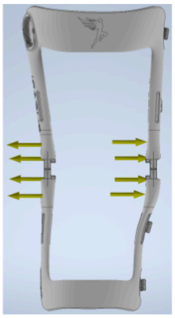
Supplemental Information



Supplemental Figure 1. Frontal view of the brace illustrating the orientation of applied forces acting on the faces/hinges of the brace.

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