DESIGN ANALYSIS AND MANUFACTURING OF KNEE ANKLE FOOT ORTHOSIS (KAFO)

A Final Year Project Report

Presented to

SCHOOL OF MECHANICAL & MANUFACTURING ENGINEERING

Department of Mechanical Engineering

NUST

ISLAMABAD, PAKISTAN

In Partial Fulfillment
of the Requirements for the Degree of
Bachelor of Mechanical Engineering

---

by

Jawad Ali

Muhammad Abbas

June 2021

EXAMINATION COMMITTEE

We hereby recommend that the final year project report prepared under our supervision by:

Jawad Ali	00000222313
Muhammad Abbas	00000193616

Titled: "DESIGN ANALYSIS AND MANUFACTURING OF KNEE ANKLE FOOT ORTHOSIS (KAFOs) " be accepted in partial fulfillment of the requirements for the award of B.E. MECHANICAL ENGINEERING degree with grade ___

Supervisor: Dr. Niaz Bahadur Khan, Assistant Professor SMME, NUST	Dated:
Committee Member:	Dated:
Committee Member:	Dated:

______________________ ____________

(Head of Department) (Date)

COUNTERSIGNED

____

(Dean / Principal

ABSTRACT

Lower limb orthosis are used to control instabilities that are primarily caused by neurological and muscular diseases, such as post-polio syndrome, spinal cord injury etc. by maintaining proper alignment and controlling motion.

Locally available orthosis are being imported mainly from Europe and thus have higher cost. The project aims at designing these orthosis locally keeping in view our manufacturing capabilities to reduce cost without compromising on quality.

ACKNOWLEDGMENTS

Dr. Niaz Bahadur Khan, our project supervisor is to be thanked for providing us the opportunity and for his support and guidance during all phases of the project. Efforts of project participants in conducting comprehensive research and coming up with creative design ideas is to be acknowledged.

ORIGINALITY REPORT

ORIGINALITY REPORT

15%	14%	13%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	link.springer.com Internet Source	4%
2	docshare.tips Internet Source	1%
3	Submitted to Engineers Australia Student Paper	1%
4	www.ncbi.nlm.nih.gov Internet Source	1%
5	www.scheckandsiress.com Internet Source	1%
6	Feng Tian, Mohamed Samir Hefzy, Mohammad Elahinia. "State of the Art Review of Knee-Ankle-Foot Orthoses", Annals of Biomedical Engineering, 2015 Publication	1%
7	studentsrepo.um.edu.my Internet Source	<1%
8	www.kencotubes.com Internet Source	<1%

9	Gil Serrancolí, Allison L. Kinney, Benjamin J. Fregly, Josep M. Font-Llagunes. "Neuromusculoskeletal Model Calibration Significantly Affects Predicted Knee Contact Forces for Walking", Journal of Biomechanical Engineering, 2016 Publication	<1 %
10	Taicong Chen, Haitao Ma, Wei Gao. "A new approach to stability analysis of frame structures using Trefftz-type elements", Journal of Constructional Steel Research, 2013 Publication	<1 %
11	opus4.kobv.de Internet Source	<1 %
12	polen.itu.edu.tr Internet Source	<1 %
13	tdx.cat Internet Source	<1 %
14	aquila.usm.edu Internet Source	<1 %
15	Tian, Feng, Mohamed Samir Hefzy, and Mohammad Elahinia. "Development of a Dynamic Knee Actuator for a KAFO Using Superelastic Alloys", Volume 3 Biomedical and Biotechnology Engineering, 2014. Publication	<1 %

<u>**TABLE OF CONTENTS**</u>

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

KAFO	Knee Ankle Foot Orthosis
CAD	Computer Aided Design
FEM	Finite Element Method
FEA	Finite Element Analysis
SCKAFO	Stance Controlled Knee Ankle Foot Orthosis
AFO	Ankle Foot Orthosis
BW	Body Weight

CHAPTER 1: INTRODUCTION

A Knee Ankle Foot Orthosis or KAFOs is a lower extremity orthotic that is used to control instabilities in the knee and lower limb primarily caused by neurological and muscular diseases, such as post-polio syndrome, spinal cord injury etc. by maintaining proper alignment and controlling motion.

Braces are devices which hold the extremities in a stable position. The goals of bracing are to increase function, prevent deformity, keep the joint in the functional position, stabilize the trunk and extremities, facilitate selective motor control, decrease spasticity and protect the extremity from injury in the postoperative phase.

Motivation for this project

Pakistan unfortunately is one of two countries in the world that has failed to eradicate polio. Being a developing country, a large percentage of the population is under the poverty line.

Orthosis in Pakistan are imported from many European countries, thus making orthosis a luxury accessory accessible to upper- and middle-class citizens only. It is the need of the hour to manufacture orthosis locally thus reducing not only the cost but also making these accessible to all.

Objectives of This Project

- The project aims at local designing of the lower limb orthosis with the focus on ease of manufacturing and enhanced safety, reliability, and convenience.
- As the wellbeing and safety of the end user is dependent on these orthoses. FEM Analysis for the design is to be performed for design validation study and making further improvements to the initial design.
- The aim for the whole exercise is to reduce the cost of the orthosis and make these accessible to all the segments of the society.

CHAPTER 2: LITERATURE REVIEW

Gait Cycle

Human walking gait cycle comprises of two parts: stance phase (about 60% of the total cycle) and swing phase (about 40% of the total cycle). The stance phase can be further divided into mid-stance, loading response, pre-swing and terminal stance. The swing phase comprises of initial swing, mid swing, and terminal swing. The stance phase begins as the foot touches the ground and lasts till the foot breaks contact with the ground. The swing phase begins when foot is above ground, lasts till the leg is in motion and ends when the foot is in contact with the ground again.

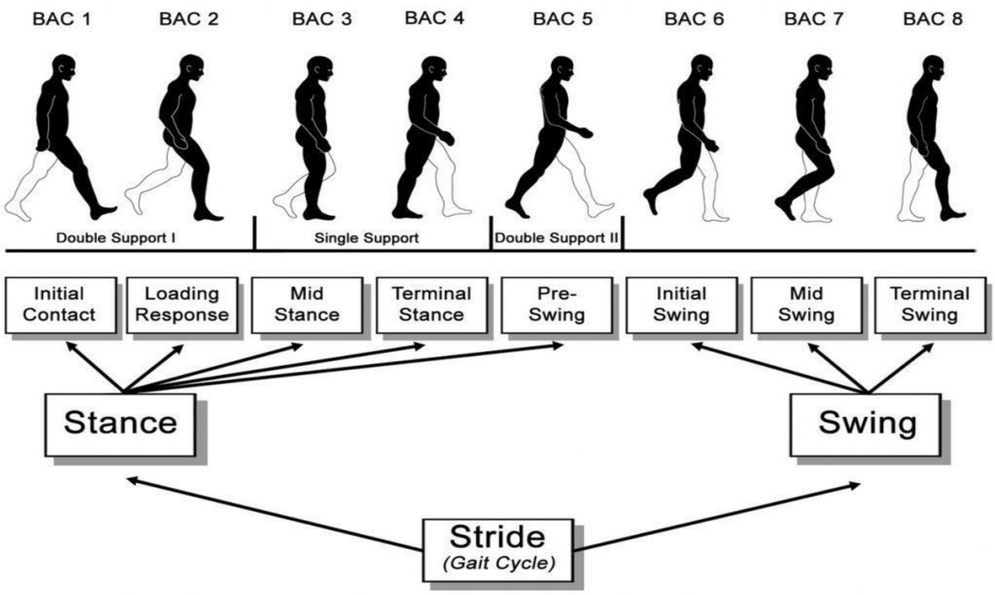

Figure 1: Human Gait Cycle

It is necessary to have the knee and leg supported during stance phase of that particular leg with the aid of ORTHOSIS as full body load falls on single leg. Thus it is desired that during stance phase knee joint remains locked, to bear maximum load. However locking of the knee joint during swing phase depends on the types of Orthosis.

Types of Orthosis

To date, several types of Orthosis have been developed: passive Orthosis, stance control Orthosis (SCOrthosis), and dynamic Orthosis. All types of Orthosis have an extension stop to restrict hyper knee extension.

Passive Orthosis:

Conventional or passive Orthosis provide stability during walking and standing by maintaining the knee joint in a fixed position. The knee joint can be unlocked manually to allow free rotation for sitting. Such devices provide strong stability for people with severe quads weakness, where the support of the joint is considered to be more important than its mobility. However, a locked knee requires compensation motions during walking including hip hiking and circumduction on the braced leg and vaulting on the contralateral leg in order to clear the foot during swing. This increases energy consumption. In many cases, these Orthosis are used only in training and are abandoned by patients in daily life.

Figure 2: Passive Orthosis

Stance Controlled Orthosis:

SC Orthosis are designed to improve the rigid walking gait that is provided by passive Orthosis. These orthoses block knee motion for weight bearing and allow free rotation in the swing phase. They have been widely developed due to their relative efficiency. However, the abnormal gait pattern still exists because of the locked knee joint in the stance phase.

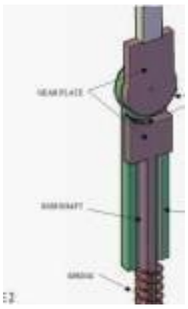

Figure 3: Stance Controlled Orthosis

Dynamic Orthosis:

Dynamic Orthosis are developed to reproduce normal walking ability throughout the whole gait cycle. They are able to control both stance and swing phases. However, those presently available are bulky, cumbersome, use complex control systems or cannot provide necessary assistance. Their use is limited to rehabilitation devices in lab environments.

Figure 4: Dynamic Orthosis

Orthosis Materials:

Historically, they were fabricated using a metal and leather design. Steel or aluminum uprights that included hinged knee joints were interconnected by curved transverse metal bands which were padded with soft leather cuffs. This design is now obsolete and has been replaced with the thermoplastic design. In this design, the ORTHOSIS is comprised of a rigid thermoplastic cast formed around the leg and is used to support the knee during walking. More recently Orthosis made of Carbon Fiber are gaining popularity, as they provide strength and stability with a reduced weight with only limitation being the cost.

Major Manufacturers:

The top manufacturers in the field of Orthotics belong to European and American region. Some of the major manufacturers includes DJO Global, Freedom Innovations LLC, Smith & Nephew Plc, Ossur Global, Stepper Inc., DeRoyal Industries, Ottobock Holding, Stryker Corporation, Thuasne and Freedom Innovations and DePuy Synthes.

Orthosis in Pakistan Region:

Being a developing country a large percentage of the population is under the poverty line. To add fuel to the fire, major chunk of the Orthosis in Pakistan are imported from many European countries, thus making ORTHOSIS a luxury accessory accessible to upper and middle class citizens only. It is the need of the hour to manufacture ORTHOSIS locally thus reducing not only the cost but also making these accessible to all.

CHAPTER 3: METHODOLOGY

Millions depend on Orthosis for their day to day activity. Thus it is very important to cater for all the factors that may play a role in the operation of these in the predefined operating range.

Some of the factors that play the major role and are discussed in detail in the upcoming paragraphs are;

1. Design of Orthosis
2. Factor of Safety
3. Ease of Use and Installation
4. Ease of maintenance
5. Appropriate Selection of Materials
6. Ease of manufacturing and machining
7. Net Cost of end product

These were the main factors that were especially taken into consideration while designing the Orthosis as well as in the analysis phase.

Following methodology has been applied in this regard

1. Initial CAD Design
2. Force Calculations based on free body diagram
3. Finite Element Analysis of the Initial CAD Design
4. Modification in design based on the analysis
5. Study of the effect of change in material etc.

Two different models were designed and were analyzed for their pros and cons.

Model 1:

Model 1 was based on an already existent product, which has been tried and tested extensively in the lab, as well as first hand tested and approved by hundreds of orthopedic surgeons all over the world. However, this is being imported and thus carries a high price tag. The aim is to reverse engineer, and copy the design and material used in the original product to manufacture it locally with necessary amendments.

Following methodology has been adopted for this model:

CAD Design

CAD design has been done keeping in view the existent model and keeping all the salient features of that model intact in the CAD design. The main factors to consider in the CAD design are;

1. Type of Joint
2. Locking Mechanism

Both the locking mechanism as well as the type of joint were kept similar to the existent model. This is to keep the designed model as close to the existent model to have all the salient features of the existent model and thus diminishing the need for extensive testing.

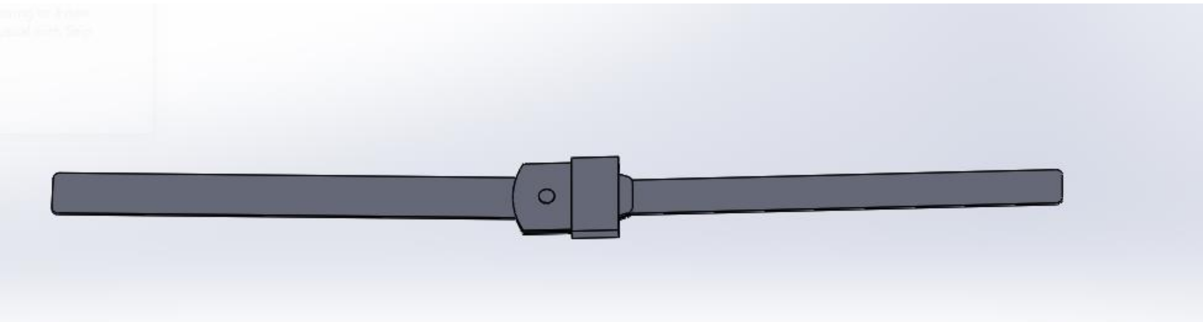

Figure 5: Model 1 – CAD Design

The Orthosis can be divided into three main parts;

1. Side Braces
2. Joint
3. Lock

Side Braces:

Side Braces make up the structural part of Orthosis. These braces are joined to the legs and take up the lateral load. Also these braces are used to fasten the Orthosis to the thigh and calf bands and supports. Side braces can be of different materials that would be discussed in detail in the Analysis section.

Joint:

The central hinge joint acts as the connection point for the braces and allows movement of the calf with respect to thigh and act as an imitation of the human knee joint. The join facilitates bending whenever desired and the movement can be locked using the lock. The central portion can be connected to braces using rivets, welding or press fitting.

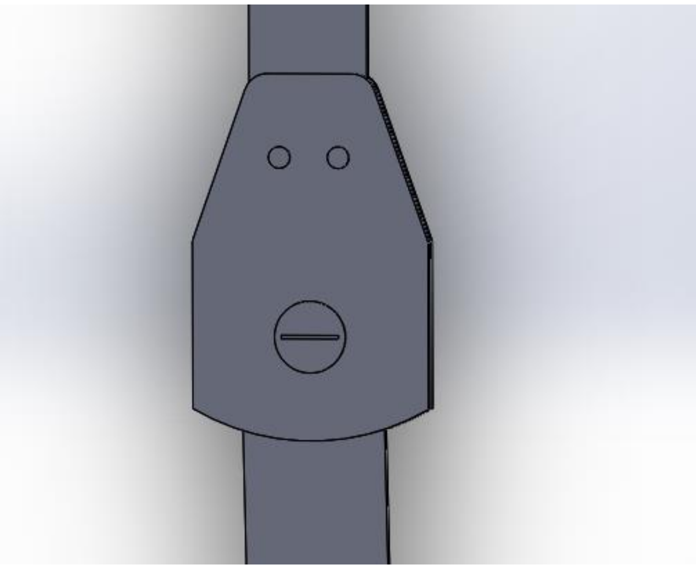

Figure 6: Model 1: Joint - CAD Design

Lock:

Lock is one of the main components of Orthosis. It is used to perform a very important function – it restricts the movement of the calf with respect to thigh and thus prevents the leg from bending. This is essential in Orthosis to support the legs to help keep them upright during walking or standing. Thus lock has to withstand all of the lateral loadin order to restrict the joint movement.

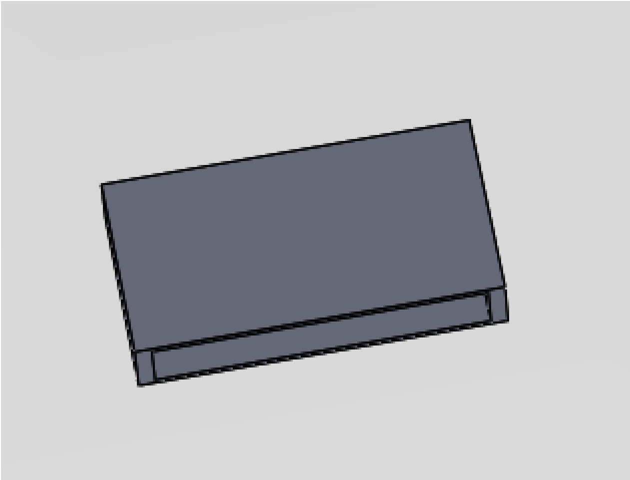

Figure 7: Model 1: Lock - CAD Diagram

Locking Mechanism:

Locking mechanism is termed as “Drop Lock Mechanism”. The locking mechanism involves locking by gravity and unlocking manually. The lock drops while standing due to the effect of gravity while standing, thus restricting motion of braces in lateral direction, preventing the legs from bending. In order to unlock, the user has to manually uplift the lock by hand. As the lock restrict all the motion, it is the epicenter of forces and require special attention during analysis.

Assembly:

The braces can be assembled with the joint with different assembly methods, including rivetting, press fitting, welding or with the help of screws. The assembly method depends on the applications and the available resources. The complete assembled CAD diagram is as following;

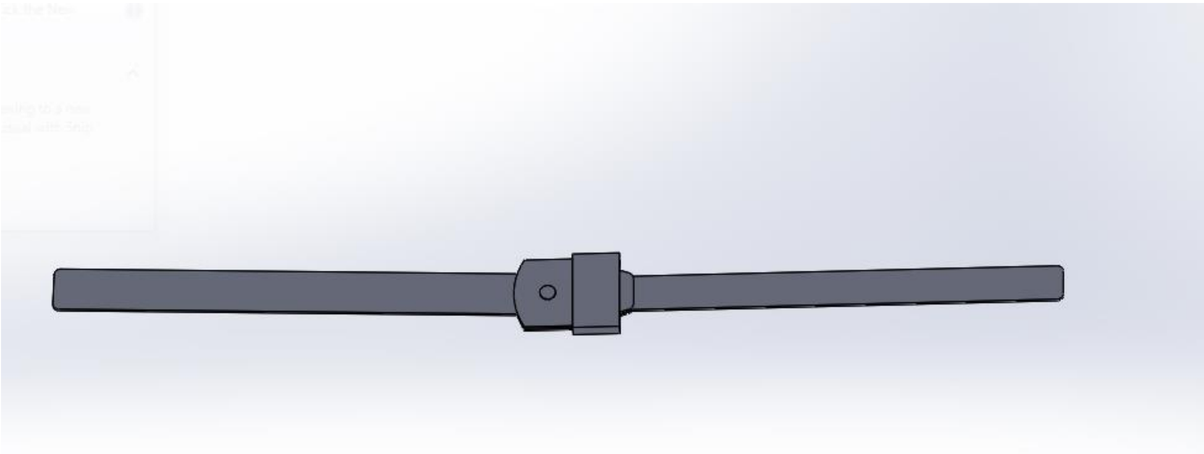

Figure 8: Model 1- Complete assembly including Side Braces, Joint and Lock

Force Calculations based on free body diagram

After the initial CAD design, the next step is to do the Finite element analysis of the design and in order to do that, Forces acting on the braces, joints and Lock need to be known. In order to calculate forces, basic statics principles are used. The main force that plays the role is the weight of the person as shown in the FBD. As one of the main functions of the braces is to withstand and support body load.

In order to have accurate force values and to double check our calculations, a literature review of the similar studies was performed. A few studies were found in this regard. These studies explained the underlying principles and methods to calculate the forces, and the magnitudes of the forces were determined experimentally. One of the methods used to calculate forces is by means of piezoelectric sensors tied to legs and measures the forces accordingly. Another method that was used is the application of the load cells to calculate the forces acting on the legs. Both these methods could be used to determine the forces as per actual. The detailed discussion of these methods can be found in Appendix-I.

Finite Element Analysis:

Orthosis being a medical device, and as the health and the wellbeing of the person directly depends on the safety of these devices, it is extremely important to make sure that these devices perform as per the desired parameters. The failure of this can lead to fatal injuries. Thus extensive analysis needs to be performed in order to ensure the safety of the device as well as of the user wearing it.

In order to do that, COMSOL software is primarily used, due to its broad spectrum and friendly user interface.

Analysis is performed on all the parts that make up these Orthosis including joints, side braces, rivets, screws etc. Main emphasis in analysis however is laid on the analysis of the lock as it has to withstand all the lateral forces in order to restrict the movement off the braces.

Side Braces:

As the side braces cater mainly for the body loads, buckling analysis is performed to determine the critical load factor. A high enough value for the critical load factor is obtained and ensures that the loads acting on the braces would not cause it to buckle. Stress analysis is also performed to ensure that the loads doesn't cause it to yield.

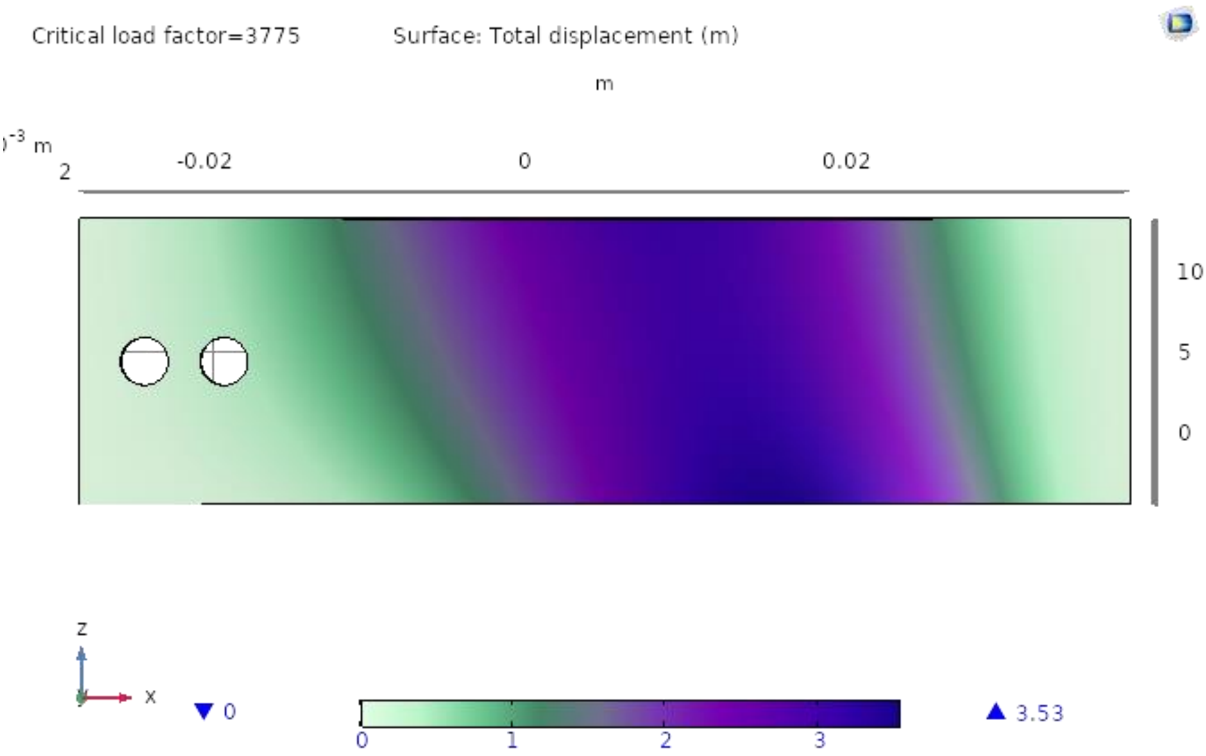

Figure 9: Side Braces – Buckling

Lock:

The lock prevents the braces from bending and thus has to cater for the majority of the loads. Lock thus holds the leg in the vertical position and thus plays the most important role in supporting the body load and its failure can result in catastrophic injuries. Stress analysis is performed to ensure that the lock and hence the complete orthosis wouldn't fail in the real life scenario. Axial force component is more prominent due to prevention from bending, as evident from the following diagram.

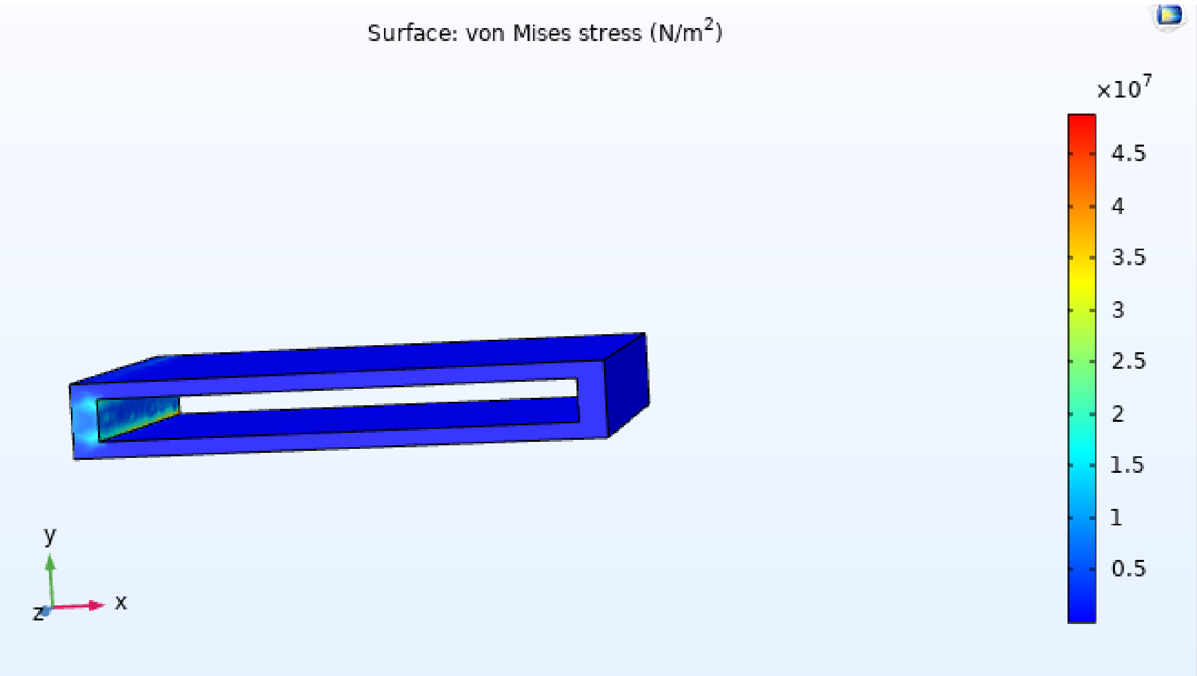

Figure 10: Model 1 – Lock – Stress Profile

Effect of Different Materials:

Different Materials are used for Side Braces, Joint and Lock in analysis. The main factors determining the materials for the end product are;

1. Safety
2. Cost
3. Weight of the device
4. Ease of Manufacturing and Machining
5. Effect of Thermal Loadings

In this regard some of the materials that were studied and were used in analysis are;

1. Stainless Steel SS 304/316
2. Structural Steel
3. WCB
4. Aluminum

The properties of each of the following is given in the table below:

Table 1 : Material Properties

SR. No.	Material	Density (g/cm3)	Tensile Strength (MPa)	Modulus of Elasticity (GPa)	Elongation at Break %	Hardness Brinell
1	SS 304	8.00	520-750	193	40	215 Max HB
2	WCB A216	7.87	420	205	25	121

3	Aluminum 7075	2.81	572	72	11	150

In the following table each of the material is ranked based on the determining factors discussed before based on the analysis performed and literature review.

Table 2 : Material Rankings (1-highest 3- lowest)

SR. No.	Material	Safety	Cost	Weight of the device	Ease of Manufacturing and Machining	Effect of Thermal Loadings
1	SS 304	1	2	1	2	3
3	WCB A216	3	3	2	1	2
4	Aluminum 7075	2	1	3	3	1

Model 2:

Model 2 is designed to provide the sane functionality but with more ease and safety. Similar to previous model, this is also a non-stance controlled orthosis. The primary difference between the two models is the joint and thus locking mechanism, with other components such as braces same and interchangeable with the previous model. Similar analysis methodology has been applied for this model as well for stress and displacement calculation under the load conditions calculated before.

Following methodology has been adopted for this model:

CAD Design

CAD design has been made by keeping the dimensions equivalent to the initial model. The salient feature of this design is its locking mechanism. Unlike previous model, which relied on gravity forced locking, this design is safer and less prone to failure.

The Orthosis can be divided into three main parts;

1. Side Braces
2. Joint
3. Lock

Side Braces:

Side Braces are similar to the ones in the previous model. They ca be interchanged for both models. Moreover, they also have the provision to be cut and used for the desired lengths.

Joint:

The differentiating feature between two models is the joint. The joint incorporates the locking mechanism as well, with a T shaped part as shown un the CAD diagram below. The joint has top and bottom covers to support and hold the T-lock in place.

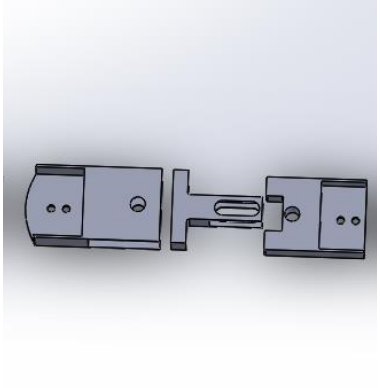

Figure 11: Model 2: Joint - CAD Diagram

Lock:

T-shaped lock is inorporated the to prevent the lower part from rotating by keeping it parallel to the lock. The lock has the slots at the top and bottom and thus can be slided to allow the motion in the lower part. As it prevents the rotation it is the epicenter of the forces and the design is made keeping in view the stresses acting on it.

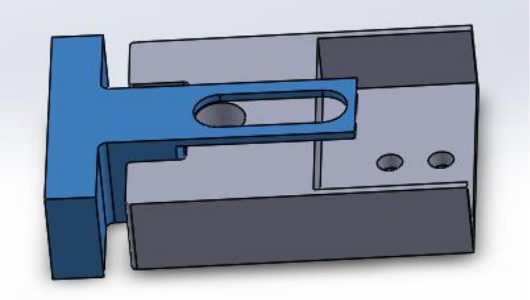

Figure 12: Model 2: Lock - CAD Diagram

Locking Mechanism

Initially, during any phase of the gait cycle when the leg is in vertical position, the lock prevents the rotation of lower part by restraining its motion against the lock body. However, to allow rotation, the lock is slide upwards through the slot in the lock's top and bottom. This allows the rotation of the lower part relative to the upper part. The lock can be lifted using either the lever or the steel wire. In case of lateral the user doesn't have to bend to unlock. The lock is slided down again while standing under the force of gravity as in this design. Alternatively springs can also be used for the same.

Assembly:

Like the previous model, the braces are connected to the central joint by either riveting or by press fitting or by screws. All of these methods have their pros and cons however final method of joining may depend on the application and the available resources.

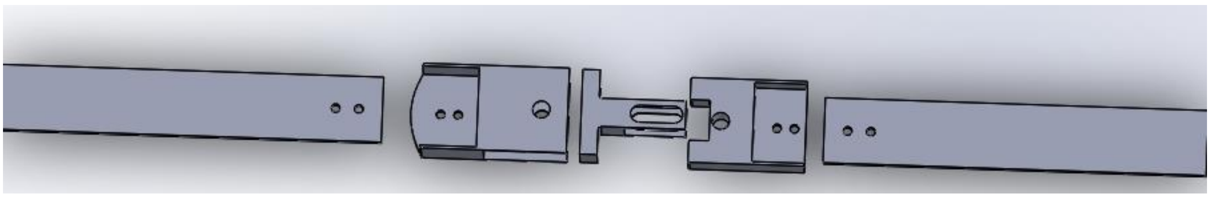

Figure 13: Model 2: Complete assembly including Side Braces, Joint and Lock

Finite Element Analysis:

Analysis is performed on all the parts that make up these Orthosis including joints, side braces, rivets, screws etc. Main emphasis in analysis however is laid on the analysis of the lock as it must withstand all the lateral forces in order to restrict the movement off the braces.

Side Braces:

Side braces from the previous model have been employed for this model as well due to similar functionality and dimensions. Thus these braces are interchangeable as they face similar stresses load conditions. This eliminates the need for analysis for the same braces for this model.

Lock:

Stress Analysis for the lock is the most crucial part as it is the part that holds the structure of complete orthosis and its failure will lead to the failure of the whole orthosis and in catastrophic injuries. Axial force component is more prominent due to prevention from bending, as evident from the following diagram.

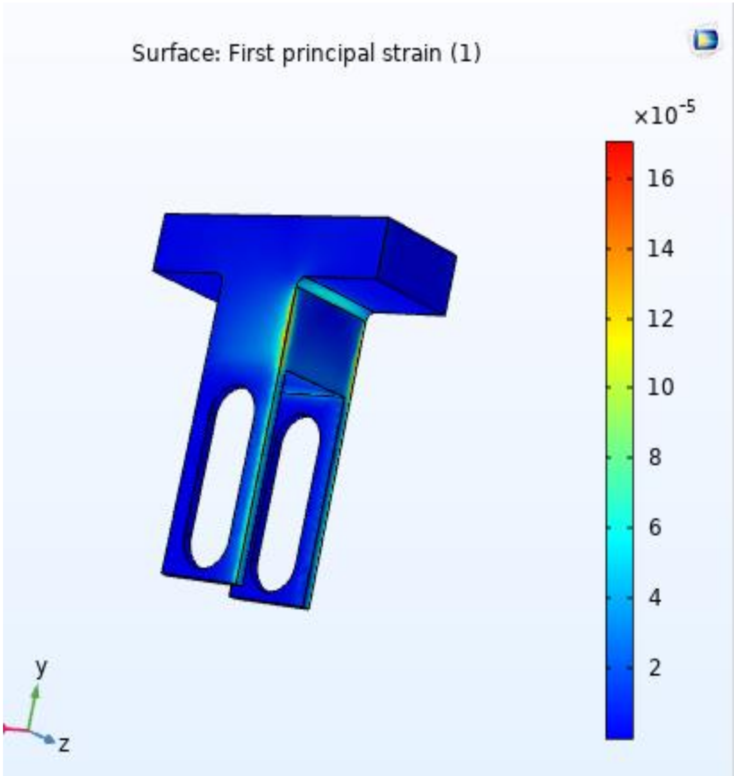

Figure 14 : Model 2 - Lock -Strain Plot

Effect of Change in Materials:

Different Materials are used for Side Braces, Joint and Lock in analysis. The main factors determining the materials for the end product are;

1. Safety
2. Cost
3. Weight of the device
4. Ease of Manufacturing and Machining
5. Effect of Thermal Loadings

In this regard some of the materials that were studied and were used in analysis are;

1. Stainless Steel SS 304/316
2. Structural Steel
3. WCB
4. Aluminum

In the following table each of the material is ranked based on the determining factors discussed before based on the analysis performed and literature review.

Table 3 : Model 2 - Material Preference criteria

SR. No.	Material	Safety	Cost	Weight of the device	Ease of Manufacturing and Machining	Effect of Thermal Loadings
1	SS 304	1	2	1	3	3
3	WCB A216	2	3	2	1	2
4	Aluminum 7075	3	1	3	2	1

CHAPTER 4: RESULTS AND DISCUSSIONS

The project is mainly focused on design and analysis of Lower limb orthosis for various applications and age groups. The primary objective behind this exercise is to reduce the cost and improve the design of the orthosis for local production, that to without compromising on the quality of the orthosis compared to the existing models in thee market though at higher cost.

The design process involved, imitating the already available design in the first phase in terms of dimensions and the locking mechanism. Not much was to change, as the model is tested not only in the lab but also in the real-life scenarios. Different materials were studied for the same design with necessary dimension changes for change in the different factors including weigh, cost and strength to name a few. The choice of final design, material and assembly method is dependent on the available resources, the type of application among other factors.

Using a lighter material, decreases the orthosis weight but also moderately increase its cost and reduces the strength and vice versa. Thus, tradeoff is necessary, requiring sacrificing few factors in favor of the other.

The salient features of both designs are the locking mechanisms. The first model incorporates an external lock that works under the influence of the gravity. FEM analysis has been performed to ensure that it will not yield under different set of forces and under different load conditions.

The forces acting on the loads were extracted from a research paper, in which the forces and loads acting during the gait cycle have been calculated using sensors. Thus, a very accurate force and load values is obtained for analysis. The analysis results were satisfactory and incorporated high enough safety factor for health applications.

The second model has been designed, keeping the salient features of the first model intact while modifying the design at the same time. The locking mechanism has been changed with a shift from external to an internal lock. This has increased the overall reliability and safety of the device and increased the convenience of the user.

Both the models have gravity forced locking mechanism. When in upright position, the lock falls to the slot and prevents the leg from bending. In the first model it is the external drop lock, while in second model it is an internal T shaped lock.

Different materials have been used and studied for their properties and effect on the desired device parameters. A tradeoff is to be made in the selection of appropriate material, compromising some parameters in favor of more desired ones. Similarly different assembly methods are discussed for their pros and cons, however the desired assembly method depends on the material, application and available resources.

CONCLUSION AND RECOMMENDATIONS

Overall, the project has achieved the goals of local designing and analysis of the orthosis, and reduction in the cost of the same. Different designs and materials have been studied for their pros and cons. However, the choice of final design and material will depend on the application.

Due to unprecedent scenario, manufacturing of the prototype was not possible. It is desired that actual prototypes be made and tested, for different materials and assembly methods discussed.during design and analysis phase. In the next stage lab stage testing could be performed to ensure the safety and reliability of the end user.

In the second model. the lock falls into the slot under the force of gravity in the current design. It is suggested that the design and reliability can be further improved by using springs to hold the lock in the slot.

For the second model, two unlocking mechanisms have been briefly discussed, either by using steel wires to unlock in the upright position (recommended) and by unlocking using levers or protruded edges by bending. Unlocking methods can be studied in detail for their ease of use, reliability and relative safety.

REFRENCES

[1] Shigley, J. E. (2011). Shigley's mechanical engineering design. Tata McGraw-Hill Education

[2] HIBBLER, R. MECHANICS of MATERIALS Fifth Edition. Chapter, 5

[3] Types of Orthoses Retrieved from: https://www.fior-gentz.de/en/orthotics/orthosis/types-of-orthoses.html

[4] Imani Nejad, Z., Khalili, K., Hosseini Nasab, S. et al. The Capacity of Generic Musculoskeletal Simulations to Predict Knee Joint Loading Using the CAMS-Knee Datasets. Ann Biomed Eng 48, 1430–1440 (2020)

APPENDIX I: KNEE FORCES

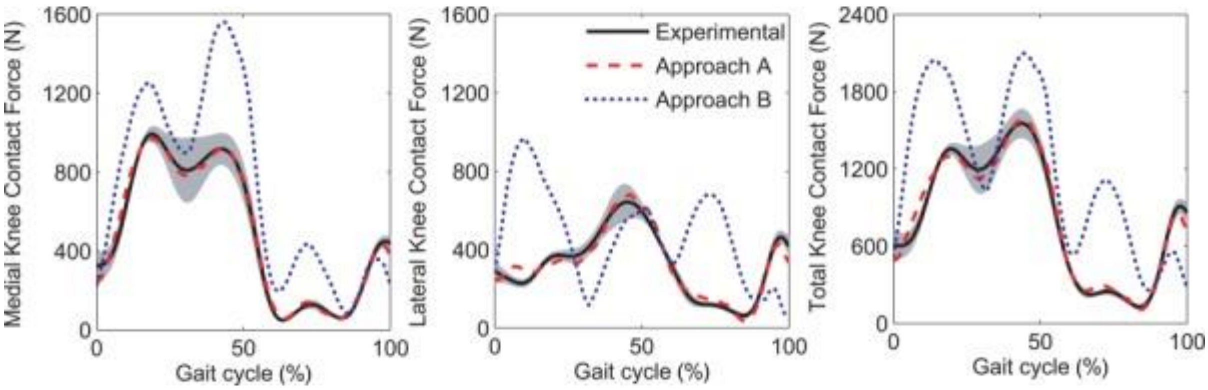

Figure A : Experimental knee contact forces and mean knee contact force The gray area corresponds to the mean ± standard deviation for the experimental forces.

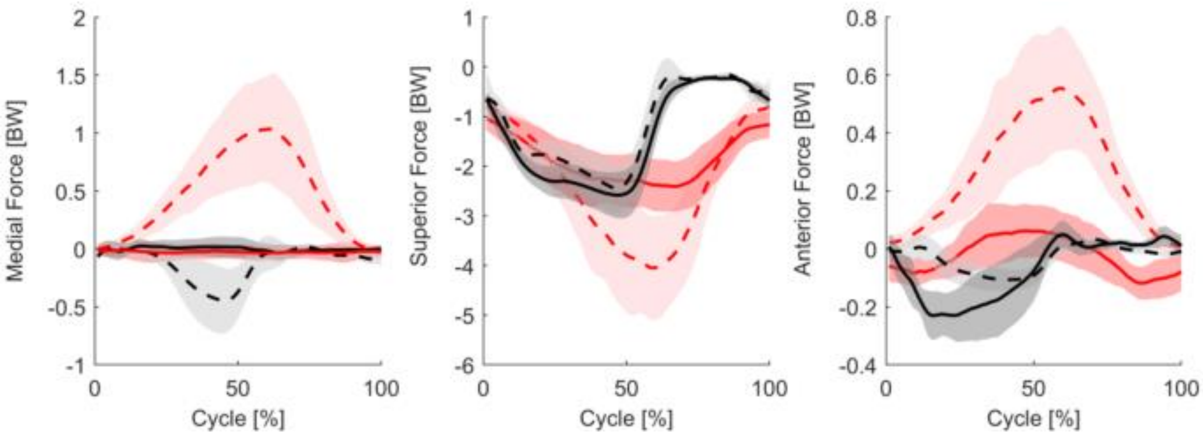

Figure B: The predicted (dashed) and measured (solid) KCFs for all subjects performing level walking (black/dark) and squatting (red/light). The bold lines represent the mean across all subjects and all trials, while the shaded areas represent ± 1SD. (BW represents Body weight)