DESIGN OF KNEE JOINTS FOR STANCE CONTROL ORTHOSES

A REPORT

submitted by

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for the award of the degree

of

BACHELOR OF TECHNOLOGY

DEPARTMENT OF MECHANICAL ENGINEERING
INDIAN INSTITUTE OF TECHNOLOGY MADRAS
MAY 2018

ACKNOWLEDGEMENTS

I would like to express my gratitude to Prof. Sujatha Srinivasan for guiding me for this project and embedding her valuable experience in this project. I am also highly indebted to Ganesh M. Bapat, a Postdoctoral Fellow at the R2D2 Lab, IIT Madras for adding immense value at each stage and directing this project actively.

I am grateful towards Mr. Praveen for assisting me with the logistics and Mr. Vignesh for helping me carry out testing. The prototype construction of the electromechanical knee joint model (Initial Prototype) wouldn’t have been possible without the involvement of Mr. Seethapathi, technician for the project. Finally, I would like to thank Mr. Nargunam and his colleagues from Sree Balamurugan Engineering Enterprises for enabling timely manufacturing of all the subsequent prototypes through laser cutting.

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ABSTRACT

KEYWORDS: Stance Control Orthoses, Passive Actuation.

A conventional Knee-Ankle-Foot Orthosis (KAFO) locks the knee during both the stance (load-bearing) and the swing (ground clearing) phase of walking which results in unnatural and tiring gait. Most of the existing devices are bulky, expensive and do not meet the needs (squatting, cross-legged sitting and ease of maintenance etc.) of people in India. Moreover, their availability is limited to the western countries. The challenge is to design an affordable, compact and functionally better KAFO to meet the needs of users in developing countries.

In the initial phase, we propose a concept of a compact, electro-mechanically operated knee joint mechanism which will serve as an affordable alternative to KAFO designs available in the market. The manufacturing phase of this joint revealed infeasibilities, due to which the design had to be upgraded to a passive joint.

The second phase focuses on the development of a purely mechanical system that is actuated by the weight of the human. This eliminates the complexity involved in using and maintenance of an electromechanical system. For example, an electromechanical system requires the person to carry a bulky battery pack and would add additional reliability issues. The prototype has been built using laser-cutting and is ideal for quick and inexpensive for bulk production. The focus has also been on the ease of assembly and maintenance. It also tries to address some of the cultural-specific elements like squatting and cross-legged sitting.

Finite Element Analysis (FEA) was performed as the most basic step for design validation. Loading on Universal Testing Machine (UTM) and able-bodied trials are two preliminary tests conducted for ensuring safe operation. After the basic capabilities are proven, the device will enter the testing on actual subjects.

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

Figure 1.1: Knee Ankle Foot Orthosis

A Knee-Ankle-Foot Orthosis (KAFO) is commonly prescribed to people with the knee extensor muscle weakness, to assist them during walking. The International Committee of the Red Cross' (ICRC) market sizing study estimates that there are more than 1 crore people in India who need such devices [1]. A conventional KAFO locks the knee during both the stance (load-bearing) and the swing (ground clearing) phase of walking which results in unnatural and tiring gait. Researchers have attempted to solve this problem by designing Stance Control Orthoses (SCO) which locks the knee during stance phase and allows free knee flexion to clear the ground thus mimicking a normal human gait [2-3]. However, these devices mostly available in Western countries are bulky, expensive and do not meet the needs (squatting, cross-legged sitting and ease of maintenance etc.) of people in India and other developing countries.

The challenge is to design an affordable, compact and functionally better KAFO to meet the needs of users in developing countries. An improved functional performance will be achieved by facilitating users to walk with more normal and energy-efficient gait. We explore different designs of the SCKAFOs, both electromechanically controlled and passive ones, and analyze their functionality.

1.1. OBJECTIVE

Through this project, we intend to establish the superiority of Stance Control Orthoses over traditional locked knee joints. From a research perspective, studying the kinematics and energetics through trials on subjects would enable us to conclude the effect.

In the context of a product, we don’t only have study the functionality but also other aspects like aesthetics and apprehension to use. The objective would therefore be to make this available to as many people as possible.

1.2. LITERATURE REVIEW

Literature review was aimed at studying the features and flaws of the existing stance control orthoses. This review also puts into perspective the challenges involved while building and testing the orthosis. We learn about different training strategies used by various research groups and how it impacts the outcome. Typically, the parameters that are considered while benchmarking a SCKAFO are broadly categorized into three groups – Kinematics, Energy and Subjective feedback. Kinematics include parameters such as cadence, step length and knee range of motion. Usually, oxygen consumption and heart rate act as the substitutes for energy measurement. Subjective feedback, although is non-technical, is vital for constructing an orthosis which accounts for aesthetics, noise and other psychological factors.

Apart from individual articles, a comprehensive review paper [2] on existing research literature has been used as a reference to summarize the outcomes. We observe a clear betterment in terms of overall kinematic parameters, except for an ambiguity in the walking speeds. Pelvic obliquity, which is caused due to vaulting, is also seen to be reduced with the use of SCKAFOs. However, very few studies (3 out of 18) include energy expenditure while all other articles suggest that a lower energy consumption would be a direct implication of improvement in kinematics. Adding over to the debate, only 2 out of 3 papers claim improved energy efficiency which makes these results highly inconclusive of any betterment in terms of expended energy. This in turn establishes a need for further examination of this class of devices, which could potentially change the lives of people wearing stiff-knee KAFOs. Also, the existing Stance Control Orthoses retail at a hefty price – around Rs 1 Lakh to Rs 5 Lakh (when converted to INR) and are only accessible to specific regions on the globe.

1.3. TIMELINE

The illustration below roughly explains the timeline of the project. The project began with a thorough understanding of the problem through literature survey and then progressed to the design phase of the electromechanical solenoid clutch mechanism. After realizing the infeasibility of manufacturing, the focus shifted on to passive SCO design which featured fastener-free laser cut assemblies.

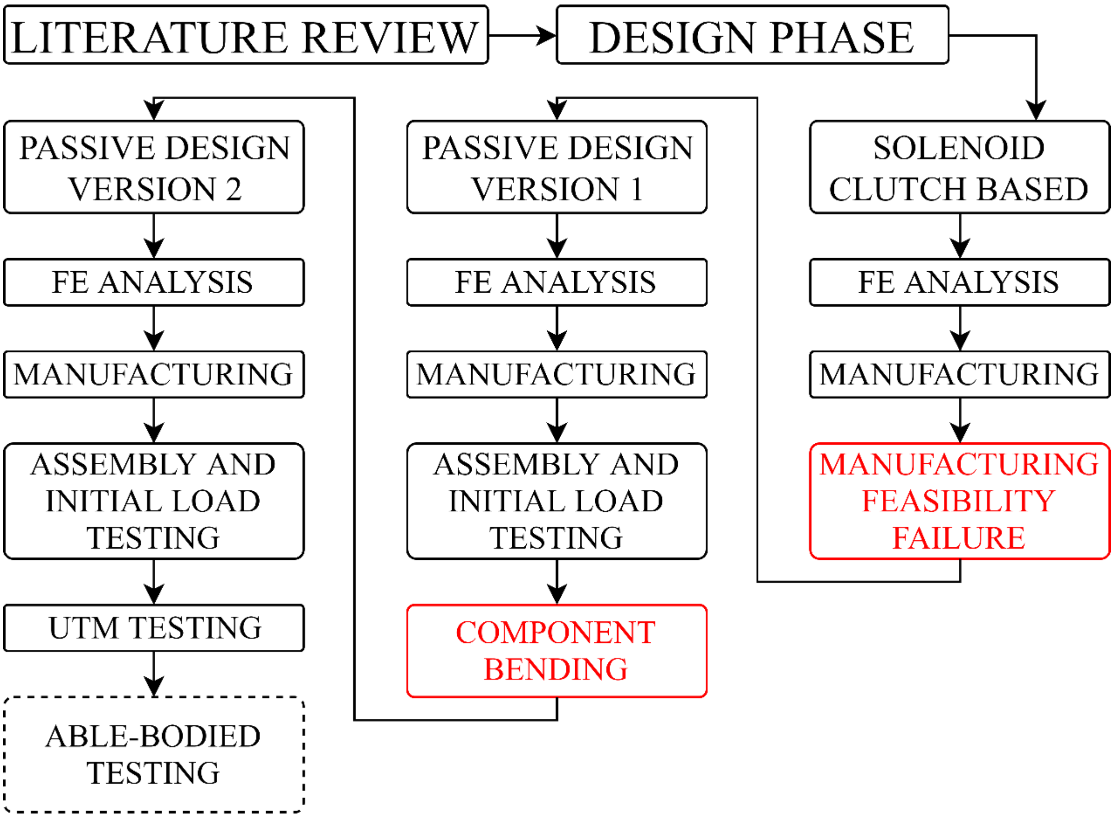

Figure 1.2: Timeline Summary

CHAPTER 2

PHASE 1

2.1. SOLENOID CLUTCH MECHANISM

2.1.1. APPROACH AND NOVELTY OF DESIGN

The research phase was followed by an ideation phase in which we explored several mechanisms to implement selective locking and feasibility in the context of Indian patients. The first idea that emerged was to integrate a linear actuator to an existing knee joint orthosis – EZ LOK [7]. EZ LOK (Easy Lever Operated Knee) was primarily built for addressing the problems which are more specific to India like squatting and cross-legged sitting. It utilizes a lever mechanism (operated by user) to engage or disengage the locking mechanism which acts like a stiff-knee joint while using but can be folded by the user when required. The idea of actuating the lever to selectively lock the joint was postponed due to feasibility issues.

Subsequently, a clutch-based mechanism was conceptualized. The proposed device uses a unique interference clutch mechanism to achieve selective locking and unlocking during different phases of gait based on the microprocessor-controlled decision making. An integrated foot pressure sensor and Inertial Measurement Unit (IMU) provide input to the microprocessor to decide on the accurate trigger time. One of the most unique features of the device is its ability to communicate wirelessly through Wi-Fi or Bluetooth. This allows for on-the-go tuning of the triggering to match patient-specific gait characteristics. This will also help researchers collect gait data of real life situations encountered by KAFO users. The new design uses readily available components in the market, which makes it cost-effective and easy to repair/maintain.

Apart from the above-mentioned ideas, mechanisms containing lockable gas springs were also considered but discarded due to the complexity in construction and inaccessibility of off-the-shelf components. This however leaves us a room for functional innovation in the future.

2.1.2. DESIGN DETAILS

The key factor in the design is the holding torque of the clutch mechanism to provide stability against the flexion of the knee joint during walking. This design utilizes wedge mechanism to push the clutch plates out and locks the knee during stance phase. A rough schematic is shown below.

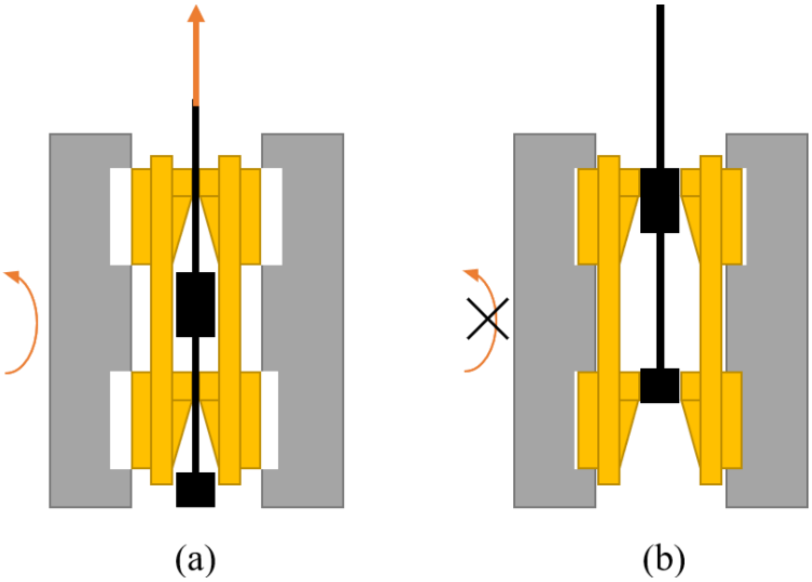

Figure 2.1: (a) Clutch is disengaged, the joint is free to rotate, (b) locked position

The motion that is observed is actuated by a solenoid. Since, we are using readily available components like the solenoid (HCNE1-0520 – 3 mm stroke and 6N pull) we need to consider the parameters such as stroke length and pulling force while designing the joint. In terms of actual scale, a vertical displacement of 3mm will result in 1mm outwards movement for each plate.

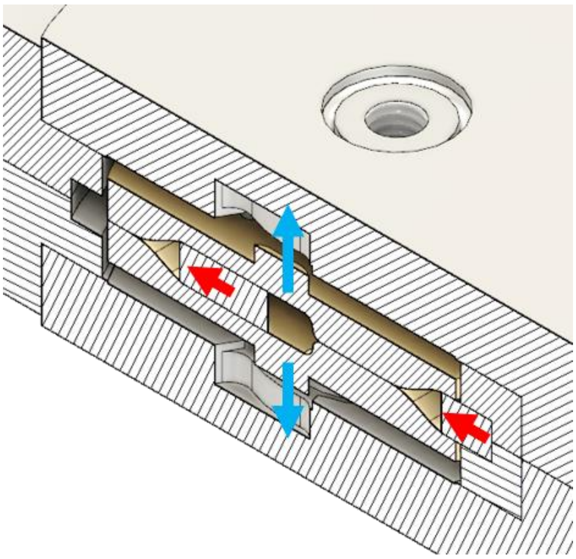

Figure 2.2: Cross Section View of Wedge Mechanism

The design is as follows:

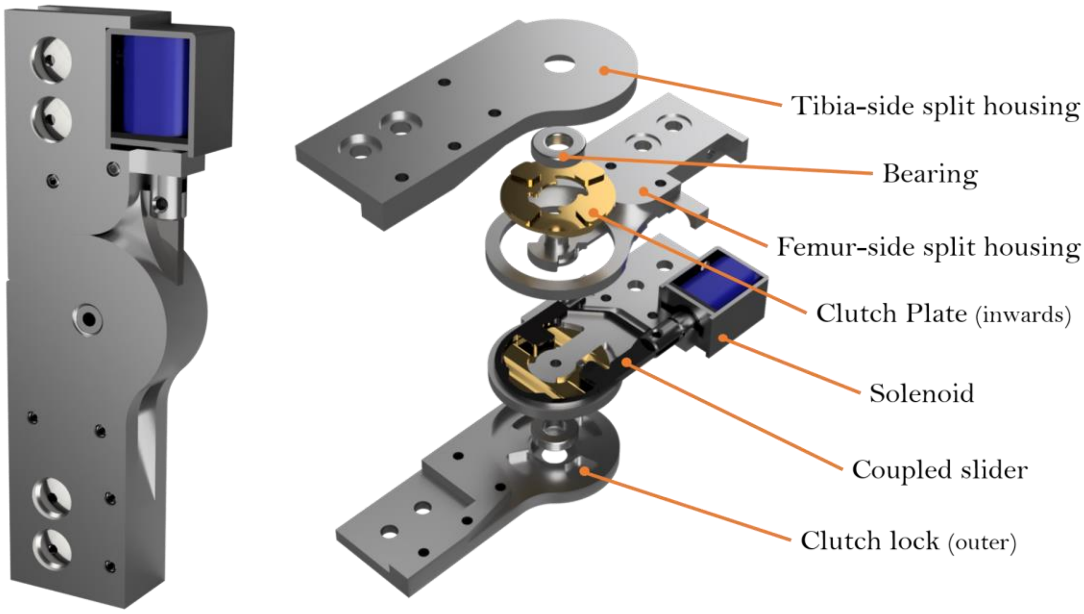

Figure 2.3: Exploded view of the knee joint assembly

On the electronics hardware side, we are using ESP32, a wireless (Bluetooth and Wi-Fi) microcontroller for performing the calculations and triggering the solenoid at the right time. The gait feedback will be obtained by fusing the data from both IMU (MPU6050) and Force Sensitive Resistor.

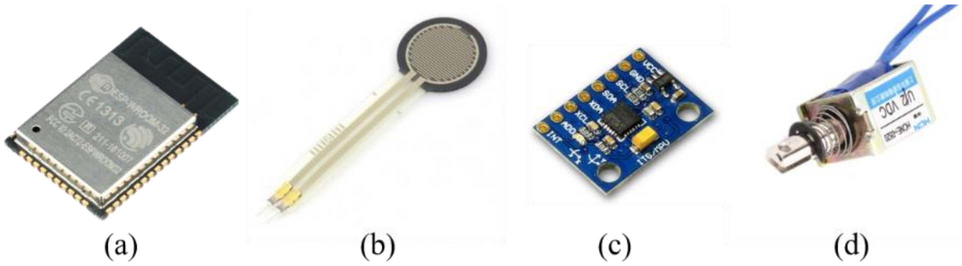
(a) (b) (c) (d)

Figure 2.4: (a)ESP32 μcontroller, (b) Force Sensor, (c) MPU6050 IMU, (d) Solenoid

As the resistive force sensor and gyroscope transmit the load and angle data respectively, the control algorithm decides when to trigger the locking and unlocking. Once the trigger occurs, the solenoid is activated, therefore, pushing the clutch plates away and locking the knee joint. However, tuning the orthosis for locking and unlocking for each user to face real time situations is a challenge, which can be solved only with personalized tuning. The interaction between different components is designed to be as follows.

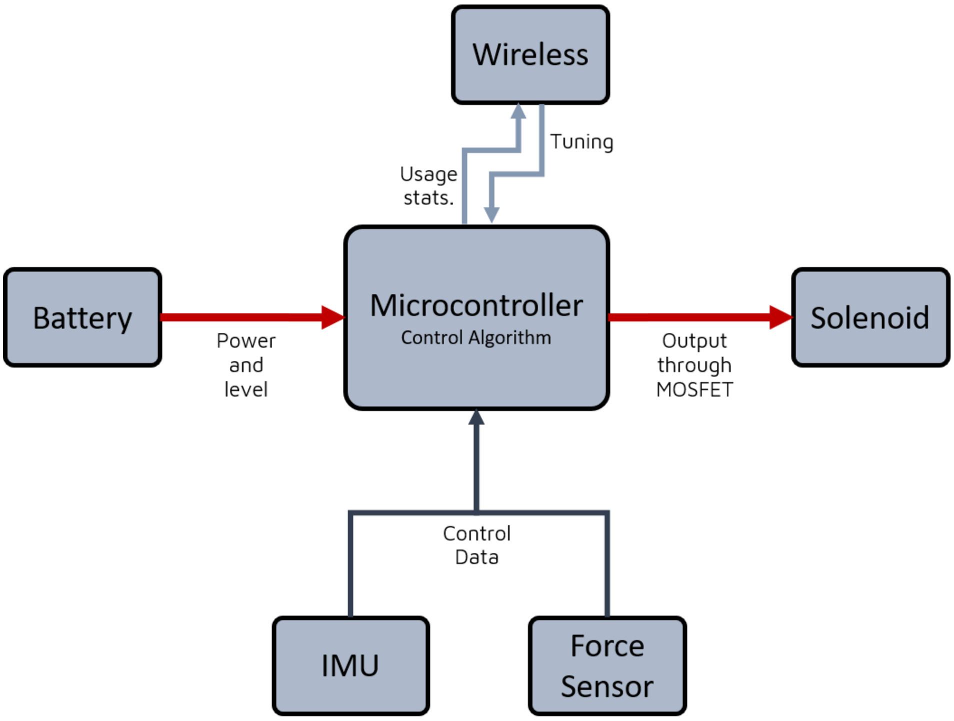

Figure 2.5: Schematic of interaction between various components

2.1.3. SIMULATIONS

Here, we see that in the stance phase, 1mm wide overlap is what is carrying the entire load and therefore, is the most critical part. The safe load case is 60 Nm and the mechanical design is validated using FEA package (Autodesk NASTRAN) integrated with the CAD software (Fusion 360). The design turns out to be safe in the given loading conditions.

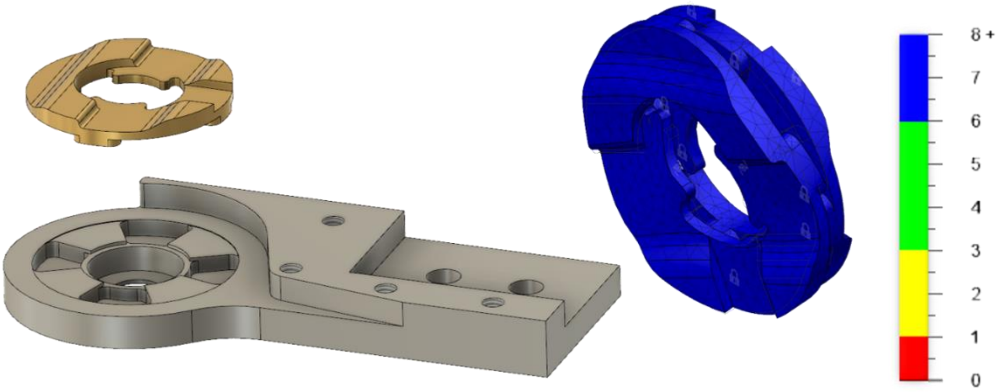

Figure 2.6: Clutch Plate Design (Left) and Factor of Safety Report (Right)

2.1.4. MANUFACTURING

The knee joint assembly, as shown in *Figure 2.7* was manufactured to validate the mechanism. The approach taken for manufacturing was to build the first prototype with easy-to-machine materials like aluminum. Majority of the parts were machined from aluminum using CNC machine followed by manual finishing by the technical staff. The slider in between was manufactured by laser cutting since it was small and contained sharp corners. Manufacturing inaccuracies have led to several problems in the assembly and has consumed more time than expected. First attempt to machine the clutch plates failed due to improper mounting and very thin design.

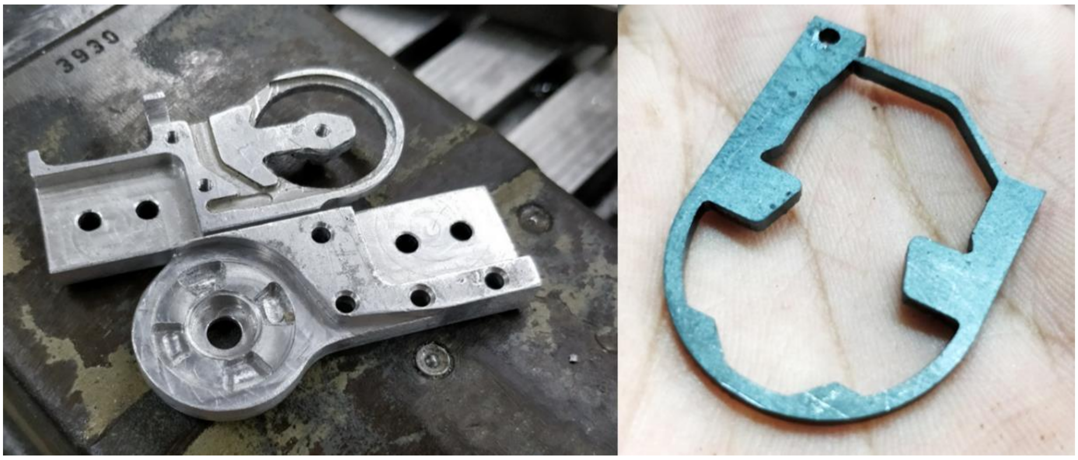

Figure 2.7: CNC machined components(left) and Laser cut slider (right)

2.2. SUMMARY

By the end of Phase 1, a prototype was constructed but it had flaws. Manufacturability of the design held a great learning experience for the next design. After several iterations of manufacturing the components, it was realized that manufacturing this design would be infeasible, at a bigger scale. Also, there were intricate things like friction in the slides which caused the mechanism to fail in practicality. The exploration on this model was discontinued for the above reasons.

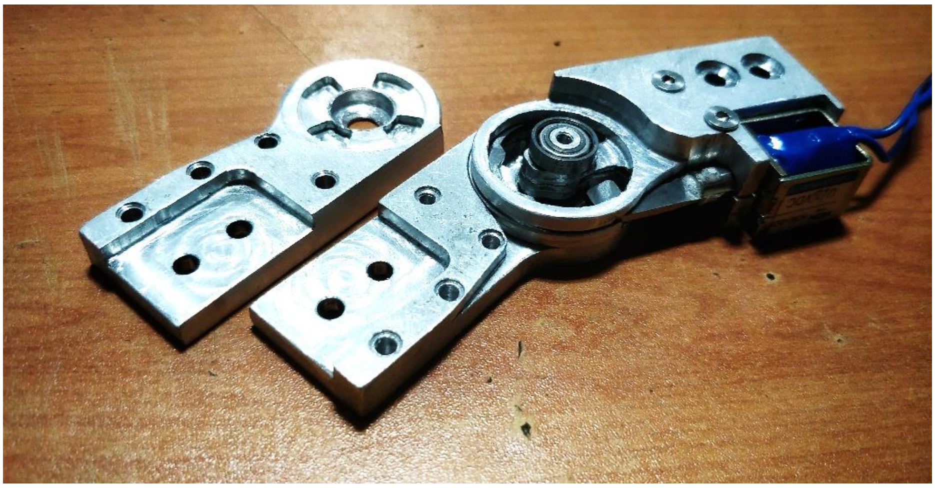

Figure 2.8: Assembled Joint

CHAPTER 3

PHASE 2

3.1 PASSIVE KNEE JOINT V1

3.1.1. APPROACH AND NOVELTY OF DESIGN

Learning from the manufacturing issues in the phase 1, this design was made to be manufactured with ease. Laser-Cutting was the choice since it was both quick, inexpensive and precise. Instead of an external element operating the locking mechanism, this mechanism works by locking when the leg is loaded. The vertical displacement is what causes the locking to actuate. It is loaded by spring, to unlock as soon as the load bearing phase is over, for the leg.

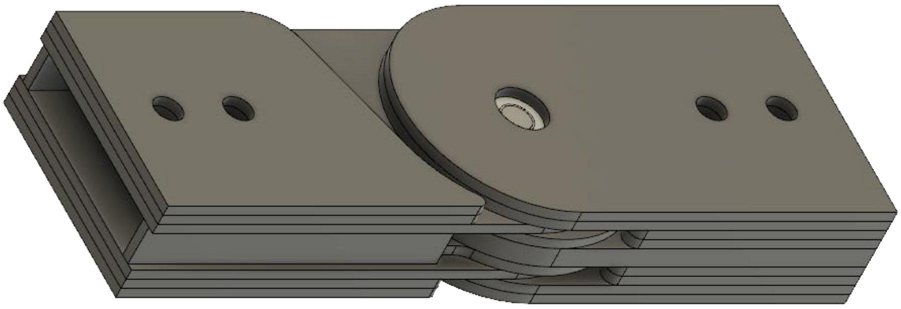

Figure 3.1: CAD Model of the passive joint v1

3.1.2. DESIGN DETAILS

All the involved components were laser-cut with remarkable accuracy except for the bearings and shafts involved. The entire joint was expected to weigh heavier than the typical ones. It was also designed to be completely fastener-free with the exception of the points where uprights were attached. This design also incorporates a feature which only locks the knee only when the load bearing is vertical. This ensures that the joint doesn’t lock itself while transitioning from sitting pose to standing.

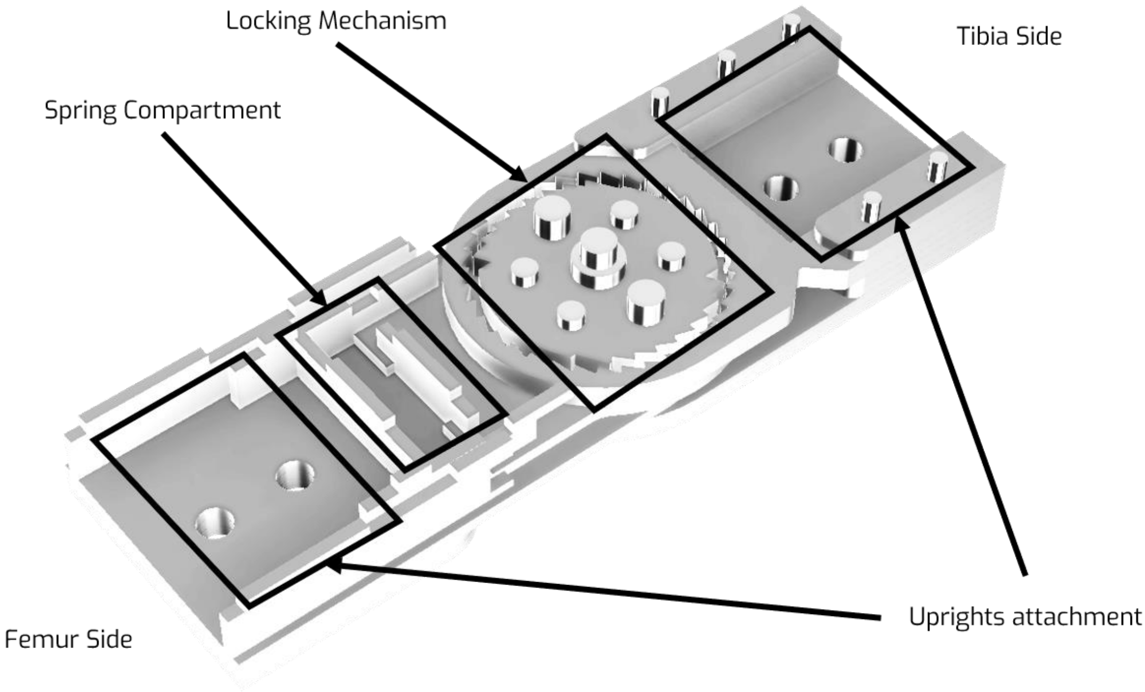

Figure 3.2: Open view of the joint

For the locking, it utilizes the human weight which causes a vertical displacement of 3 mm, which in turn due to the wedge mechanism causes horizontal expansion in the locking plates by 1.5 mm. Although a displacement in the knee joint is expected to cause discomfort due to relative sliding, since the displacement is 3 mm, it is considered negligible.

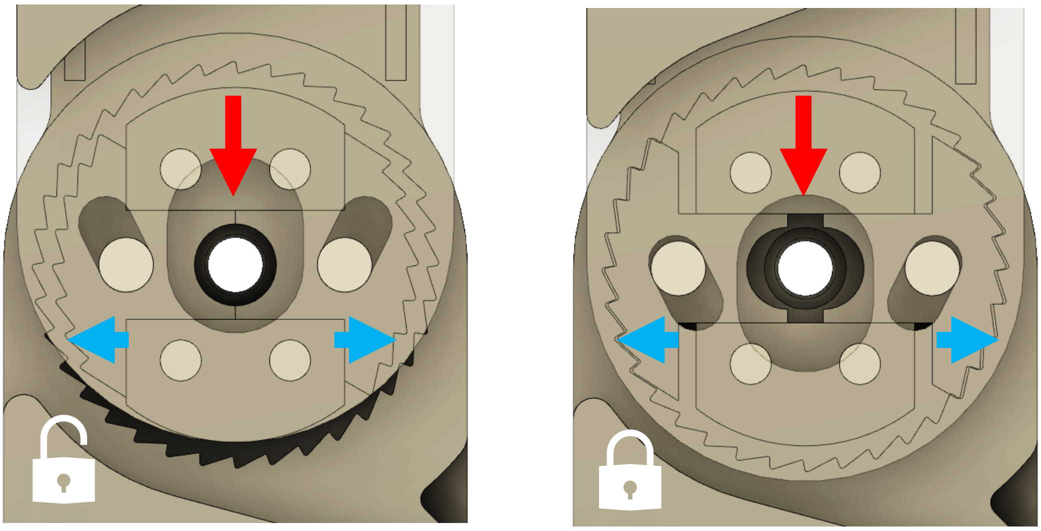

Figure 3.3: Locking Mechanism

3.1.3. SIMULATIONS

As the first step, even before the entire design was made, the ratchet pattern was tested for it’s strength. From the results, 3 mm thickness of the ratchet would suffice for bearing the test torque of 60 Nm.

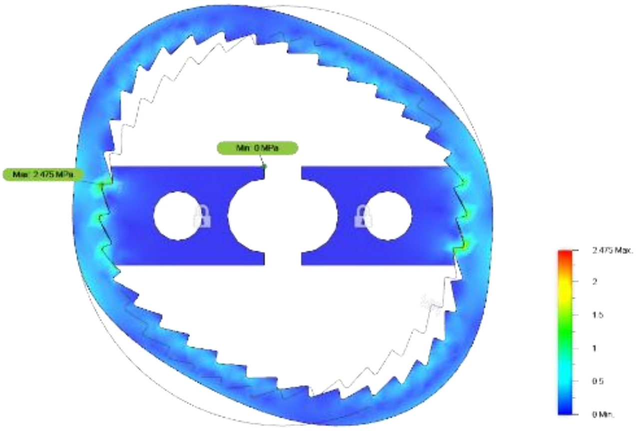

Figure 3.4: Simulation Results on Ratchet (FOS)

After validating the strength of the core mechanism, since all the parts were laser cut, FEA was performed on the entire assembly. Three different cases were considered:

- Only Force (500N)
- Only Moment (60Nm)
- Combined Load (500N + 60Nm)

These three cases cover all the situations along a gait cycle and can be assumed safe if it passes through all the cases. The results suggest that the entire assembly would be safe in operation. Also, it's important to note that the effect of plain force is minimal, and moment is the major influence.

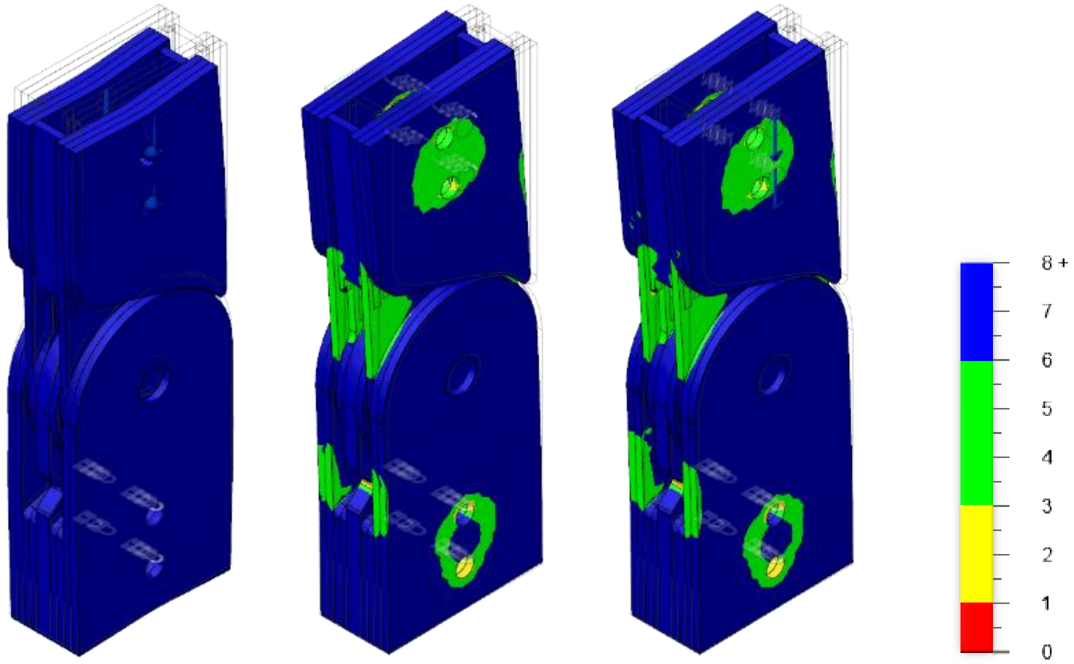

Figure 3.5: Simulation Results on assembly (FOS)

3.1.4. MANUFACTURING & ASSEMBLY

As discussed earlier, manufacturing was done using laser cutting and the process was accurate, inexpensive and fast. It requires a *dxf* format file, which was created on the CAD software by laying all the components flat.

Figure 3.6: Laser Cut Components

The assembly was also easy enough but the several copies of this had to be cut for perfecting the tolerances and increasing the repeatability. The tolerances were corrected by tweaking the laser cutting parameters such as feed rate, offset, etc.

3.1.5. SUMMARY

Four joints were then assembled for testing purposes, of which two of them were worn on a KAFO made for the author. Initial trials were carried out by the author walking with the joints on the KAFO. The initial trials demonstrated the functioning of the mechanism but due to obliquity in the axes of the KAFO, the swing phase displayed friction.

Figure 3.7: Assembled Joint

Due to the above-mentioned issues, the joint after loading for 10-15 times got jammed. This was diagnosed to be because of bending of two components which would cause misalignment in the locking mechanism. Therefore, the design was upgraded to eliminate the weak members of the assembly.

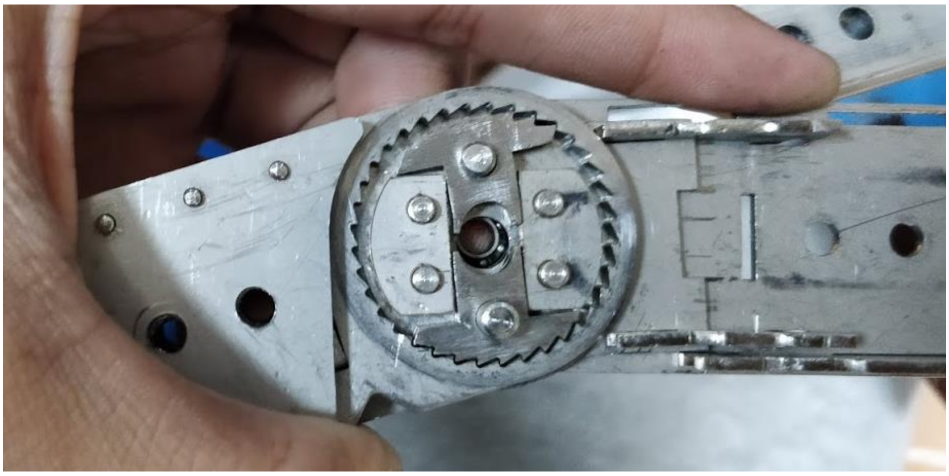

Figure 3.8: Inspection of Mechanism after Initial Testing

3.2 PASSIVE KNEE JOINT V2

3.2.1. APPROACH AND NOVELTY OF DESIGN

This design was done in parallel with V1. The main idea behind this design was to incorporate the same features of the earlier version but with a lesser amount of displacement involved. As it can be understood, displacement in the knee joint could potentially cause relative motion between the frame and the thigh which could lead to discomfort. This design attempts to minimize the vertical displacement by utilizing a four-bar linkage mechanism.

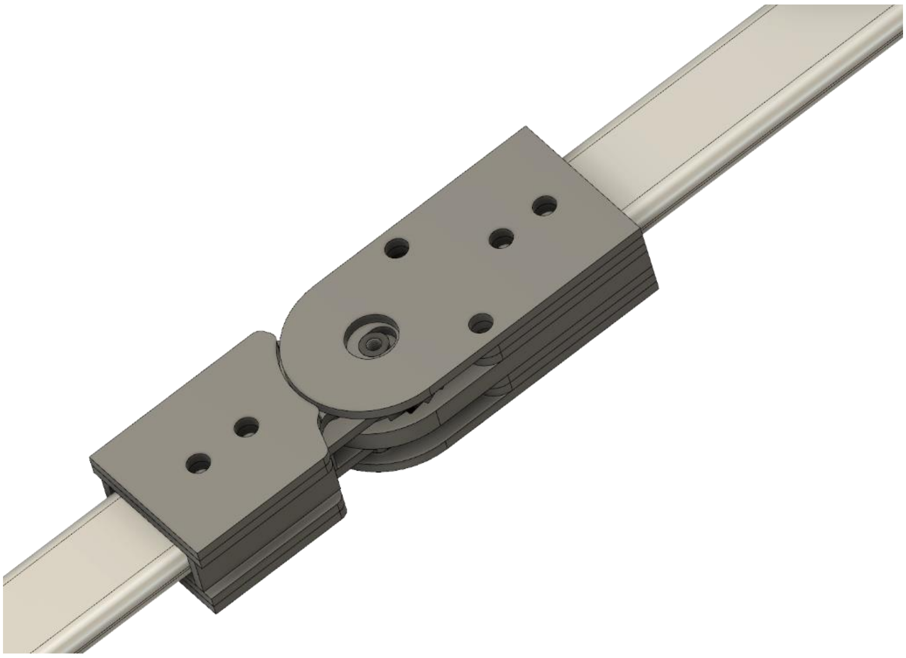

Figure 3.9: CAD Model of the passive joint v2

3.2.2. DESIGN DETAILS

The objective was to reduce the displacement and we were able to attain a reduction to 1.5mm from 3mm. This design was based on pawl-ratchet mechanism, which would be engaged by a four-bar mechanism.

The same can be understood from the mechanism described through an illustration below.

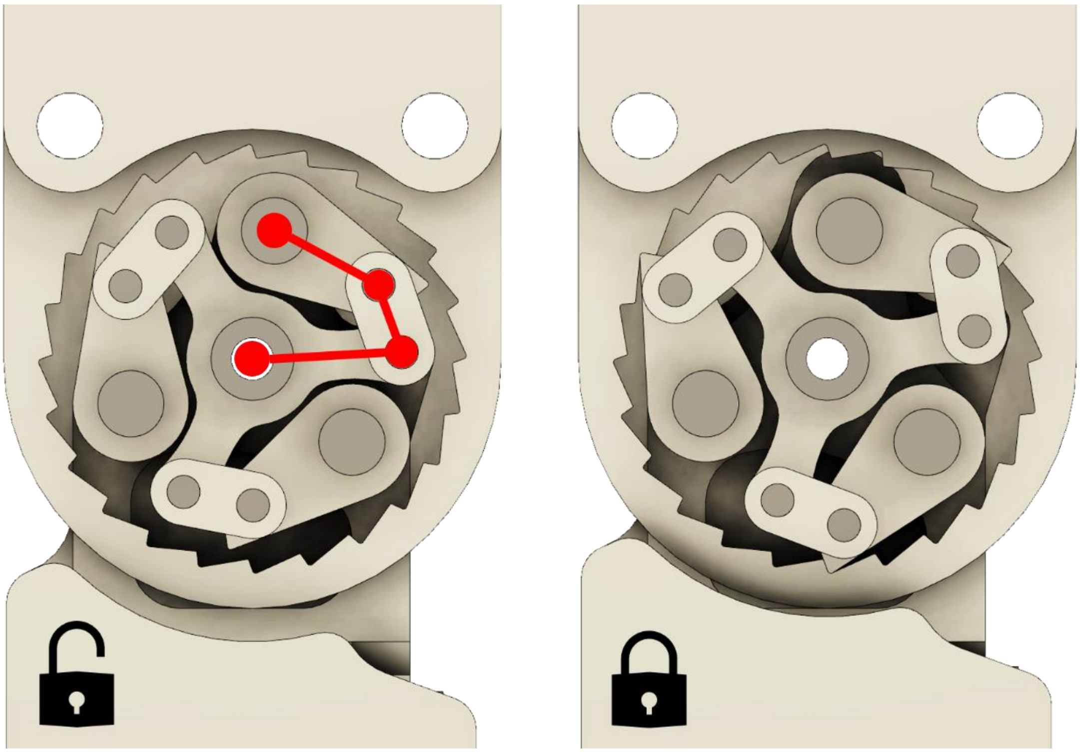

Figure 3.10: Locking Mechanism

The actuation layer is as shown below:

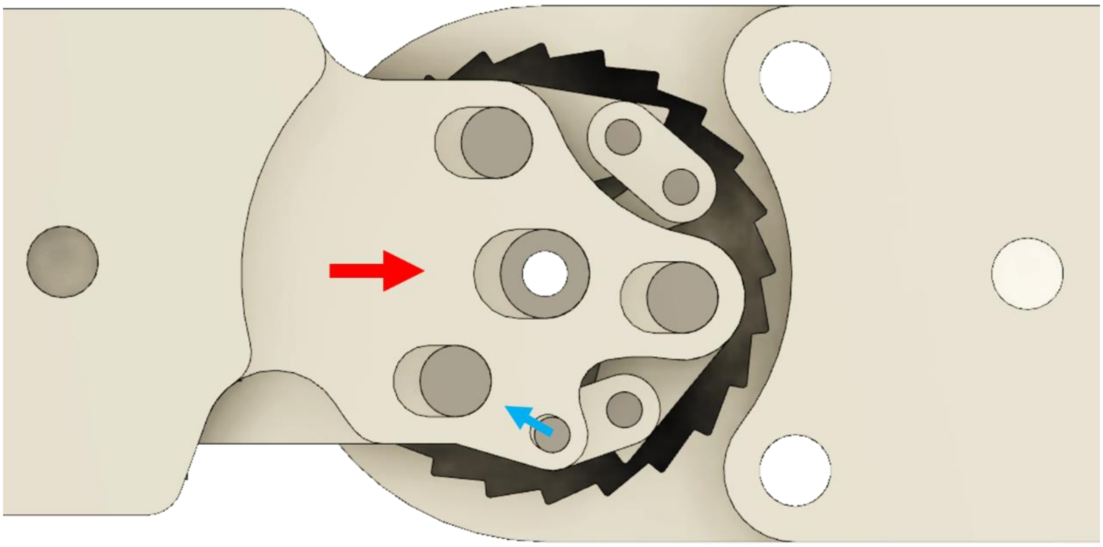

Figure 3.11: Actuation Mechanism (Red – Actuated, Blue - Locking)

3.2.3. SUMMARY

As we can observe, this design contains lot of small intricate moving parts which would cause problems in manufacturing and majorly during assembly. Also, FEA proved these small parts to be vulnerable to failure. Due to these reasons, this prototype was not constructed. This prototype design proposes a mechanism that could potentially serve the purpose at a later stage.

3.3 PASSIVE KNEE JOINT V3

3.3.1. APPROACH AND NOVELTY OF DESIGN

This design attempts to address the failure points of the above proposed mechanisms. This revision manages to bring the same features without compromising on the locking strength. This iteration retains the design philosophy of the previous two, while simplifying the mechanism by a huge margin. This also resolves the issue of excessive friction encountered in v1 when the upright fasteners were tightened. Small features like filleted corners and hyperextension block were a result of suggestions made on v1 design.

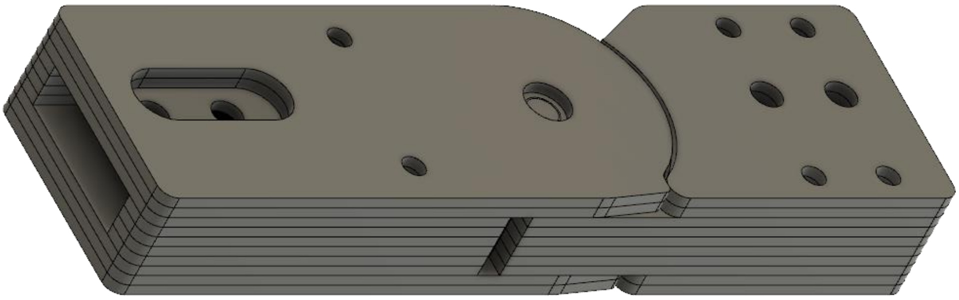

Figure 3.12: CAD Model of the passive joint v3

3.3.2. DESIGN DETAILS

All the involved components were laser-cut with remarkable accuracy except for the bearings and shafts involved. This design involves only 21 laser cut components in contrast to v1, which contained 33 parts. Unlike the previous joint, this is not fully-fastener free because of the screws coupling plates with the spacer. This inherits all the other features that belonged to first version of passive joint.

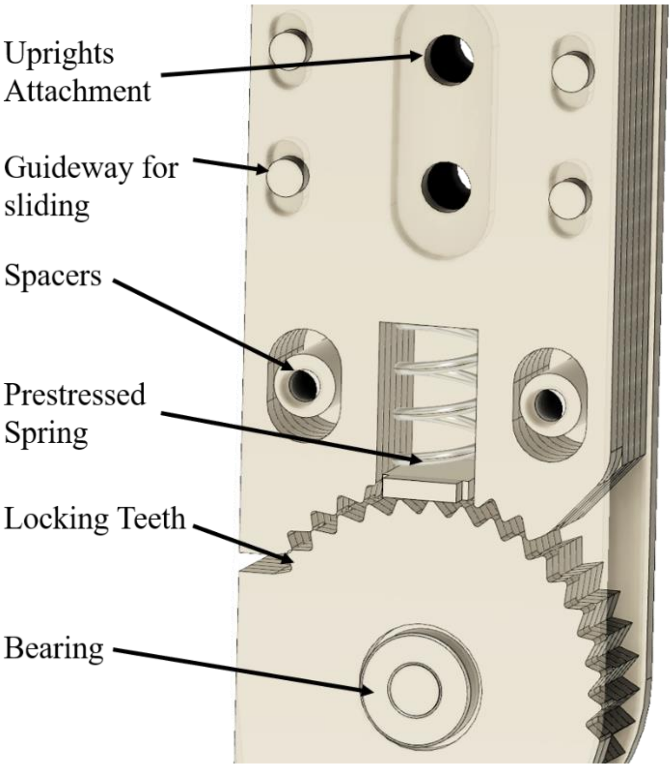

Figure 3.13: Open view of the joint

As a part of exploration, two different teeth patterns were laser-cut. These both were simulated for load bearing capacity and were able to withstand the load easily. Both had different geometries as we can notice in the picture below. Using pattern (a) resulted in joint locking itself and not releasing itself. Pattern (b) proved to be reliable when it came to lock. Using pattern (b) on the femur side and pattern (a) on the tibia side yielded an unusual effect. It provided a smoother transition to the locking phase allowing a slight stance flexion, feeling more natural. The locking capacity is still a challenge and must be tested sufficiently. Playing with the teeth pattern opens possibilities to incorporate the ability to flex in stance smoothly.

Figure 3.14: Various teeth patterns (a)deep, (b)shallow, (c)hybrid

For the locking, it utilizes the human weight which causes a vertical displacement of 3mm, which directly engages the teeth, hence locking it. The load is now borne by a width of 9mm instead of 3mm in the old design. This massively increases the load bearing capacity of the joint.

The spring used over here has been designed according to the loading needs. The calculations have been made according to the statistical data obtained from a gait cycle. The locking load has been chosen to be the load corresponding to point where the stance flexion is 5 degrees. The spring was prestressed to around 50N, which adds initial threshold to the joint where joint only locks after crossing the threshold. This spring lets us tune the locking time and will be a crucial part in the design.

3.3.3. SIMULATIONS

FEA was performed on the entire assembly by applying loading in 3 cases as mentioned in the simulation section of v1 – Force, Moment and Combined. These three cases cover all the situations along a gait cycle and can be assumed safe if it passes through all the cases. The results suggest that the entire assembly would be safe in operation.

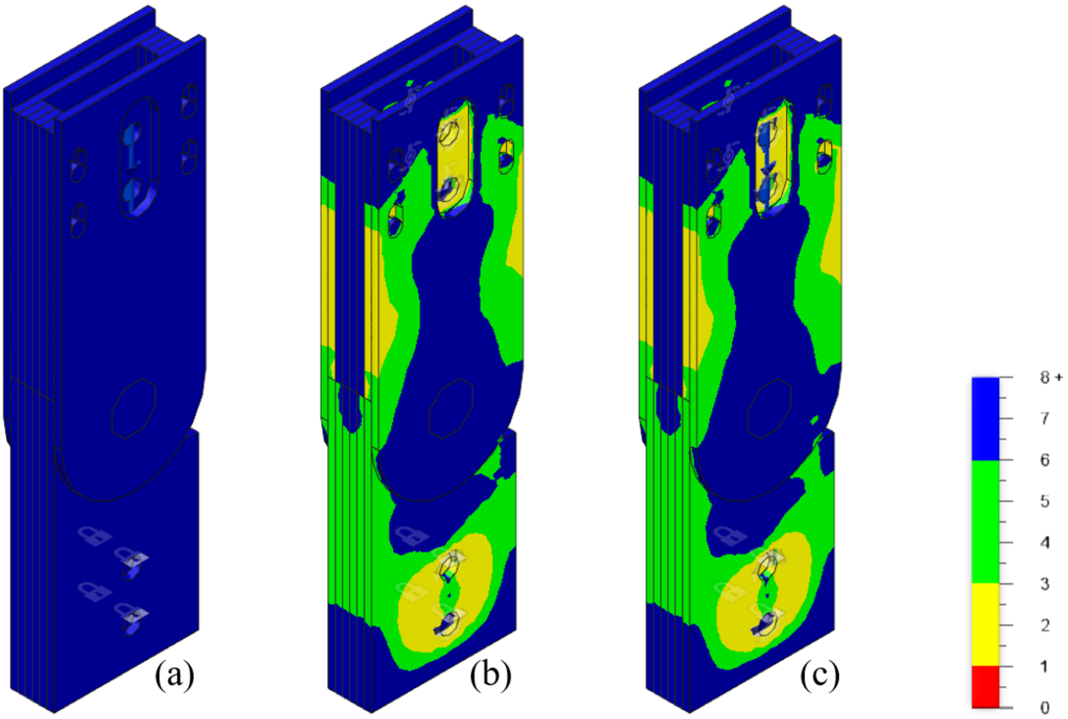

Figure 3.15: Simulation Results on assembly (a)Only Force (b)Only Moment (c)Combined Load (Factor of Safety)

3.3.4. MANUFACTURING AND ASSEMBLY

Manufacturing was majorly done using laser cutting and the process was accurate, inexpensive and fast. Having lesser number of parts in this iteration helped reduce the manufacturing time and consumed less footprint. The left-over sheet can be seen in the picture below.

Figure 3.16: Cut-out on sheet after laser cutting

Figure 3.17: Assembled Prototype

The assembly was simple considering the experience gained in the fabrication of the first version. Suitable shafts and dowel pins were bought/manufactured for the assembly.

3.3.5. SUMMARY

Two joints have been assembled for testing purposes and initial testing has been carried out by wearing it on to the author’s KAFO. The prototype will undergo testing on a Universal Testing Machine where a suitable static load will be applied on to the joint and it will be tested for its endurance.

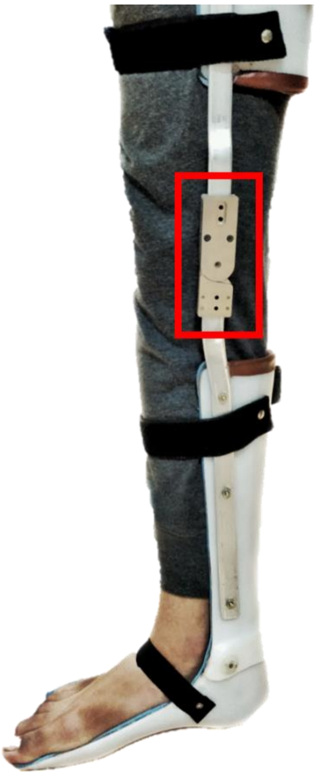

Figure 4.1: Knee joint assembled with KAFO

Summing up, this design variant of the knee joint not only inherits the features from the first variant but also adds some major assembly benefits while maintaining the design philosophy. Laser-cutting has been the choice for fabrication not only because of speed and cost benefits but also because of it’s ability to machine intricate shapes.

Costing of this prototype is as follows:

No.	Component Description	Cost (Rs)
1	1.5mm SS sheet	100
2	Laser Cutting	600
2	Bearings (x2)	140
3	Shafts and Dowel pins	50
Total		**890**

Table 4.1: Costing of the prototype

CHAPTER 4

CONCLUSION

4.1. CONCLUSION

Over the course of this project, various mechanisms have been explored for building a knee joint for stance control orthosis. These designs represent different interpretations of the solution and must be tested rigorously for their functionality. The road ahead is to test the mechanism first on able bodied subjects and then go for clinical trials.

Through this project, we intend to establish a statistical evidence of betterment in the gait parameters for SCKAFO users. This project is aimed not only at bringing out the design and research aspects of building a SCKAFO but also to add some value to the society by churning out a product. This project can be considered incomplete without either of these two major elements. Finally, this project also attempts to bridge the gap between existing commercial devices and the patients of India, by addressing affordability and cultural relevance of the device.

4.2. FUTURE WORK

Although the above model would be functionally validated, it is extremely important to check the feasibility of manufacturing such components on a bigger scale. The current prototype has proved to be quite favorable with manufacturing due the presence of laser cutting components. Iterations must be carried out in the design to optimize the design on the basis of weight and add additional features like manual lock.

Getting this project out into the market is a great challenge and cannot be achieved without rigorous testing of the design. The planned progression includes loading on UTM in the initial phase to verify its functionality and then conduct testing on able-bodied subjects. This is precisely where we might find the literature survey to be extremely useful - to understand the training procedure adopted by different research groups. A full-fledged testing needs to be carried out for establishing a statistical evidence of betterment.

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