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Design and Fabrication of an Economical Orthotic Device

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Abstract - Stroke can affect the effective functionality of the various motions of the body, especially the walking ability gets hindered. Stroke patients with such disability suffer from lots of problem in daily living emotionally and mentally. To recover from this type of disabilities requires strong will power and mental strength. Repetitive task training is an effective form of rehabilitation for people suffering from debilitating injuries of stroke. We ought to present the design and working of a spring-operated economical rehabilitation device to assist stroke patients during walking gait motion (KAF Orthosis). Currently available devices are either motor-operated or controlled using an electronic control system. As far as these devices are efficient and advanced, the economic aspects are not feasible for a common man suffering from a stroke. The device aims at trying to recover the walking motion with a significant growth rate and not only assisting the patient for life long. A patient should have the access to rehabilitation devices for the utmost time and not only for a particular scheduled interval. With this device being economical and easy to operate on its own, this helps in the recovery rate very significantly.

Key Words: Stroke, Repetitive tasks, KAF Orthosis, Feasibility, Recovery

1. INTRODUCTION

Paralysis, the loss of motor function of a limb or limbs, can be attributed to some of these causes such as stroke, brain trauma, and spinal cord injury. Roughly one of every one hundred Indian has experienced a stroke. The likelihood of having a stroke doubles by the decade once reaching the age of 55-60 years. With the baby boomer era growing older, the number of stroke patients in India will be on the rise and will therefore require more accessible rehabilitation techniques. A stroke can cause a variety of different forms of paralysis such as hemiparesis, paraplegia, quadriplegia, and tetraplegia. These types of paralysis are caused by damage to the spinal cord and nervous system.

Stroke is one of the leading causes of physical disability with hemiparesis affecting many survivors. This common impairment contributes significantly to low velocity, asymmetric, and inefficient gait. Stroke patients undergo rehabilitation therapy to regain their mobility. However only 39% of patients will regain independent walking by 3 months post-stroke, 26% will not have achieved independent walking at 12 months, and many of those who can walk have persistent and inefficient hemiparetic gait patterns. Gait rehabilitation involves moving the limb

repeatedly in a near-normal trajectory to restore normal movement. This therapy is time-consuming and labour intensive for both patients and therapists.

e-ISSN: 2395-0056

p-ISSN: 2395-0072

Robotic gait rehabilitation has recently been introduced to reduce therapists' workloads as well as provide a higher dose of more repeatable and consistent therapy than can be delivered by therapists. Robotic gait training combined with physiotherapy has been shown to increase the likelihood of regaining the ability to independently walk after stroke, and various nonparetic limb constraint-induced therapies have shown promise.

1.1 Problem Statement

To design and analyze a robust human walking assistance device (Knee-Ankle-Foot orthosis) for middle and economy class patients suffering from a stroke. The device should be easy to operate, less maintenance requirement and significant recovery-oriented.

1.2 Objectives

Rehabilitation therapy encourages surviving neural pathways to regain motor control. This ability to recover and relearn is 'Neuroplasticity'. When a person experiences a stroke, many cortical neurons die while others survive but are temporarily affected and may resume functioning at least to a limited extent. In some cases, the brain can reorganize and a region of the brain will 'take over' for a region of the brain that was damaged by the stroke.

Early after stroke, patients are encouraged to try and 'relearn' to walk, typically with the help of a physiotherapist and aids such as walking sticks and frames. It is suggested that because they are initially unable to produce a correct gait pattern, their neural reorganization in response to suboptimal practice results in suboptimal reprogramming of the neuromuscular control of gait. This likely happens during the critical acute stage of recovery when the potential for brain repair is at its peak.

Although patients can often regain adequate strength and balance to walk, it is rare for a stroke patient to fully regain their original gait pattern. Even intensive therapy (including robotic therapy) in the chronic stage makes little permanent change to gait patterns developed soon after a stroke.

The main hypothesis of this project is that constraining the paretic leg of a stroke patient in a

RJET Volume: 08 Issue: 04 | Apr 2021 www.irjet.net

physiologically normal trajectory and symmetrical gait pattern at the acute stage of recovery will result in a persistent and more normal spatiotemporal gait pattern than when the constraint is not imposed.

The orthotic device is expected to prevent a patient's motor system from learning an abnormal gait pattern or at least minimize the likelihood of them developing an abnormal gait pattern. Once the initial major neural reorganization under these constraints has been completed, it is expected that the acquired gait pattern will persist and be closer to normal gait motion.

The target population for the device is stroke patients with hemiparesis, particularly at the early stage of rehabilitation. The device was designed to be used as a tool in the clinic as well as for in-home walking training. It has the following design specifications and implementing objectives-

- Easy to get into and set up (can be used at home without a therapist's help).
- Inherently stable (i.e., very difficult to tip over, and supports patients with poor balance).
- Ability to support body weight
- Able to negotiate small inclines on even terrains
- Fits a range of patient sizes
- Ability to constrain hip position to avoid knee hyperextension.
- Portable for walking in everyday life as well as in acute stroke units.
- Low manufacturing costs to encourage clinics and some patients to purchase the device.

1.3 Scope

Massachusetts Institute of Technology and the University of Miami School of Medicine have made significant strides in developing treatments for paralysis patients. Engineers at MIT have announced their success with a robotic brace that helps people with paralysis retrain their muscles to regain movement in their limbs. Researchers reported an average of 23% improvement in lower limb function after testing the therapeutic device on patients.

There are two major types of robotic gait rehabilitation devices, an end-effector device and an exoskeleton device. Robotic exoskeletons are attached to human limbs at multiple interaction points and the movement of these devices affect the movements of the patient's joints. Examples of this type include Lokomat, LOPES, Auto ambulator, and HAL. On the other hand, with

end-effector devices, the feet of a patient is placed on footplates that are designed to follow normal gait trajectories.

e-ISSN: 2395-0056

p-ISSN: 2395-0072

There are many devices developed using this concept. For example, Gait Trainer GT, I, LokoHelp, Haptic Walker, G-EO, LYRA (ABILITY, Switzerland) and elliptical exercisers.

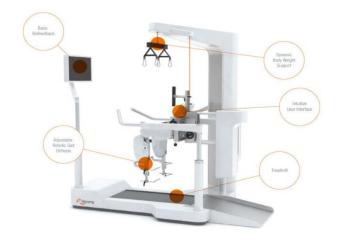


Fig-1: Lokomat Device

1.4 Methodologies

The following section will explain our methods for completing our project. Our Project's success will be contingent upon the accomplishment of the following individual objectives:

- Design a device to move in a precise human walking motion.
- The device must be adjustable to provide comfort to different sized patients.
- Manufacture the device with materials that will satisfy the needs of the design but also fall under our estimated budget

It will outline specifically what should be done to achieve these objectives and fulfil the requirements set forth by the project group.

2. LITERATURE SURVEY

The following section outlines important concepts that surround and affect our project. Since there are many external issues involved, this chapter provides the reader with a fundamental background of such issues. Past research done on rehabilitation is quite extensive. Even though today this field of study is making huge strides, its subject matter is still in the beginning stages of development. Our research was focused on the different kinds of paralysis, related projects, and current treatments. Also, research was conducted on the different types of information that will be needed for our project design to be put into realization. This information includes motion analysis on the joints as well as

the technology that will be used in our design to move these joints.

Although there are many different types of paralysis, these can be broadly categorised into four main types: Monoplegia, Hemiplegia, Paraplegia and Quadriplegia. The survey by 'Spine-health Organisation', one of the NGO's which works extensively for paralysis patients, depicts the various causes of paralysis through a pie-chart inferring to root cause as 'Stroke'.

The recovery success rate in the rehabilitation of Plegic patients is very poor as compared to the recovery rate in Paresis patients. This was a very important aspect that helped us to focus on the problems for Hemiparesis and Stroke Patients. The Plegic patients are rather more comfortable in wheelchair rehab format than getting the rehab in an orthotic device.

People with hemiparesis often have difficulties maintaining their balance due to limb weaknesses leading to an inability to properly shift body weight.

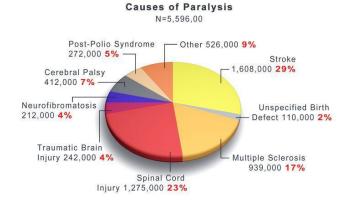


Fig-2: Statistical Pie Chart - Causes of Paralysis

This makes performing everyday activities such as dressing, eating, grabbing objects, or using the bathroom more difficult. Hemiparesis with origin in the lower section of the brain creates a condition known as 'Ataxia', a loss of both gross and fine motor skills, often manifesting as staggering and stumbling. Pure Motor Hemiparesis, a form of hemiparesis characterized by sided weakness in the leg, arm, and face, is the most commonly diagnosed form of hemiparesis.

2.1 Kinematic Model Research

Our project calls for the study of three major joints: the hip, knee, and ankle. For us the manufacture a product that will work we need to know the specifics for the kinematics of these joint motions. Figure 3, Figure 4, and Figure 5 help show the joint angle limitations for these joints.

To know the kinematics of the walking motion we had to know the Degrees of freedom for each joint. The kinematics structure of the leg contains six joint Degrees of Freedom or DOF. Each hip joint contains 3 DOF, each knee joint contains 2 DOF, and the ankle can be separated into 3 DOF. When walking, the pelvis area swings the hip joint forward in the range of 8 degrees. Well, the thigh shows a similar pattern of rotation, but the angle is larger, the total range is about 14 degrees. In the leg, the shank shows the same pattern, but with an even greater range of rotation, there are about 18 degrees of freedom. These Degrees of freedom deal with the different joint angles that are involved with the gait motion of biomechanics.

e-ISSN: 2395-0056

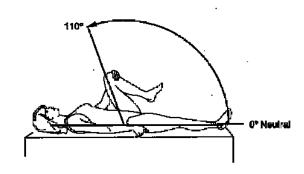


Fig-3: Forward hip joint angle limitation

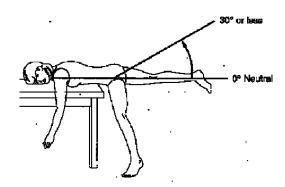


Fig-4: Backward hip joint angle limitation

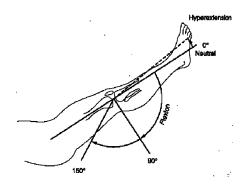


Fig-5: Knee joint angle limitation

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Biomechanics research provides evidence that Sagittal elevation angle may be more reusable than joint angles. The sagittal elevation angle is a new representation for motion, it exhibits less intrasubject variation than joint angles during walking; therefore, they form a more canonical data representation for gait, which can be used to drive walking animation over curved paths and uneven terrain. This is good to know and understand but our device will not go on curved paths or uneven terrain. Although this might give more comfort to our patient when walking if the variance is lower in sagittal elevation angles than joint angles.

2.2 Field Visit to Paraplegic Rehabilitation Centre, Khadki, Pune

Field Visit is essential to understand the true nature of the problem around us in the world. One of the visits was to the Paraplegic Rehab Centre, Khadki, Pune. The prime objective of the visit was to acquire thorough information regarding the problems and difficulties faced by the paralyzed patients. Also, to get the info regarding the ongoing rehab techniques and the regime followed by them.

Although our device does not aim to work for Plegic patients, it is very essential to know about the problems faced by a patient undergoing rehab.



Fig-6: PRC, Khadki, Pune

2.2.1 Brief History of PRC, Pune

The idea of building a Home (now named Paraplegic Rehabilitation Centre) was conceived after the 1971 Indo-Pak War when there were 60 Spinal Cord Injury (SCI) casualties. The idea was based on already existing such Centre's in the USA (Veterans Home), UK (Spinal Cord Injury Centre Stokes Mandeville Aylesbury) and other European countries.

The foundation stone was laid by General (Late) GG Bewoor, PVSM, the then Chief of Army Staff on 23 June 1973 and the Centre was inaugurated by (Late) Shri Fakhruddin Ali Ahmed, the then President of India on 20 Sep 1974.

2.2.2 Overview of the Visit

We visited the PRC, Khadki on Friday 19th September 2019. We prepared a set of questions before the

visit, a war veteran Mr Pereira briefed us regarding our questions. Following responses were quoted by him,

e-ISSN: 2395-0056

- The main reason for paralysis Most of the patients undergoing rehab here are the victims of severe war injuries, rather than spinal cord injury, the frequency of limb affected injuries is more during the war. Hence patients having limb injuries are undergoing rehab here.
- The severity of inability on the body Once the limbs become non-functional, it hampers the movement of the bottom hip region, which in turn affects the gall bladder and the digestive parts.
- Rehabilitation regimen A patient's rehabilitation regimen depends mainly on the severity of their disability. These exercises range from walking on a treadmill to the bending of their fingers. Playing light chair sports also helps.
- Care to be taken during designing Sometimes the paralysis is so severe that the patient cannot support their body weight or lift the weight of their limbs. Crutches are the most common instrument used for the supports to arms, so the important factors if you want to design an instrument to be considered are that the arms should not experience a high amount of force, the region below-knee should move intact with the support.
- The extent to which rehab helps The major problem with these standard rehabilitation techniques is that the percentage of motor function that is recovered is poor. The lack of feeling of walking affects the recovery process. The recovery also depends on the will power of the patient. Mostly recovery is around 15-20%.
- **Concluding Remark** The Medical Director of the centre advised for the visit to the Artificial Limb Centre for exact design details and the kinematics of the model.

2.3 Field Visit to Artificial Limb Centre, Wanowrie, Pune

During the brainstorming sessions, various unknown aspects were encountered and there was no better place than ALC, Pune to find answers regarding those. The objective of the visit was to gather information on the designing aspects of the model, details about the kinematic aspects regarding the model and the concept of the initial designs.

2.3.1 Brief History of ALC, Pune

The Artificial Limb Centre was established at Poona in 1944 under the command of Lt Col DS Vohra to provide artificial limb, appliances and deliver rehabilitative care to the gallant soldiers of the Indian Army, who lost their limbs in combat.

Although ALC was raised with the primary objective of meeting the prosthetic and orthotic requirements of disabled personnel of the armed forces, from 1951 the

facilities were gradually extended to civilians as well. In 1958, a 70 bedded civilian wing was added to this Centre. In 1964, a sub-centre was established in Delhi and Lucknow to provide repair facilities. Additional sub-centre has since been established at Chand mandir, Guwahati and Bangalore.



Fig-7: ALC, Wanowrie, Pune

2.3.2 Overview of the Visit

We visited the ALC on Monday 14th October 2019. Similar to previous we prepared a set of questions before the visit, JCO Mr Gundlur briefed us regarding our questions. The suggestions were as follows:

- Parameters to precisely focus on First off, all they told us to focus on the knee, the hip and the ankle region. To study the motion parameters and the forces acting on the joints and the limitations regarding them.
- Comfort Requirements Mainly comfort depends on material procurement, the material should be in conformance with the body and it should be able to withstand the body weight. Soft Light Weight material should be preferred.
- Preliminary Design Concept Concerning our ideas, they suggested us to go for two basic concepts in the design. One being the Two motor Design and the other Four motor. This was the most important suggestion regarding our design as this forms the base of our Final Product Idea.
- Various adjustments The device should be adjustable as the dimensions and weight change from person to person. The device should be confined to the normal door area as the person should be able to move in and out while using it.

2.3.3 Lower Limb Orthosis is mainly classified as:

- Externally Actuated Devices (Electronically Controlled)
- Self-Actuated Devices (Mechanically Controlled)
- Electronically Controlled Devices -

This type of orthotic devices can be used for complete control of the deficient lower leg. Most of the advanced devices are mostly controlled by an electric motor and actuated the electrical impulse signals received from the body muscles. These devices are commonly referred to as myoelectric orthosis. However, this type of orthosis tends to be the most expensive of the available options, as it makes use of sophisticated circuitry, sensors and actuators.

e-ISSN: 2395-0056

• Self-Actuated (Mechanical) Devices -

The user has actuation control rather than controlling through a particular electric system. This helps in reducing complications in designs and allowance for more modifications as per the requirement. This is possible due to the use of mechanical linkages and the leverage allowed. Of course, these devices do not give exact precision as the electric one's but is advantageous in terms of economical aspect.

2.4 Current Designs Available in Market

Extensive research in the field of knee-ankle-foot orthosis rehabilitation is aimed at treating millions of people suffering each year from paralysis as a result of a stroke. The trademark orthotic devices are mainly manufactured by major companies like Ottobock, Stryker Orthopaedics, Honda Walking Assistance Device etc. The highest-level advancement in the orthotic devices are achieved by them are mostly the trendsetter for the rehab devices in the various rehabilitation process.

This C-Brace by Ottobock opens up entirely new possibilities for users with its microprocessor sensor technology. Flexing under load while sitting down, navigating slopes, walking on uneven terrain, or going downstairs step overstep—all this defines a new level of mobility. The C-Brace is smaller and lighter, so the user does not need to exert as much energy while walking. This also allows the user to wear the orthosis underneath their clothing. The microprocessor sensor makes the entire gait pattern more dynamic and responsive. The user can also change settings on their joint: switching to cycling mode, using the smartphone app.

As these devices provide more flexibility and comfort as well as precise control but the economic aspects does not allow them to be purchased for a particular individual or a small rehab clinic.

3. DESIGN OF ORTHOTIC DEVICE

The orthotic device designed for our project trades aesthetics for functionality. The high-performance needs are met by using the material synthetically modified for various parts as per requirement. The base for the design of our device is a 'Spring Compression-Retention Arrangement' which actuates the walking motion and assists during the walking motion.

3.1 Preliminary Conceptual Designs

Brainstorming sessions were conducted by the group to formulate ideas that would solve the objectives. These designs were preliminary and were used to get an idea of what the team members were thinking for design concepts. The sections to follow will show the most important designs that were discussed during the brainstorming sessions.





Fig-8: C-Brace Ottobock

When coming up with these preliminary designs, the project group was formed to establish a set of design specifications so that they were able to have guidelines with regards to how they should design the mechanism. A list of the most important design specifications as follows:

- One degree of freedom for each joint (both hips and knees).
- Cycle time: 0.52-0.65s per pace.
- The structure must be shaped similar to the human legs.
- The trajectory of each joint must simulate the actual motion of each human joint.
- The budget must be limited to INR 15000 to 20000.
- The design should be compact and in compliance with body shape.

3.1.1 Two Motor Design

The team first thought for mechanical design was a two-motor design. This design would have one motor per leg. The design needed to be able to move the thigh and the shin of the patient all using one motor. This would allow for a less complicated electronic control system. The way we would accomplish this mechanism would use a complicated linkage system that was inspired by the transfer of Rotating motion to Reciprocating. This ideology was based on the walking simulation of a horse. The linkage system that was used by them was very helpful in our design of the linkage system that would be used for a two-motor design.

3.1.2 Solid Modelling

Using the CAD-CAM software, the design team was able to visualize their conceptual designs to see what was practical and what didn't work. The preliminary design that was modelled was concepts of the two motor Figure 9 shows a wooden model of the two-motor linkage design that the team developed. Using the software, the design team was able to modify their design to simulate the walking motion of a human. It allowed them to check for interferences between the links and make sure that the motion was what they wanted. As you can see in Figure 10, the design team used a four-bar linkage system, with the small green link as the crank and the red and yellow links forming the leg. An example of the usefulness of solid modelling can be shown by the project team's assessment of the two-motor design concept. This design seemed to solve the accurate leg motion objective, but when addressing the comfort objective, this design was not useful. By using the animation software, the team was able to see that the linkages would be too difficult to adjust to different sized patients. This almost eliminates it as a possible design option because one of the major objectives for the project was to make the device comfortable for different sized patients. This means it needed to be adjustable in some way. Also, the motor operation requires an externally controlled electronic system for which a specialist handler will be required to operate that. This was not user friendly which was a very crucial point in not going ahead with this design.

e-ISSN: 2395-0056

3.1.3 Spring Actuated Mechanism

The drawbacks in Two-motor design called for more outlook towards the mechanical actuation process rather than the electronically controlled actuation. The team's initial thought was on using spring force as an actuating force. The stiffness of the spring accounts for the spring and the retention mechanism is also less rigid.

3.2. Initial Design

The conversion of the potential energy of the spring into kinetic energy and vice versa during walking is the core concept of the device, Supported by a lightweight and comfortable structure that stabilizes the hip and leg. The core technology is the Exotendon that actively assists leg movement and amplifies your ability to take each step properly. The Exotendon provides a spring-based assist that gently lifts and swings your leg through each step without electronic stimulation. With added guidance for proper walking motions, each step you take it also helps you gain confidence and control.

3.3 Final Design

After the preliminary conceptual design, we understood the specifications and features to be provided in our device. With the consult specialist doctor in the field, we got to know the aspect with which prime importance to be

given to provide features in the device. We listed down the below prime features to be given importance in our device :

- It should support early walking practice and prevent bone deformities.
- Be easily adjustable for growth (changes in height, waist size).

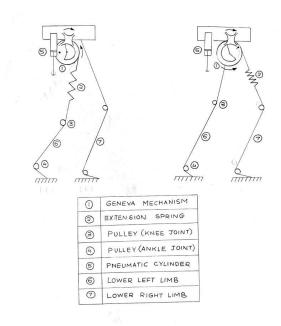


Fig-9: Sketch View of the Spring Mechanism

- Be easily don/doffed by the therapist and/or parent.
- Increase walking time outside of therapy.
- Promote fluid movement (minimize jerk during gait transitions).
- Fail predictably.
- Prevent scratching or breaking of the skin.
- Remain durable.

From the above core functions set of specifications was developed :

- Fit / Growth: Leg length adjustable between 17.4 24.5 in (Kuczmarski 2002)
- \bullet Fit / Range of motion: hip abduction/adduction 13°, hip flexion/extension 45°, hip rotation 16°
- Don/doff and adjust within 5 minutes
- Fluid movement: Tibial accelerations of -2.09 g's peak negative anterior-posterior, 0.90 g's peak lateral, and 1.70 g's peak axial.

- Fail predictably.
- Prevent scratching or breaking of skin
- Remain durable

The design consists of the application of scientific principles, technical information and imagination for the development of new or improvised machine or mechanism to perform a specific function with maximum efficiency. Hence a careful design approach should be adopted. The total design work has been split up into two parts;

e-ISSN: 2395-0056

1. System Design

2. Mechanical Design

System design mainly concerns the various physical constraints and ergonomics, space requirements, arrangement of various components on the mainframe of a system, man + system interactions, the position of controls, working environment of the overall system, chances of failure, safety, measures to be provided, servicing aids, ease of maintenance, the scope of improvement, the weight of the system and individual parts, adjustability, feasibility and lot more. In mechanical design, the components are listed down and stored based on procurement, design in two categories namely,

- Designed parts.
- Parts to be purchased

For designed parts, detached design is done & distinctions thus obtained are compared to the next highest dimensions which are readily available in the market. This amplifies the assembly as well as postproduction maintenance work. The various tolerances on the works are specified. The process charts are prepared and passed on to the manufacturing stage. The parts which are to be purchased directly are selected from various catalogues and specified so that anybody can purchase the same from the retail shop with given specifications.

3.3.1 System Design

In system design, we mainly concentrated on the following parameters:

1. System Selection based on Physical Constraints

While selecting any system it must consider where it is going to be used. In our case, it is going to be used in medical application and patients need to carry it with them. The system needs to be very compact so that it would be feasible for patients to wear while undergoing leg rehabilitation therapy and maintain it.

The mechanical designs have direct norms with the system design. Hence the foremost job is to control the

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physical parameters, so the distinctions obtained after

2. Arrangement of Various components

mechanical design can be well fitted into that.

Keeping the size as compact as possible without reducing the strength of the exoskeleton is necessary to make the device more efficient. Interchangeability and maintenance of every part of the exoskeleton and device should be possible.

3. Components of the system

Here various components used such as pulleys, spring, adjusting strips, energy storage subsystem are to be optimized to achieve greater efficiency. Expensive components must be given special protection.

4. Patient-Device interaction

The friendliness of the orthotic device with the patient is an important criterion of design. The patient should feel comfortable wearing the device so it should not be bulky at all. It must be easy to get into and set up.

5. Chances of failure

The losses incurred by the user in case of any failure are important criteria of design. As it is a special-purpose device for the rehabilitation of a patient, special care should be taken. The factor of safety in mechanical design is kept high so that there are fewer chances of failure. Even in the worst case, it fails patient should be safe from any injury.

6. Adjustability

The height of the exoskeleton should be adjustable according to the leg length of the patient. This adjustability is achieved by providing slotted holes along with the exoskeleton. Also, the belt attached to the hips pulley should be adjustable according to the waist size of the patient.

7. Weight of the system

The total weight depends upon the selection of material as well as the dimensions of components. It should be kept light weighted as much as possible without compromising the strength of the overall system.

3.3.2 Mechanical Design

The mechanical design phase is very important as the whole success of the project depends on the correct design analysis of the problem. In this phase, we gathered knowledge about the physical properties of material, loads, stresses, deformation and failure theories. Also determined the internal and external forces acting on the exoskeleton, pulleys (Hip, Knee and Ankle), Rope and other components.

Here are some of the assumptions made while designing the components of the device.

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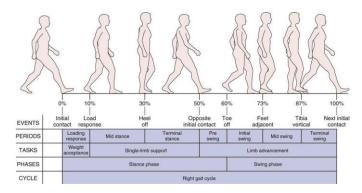


Fig-10: Human Gait Cycle

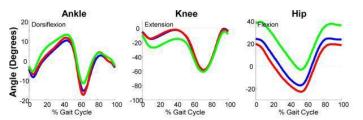


Fig-11: Kinematic data for Ankle, Knee & Hip Joints

Population Minimization	Slack Length (mm)	Radius of Knee Pulley (mm)
Small C _{pow}	-31	27
Large C _{pow}	-104	23
Small C _{mom}	-33	7
Large C _{mom}	-94	17

Table-1: Knee pulley radius as a function of parameter minimized and slack length

- i. For Small C_{pow} and C_{mom} , in consideration Spring extension away from slack length is L_s = -33 mm
- ii. The maximum angular deflection at Ankle, Knee and Hip joint will occur at 67 % of the gait cycle i.e. at the pre-swing phase.

The Data Variables are as follows:		
JA ₁	Joint Angle of the ankle	
JA ₂	Joint Angle of the knee	
JA ₃	Joint Angle of the hip	
JM ₁	Joint Moment of the ankle	



Volume: 08 Issue: 04 | Apr 2021 www.irjet.net

JM ₂	Joint Moment of the knee
JM ₃	Joint Moment of the hip
EF	Exotendon Force
RM ₁	Residual Moment at the ankle
RM ₂	Residual Moment at the knee
RM ₃	Residual Moment at the hip
AV ₁	Angular Velocity at the ankle
AV ₂	Angular Velocity at the knee
AV ₃	Angular Velocity at the hip
RP ₁	Residual Power at the ankle
RP ₂	Residual Power at the knee
RP ₃	Residual Power at the hip
R ₁	Pulley Radius at the ankle
R ₂	Pulley Radius at the knee
R ₃	Pulley Radius at the hip
K	Spring Constant
Ls	Spring extension away from the slack length

Table-2: Notations for Exoskeleton Parameters

JA ₁	Joint Angle of the ankle	10.3° to -17.7°
JA ₂	Joint Angle of the knee	0.6° to -60.5°
JA ₃	Joint Angle of the hip	25.4° to -17.8°

Table-3: Joint Angles during a specific time in the gait cycle

JM ₁	Joint Moment of the ankle	- 0 .02 to - 9 .0 Nm
JM ₂	Joint Moment of the knee	0 .0035 to 1.60 Nm
JM ₃	Joint Moment of the hip	0 .025 to 12 Nm

Table-4: Joint Moments during the specific time in the gait cycle

R ₁	Pulley Radius at the ankle	54 mm
R ₂	Pulley Radius at the knee	4.76 mm
R ₃	Pulley Radius at the hip	67 m

e-ISSN: 2395-0056

p-ISSN: 2395-0072

Table-5: Pulley Radius

• Design of Exoskeleton

At pre-swing phase i.e. 67 % of the gait cycle,

$$JA_1 = -15.2^{\circ}$$
, $JA_2 = -57.8^{\circ}$, $JA_3 = -5.2^{\circ}$

Exotendon Force	
-	(((A + P) ((A + P) ((A + P)) + #] ;
E.F. = Max $[0, K^{\perp}]$	$\frac{\left(-(JA_{1}\times R_{1})-(JA_{2}\times R_{2})-(JA_{3}\times R_{3})\right)\times\frac{\pi}{180}\right]-Ls}{1000} =$
Max[0 K	$ \begin{array}{c} 1000 \\ 2^{\circ} \times 54) - (-57.8^{\circ} \times 4.76) - (-5.2^{\circ} \times 67)) \times \frac{\pi}{180} + 33 \\ \hline 1000 \\ 1000$
Max[U, A	1000
= 40.7458 N	

Average Residual Joint Moment

$$\begin{aligned} &C_{mom} = Mean \left[\frac{|RM1| + |RM2| + |RM3|}{3} \right] \\ &= \left[\frac{|-2.209273| + |-0.19235| + |-2.7179|}{3} \right] \\ &= 1.706508 \text{ Nm} \end{aligned}$$

Average Residual Power

= 27.776172 W

$$\begin{aligned} & C_{pow} = \text{Mean} \left[\frac{|RP1| + |RP2| + |RP3|}{3} \right] \\ & = \left[\frac{|-26.97| + |-5.1261| + |-51.232415|}{3} \right] \end{aligned}$$

27.77 O 17 2 VV	
Residual Moment	Residual Power
$RM_1 = \frac{JM1 - (R_1 \times EF)}{1000}$ $= \frac{-9 - (54 \times 40.7458)}{1000}$ $= -2.209273 Nm$	$RP_1 = RM_1 \times AV_1$ = (-2.209273) (12.21) = -26.97 W
$RM_2 = \frac{JM2 - (R_2 \times EF)}{1000}$ $= \frac{1.6 - (4.76 \times 40.7458)}{1000}$ $= -0.19235 Nm$	$RP_2 = RM_2 \times AV_2$ = (-0.19235) (26.65) = - 5.1261 W
$RM_3 = \frac{JM3 - (R_3 \times EF)}{1000}$ $= \frac{12 - (67 \times 40.7458)}{1000}$ $= -2.7179 Nm$	$\mathbf{RP_3} = \mathbf{RM_3} \times \mathbf{AV_3}$ = (-2.7179) (18.85) = -51.232415 W
Angular Velocity	

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$$AV_1 = \frac{(JA1_{t_2} - JA1_{t_1})}{1/25} \times (\frac{\pi}{180})$$

$$=\frac{(10.3+17.7)}{1/25} \times (\frac{\pi}{180})$$

 $= 12.21 \, rad/s$

$$AV_2 = \frac{(JA2_{t_2} - JA2_{t_1})}{1/25} \times (\frac{\pi}{180})$$

$$=\frac{(0.6+60.5)}{1/25} \times (\frac{\pi}{180})$$

 $= 26.65 \ rad/s$

$$AV_3 = \frac{(JA3_{t_2} - JA3_{t_1})}{1/25} \times (\frac{\pi}{180})$$

$$=\frac{(25.4+17.8)}{1/25}\times\frac{\pi}{180}$$

= 18.85 rad/s

Design of Spiral Spring

We have, $P = 40.7458 \text{ N}, \theta = 45^{\circ}, r = 0.067 \text{ mm},$

 $\sigma_{\rm b}$ = 552 MPa, $\sigma_{\rm ut}$ = 2800 MPa,

 $E = 206 \times 10^3 \text{ MPa, b} = 30 \text{ mm}$

The following notations are used in the analysis of spiral spring:		Units
P	Induced force at the outer end <i>A</i> due to winding of the arbour	N
r	Distance of centre of gravity of spiral from the outer end	mm
t	Thickness of strip	mm
b	Width of strip perpendicular to the plane of the paper	mm
1	Length of the strip from the outer end to the inner end	mm

Table-6: Notations for Spiral Spring

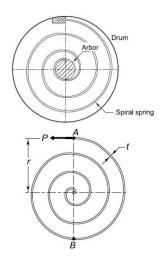


Fig-12: Spiral Spring

Step 1: Calculating Bending Moment (M)

The outer end *A* of the spring is pulled by the force *P*. The bending moment *M* due to the force *P* acting at a distance *r* is given by,

M = Pr

 $=40.7458 \times 0.067$

= 2.7305 Nm

Step 2: Calculating Maximum Bending Moment (Mb)

Point *B* is at the farthest distance from the line of action of the force P. Therefore, the bending moment is maximum at point B. The maximum bending moment (Mb) is given by,

$$M_b = P(2r) = 2(Pr) = 2M$$

 $= 2 \times 2.7305$

= 5.4611 Nm

Step 3: Calculating Thickness of the strip (t)

The maximum bending stress induced at the point *B* is given

$$\sigma_{b} = \frac{Mb \times y}{I}$$

where,
$$M_b = 2M$$
, $y = \frac{t}{2}$ and $I = \frac{bt^3}{12}$

Thus,
$$\sigma_b = \frac{12M}{ht^2}$$

$$\therefore t^2 = \frac{12M}{\sigma_b b}$$



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12×2.7305 552×10⁶×30×10⁻³

 $= 1.9786 \times 10^{-6}$

 $t = 1.4066 \times 10^{-3} \,\mathrm{m}$

≈ 1.5 mm

Step 4: Calculating Length of the strip from the outer end to the inner end (l)

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When both ends are clamped, the angle of rotation of the arbour (θ) to the drum or the point A is given by,

$$\theta = \frac{Ml}{EI} \text{or } \theta = \frac{12Ml}{Ebt^3}$$

 $\theta = 45^{\circ} i. e. 0.125 \times 2\pi$

: 0.125 revolutions of the strip

Now,

$$0.125 \times 2\pi = \frac{12 \times 2.7305 \times l}{206000 \times 10^{6} \times 30 \times 10^{-3} \times (0.0015)^{3}}$$

 $l = 500 \, \mathrm{mm}$

Step 5: Calculating The deflection of one end of the spring with respect to the other (δ)

The deflection (δ) of one end of the spring with respect to the other is given by, $\delta = r\theta$ or $\delta = \frac{12Mlr}{Eb^{+3}}$

Now,

$$\delta = 0.125 \times 2\pi \times 0.067$$

 $\delta = 52.6 \,\mathrm{mm}$

Step 6: Calculating Strain energy stored in the spring (U)

The strain energy (U) stored in the spring is given by,

$$U = \frac{1}{2} M \theta = \frac{1}{2} M (\frac{12Ml}{Eb+^2})$$

or
$$U = \frac{6M^2l}{Eht^2}$$

Now,

$$U = \frac{1}{2} \times 2.7305 \times 0.125 \times 2\pi$$

∴ U = 1.0723 J

• Design of Exotendon

#95 Single Strand Paracord Type I - Gray Colors

95 paracord falls between 275 paracord and Micro paracord: smaller than 275, but with a higher tensile strength than Micro. With a diameter of 1.85mm it is an ideal choice for crafting projects like macramé, bracelets, wind chimes, or other weaving projects.

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- Great for finer crafts like beading, jewellery, and macramé
- 1.85mm
- Available in a variety of Colours!
- 1/14"
- Will Not Rot or Fade to UV
- Made in the USA
- 95LB Tensile Strength

3.3.3 Selection of Material for the stages

Sr. No.	Component	Material	
1.	Energy Storage system	Acrylonitrile Butadiene Styrene (ABS)	
2.	Adjustable leg struts	Aluminium 7000 series alloy	
3.	Spiral spring	Hot-rolled spring steel	
4.	Exotendon Rope	Lightweight nylon kernmantle	
5.	Ankle, Knee & Hip Pulleys	Polymer rope pulley	

Table-7: Components and Materials

3.4 Constructional Details

This custom kinetic orthosis mechanism provides immediate walking assistance for those with lower extremity weakness. The Four major components are Hip Belt which secures the device around the hip region, the Upright Supports for providing medial-lateral support and stability, Custom moulded **Insole support** at the foot and the **Kinetic** Assist Components comprising of Pulley, Wire rope and Spring.

1. Exoskeleton

The disclosed exoskeleton features an innovative ratcheting hip pulley that houses a passive energy storage device in combination with an exotendon running. All three pulleys(Hip, Knee, Ankle) are mounted and supported on the exoskeleton. Overall is a combination of struts and their linkages with the help of connecting pins and nut-bolts. The

exoskeleton includes a belt that is configured to secure the hip/waist of a user to position the exoskeleton properly concerning the user's body. The belt includes a backplate and two hip pieces. Each hip piece is independently secured to the backplate using binding barrels and screws. The hip pieces may slide medially or laterally along the horizontal slots in the backplate and then be fastened down where necessary to adjust the width of the belt. The adjustable width range accommodates the waist size of different patients.

2. Energy Storage Subsystem

An energy storage subsystem coupled to the hip attachment mechanism and the leg frame, the energy storage subsystem comprising.

- 2.1 An exotendon extending from the hip attachment to the distal portion of the leg frame, the exoskeleton configured to store energy as the user's leg moves posteriorly and release stored energy to aid the user with moving the leg anteriorly.
- 2.2 A biasing member disposed along the exotendon, the biasing member configured for storing and releasing energy.
- 2.3 A two-way ratchet disposed along the exotendon in proximity to the hip attachment mechanism, the two-way ratchet configured for adjusting tension in the biasing member.

3. Optimized pulleys

In total, we used three pulleys which are mounted on exoskeleton namely Hip, Ankle, Knee pulleys. Every Pulley performs one common function that is to guide the exotendon along the leg struts and exoskeleton. Also, the Hip pulley accommodates the biasing member (in this case it is a Spiral spring). One end of the spiral spring is attached or pivoted inside the circular slotted grooves of the hip pulley.

4. Rope (Exotendon)

Exotendon runs along the leg strut, exoskeleton with the help of all the pulleys and ends on the ankle pulley. One end of the exotendon is attached to the end of the spiral spring due to which it runs over the pulleys as a result of compression and expansion of spiral spring.

5. Spring (Spiral)

Introducing a spiral spring instead of a helical extension spring was decided to overcome the drawbacks of the extension spring. Spiral spring gets compressed when the affected leg is anterior to other and stores the energy. This stored energy is then released when the affected leg tries to move ahead by producing some amount of torque to help the patient.

6. Adjustable strips

The lower leg member is similar in design to the upper leg member in that it is adjustable in length to customize fit to a particular user's leg dimensions. Accordingly, in one embodiment the leg frame has an adjustable length. Fig illustrates the construction of the representative lower leg member, which includes a front plate, a backplate, central support, and a positioning plate having a plurality of holes, into which a positioning pin is placed to adjust the distance between the knee joint and the ankle pulley. The upper leg member is similarly constructed and is adjustable.

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3.5 Modelling

Implementing the device on the human body is the most important aspect of the project. To mount the device on the human body we prepared an Exo-Skeleton Structure of the human body. The below figure also shows the slot arrangement for size adjustment purpose. The Modelling was done keeping in mind the average body dimensions of an aged person.

3.6 Drafting



Fig-13: Isometric View of the Assembly

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Fig-14: Front View of the Assembly

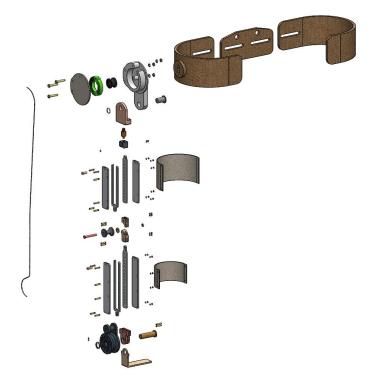


Fig-15: Subassemblies



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Fig-16: Hip Casing Pulley

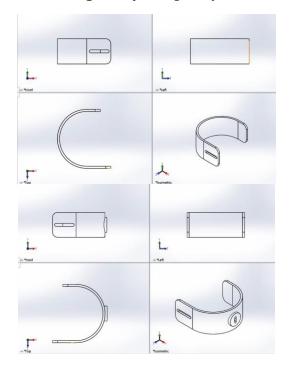


Fig-17: Hip Support Pieces

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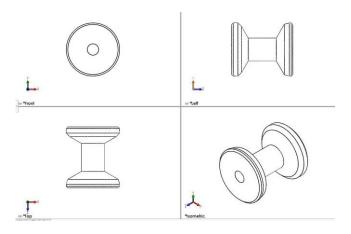


Fig-18: Knee Pulley

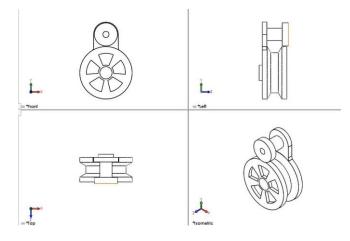


Fig-19: Ankle Pulley

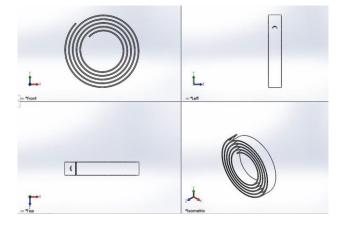
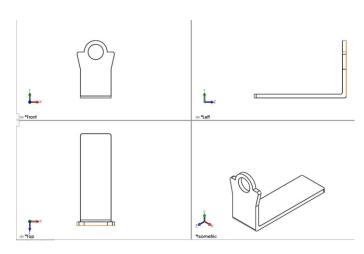


Fig-20: Spiral Spring



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Fig-21: Foot Plate

3.7 Components of Exoskeleton

Sr. No.	Component	Uses	Material
1.	Hip Belt	It is secured at a hip position	Leather (Light)
2.	Extension Spring	Acts as a biasing member which stores and releases energy	Stainless steel
3.	Thigh Brace	For Resistive Support from back to lower limb	Polypropylene Plastic
4.	Calf Brace	For Support purpose	Polypropylene Plastic
5.	Pulley (Knee Joint)	To Guide the extensions of steel ropes	Leather (Light)
6.	Pulley (Ankle Joint)	To confine the wire rope extension (Pivot type)	Stainless steel
7	Custom Moulded Insole	Support for the Foot	High-Grade Polymer
8.	Wire Rope	Operating Pulleys	Steel
9.	Upright Supports	Medial Lateral Support	Aluminium 7000 series

Table-8: List of Components



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4. FABRICATION OF THE ORTHOTIC DEVICE

4.1 Manufacturing

After the design stage we categorized the list of components as follows:

List of components to be manufactured:

- 1. Spiral Torsion Spring
- 2. Hip case, Hip case pulley, hip case cover
- 3. Hip pieces
- 4. Upper and lower leg struts
- 5. All the pulleys (Hip, Knee, Ankle)

List of components to be purchased (standard parts used):

- 1. Various types of joints (threaded, L-shaped, box type)
- 2. Locking pin for connecting parts.
- 3. Knee supports
- 4. Upper and lower cuffs (Adjustable)
- 5. Locking pin for struts
- 6. Washers, Nut, Bolts
- 7. Rope (exotendon)
- 8. Hip belt

A feasible device should be manufactured as easily as possible. To that end, as many parts as possible were designed to be mass-produced using conventional manufacturing methods though some of the parts were made using non - conventional methods for the initial prototype.

- Components like the hip belt to be purchased from the market are manufactured by stitching. High impact polystyrene material is used for manufacturing. They are custom made as per requirements.
- Polypropylene plastic made braces for knee and calf supports can be manufactured by 3D printing techniques or by injection moulding.
- Aluminium upright supports can be fabricated by forging, blanking and punching the strips of raw material.
- Polymer made components like foot insole is manufactured by polymerization techniques.

 An extensible lightweight nylon exotendon is available in the market as per the required standard.

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- The components of the upper and lower leg struts, as well as various internal parts that make up the hip pulley mechanism, were designed such that they could be made out of plate material using either a water jet or laser cutter. Acrylonitrile Butadiene Styrene (ABS) material is used to 3D print the energy storage device. These manufacturing methods are ideal for mass productions.
- The spring housing and joints have to be CNC machined out of aluminium due to the specific three - dimensional geometries.
- For interlocking joints, different alloys were used to ensure that both parts would induce wear. If these parts were to be mass-produced, they would be cast in the same material and then post-processed to reduce the time and cost required to make them.
 For this time we bought the standard joints from the catalogue as per the requirements.

4.1.1 Process Planning Sheet

Pulleys

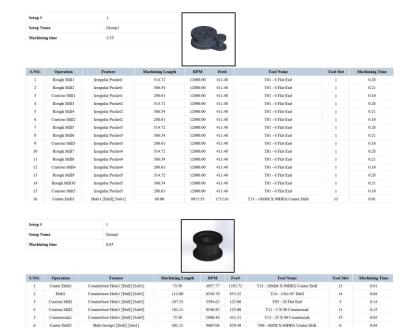




Fig-22: Process Planning Sheet for Pulleys

- Spiral Spring
- 1. Raw Material Selection

Spring Steel with σ_b = 552 MPa, σ_{ut} = 2800 MPa, E = 206 \times 10³ MPa

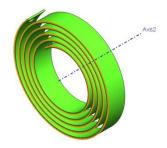


Fig-23: Spiral Springs

2. Design

Various mathematical equations have been developed to describe the properties of springs, based on such factors as wire composition and size, spring coil diameter, the number of coils, and the amount of expected external force. These equations have been incorporated into computer software to simplify the design process.

3. The Manufacturing Process

The following description focuses on the manufacture of steel-alloy, coiled springs.

- a) Coiling Hot winding
- b) Hardening Heat treating
- Finishing Grinding, Shot peening, Setting, Coating, Electroplating, Packaging

4. Quality Control

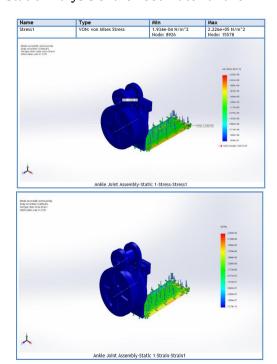
4.1.2 Assembly

• First of all the leg struts which are manufactured in the workshop is jointed with the help of joints to make a whole exoskeleton as a piece.

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- Later pulleys are to be mounted on the exoskeleton with the help of joints.
- Then spiral torsion spring is pressed inside the slotted grooves provide on the hip pulley, where one end is fixed inside and the other end is attached to the rope.
- The assembly is mounted on the exoskeleton by riveting it to the frames.
- Nut and bolts are used for assembling the parts.
- The parts should be fitted tightly and compactly.
- Various pin joints are used for connecting turning pairs.

4.1.3 Static Analysis of the Foot Plate Failure



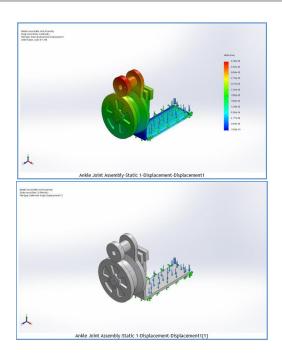


Fig-24: Ankle assembly static analysis results

4.1.4 Performance Testing of our Model

The disclosed exoskeleton is to be tested to validate that the design meets the design specifications and core function. These tests include,

- Adjustability and range of motion tests
- 3 point bend test on the knee joint
- A pendulum test for acceleration
- A scratch test for safety
- Preliminary comfort and fitting test

1. Range of Motion & Adjustability:

Both ranges of motion and adjustability should be tested manually by moving the device and measuring the minimum and maximum values. For adjustability, the design specification required 228 .6mm for vertical adjustments well as 203.2mm of adjustment around the waist. The exoskeleton needs to be measured in both its shortest and tallest configurations to confirm the leg struts will accommodate the desired range of patients. The hip belt is not tested for a circumferential range of motion because it was prototyped out of a much more rigid material than designed for. The angular ranges of motion are figured out in this test.

2. Pendulum Test:

This test is to be conducted to confirm that disclosed exoskeleton does not prevent an unimpaired gait, either through jerk during the swing phase of walking or overall reducing the tibial acceleration.

3. 3-Point Test:

To ensure that the disclosed exoskeleton will not fail at the knee and cause injury to the wearer, the knee joint was tested until failure. In 3 - point loading, as illustrated. The test was conducted on a partially assembled leg, consisting of an upper leg strut, knee joint, and lower leg strut. The assembly was placed with the force applied laterally to the centre of the knee and with the supports located 65 mm to the left and right. Because the test is meant to evaluate the knee, the supports were placed fairly close, rather than at the end of the struts. The load was applied at a rate of 3 mm per minute until failure occurred. The readings or observations are to be presented in the form of a load vs extension curve.

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- Components like a hip belt to be purchased from the market are manufactured by stitching. High impact polystyrene material is used for manufacturing. They are custom made as per requirements.
- Polypropylene plastic made braces for knee and calf supports can be manufactured by 3D printing techniques or by injection moulding.
- Aluminium upright supports can be fabricated by forging, blanking and punching the strips of raw material.
- Polymer made components like foot insole is manufactured by polymerization techniques.
- An extensible steel wire rope is available in the market as per the required standard.

4.2 Estimated Cost Table

Sr. No.	Component	Material	Qty.	Est. Cost/ Piece in INR
1	Hip Belt	Leather (Light)	1	600-700
2	Energy storage subsystem	ABS	1	2500- 5000
3	Spiral Spring	Stainless steel	1	150-200
4	Calf Brace	Polypropylene Plastic	1	1000
5	Thigh Brace	Polypropylene Plastic	1	1600
6	Pulley (Hip)	Polymer	1	100-500



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7	Pulley (Knee Joint)	Nylon	1	600-700
8	Pulley (Ankle Joint)	Nylon	1	600-700
9	Custom Moulded Insole	High Grade Polymer	1	1200- 1500
10	Wire Rope	Steel	2	75
11	Upright Supports	Aluminium	2	185
12	Miscellaneous			1000- 2000
	Total			12110- 14160

Table-9: Estimated Cost Table

4.3 Cost Comparison Table

Our proposed device was compared with a standard Ottobock orthotic device.

Following results were obtained -

Sr. No.	Orthotic Device	Description	Cost (INR)
1	Ottobock Orthotic Device	Best available in the market	56000
2	Honda Walking Assistance Device	Precision Control but only for assisting	45500
3.	Economical Orthotic Device	Moderate Precision but with a self- actuating mechanism	14160 (Estimated)

Table-10: Estimated Cost Table

5. CONCLUSION

5.1 Advantages and Drawbacks of our Device

A few **advantages** of our orthotic device are mentioned as follows: -

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- We plan to make our orthotic device as affordable for the common man as possible. Accordingly, unlike the other devices currently in the market, we believe our device will range between INR 15000-18000.
- It can significantly help in the growth recovery rate of 'Neuroplasticity', at a very low-cost price.
- A person could be able to walk with 'Proper Human Gait Motion' rather than moving through an abnormal gait motion.
- No external power source required as it is fully manually operated and self-actuated.
- It can be adjusted as per the required sizes by using slotted pinholes and use of braces.

A few **drawbacks** of our device are listed below: -

- Not as efficient as electrically controlled orthotic exoskeleton devices as they provide smooth assistance while walking.
- Not as précised as a myoelectric controlled device as they provide great precision and repeatability.
- Low-grade performance on uneven terrain. May feel uncomfortable due to the use of rigid linkages.

5.2 Scope for Future Work

During the **20th century**, investments in human-mobility technology primarily focused on **wheeled devices**. Relatively little investment was focused on the advancement of anthropomorphic exoskeletal technologies that allow humans to move bipedally at enhanced speeds and with reduced effort and metabolic cost. It seems likely that in the 21st century more investments will be made to drive innovation in this important area.

The fact that large automobile companies, such as **Honda** and **Toyota**, have recently begun exoskeletal research programs is an indication of this technological shift. Perhaps in the latter half of this century, **exoskeletons and orthoses will be as pervasive** in society as wheeled vehicles are today.

That would allow the elderly, the physically challenged and persons with normal intact physiologies to achieve a level of mobility not yet achieved. Nowadays **Artificial Intelligence operated** exoskeleton devices are in the research phase

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which will promote greater comfort, low weight and a high sense of reliability.

This orthotic device will be considered as a bench-mark device over which more further innovation or modifications can be made. We can add Geneva Mechanism to adjust the exotendon force according to the patient's need for support. Even there is also scope in changing the materials used for various components to make the device light in weight.

5.3 Inference after Project

From the above experimentation and research, we have made the following inferences: -

- Orthotic Devices are extremely useful but should be designed and fabricated with utmost care.
- It is necessary to make cheaper options available for the common man so that one can regain the lost control of the body part with the almost same level of efficiency as that of high-cost advanced devices.
- For the orthotic devices balancing and proper orientation holds the key, if the proper gait motion has to be recovered.
- We are hopeful of completing the remaining manufacturing process.
- We should focus more on functionality rather than the aesthetic aspects.
- The safety of the patient should be a primary concern.

ACKNOWLEDGEMENT

It gives us a great pleasure to present a project stage one report on 'Design and Fabrication of an Economical Orthotic Device'. In preparing this project to date number of hands helped us directly and indirectly. Therefore, it becomes our duty to express gratitude towards them.

We are very much obliged to subject guide **Prof. (Dr.) M. D. Hambarde**, in Mechanical Engineering Department, for helping and giving us proper guidance. His timely suggestions made it possible to complete this project so far for us. All efforts might have gone in vain without his valuable guidance.

We will fail in our duty if we don't acknowledge a great sense of gratitude to the principal **Prof. (Dr.) Lalit Kumar K. Kshirsagar**, head of mechanical engineering **Prof. P. B. Joshi** sir and the entire staff members in Mechanical Engineering Department for their cooperation.

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BIOGRAPHIES



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e-ISSN: 2395-0056

p-ISSN: 2395-0072