DESIGN AND DEVELOPMENT OF THERAPEUTIC DEVICE FOR KNEE JOINT AND ASSOCIATED MUSCLES REHABILITATION



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Design and Development of Therapeutic Device for Knee Joint and Associated Muscles Rehabilitation

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Thesis Supervisor

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ABSTRACT

Motor control of the knee joint is compromised due to various deficiencies that act on neurological areas and musculoskeletal systems and leads to deformities and other everyday life complications. The mobilization of a disabled person is a tedious job which causes discomfort for both the subject and the caregiver. The treatment involves long term therapy sessions with therapists, and even later stages of self-treatment require a trained attendant for the subject. Manual therapy is physically demanding for subjects and therapists alike therefore, automated electromechanical devices are being developed to regain the muscle control, increase muscular strength, mobility and motor coordination. Different exercises can be performed by using these special types of active and passive devices. However, the automatized solution available in the market are very costly and out of reach of an average household. The proposed device is an electromechanical knee joint physiotherapy system that provides controlled therapeutic flexion and extension motion to lower limb according to user defined speed and range of motion. The device has simple user interface for entering exercise parameters. Fail safes and emergency stops are installed to limit/stop any undesirable movement. The device is portable and can be adjusted to be used for subjects of any height. The hardware includes latest orthosis manufacturing techniques and tools for the development of support structure of the lower limb. The device is powered and actuated using mounted electronics circuits boards and controlled via control algorithms running on microcontroller. Inputs and outputs of the device are monitored through control feedback loops. This device can help break the cycle of trauma, and inflammation in the joint, help in prevention joint stiffness and speed up the recovery of postoperative range of motion.

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LIST OF ABBREVIATIONS

MCL **Medial Collateral Ligament** LCL Lateral Collateral Ligament ACL **Anterior Cruciate Ligaments Posterior Cruciate Ligaments** PCL **Continuous Passive Motion** CPM TENS **Transcutaneous Electrical Nerve Stimulation** C.G. **Center of Gravity** B.E.C. **Built in Electronics Circuit** DPDT **Double Pole Double Throw** TKA **Total Knee Arthroplasty** Liquid Crystal Display LCD CAD **Computer Aided Design** MoI **Moment of Inertia**

CHAPTER 1: INTRODUCTION

Knee joint is pone the main weight bearing joint of human body. It is prone to injuries and other degenerative diseases that hamper the normal motion of knee joint. Number of total hip and knee replacements being performed around the world are rising and is a common surgical technique for the treatment of osteoarthritis[1-3]. Once the patient is stable medically and surgically, the focus shifts to acute management of the patients population for early and safe discharge from hospital in the shortest time[4]. Early mobilization of patients has been shown to improve functional status along with cardiovascular health[5].

Functional recovery of knee is accelerated by early and intensive physiotherapy. Extensive postoperative knee flexion has shown to prevent deleterious effects of joint immobilization[6, 7]. Physiotherapy is typically provided to patient through manual exercises by a certified physiotherapist. Physiotherapists ensure proper form during the prescribed exercise session. In addition, the physiotherapists determine and administer appropriate range of motion though which the joint motion is performed. Finally, the physiotherapist adjusts the pace at which to perform the exercise. Physiotherapy sessions may be performed for a few days to months at stretch depending upon the kind of condition of subject. This continued support and assistance is demanding on both physiotherapists and patients. In many cases physiotherapist or any other caregiver must perform the repeated the laborious task of manual exercise daily and over an extended period. Like in most modern solution to repetitive activities, manual physiotherapy has been replaced by automated physiotherapy machines. These machines have been assisting physiotherapist in providing quality health care to subjects. The automated electromechanical devices provide physiotherapy to subjects recovering from surgeries or suffering from chronic illness alike. Automated physiotherapy solutions have since been employed at hospitals, physiotherapy centers and at homes. The knee joint automated physiotherapy devices sector has mostly been dominated by Continuously Passive Machines (CPMs). There have however been little improvements in overall exercise form provided by CPMs. Attempts have also been made to by devices specifically targeting knee joint, but the attempts have been very limited and not without their own shortcomings. The device presented in this thesis attempts to come up with an automated solution that provides a unique and specific solution to automated physiotherapy of knee joint. The device aims at providing a solution that is beneficial for both caregiver and the subject.

1.1 Problem Statement:

To perform controlled and automated extension and flexion of human leg to provide physiotherapy to knee joint thus allowing the knee to move through complete its full range of motion to help in rehabilitation of knee joint and its associated muscles.

1.2 Significance of Study

This study relates to design and manufacture of knee joint physiotherapy device. As knee joint is one the main weight bearing joint of the body its injuries and problems are very common as well. So, such a device shall be useful for the physio therapists and subjects alike. The design is unique and can usher a new range of devices in physiotherapy field.

1.3 Objectives of study

To design and develop a therapeutic device for knee joint that assists the subject in controlled flexion and extension movements around knee joints with following control parameters:

- User defined speeds
- User defined angle limits
- User defined repetition/cycles

Following are the aspects that are to be ensured with respect to user experience:

- User friendly
- Safe to operate
- Easy to equip
- Easy to operate
- Allowing comfortable posture for the user during therapy session
- Portable

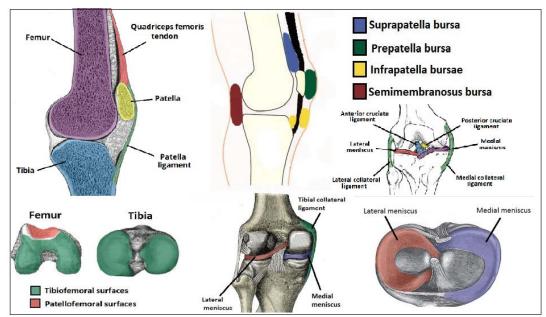
1.4 Thesis Layout

This dissertation has five chapters. Chapter 1 introduces the research topic and discusses the problem statement, significance and objectives of the research. Chapter 2 gives an extensive literature review about anatomy and physiology of human leg and knee joint, pathophysiology of knee joint, treatments for knee joint problems, electromechanical physiotherapy devices, previous studies and their limitations. Chapter 3 discusses the methodology adopted to implement this research. The chapter sequentially elaborates the steps taken to develop this study. It covers the entire methodology including engineering conceptual design, selection of components, hardware and software development. The chapter also covers design evolution from bench testing to final device. Chapter 4 discusses results and elaborates how the device performed against set objectives. Chapter 5 concludes the projects work, describes device limitations and explains all the future work that can be done on this project.

CHAPTER 2:LITERATURE REVIEW

2.1 Anatomy of Human leg

The human leg by definition starts from knee joint till the ankle area. The basic function of leg is to bear weight, help in locomotion and recreational activities. Major bones include femur, tibia and fibula. All of these joints together to form the knee joint. In addition, patella is also a sesamoid bone lies in front of the knee joint. Anatomical and mechanical axes coincide in the tibial shaft but diverge up to 6° in femoral shaft. In normal axial alignment, the femorotibial angle is 174° [8].



2.1.1 Anatomy of Knee Joint

Figure 1 Anatomy of knee joint explaining different sections of knee joint

Everyday activities are dependent on the knee joint, the most important and the strongest joint of human body. It helps in supporting weight, movement of legs relative to thighs as well as complex activities like sitting, standing, walking, running and dancing etc.

Anatomically, knee joint is also called as tibiofemoral joint, the synovial hinge joint. Three bones are involved in the joint formation that are: femur, tibia and the patella. The convex and concave surfaces of the bones allow the structure to stay together in addition to supporting ligaments, tendons and muscles. [9]

On the anterior surface of femur, there is a sesamoid bone patella, it has smooth joint forming process at its posterior surface. [10] The hyaline cartilage is present at the articular

surfaces for smooth movement of the joint surfaces. For providing the strength and lubrication to the knee joint, a joint capsule is present. [11] For retaining the proper alignment of the joint, there are many strong ligaments present externally as well as internally that includes medial collateral ligament (MCL) lateral collateral ligament (LCL), the anterior and posterior cruciate ligaments (ACL,PCL) [12]

As being a hinge joint, the basic function of the knee joint is to provide flexion and extension. The movement occurs in the lower leg relative to the thigh. As the joint is formed between the concave and convex surfaces movements are limited. The major movements of the joint are extension and flexion. In contrast to the other hinge joints, knee joint also allows a little medial and lateral rotation. [13]

The list of muscles that control the movements of knee joint are as follows:

- At the front:
 - Quadriceps muscles (vastus medialis, vastus lateralis, vastus intermedius)
 - Rectus femoris
- At the back:
 - o Hamstring muscles (semitendinosis, semimembranosus and biceps femoris)
 - Popliteus muscle [14]

Knee flexors: these are the muscles that decreases the angle between the thigh and the lower leg. A large group of muscles control the flexion at the knee joint that includes biceps femoris, semimebranosus, semitendinosus, popliteus, gracilis, Sartorius and gastrocnemius (calf muscle).

Knee extensors: these are the muscles that increases the angle between the thigh and the lower leg. It includes all the four muscles collectively called as quadriceps femoris.

Both flexion and extension together are required for any type of complex movement that are walking, kicking a ball as well as climbing the stair etc. [15].

2.1.2 Movements and Motions

There are four main movements that the knee joint permits:

- Knee flexion: it is produced by knee flexors (120-150 degrees) [16]
- Knee extension: it is produced by knee extensors [17]

- Lateral rotation: this movement is produced by a muscle called as biceps femoris (30-40 degrees). It occurs during the initial stages of flexion.
- Medial rotation: A group of five muscles help to produce this movement that includes gracilis, semimembranosus, semitendinosus, sartorius and popliteus (10 degrees). It occurs during the last 30 degrees of extension.

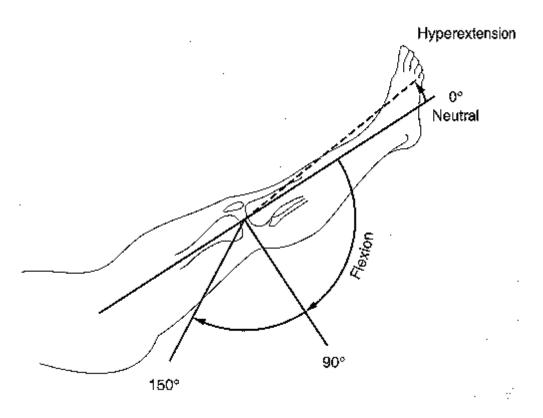


Figure 2 Range of motion allowed by knee joint

2.2 Disorders of human knee

As the knee joint is a complex synovial joint, so there is a great range of disorders. It is prone to several issues because it's the weight bearing joint. Trauma, overuse, long standing jobs can result in damage to any part of joint. Aging is a great factor that results in wear and tear of knee joint. Some of the disorders of knee joint are listed as: osteoarthritis, bursitis, articular surface injury, torn meniscus, ligament instability etc.

The pathophysiology stages involved in causing the knee disorders - mainly the stiffness is as follows:

- 1. Bleeding
- 2. Edema
- 3. Granulation Tissue

4. Fibrosis

All the stages are explained below

• Stage 1: Bleeding

Initially, after the trauma or surgery, bleeding results. It can occur within minutes to hours and results in swelling of periarticular tissues as well as distension and stretching of joint capsule. At a certain angle, joint achieves its maximum potential volume e.g. for knee joint the maximum capacity is around 35 Q of flexion. Moving the joint beyond capacity can results in high hydrostatic pressure and results in pain and decreased range of motion.[18-21].

• Stage 2: Edema

Happening after few hours or can take days is the stage of edema. It is defined as "**Edema** (or Oedema) is the abnormal accumulation of fluid in certain tissues within the body". As the cells die or injured – they release inflammatory mediators. These mediators dilate the blood vessels and plasma is released and so edema. It further aggravates the condition, add up the pain and difficulty in movement [22]

• Stage 3: Granulation Tissue

Lasting few days to weeks, results in formation of granulation tissue, having properties lies between loose areolar fibrous tissue and the blood clot. It occurs in the joint and around, so further increases the stiffness as by adding extracellular matrix.

• Stage 4: Fibrosis

It is the stage after granulation tissues matures, and transforms in to rigid scar, with a high concentration of type I collagen fibers.

2.3 Approaches to Solving the Problems of Human Knee

There are various approaches to solve the problems of knee joint and to resolve issue. Some of the various treatment options are as under:

2.3.1 Pain medications:

the most basic treatment option is to go for medication. The medications are mostly pain relievers and help in providing comfort to the subject. Some of the examples include naproxen (Aleve), ibuprofen (Motrin) and acetaminophen (Tylenol) etc.

2.3.2 Surgery:

It is needed in cases where there is some wear and tear and medication can't help to repair the structure, as in case of meniscal tear, fracture cases or ligaments tear etc.

2.3.3 Physiotherapy:

Physiotherapy, also known as, Physical therapy (PT) involves using mechanical force and movements (bio-mechanics or kinesiology), exercise therapy, manual therapy, and promotes mobility and function. Physiotherapy helps in restoring movement and function of that specific part of body being affected by any type of disability, illness or trauma. It is a noninvasive technique with no side effects if performed correctly. This is the therapy-based treatment for disorders of knee joint. It can be prescribed to the subjects presenting with pain, any structural problem, and have a great pre-operative and post-operative scope. It helps in improving range of motions after accidents, operations and in contracture cases. It is prescribed on the bases of case, can be only composed of exercise program as the muscle strengthening, improving stability at the knee joint or both. Various machines can be utilized for improving functionality such as TENS (Transcutaneous electrical nerve stimulation) and Continuously Passive Motion Machines (CPMs).

There are many types of physiotherapy options, some are as below:

- Stretches and exercises (are used for reliving pain, improving muscle strength and joint stability)
- Ice and heat (mostly used as a pain-relieving modality)[23].
- Ultrasound massage (soothing, relaxing the part, improving blood circulation)

Electrical nerve or muscle stimulation (are used for pain reduction as well as improving strength)

2.3.3.1 Electromechanical physiotherapy solutions for knee joint

Some of the modified modalities of physiotherapy includes the use of electromechanical devices, that started emerging at 1970s. Since than till yet, these days are emerging day by day and are modified, more specifications and functionalities are being added up to give maximum output to the subject with least or no discomfort[24].

There are numerous benefits of electromechanical devices over the manual therapies, these include:

- i. Precision
- ii. Accuracy
- iii. Efficiency
- iv. Subject high compliance
- v. Purchasable
- vi. User friendly
- vii. Maximum output
- viii. Least or no discomfort

2.3.3.2 Pervious Work in field of electro-mechanical knee joint therapies

Electro-mechanical physiotherapy devices work on two basic principles. Firstly, articular cartilage maintenance is ensured by joint motion. Second, maintenance of normal periarticular soft tissue compliance is required for joint homeostasis. To meet these requirements CPMs operate in the prescribed range of motion. In order to prevent swelling immediately after surgery the soft tissues are needed to be subjected to tension. Joint's long-term mobility is largely dependent on this early maintenance provided by the CPM[19].

2.3.3.2.1 Continuous Passive Motion (CPM) Machines

Continuous Passive Motion device, abbreviated as CPM, is a device that helps in improving the flexion angle of knee joint in the patients where range of motion is reduced.

This device is targeted to improve flexion and extension of knee joint by overcoming the actual problem of the patient of unable to perform the exercise themselves. These are based and safe to use. [25]



Figure 3: Portea® - Continuously Passive Motion Machine

Advantages

There are various reasons for reduced range of motion that includes stiff muscles, polio, accidental injuries, hemiplegia, post-operative, paralysis

Technically the machine can be programmed at any required angle from 5° angle to 110° flexion. It can be speed up or down depending upon subject requirement. [19]



Figure 4: BTL-CPMotion K Elite

• Research done and Benefits

A study by Vince, Kelly G., et al, includes 62 patients with total knee arthroplasty, out of them 42 patients were provided with CPM therapy and the others as control. Results have shown that CPM have shown to improve flexion recovery as well as some evidence of reducing chances of deep venous thrombosis.[8] In contrast, in a recent study on CPMs, a contradictory result was highlighted. This study document the findings as: "Despite the theoretical effectiveness and widespread use of CPM, there are still differing views on the effectiveness of CPM as prophylaxis against thrombosis after TKA." [26] Previously a review also published in 2012, this study basically tried to update that. [27]

Furthermore, a study compared beneficial effects of CPM and a newly induced sling exercise in 2014, the results were analyzed for total knee arthroplasty cases. It was found that sling exercise was found to have shown beneficial results compared to CPM. The study was in support of sling exercise. [28] One of the contradictory study "The effect of a rehabilitation sliding machine and conventional neurological physical therapy on the balance of patients with hemiplegia" compared the beneficial effect of sling exercise verses conventional neurological physical therapy. It demonstrated that the in contrast to sling exercise, the conventional neurological physical therapy is more effective. [29]

Shortcomings

Since the introduction of the device, there has been little to no modifications. It is documented by a famous orthopedic surgeon, Rick Hammesfahr, MD at "Center for Orthopaedics & Sports Medicine" in Marietta, that in past many years there is nothing changed in the CPM. Normally with new technological advancements the previous models are modified and are focused to update. But such things don't happen and so they further said these devices are "more readily accepted by insurance companies." Furthermore, Hammesfahr also stated that "The insurance companies have pretty much come around on that point."

Another shortcoming is that it mainly targets on most critical cases, post-operative, hemiplegia, paraplegias but the general knee pain resolving is not the major concern here. More than 80% of elderly adults are having some sort of general knee pain that are out of scope here. [30, 31]

One of the major setback in CPMs is the exercise form. The subject must lie back on a surface for the duration of the exercise. This is not a very comfortable posture for longer duration exercises. Especially if the subject is healthy otherwise and has to perform only knee exercise daily.

2.3.3.2.2 X-10 therapy

It is basically a knee recovery system that mainly targets the knee surgery cases, partial or complete knee replacements, knee arthroplasties, fractures of born, torn ligaments and meniscal tears etc.



Figure 5: X-10 Therapy Device

Advantages

It has shown actually good results as comparing to the manual physiotherapy for such critical cases as the manual therapy was much more painful so there was a reduced patient compliance. This hurdle was sorted out by this device that have provided comfort to the patient with minimum discomfort while therapy. It has reduced the recovery time that is also a great milestone achieved.



Figure 6: X-10 therapy next to a chair for seating subject

• Research done and Benefits

Previous research has shown that X-10 is successful in providing therapy to the patients with minimum pain as compared to extremely painful manual therapy. But still, there is very rare literature review regarding this and results are not properly documented and published. Mostly the benefits claimed are those by the companies with almost no publication, so the results claimed by them are in doubt.

• Shortcomings

It covers the majority of critical cases as that of CPM, but the major issue here is again the 80% of general adult community being affected by knee pain issues. There is a need of some portable device without a huge computer unit to help general community and relieve the pain related issues of knee joint and to sort out minor issues before the condition worsens. Also, least literature and published results are found so the claims are still in doubt and further research should be done to prove the benefits of device. Finally, there is a problem not fixing knee position that would result in optimum exercise position.

2.4 Needs and targets for a new device

The literature has shown varying results. Research shows that CPMs do help in rehabilitation of knee joint by help in improving range on joint stiffness, knee joint pain level, and functional ability[32, 33]. But the results are not usually significantly better than manual

physiotherapy sessions in same conditions.[32, 34, 35] Fore mentioned in view the CPMs if to become effective need to improve on design and cost to be competitive and useful to physiotherapists and other care givers.

So, there is a need to develop a new modified, portable electro-mechanical machine that will help to target general knee pain related issues and to overcome the problems found in existing machines e.g. device should be portable, easy to use, low cost and easy to handle etc.

2.5 Chapter Summary

In this chapter, an in-depth review of literature has been presented. Important study parameters related to research objectives have been elaborated which include anatomy and physiology of human leg and knee joint, Pathophysiology of knee joint, solution to knee problems in general and physiotherapy in specific. The chapter also discusses about the research gaps in previous work and how to mitigate them

CHAPTER 3: RESEARCH METHODOLOGY

Based on literature review it is concluded that a novel device is needed to meet the identified gaps in devices related to automated knee joint therapy. In order to design and develop a medical device the capable of meeting the identified needs a work plan is created that outlines guidelines for design development and testing including verification and validation.

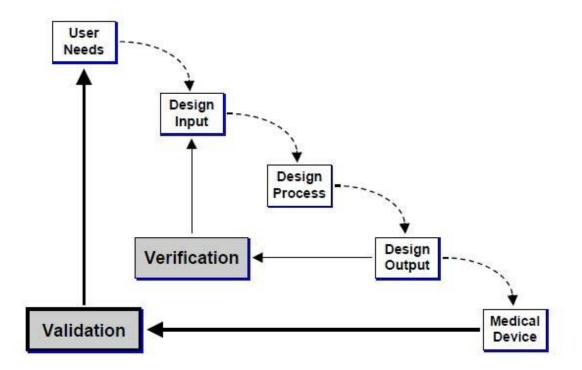


Figure 7: Waterfall Model [US FDA, 1997a]]

This chapter explains various steps of research methodology in detail.

3.1 Work Flow

Workflow for the device design is as under:

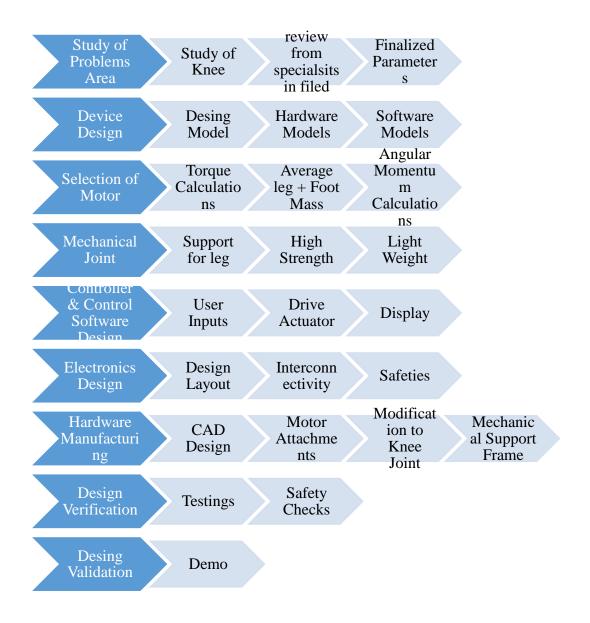


Figure 8 Workflow Chart

Different sections of above flow chart are explained below:

3.2 Study of Problem Area

As explained in the literature review section, the in order to better understand the problem at hand detailed study was carried out.

3.2.1 Study of Knee

Anatomy and physiology of human leg and knee joint was studied. Different problems and their solutions were studied. Physiotherapy in general and automated physiotherapy solution for the identified problems were studied in detail. Previously developed devices were studied in detail. The pros and cons along with various research done on previously developed was thoroughly studied. Finally based on the study the need for development of a new device was identified.

3.2.2 Review from Specialists in Filed

Physiotherapy departments are various hospitals were visited. Detailed discussions on the subject problem were carried out with specialists in the field. Gaps identified in literature review were presented to the physiotherapists/specialists and their valued opinion was incorporated into the research objectives to make them more realistic. Device output parameters were finalized after consultation with physiotherapy field specialists.

3.2.3 Finalized Device Parameters

Based on literature review and in consultation with physiotherapy field specialists it was decided that main therapeutic exercise for knee joint is controlled flexion and extension of lower limb around knee joint. To perform this controlled knee joint extension and flexion following device parameters were finalized:

- Angular Speed: 0.5 to 1 rpm: Typical CPMs operate around 0.5 rpm. The device is designed to operate at a rate double of typical CPMs so that the device may be operated at higher rates for research purposes.
- Knee Flexion of 0 degrees to 140 degrees: This range can be extended to max range to the maximum range of -10 degrees to 145 degrees after device validation
- User defined number of repetitions: One flexion and extension of lower limb around knee joint constitutes one repetition. Depending on the subject requirement 10 to 100 repetitions may be provided to subject.

3.3 Selection of Critical Device Components

Based on design parameters explained in section 3.2.3. of this document, critical components were selected of the device were being selected. These include the actuator motor, the mechanical support structures, control software and control circuitry. The selection procedure is described in the sections below.

3.3.1 Selection of Motor

Being the main driving force in the device, the motor is most critical component of this device. Motor torque was calculated on two major factors

- a) Torque applied at knee joint due to weight of lower limb and foot
- b) Torque requirement to overcome the moment of inertia at given max speed

Torque requirements for above factors are therefore needed to be calculated. Motor needs to be selected based on higher toque requirement of the two factors above.

3.3.1.1 Torque at knee joint due to weight of lower limb and foot

Torque at knee joint is calculated on base of weight of foot and lower and their distance from knee joint. Distance and weight data is calculated from human anatomical data by plagenhoef et al. and [36] de Leva [37].

3.3.1.1.1 Determination of average weight of lower limb and foot

Mass data for human lower limb and foot is obtained from human anatomical data by plagenhoef et al. and [36] de Leva [37]. Relevant lower limb and foot data extracted from plagenhoef body segment data is as following:

Masses, kg				
	67.495			
5.05%	3.408498			
1.38%	0.931431			
Combined average mass kg				
Weights, N				
Gravity				
average body weight				
average leg weight				
average foot weight				
Total Weight of Leg + Foot				
	1.38% ss kg nt t			

 Table 1 Average Human Lower Limb and Foot Weight Calculation

Above in view, mass of about 4.33 kg or weight of about 42.5 N needs to be handled by our machine. It is assumed for ease of calculation that mass is accumulated at center of mass of lower limb and foot. The next step is to calculate the moment arm to calculate the torque.

3.3.1.1.2 Determination of moment arm of for torque calculation

Moment arm needs to be determined for torque calculation i.e. the distance from knee joint at which the mass needs to be rotated. This data was again extracted from plagenhoef body segment data [36]. The length of lower limb distal from knee joint is used. Similarly, length of foot distal from ankle joint is used.

Lengths, cm		
average body length		173
length of leg	25.20%	43.596
length of foot	4.25%	7.3525
CG, cm		
	42.65% of	
CG (% of leg length)	leg length	18.59369
	50.00% of	
	foot	
CG (% of foot length)	length	3.67625

Table 2 Average human Leg and Foot Length and C.G. calculations

3.3.1.1.3 Torque due to weight calculation

Torque exerted due to weight of leg and foot about knee joint due their weight is calculated as follows:

Torque (N. cm)	
Torque of leg @knee= Leg weight x distance from	
knee	621.0903
Torque of Foot @ knee= Foot weight x distance from	
knee	431.5022
Combined Torque of leg + foot	1052.593

Table 3 Lower Limb and Foot Torque Calculation at Knee Joint

Converting the Torque into appropriate units for DC motor selection:

Torque (kg. cm) = Torque (N.m) / 10

Torque = 105.2593 kg.cm

Total Toque is the torque of foot and lower limb around knee joint

Total Toque = (Weight of Foot xDistnce of Foot C.G. from Knee) + (Weight of Lower Limb xDistnce of Foot C.G. from Lower Limb) (1) Combined center of gravity however is calculated for lower limb and foot based on distal distance of gravity of both segments from the knee joint. The formula for combined C.G. is as follows:

$$Combined \ C.G. = \frac{Total \ Toque}{Combined \ Weight \ of \ Leg \ and \ Foot}$$
(2)

Putting values in equation (1) and (2) from table 3 above, we have

Combined CG (cm)= 24.74866 cm

Based on above it is concluded that a motor of torque 105.2 kg.cm would be enough to carry load of lower and foot of an average human. A motor of double the torque rating should be used in development of device to ensure adequate torque is available for any subject using the device.

3.3.1.2 Torque requirement to overcome the moment of inertia

The device needs to perform extension and flexion of knee joint at specified angular speed. The standard knee joint exercise machines product specifications indicate flexion and extension at 4 degrees per second. Other design papers suggest operation at 10 rpm at max i.e. 60 degrees per second. [38] The device is designed to achieve max speeds which might be useful for other high-speed testing related research later.

3.3.1.2.1 Moment of Inertia calculation

Leg and foot were considered one cylindrical body for ease of calculation. The moment of inertia for a cylinder about its central diameter is calculated as:

$$I = \frac{1}{4}MR^2 + \frac{1}{12}ML^2 \tag{3}$$

Here combined average mass M of lower limb and foot is 4.5 kg. Average radius of lower limb is 8 cm and length of leg and foot combined is 48 cm.

Based on values above moment of inertia at equation (3) is approximated as

I= 0.0936 kgm²

3.3.1.2.2 Angular acceleration calculation

Angular acceleration is calculated based on max angular velocity requirement. The formula for calculation of angular acceleration is as follows:

$$\alpha = \frac{\omega f^2 - \omega i^2}{2\theta} \tag{4}$$

As discussed above ωf is max angular velocity of 60 deg/sec or apprx 1 rad/ sec to be reached. Initial velocity ωi will be zero in out case. θ during which this final velocity is to achieved is assumed at 2 degrees.

Putting values in equation (4) results in

$$\alpha = 900 \ deg/sec^2 = 15.7 \ rad/sec^2$$

3.3.1.2.3 Torque requirement to meet moment of inertia and angular acceleration requirement

Torque required to move the load at such speeds require the are calculated based on following formula:

$$Toque = Moment of Inertia x Angular Acceleration$$
(5)

Substituting values of moment of inertia and angular acceleration in equation (5)

$$\Gamma$$
 orque = I. α = **1460** N.cm = **146** kg.cm

3.3.1.3 Selection of motor based on calculated torque requirements

Based on calculations at section 3.3.1.1 and 3.3.1.2 the higher of the two torque requirements i.e. **146 kg.cm is chosen as design criteria**. This criterion however limits the usage to average human body segments. Therefore, for actual use a motor with double the torque i.e. 300kg.cm is used for development of device.

3.3.2 Mechanical Support

Normal knee joint range of motion is about 140 degrees as shown in figure below.

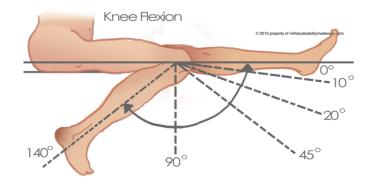


Figure 9 Knee joint Range of Motion

To achieve this range of motion a mechanical support structure is needed that not only is strong enough to carry the weight of human lower limb and foot and is flexible enough to withstand any deflections in motion. Finally, the support structure weight may be kept to a minimum so that there is minimum additional weight for the motor to be carried. All above in view titanium is chosen as material for mechanical support structure of lower limb. In order to cater for all the aspects discussed above standard titanium joints used in manufacturing of lower leg brace in orthotics have been used. This mechanical titanium joint provides an additional important feature. The joint movement is restricted to 0 degrees at one end and 140 degrees at the other end with help of a mechanical lock. This provides the device with an inherit mechanical safety feature which is of utmost importance as the device is to be equipped directly on to a human for testing purposes.



Figure 10 Knee joint Side bar support at different angles



Figure 11 Figure showing mechanical lock at 0 degree

3.3.3 Controller & Software Design

This is an automatic device that takes user inputs and converts those commands into relevant movements of knee joint. To achieve this objective there is need of a controller that can read user inputs (as defined in section 3.2.3.), translates it into codes that can actuate the motor according to user input, take feedback from various sensors that ensure safety and optimum performance of the device and finally display the device state and stats to the user.

3.3.3.1 Controller

Above in view Arduino Uno is chosen as the microcontroller as it is powerful enough to process the inputs and control the motor. Also, the size of the controller is very handy with enough I/Os to handle the requirements of this device.



Figure 12 Arduino Uno

3.3.3.2 Display and user input

Few input parameters are stored as default. The user can update the values after entering the user input mode (this will be described in upcoming section). Multiple inputs are needed to be acquired from user as indicated in section 3.2.3. An interface is required for taking these inputs. All the input parameters, either default or input by user, are to be displayed to user before start of exercise. Exercise status i.e. number of repetition or angle at which the device is operating is displayed to user. An Arduino keypad shield is used to meet all the above requirements. DFRobot Arduino keypad shield is used in this device as it has a useful pin layout plan onboard as shown in the fig below.

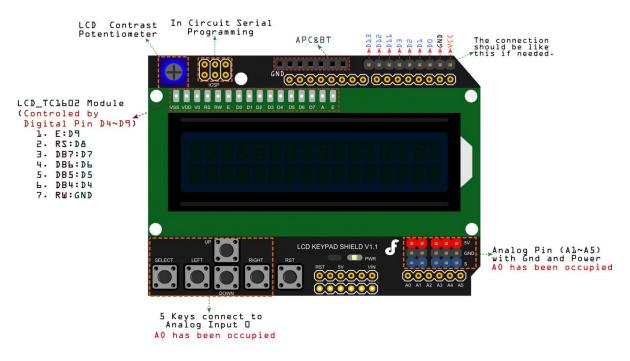


Figure 13 DFRobot Keypad Shield Pinout Diagram

The keypad shield has 5 keys connected to analogue pin of Arduino which are used as input keys. Values of these keys are processed at Arduino and respective outputs for motors/ sensors can also be sent though this shield. Finally, the shield has an 16x2 LCD display on which any information for the user can be displayed. Other features of board include adjustable brightness screen and additional power outlets for connecting multiple devices to the same board.

3.3.3.3 Software design

The controller takes user inputs and processes it to make relevant output. This output is in form of LCD screen display or the motor being actuated. The feedback is also incorporated, and necessary adjustments are made to the output accordingly. The control software thus manages all these aspects. The flow diagram for control software of this device is shown in figure below:

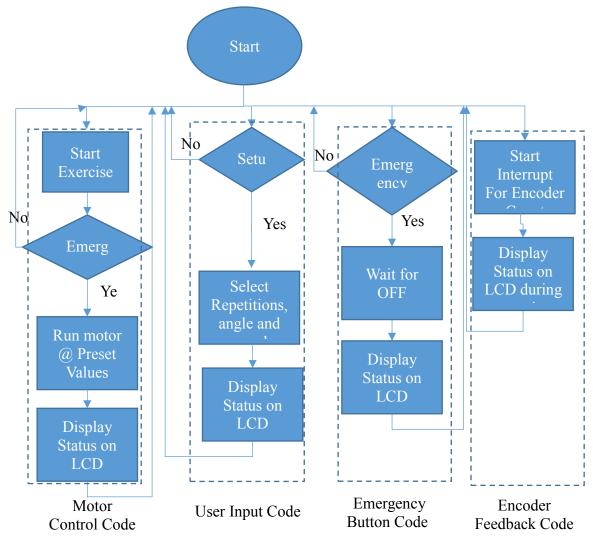


Figure 14 Software flowchart

As shown in the software flow chart above there are four main tasks that the control software handles explained below.

3.3.3.3.1 Motor Control Code

This code generates command for the motor to run at user selected speed, user selected angles and for specified no. of repetitions. Based on these user inputs specific code is generated to run the servo motor. The motor runs at specific length pulses therefore that is being calculated here and given to motor control board on servo motor.

3.3.3.3.2 User Input Code

This section of code manages the interactive user input mode. The mode asks the user to input all the input parameters one by one. Also, it limits the input ranges so that unrealistic values are not entered as inputs.

3.3.3.3 Emergency Button Code

This section of code looks for pressing or depressing of emergency button. The emergency button is a manual safety switch that allows the user to stop the exercise at any point during exercise routine. Also, this safety needs to be turned off before start of exercise.

3.3.3.4 Encoder Feedback Code

This section of looks for encoder feedback signal and then displays the same information on LCD Display. This can be utilized to track the angle covered by lower limb.

3.4 Electronics Design

The device uses an array of electronic printed circuit boards for control purposes. The layout of electronic circuits of the device are shown in figure below.

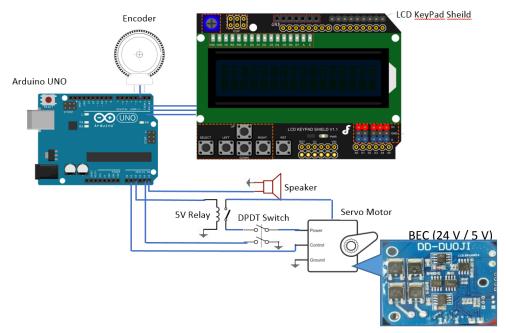


Figure 15 Electronics Layout of device

The figure above shows interconnectivity amongst various electronics components of the device. Arduino UNO sits at the heart of the device layout as it connects and controls all the electronics components onboard the device. Electronics components attached to Arduino are as follows:

- Encoder: Checks the rotation of motor/lower limb
- 5 V Relay: Electromechanical switch that cuts/resumes power to motor coil. Controlled by logic level signal from Arduino with output power range of 30 V 10 A.
- DPDT Switch: Manual safety switch that allows user to cut/resume power to motor coil. Also connected to Arduino for communication of ON/OFF state of the switch.
- Speaker: 5 V speaker connected and controlled by Arduino. Used to alarm the start/end of exercise session and other emergency situations.
- LCD Keypad Shield: Arduino helps display necessary information on LCD screen. Also input buttons on keypad shield are connected to analogue input of Arduino via resistor of different values. User inputs are read with help of these input buttons. Also, power output to various modules are outlet from this keypad shield.
- Servo Motor with BEC: Servo motor is connected and controlled to Arduino via Built in Electronics Circuit (BEC). The circuit is controlled via logic level signals form Arduino. Also, this circuit provides controlled 24 V power to servo motor according to control input signal.

3.5 Hardware Manufacturing

Hardware manufacturing for the device included design, manufacturing and modification of mechanical components. Most of the mechanical manufacturing work has been performed at the prosthetics workshop at ISRA university. The manufacturing techniques used involved/assemblies. milling, drilling, cutting, grinding, plastic soldering and manufacturing of different attachments.



Figure 16 Grinding of mechaicnal parts to acqurie shape

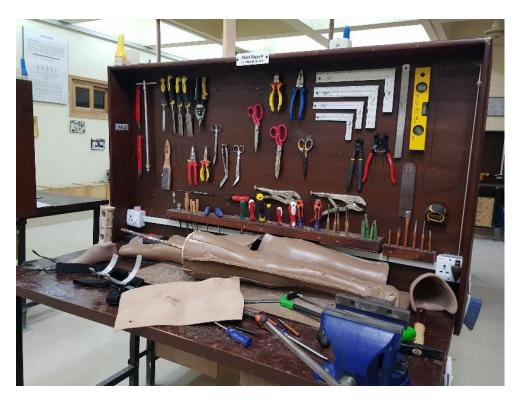


Figure 17 Tool table at prosthetic workshop where mehcanical manfuacturing was performed Various steps to hardware manufacturing is explained below.

3.5.1 CAD Design

First, a CAD design for developed for the device. This helps bring the concept into and actuated assembly for better understanding of device. The design is improved upon and minor adjustment made to make the mechanism more practical and less complicated. Once the design modification iteration completes the design is frozen.



Figure 18 CAD Design of device modeling mechancial portion of device

3.5.2 Mechanical Support Structures

Mechanical support structures include a metal seat, lower limb support including its motor attachment and leg support modification. These are explained in sections below.

3.5.2.1 Metal Seat with joint attachments

A metal seat is manufactured for seating the subject also the same acts as a strong attachment for the titanium joint. The structure is welded out of steel angle irons that gives the structures enough strength to handle loads applied by 300kg.cm motor. Side of the metal seat are drilled to provide attachment points for mechanical joint. Finally, foams are placed on arms and base of the seat for cushioning purposes. Fine leather sheet is wrapped and stapled around the foam for finishing effects.

3.5.2.2 Motor Attachment on titanium joint

Titanium knee joint is modified for motor attachment. Motor is attached on point of rotation of the joint which further is aligned to subject's knee joint axis of rotation. This ensure the rotation of motor is same as rotation of knee joint.



Figure 19 Titanium joint modification for motor attachment

The titanium knee joint is modified by adding straps and metal support rings to support and tightly secure lower limb to the support.

3.5.2.3 Lower Limb Support Modification

Titanium knee joint is fixed with straps and semicircular metal rings for support of lower leg. This modification helps tightly secure the lower leg to the device.

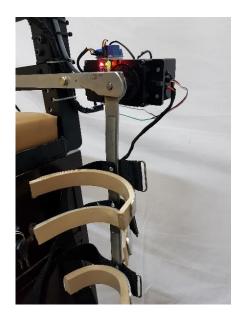


Figure 20 Joint modification for securing leg

3.6 Design Evolution

Manufacturing of device started with bench level testing of device components to final working device with all modules. Design evolution of this device is explained below.

3.6.1 Workbench testing

All components are initially tested at the bench testing. Interconnectivity is verified between various components. Controls of components by Arduino is verified.



Figure 21 Bench level testing of device

3.6.2 Initial Model

Initial model of the device had a simple basic frame. It acted as a proof of concept that such a device could work. All the control related issues were identified and solved in this phase.



Figure 22 Basic Working Model of Device

3.6.3 Refined model with improved safeties

Once the basic model had been verified to perform all tasks, the device was attached with various feedback and safety modules. These include an encoder to provide angular positional feedback, DPDT manual switch and electronically controlled relay. Cosmetics of the device were also improved with foams at base and arms for resting. The device was also painted for aesthetics and protection from rust. Power supply is protected inside a wood and plastic box for protection from box. Wires are covered in plastic shrink sleeve and routed along the body of device. Remote control is attached at a metal bar for easy access of user.



Figure 23 24 V Power supply protected inside a wooden frame and covered in plastic covers



Figure 24 Final Device with improved aesthetics

CHAPTER 4: RESULTS AND DISCUSSION

As discussed in chapter 2 of this document, primary motion of knee joint is a single degree of freedom angular motion. The range of motion is from 0 degrees to 140 degrees. Physiotherapy is provided to the subject in this range. The device successfully met all the objectives laid down at section 1.3. of this document. Each result is discussed in section below.

4.1 User Defined Angle

One of the basic objectives of the device is to provide movement of lower limb at different angles. The device successfully performs the required function. Angles input are translated into relevant motor movement though a conversion formula implemented into the Arduino code. Examples are shown in fig below.



Figure 25 Start of Motion of lower limb



Figure 26 Lower Limb moved to an extended position

The input value has been given to move from 7 degrees to 80 degrees. Photographs are taken at different angles. Pictures show movement of lower limb with respect to support rod attached to the base seat. The lines of both bars are extended with red color lines. The intersection angle provides the angle through which the lower limb moved due to rotation of motor shaft. Angles are drawn using online protractor link for which is given at reference [39]. Table below shows movement of lower limb with respect to support rod attached to the base seat.

Sr	Movement Picture	Angle Input	Angle
#			detected
1		7 degrees	7 degrees
2		12 degrees	11 degrees

3	30 degrees	30 degrees
4	40 degrees	41 degrees
5	52 degrees	52 degrees

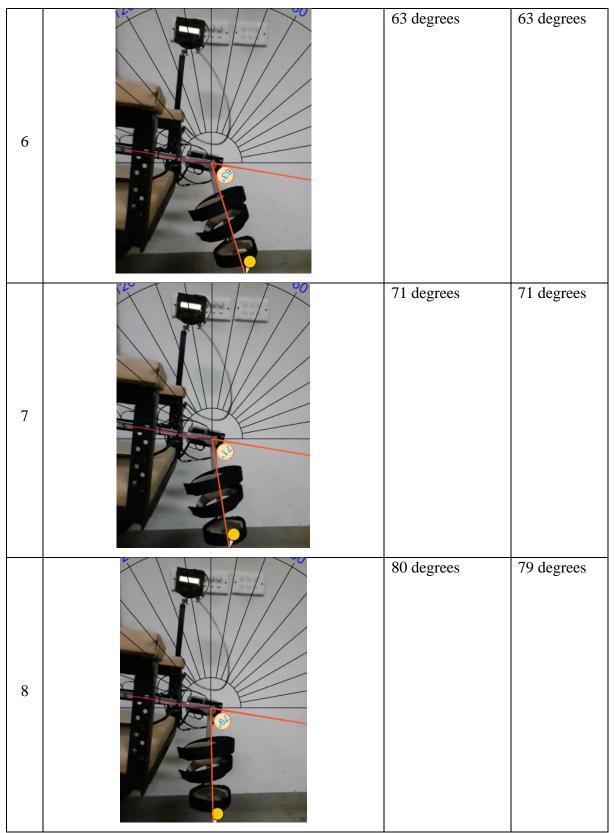


Table 4 Table showing angle input vs actual angle detected

4.2 User Defined Speeds

The device works at 5 different speed levels. Ranging from 2 RPM to 10 RPM. The speeds are set to meet the research requirements of high speed exercise to user. The speeds however can be adjusted to much lower or higher levels through code manipulation.

4.3 Safe to operate

The subject shall be strapped to the device incorporates various safeties including both mechanical and electromechanical safeties. The device has fail-safe safety mechanisms. Power can only be provided to motor coils once both manual and electronics safeties are tuned off.

The device has been tested with various anomalous conditions such as sudden power shut down, power cut-off to controller, supply cutoff to servo motor BEC circuit, safety button release before start of exercise, floating signal due to control signal disconnection and irregular power supply. The device has been subjected to all the erroneous conditions repeatedly both intentionally and during testing.

4.4 User friendly

The device has been designed as such to provide a simple user interface. This user interface is displayed on a and LCD that mounts like remote and can be mounted and on bar for easy access of user. All the useful parameters are displayed on this display both before and during the exercise.



Figure 27 Parameters displayed at LCD display



Figure 28 Controller with display mounted on a bar adjecent to device

The device is easy to equip with straps to secure the subject. Once in place the device can easily be strapped by user himself or any care giver. Then the operation is simple one man job provided right in front of user for easy controls.

It is portable and the base which is 1.5 ft. x 1.5 ft. can be placed on any chair, bench or table for exercise session. There is only one power cord that plugs into 220 V which powers all devices onboard the device. So, there is no hassle for power management.

4.5 Device Load Carrying Capacity

Dead weight of 12 kg was testing on the titanium joint at a distance of 25 cm to verify the 300 kg.cm torque output. The motor was able to hold the weight at this moment arm. Further 10 kg weight has been tested to be moved through the preset angle verifying device operation at torque of 250 kg.cm which is well above the design requirement of 150kg.cm.

4.6 User Defined Repetitions

Number of repetitions/cycles have been verified in thousands of repetitive cycles during device testing.

4.7 Chapter Summary

The chapter discusses the results according to design objectives All the objectives are achieved successfully. These features make the device useful for knee joint physiotherapy subject and it is also user friendly which was one the main objective of this device design.

CHAPTER 5: CONCLUSION AND FUTURE WORK

The electromechanical knee joint physiotherapy device describes in this thesis has a unique design. Such a low cost portable and efficient device is unlike any other device in the market. It addresses the issues of commonly used CPMs and improves upon them in variety of ways. The conclusion for this thesis work is as below.

5.1 Conclusion The device explained in this thesis work is an electromechanical physiotherapy device that shall assists the subjects that require knee joint physiotherapy. The device is a very powerful device able to handle a variety of subjects and at the same time it is very safe to operate. The equipment used has been tested rigorously and allows to be used for 4 hours under normal load conditions. It would be useful to both physiotherapist at rehab centers and subjects who want to manage the exercise routines at their own. The device is easy to equip and easy to operate. The device can be a great use at hospitals, medical centers, rehabilitation centers and at home. It is easy to adjust for different body /leg sizes. It is. Thus, the device will provide improvement in the mobility range, muscle strength and will give a new hope to the subject increasing the subject's self-esteem and confidence.

5.2 Device Limitations

The device has limitations as such that over use may cause wear in motor-joint attachment. This wear shall directly affect the motion in form of a minor jerk at a start of device motion. Another aspect is that a separate motor-joint assembly is required for each leg. Though both can be mounted on the same base seat, the cost of device doubles as independent controllers are required in this design. This however can easily be managed if there is a demand form user to make a device controlled from a single controller.

5.3 Future Work

Future works on this device include incorporation active resistance by device to a force exerted by subject. This force feedback can then be used to monitor real time actual progress of subject muscles.

The user data though is displayed for many sessions in one go. But this data is not saved on device. Therefore, a subject profile management system can be incorporated into the device that allows users to record and later monitor their data. As described in device limitations above, the system can be upgraded so that one controller controls motion for both legs.

Finally, the steel base structure was made from very heavy and strong steel. This was to ensure that device doesn't give away in any sorts of unexpected loads. This steel structure can alternatively be made from lighter materials with reinforcements only in critical areas according to stress analysis results. This shall help reduce the overall weight from 7 kg to 4 kg that shall help make the device more portable.

5.4 Chapter Summary

The chapter encloses the merits and usage of the device in the society. It discusses specifications and functions it can perform in present as well as in the future. It can be a genuine and constructive option for the subjects as well as for the physiotherapists.

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