A study to design a novel device for improving knee range of motion and reducing hamstring muscle tightness

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Abstract
Background-Restoration of knee joint mobility and stretching of surrounding muscles are critical aspects in both post-operative and athletic conditions. The functional impairments could be due to joint stiffness or because of hamstring muscle tightness. The conventional rehabilitation protocols for limited mobility of the knee often include a range of motion (ROM) manual exercises by the therapist may result in time-consuming, reduced patient-control, and a documentation of treatment progress report may be challenging. Considering this proposed machine facilitates controlled, small incremental movement and integrates ROM and hamstring muscle stretching at once. Methods-The proposed novel design has features for individual care and records progress data of activity performed on the equipment, including the maximum achieved angle of knee movement. The current design will prioritize the precise 0.3º step incremental movement with combined action required for improving joint stiffness and reducing hamstring muscle tightness with the use of a linear actuator, thus preventing microtrauma from occurring to patients. Result-This novel device will offer a precise, controlled, patient-centered approach in addressing two important clinical problems in a single setting without causing extra cost for the treatment. Discussion-The study is on precise design and automated feedback system facilitate effective home-based physiotherapy and rehabilitation applications.

1. Introduction

Biological systems in humans (such as the musculoskeletal system) are in a continuous state of dynamic equilibrium. Because of this constant dynamic equilibrium, homeostasis of the systems is achieved.[1] Musculoskeletal conditions include various joint, bone, muscle, ligament, tendon, and related disorders. Globally, it has been noticed that the prevalence of musculoskeletal dysfunctions is continuously rising. In previous research done by Dr. Manasi Murthy Mittinty et al. in 2020, generally, 0.494 billion (95% confidence interval 431–564) people are suffering from musculoskeletal conditions, and this is increasing compared to the prevalence of 221 million (192–253) in the year 1990.[1] As per the World

Health Organization, conditions related to the muscles and bones are characterized by pain and restriction in joint movement, which affects the individual's ability to carry out their daily activities and causes them to suffer from restricted participation.[2] Different healthcare professionals are associated with the planning of care for treating such musculoskeletal conditions. These professionals are orthopaedic surgeons, general medicine practitioners, rehabilitation physicians (e.g., physiatrists), and physiotherapists.[3]

Physiotherapy is recognized as an effective way of assessing and managing various musculoskeletal disorders. Clinical trial results reveal physiotherapy's effectiveness in improving mobility and relieving pain in musculoskeletal conditions such as osteoarthritis, rheumatoid arthritis, and fibromyalgia.[4] The exercises given in musculoskeletal conditions, which mainly include stretching and strengthening exercises, are likely to show effects on improvements through muscle sensory-motor function, joint stability, and biomechanics.[5,6]

Zeng C.Y. et al. also noted that, for general fitness purposes, physiotherapy can be included in a functioning program that benefits psychosocial variables such as confidence, self-esteem, and depression.[5,6] Physical therapy focuses on the movement needs and potential of individuals; it also provides treatment and rehabilitation for developing, maintaining, and restoring the maximum movement and functional ability over the course of a lifespan.[7]

Musculoskeletal conditions can be classified based on the region affected like neck pain, back pain, ankle pain, etc.; based on presence or absence of inflammatory signs for example rheumatoid arthritis, osteoarthritis, osteoporosis, etc.; or based on systemic affection, like Systemic Lupus Erythematosus (SLE), connective tissue diseases, etc. or traumatic conditions like fracture, sprain, strain, etc. can occur.[8]

Conditions like osteoarthritis, rheumatoid arthritis, and gout can lead to the development of restriction in mobility. Physiotherapy is a useful tool for the prevention of such conditions and also for managing them.[4] Osteoarthritis (OA) is a condition that involves the entire joint, but it primarily affects the cartilage, causing it to degenerate. The joints that are commonly affected by OA are the facet joints of the spine, interphalangeal joints (IP), carpometacarpal joint (CMC), 1st metatarsophalangeal joint (MTP), knee, hip, and patellofemoral joint.[9] Humphreys et al. have suggested that as age progresses, repeated stress on the joint leads to biomechanical loading that damages the synovial membrane and causes inflammation and cytokine release. This eventually leads to degeneration of the cartilage, and ultimately, bone loss occurs.[8]

The knee is one of the most commonly affected joints, which is weight-bearing in nature. Osteoarthritis of the knee (OA knee/knee OA) causes pain and stiffness and gradually alters the alignment of the joint, leading to genu valgus or varus and fixed flexion deformity of the knee.[10] Limitations in joint range of motion can lead to osteophyte formation, contractures surrounding the joint, muscle spasm, and muscular imbalance. Many patients complain of nighttime pain and difficulty in walking, and the presence of crepitus in the knee joint is usually associated with pain.[5]

The treatment options available for osteoarthritis are conservative management, which includes medicines and physiotherapy, and surgical management, which includes joint replacement surgeries. Following joint replacement surgeries to regain mobility, physiotherapy is advised for the patients.[11]

Also, for traumatic conditions for lower-limb musculoskeletal conditions, treatment options available are conservative in the form of immobilization in a splint or plaster of Paris cast, or operative management in the form of internal fixation or external fixation. In both conditions, post-traumatic stiffness is commonly observed.[11,12]

Injuries around the knee are one of the common physical problems that not only affect the activity of daily living but also adversely affect the mental health of these patients.[13] Reduction in the knee joint range of motion (ROM) can cause adverse effects on the function of the entire lower extremity.[14] Reduced ROM and hamstring tightness are prevalent issues among individuals with various musculoskeletal conditions, such as knee osteoarthritis, ligamentous injuries, and patellofemoral pain syndrome.[15,16]

In any sport, serious knee ligament injury can commonly occur, and these injuries can lead to alterations in the normal biomechanics. According to where the injury hits, the knee ligament injury can be divided into anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), tibial collateral ligament, and fibular collateral ligament (FCL) injuries. There is an ample amount of research that points out that the secondary injuries, like damage to the cartilage, meniscus, and knee OA, may result from the ligament injuries that are not treated in time. Ligament repair and reconstruction surgeries are crucial procedures for these injuries. After the surgeries for ligament reconstruction, the biomechanics of the knee can be improved, but the reduction in the range of motion is usually identified in most cases following the ACL reconstruction.[13] The aim behind the ACL reconstruction is to regain the stability of the knee and to prevent the early onset of post-traumatic osteoarthritis changes, which can be caused by instability of the joint.[17] Restricted flexion of the hips and restricted flexion of the knees were strong risk factors for locomotor disability (disability in activities primarily involving the lower extremities, such as walking, climbing stairs, and rising from and sitting down in a chair).[18]

The hamstring group of muscles is an agonist for flexion of the knee, although they also help in extending the hip joint. When an individual ambulates, hamstring muscles stabilize the knee at the heel strike phase by contracting isometrically along with the vastii muscles, and in the last phase of the swing, deceleration of the tibia occurs by hamstring eccentric contraction. Another common cause of restriction in the knee range of motion is hamstring tightness. Also, when the hip flexion occurs with the knee in an extended position, it can lead to a significant reduction in ankle dorsiflexion range of motion.[19]

Also, when the hip flexion and ankle dorsiflexion occur simultaneously, there is a reduction in the ROM of the knee joint.[19] In the lower limb, motion can be altered or controlled by the muscular effort and by non-muscular structures like fascia and inert tissues that produce forces working on distal joint mechanics. When the hamstring group of muscles is not able to deform, it can lead to a reduction in hip flexion ROM, alteration in hip extension motion, and posterior tilting of the pelvis, further causing decreased lumbar lordosis and back pain.[20]

Hamstring tightness also leads to increased quadriceps activity, which could lead to tendinopathies.[21]Tightness of the hamstring muscle is one of the factors affecting the dynamic balance because it loses the ability to deform while being stretched. When the tightness in the hamstring muscles increases, it can lead to prolonged forefoot loading, which can be understood by the windlass mechanism. This loading can lead to repetitive damage of the plantar fascia, causing plantar fasciitis.[22]

Yakkanti, R. R., et al. conducted a study on how early mobilization can affect the length of hospital stay after primary total knee arthroplasty and concluded that if early mobilization is provided, the length of stay can be significantly reduced. And the differences in discharge disposition between patients who mobilized on postoperative day 0 compared with postoperative day 1, with more patients mobilized on postoperative day 0 being discharged home.[23]

Wirries, N et al. conducted a study on the impact of continuous passive motion on rehabilitation following total knee arthroplasty and concluded that the addition of continuous passive movement did significantly improve knee flexion in the early postoperative stage.[24]

A meta-analysis conducted by Brosseau et al. from the literature available till 2003 included a comparative study between a continuous passive movement device and conventional techniques for a patient who had a procedure of total knee arthroplasty surgery due to degeneration of the joint. As per this study, the inclusion criteria were that two groups should be divided so that one group received treatment from a continuous passive movement device along with conventional physiotherapy. While the other group received only conventional physiotherapy. In accordance with this, 14 studies were included with a total of 952 patients. The author has concluded that, on the basis of this study, the continuous passive movement device provides promising results by reducing the hospital stay by 1 day, and postoperative complications were also limited (0.12 at 95% CI, based on three trials) as compared to the conventional group.[25]

Another prospective study conducted by Bennett et. al. including 147 subjects who underwent surgery were placed in the three treatment groups, and concluded that subjects receiving the treatment with a continuous passive movement device from 0 to 40° have increased range of motion by 10° per day, and another group receiving continuous passive movement device from 50 to 90°, which led to full extension within 3 days.[26]

The devices that are currently available have gone through many modifications. Brisson et al. conducted a study on a new multifunctional device for guided knee motion that can create loading during dynamic magnetic resonance imaging—it was designed using a motorized pneumatic system, and a muscle-driven active method was used to keep the knee in a particular ROM while taking dynamic MRI scans. However, this device achieves ROM only up to 40° of knee flexion.[27] Another device called the JAS EZ Knee Flexion offers a range of motion to the limited knee ROM from 50° to 148° of knee flexion only. The drawback is that it does not provide complete knee extension and can be used by a single person only, like a customized orthosis.[28]

Previous research was conducted by Issa et al. for building a continuous passive movement device that can function using a mobile application and a microcontroller. This design can connect the Arduino board to a phone with the help of a Bluetooth device; for this, the C++ language was used. However, in this device, the problem of hamstring tightness was not addressed; hence, it can be used for improving knee mobility due to joint stiffness only.[29]

Also, the devices called the 480E Knee CPM Device and the OptiFlex3 CPM Device have the same drawbacks as above. Traditional CPM is a widely used device in multi-specialty hospitals and government organizations, as well as private clinics. The drawbacks of this instrument are that this device does not achieve complete Knee ROM

The current therapeutic interventions for improving knee mobility, including physical therapy, manual stretching, and surgical options (like mobilization under general anesthesia to break adhesions), often have limitations. Physical therapy requires consistent attendance and active participation, which may not be feasible for all patients. Manual stretching techniques rely heavily on the therapist's expertise and can be inconsistent. Surgical options, while effective in some cases, are invasive and costly and come with significant recovery times and risks of complications like joint swelling and pain following the procedure.[30]

JE Cromie et al. have identified that the prevalence of musculoskeletal disorders because of work (WMSDs) was 91%, and out of 6 physiotherapists, 1 has moved within or left the profession as a result of work-related musculoskeletal stress. It has been reported that a higher prevalence of profession-related musculoskeletal disorders is found in younger professionals in most body areas.[31]

The same findings with an increased prevalence of 92% were identified by Zaheen Iqbal et al.[32] Hence, to reduce the stress of physiotherapists, a device to assist the therapist may be developed. The area of the limited mobility of the knee lacks a validated novel device that gives a complete range of motion to the patient, leading to a significant research gap. This gap hinders the improvement of early mobility and self-treatment or home utility of a patient undergoing knee surgery. Research is needed to develop a novel device that can provide complete knee mobility and improve patient outcomes. Research supports that when early mobilization is done following immobilization or surgery, it will provide early recovery to the patient; also, the patient can achieve early functional independence.[23] Restriction in knee mobility may be due to muscular tightness. According to the current research available, stretching is an effective way to deal with tightness. So, a novel device that can satisfy both requirements can be developed to assist the patient for self-treatment or home utility.

2. Methodology

2.1 Research Methodology

First prototype of the novel device will be developed, then its reliability and validity will be established. To establish the reliability and validity of the device, first, a pilot study will be conducted after developing a prototype. For conducting a pilot study, ethical permission from the institute will be sought. After getting ethical approval, the selection of the subject will be done based on the selection criteria. The criteria for selection are as follows:

2.1.1 For knee mobility restriction[33]

Inclusion criteria include subjects who are 30-50 years of age, implanted with a primary total knee arthroplasty (TKA), or after surgical ACL reconstruction. Exclusion criteria will be neurologic/myopathic diseases, previous surgery, and secondary osteoarthritis.[34]

2.1.2 For Hamstring Flexibility [35]

Inclusion criteria include subjects having an age of 18–35 and 20°–50°, athletes active knee extension loss with the hip in 90° flexion (90-90 Straight Leg Raising Test). Exclusion criteria will be neurologic/myopathic diseases, previous surgery, and secondary osteoarthritis.[34]

2.2 Materials and Methods for a Pilot Study

Study Design: An Exploratory Study
Study Area: Rajkot
Study Population: Both males and females
Sample size: 12 in each group [36]
Sampling: Purposive
Purposive: Sampling for the selection of subjects

In this pilot study, the effectiveness of the novel device will be compared with a control group. Initially, a pilot study consisting of 12 subjects in the experimental and control groups will be conducted. The control group will be given conventional treatment. Outcome measures will be knee ROM using a universal goniometer for identifying knee mobility and the SLR 90-90 special test for hamstring tightness.[37] Conventional treatment in case of postoperative knee mobility can include free exercises like open kinetic chain and quadriceps setting exercises. Conventional treatment for hamstring tightness includes static stretching, 3 repetitions, and a 30-second hold.[35] After the data collection, statistical analysis will be done using SPSS.[38]

2.3 Design Features of the New Machine

In physiotherapy rehabilitation, there are several available devices related to the improvement of knee mobility, though they have certain limitations. A machine commercially used in multispecialty hospitals/clinics does not provide a complete range of motion, which is a prime requirement in several cases. Further, during the exercise, in case of emergency or when the limit for the pain tolerance is reached. Such an emergency stop at a particular position is essential to have an onboard stop provision, which is lacking in the current instrument. Simultaneously, mobility exercises require a long period, and the progress of angle movement from the previous session is more useful; based on that, the next day's angle movement progress target can be set. The current instrument does not facilitate this type of data saving on angular movement. Further design of the device must incorporate the full range of knee movement, and the prime feature of hamstring stretching is equally important.

2.4 Treatments Addressed by the New Machine

This device will provide passive movement for improving knee flexion following any knee surgeries; besides that, this device will provide passive stretching to the hamstring group of muscles and improve its flexibility.

2.5 Technical Specifications

The current design of the novel device features individual care progress, and thus it records the data of activity performed on the equipment, including the last highest angle of knee movement. A linear actuator is used to feed the motion, and the device can have a 0.33º minimum step angular movement, thus preventing hazardous or sudden impact on the joints. Using the designed device, a complete range of motion of the knee joint, i.e., 0º to 140º, is possible, and additionally, 10º movement is given in case of requirement. The device's second most important feature is the possibility of hamstring stretching on the same machine, and it has a range from 90º to 0º of knee extension. This facilitates having both exercises on the same machine without any delay or change of position or machine. A display with an input system is there to feed the patient data and record it for successive exercise and future analysis.

As mentioned in the introductory part of the article, this device will help the patient undergoing surgery for the knee joint or having hamstring muscle tightness. This will be achieved by performing passive movement of the joint gradually through the complete range of movement as tolerated by the patient without any discomfort.

Therefore, current study focuses on the conceptual design of a novel device to address the limitations of the available device.

2.6 Prototype Design

Initially, the first design aspects were concentrated on the full range of movement of the knee, and later, a literature review and strong requirements motivated the inclusion of hamstring stretching facilities in the device. As shown in Figure S1, the device designed with a linear actuator having a repeatability of 0.01 mm and an accuracy of 0.2 mm represents the precise motion of the leg. With a repeatability of 0.3º, this device has the possibility of 0.3º precise angular movement and does not provide any jerk during the movement. A single linear actuator will be used for the full movement of the knee and the hamstring stretching range. There are two support beds provided; the longer is for the support of the leg part (below the knee), and the shorter is for the thigh part (above the knee). These two beds move around a pin joint, and on that pin joint, a rotary encoder is mounted to have angular positioning of both parts. A knob is provided in the device to restrict both movements simultaneously. For knee range of motion, the horizontal mode will be used, and an actuator aligned with the tibial axis will provide controlled passive knee flexion and extension. While for hamstring vertical mode activates and actuators lift the limb vertically for progressive hamstring stretching. The proposed design considers the ergonomics; the design is lightweight and compact for clinical or home use, and even provides continuous feedback to consulting physiotherapists using controller data transfer capabilities. In the proposed design, adjustable settings are considered to accommodate patient-specific needs.

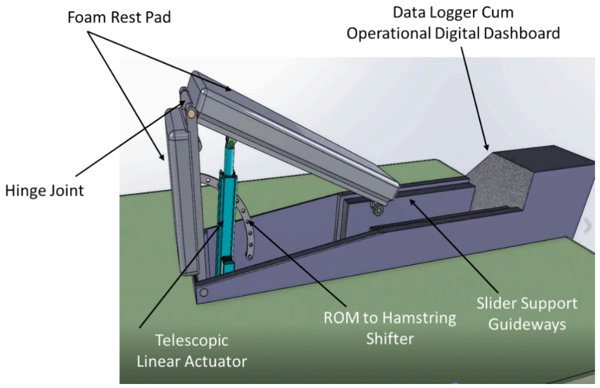

Figure S1 - Proposed Design Isometric View of Combined Exercising

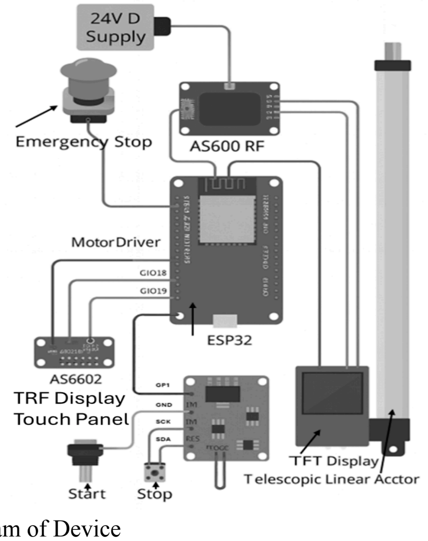

Figure S2 - Circuit Diagram of Device

An open-source microcontroller will be used to fetch the data of angular movement on the screen and the database. The ESP32 microcontroller consumes low power for long-term data logging and has good feasibility to integrate sensors. ESP32 CPU is a dual-core Tensilica LX6 (up to 240 MHz), and ROM/Flash Up to 4MB external SPI Flash makes them suitable for time-sensitive and control-based research. ESP32 is an open-source programmable platform that encourages modifiable development and has always scope for changes in the circuit and outputs. It will contain the 34 General Purpose Input and Output (GPIO) pins, which make it more flexible, and a number of sensors can be utilized as input. Detailed circuit design is presented in Figure S2 with a wiring diagram and positioning of all the components. The core components also include the emergency stop switch, and internal programming of the microcontroller includes the load limiters and angle restrictions.

3 Results

Previous literature reports that a strong clinical and functional requirement exists for combining knee range of motion (ROM) improvement and hamstring muscle stretching in rehabilitation and training programs or equipment, especially following surgery, injury, or in high-performance athletics. Thus, there is a strong need for combined exercising in rehabilitation after knee injury or surgery, functional movement and performance, muscle development and adaptation, and rapid and complete rehabilitation. The novel design fulfills the purpose and provides both the exercise requirement in the same device and reduces the overall recovery time.

The device will also use a single linear actuator and thus reduces the power consumption and provides the 0.3° angular movement, and there is no microtrauma or the stress on bones. The proposed device will further help to reduce the overall physical stress on the physiotherapist and increase the effectiveness of the treatment. Furthermore, the data logging and retrieving facilities may help to predict the cure time and further research.

The development of this novel device may be beneficial in improving the mobility of the knee joint, and there can also be a shorter hospital stay following the operation. With some modification in the device, this can be useful for improving ankle mobility and stretching the calf muscle as well. There is future scope for the development of a physical device and clinical trial for the effectiveness, biomechanical analysis, and clinical validation.

4 Discussion

At the time of the design stage, flexibility and ease of structurization have been kept in mind; thus, the manufacturing process will become easy. As physiotherapy aspects and future requirements have been considered, data-capturing options are open. Further in the design steps, the tissue damage's slow incremental movement is considered, and as a result, the design developed equipment as per the physiotherapist's requirement.

This novel device will be helpful in improving knee ROM and the flexibility of the hamstring group of muscles. Hence, this instrument can be useful for a patient who have undergone any operative management following severe knee osteoarthritis, ligament injuries, sports injuries, or a traumatic event leading to fracture. Also, this can be useful for improving hamstring flexibility in an individual having tightness due to prolonged sitting, lower crossed syndrome, mechanical muscular imbalance, etc.

4.1 Impact on Recovery Time

The coexistence of the knee ROM and hamstring muscle tightness has possibilities, though independent occurrence may present. Hamstring tightness is a significant factor that can limit the knee joint's ROM, possibly leading to decreased ROM and increased susceptibility to injuries. On the other side, knee stiffness, often seen post-surgery, like total knee arthroplasty, can also affect ROM. Coexistence and exercise solutions in a single piece of equipment will reduce the patient's overall time to recover, and on the other hand, data on recovery can be maintained on the same equipment with the current innovation.

4.2 Timesaving for Patients and Physiotherapists

The conventional machine does not provide stretching for the hamstring muscle; hence, to date, therapists have been giving manual stretching, or self-stretching is done by the patient themselves. A novel device will provide passive stretching to the patient, saving both time and energy of the therapist. Besides, this will be patient-controlled; hence, the patient can stop immediately if they feel any discomfort.

4.3 Benefits of Automation

Conventional devices do give inputs on ROM, but they do not provide real-time feedback to the patient; also, they are not under patient control. Hence, this novel device will address this problem by providing real-time feedback, having good patient control, and having an emergency switch to stop the device.

5 Implications of physiotherapy practice

The creation of a proposed novel device has important ramifications for the practice of physical therapy. By making automated, controlled, and regular passive stretching, it improves treatment effectiveness by lowering therapist fatigue and raising output. By offering accurate, repeatable movements, the device standardizes stretching protocols and guarantees consistent treatment delivery. While integrated sensors enable objective monitoring and progress documentation, their patient-controlled design encourages safety and compliance. The automated, small design facilitates home-based rehabilitation and encourages post-discharge continuity of care. It can also be used for prevention and education, assisting physiotherapists in treating tight hamstrings, increasing range of motion, and implementing patient-centered, evidence-based rehabilitation in clinical and research settings.

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