Project Proposal

Assisted Leg Holding Device For Medical Procedures

By:
Jennifer Bruno
Katherine Etter
Gehendra Kunwar

Team 1
Funded by:
Rehabilitation Education Research Center
Client Contact Information:
Dr. John D. Enderle
University of Connecticut: Biomedical Engineering Department
Program Director & Professor for Biomedical Engineering Bronwell Building,
Room 217C 260 Glenbrook Road Storrs, Connecticut 06269-2247
Voice: (860) 486-5521; FAX: (860) 486-2500
Email: jenderle@bme.uconn.edu
Executive Summary

The following proposal details the assisted leg holding device for medical procedures, which will be built for the Rehabilitation Engineering Research Centers (RERC) student design competition. This device will aid people who experience weakened muscles, are paralyzed, amputated, or fall outsize of the normal ranges in height and weight. Currently used devices offer limited adjustability and additional cushioning methods that would account for clients with these requirements. The proposal introduces the patients from RERC that this device would apply to and some basic information about their disabilities. It also explains the purpose of the project, and compares it to patents on similar products, and current devices on the market. The objects for the device are presented followed by the methods of construction. Figures have been created to aid in understanding the proposal and a flow chart of objective dates. A budget with estimated cost and comparative to current products is followed by the conclusion.

Overall, the proposal will provide readers with a full and detailed description of the procedure for completing this project while providing reasoning on the positive effect on the associated medical procedures.
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1. Introduction

1.1 Background

In the United States, about 51.2 million people are disabled where one-third; about 15 million people, are of age 65 or older. Arthritis and other rheumatic conditions are a leading cause of disability in the United States. Also, about 13.4 million Americans have serious physical disabilities such as back problems, arthritis and orthopedic injuries. Patients with the physical disabilities as stated above in combination to paralysis, amputation, muscle atrophy, or obesity often have problems with traditional leg-holding devices. These problems stem from the lack of adjustability of such devices. The use of an assisted leg holding device is required for many medical procedures; such as knee surgery and physical check-ups. Such devices currently cannot be adjusted to accommodate patients outside of the “normal” range. In these devices, it is difficult for a medical practitioner to position patients who have muscle weakness or disability, Parkinson’s disease, arthritis, spinal injuries, or those overweight. Therefore, a modification to existing technology is desired by the medical society that opposes gravity, in order to simplify the positioning process. Finally, current models lack padding and coating to increase comfort for people in the populations mentioned above.

Several specific patient populations are targeted in the RERC competition. All of the clients that must be accommodated using the assisted leg-holding device have some form of disability. The most difficult clients to consider are the two with amputated legs. Many traditional leg holding devices rely on supporting only the foot of the patient. The proposed device must allow for support in other areas of the leg as well as the foot so that these patient’s limbs can be positioned. One client has a spinal cord injury, causing difficulties for the practitioner who has to position the patient’s legs without any help from the patient. Several of the clients have joint pain, which may be exacerbated if they are placed in leg holding devices. The device detailed below will have controlled range of motion and ample padding in order to secure the most comfortable position for the patient, and will adjust from a comfortable sitting position so that it is not difficult to get these patients into the device. The patient with Parkinson’s has tremors as well as weak joints, so straps will be included in the design to prevent him from moving too much during a procedure. Finally, the device will be adjustable so that even the patient with very short stature can use it comfortably.

1.2 Purpose

It is important for the patient to have a positive experience to increase likelihood of completing a screening test. Where traditional devices are used, patients often experience anxiety in addition to physical pain caused by the supports. Part of this anxiety could be alleviated by creating a device that is comfortable to sit in, and does not require difficult or awkward

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positioning by the patient. The proposed clients require an anti-gravity device that will allow positioning of the legs either by the patient themselves or the practitioner. The device should be comfortable, versatile enough to be used by a wide variety of patients, and should adhere to medical standards.

Patients with physical disabilities such as paralysis, amputation, arthritis, muscle atrophy, or obesity often have problems with traditional leg-holding devices. These problems stem from the lack of adjustability of such devices. The main purpose of this project, therefore, is to produce an alternative leg-holding device that is low in cost and easily adjustable, as well as reduces strain on the patient and practitioner. The proposed device should be compact and easy to relocate so as not to hinder other examinations. It must meet medical sterilization requirements, and must be easy to clean in between examinations. In order to improve a patient’s experience with this type of procedure, the device should not be imposing or intimidating, and should look and feel as comfortable as possible. Finally, the device should be durable and reliable so that it can withstand many examinations.

1.3 Previous work done by others

Drs. Tariq Rahman, Rungun Ramanathan, Rahamim Seliktar, William Harwin have conducted research on simple techniques for anti-gravity articulated mechanism. According to the article, kinematics and linear springs were used to produce a non-linear restoring force to oppose the gravitational moment. The researchers examined two of their experimental techniques. One of the techniques was done using passive balance system where one could add a counterweight so that the mass center was coincident with the pivot point and the other was done using stored energy in springs to counter the effects of gravity. In conclusion, they found that the easiest method for anti gravity mechanism was to use spring system because no undue energy was added to the device which provided a non linear spring system.

The second research paper was also done by Dr. Tariq Rahman and his groups where they researched on the development and preliminary testing of a functional upper limb orthosis for people with physical disabilities. In this article, they used linear elastic techniques to counter effect the gravity and four degrees of freedom at two links for better movement and stability. According to their report, they developed a prototype that would assist disabled people for their daily routines such as eating, reading and doing simple house activities unassisted. Hence, although the research was done for the hand orthosis, similar mechanism would be taken in consideration to our design.

1.3.1 Products Research

Current designs for leg holders for medical procedures vary only slightly in positioning techniques. Most competitors offer an anti-gravity system that can be adjusted by the physician, however, current models offer limited supports built into the system for the comfort of the patient. Additionally, many systems are designed to only meet a limited range of operations and are not flexible enough to accommodate the variety of medical needs to leg holders.
Allen Yellofin™ Lithotomy Stirrups- this innovated design allows for intra-operative re-positing of patients and is ideal for laparoscopy. Additionally, the Yellofin™ uses a Biotrac Joing Technology™ that mimics natural motion of the hip. Ergonomic boot design helps eliminate pressure under the fossa where the peroneous nerve is superficial. The slip boot clamp prevents excessive pressure on the calf. The system accommodates patients up to 350lbs and is available in a 500lb. version.

PAL Pro Power Assisted Lithotomy Stirrups- Power assisted for controllable level of lithomo and abduction, these stirrups come with a self adjusting floating boat to minimize pressure on the calf. The Feather Lift™ hand lets you control the stirrups through the lithitomy safe zone. The power-assist mechanism is protected by a rigid, durable cover. Abduction adjustments are made quickly from the end of the boot.
Candy Cane Stirrups by AliMed- A viscoelastic gel with the same density of adipose tissue is used to support the malleolus and lateral portion of the knee with this simple and convenient device.

Allen R Deluxe Arthroscopic Legholder System for Knee Surgery- The hinged upper brace accommodates all patients seizes with this uni-directional locking mechanism that ensures a rigid fixation. The structurally enhanced design enables staff to apply pressure both medially and laterally. The straps allow for easy adjustment for the precise amount of compression.
1.3.2 Patent Search Results

Before undertaking the design of any new invention, it is important to understand any devices that have already been created and patented, so as not to infringe upon these designs. Patents can be very helpful when trying to invent a new device such as the assisted leg holders, as most patent authors admit that those with knowledge of their designs should be able to come up with adjustments and improvements. Many of the patents that were found incorporated some component of what should be accomplished with the proposed device, and these can be combined and then modified in order to create an optimum design.

One of the earliest patents found pertaining to leg holding devices was patent number 2714541, approved in August, 1955. This patent describes a design for the improvement of stirrups used in operating procedures. These are the simplest type of leg holding devices, which only support the patient’s foot. The benefit of this design is that it is extremely compact and can be easily stored to maximize space within the operating room.

Patent 3833211, approved in September of 1974, describes a clamping device that can be used for attaching the leg holding device to an operating table. This is an important consideration, as a sturdy connection must be made in order to prevent movement or slipping during a procedure.

In September, 1976, patent number 3982742 was approved. This patent is similar to 2714541 in that only the foot of the patient is supported. However, it suggests that a curvilinear rod should be used that extends from the edge of the operating table. This support system is supposed to enhance safety and comfort of the patient, as well as isolate the patient from any electrical shocks that might occur by making the device non-conductive.

Patent 4809687, which was approved in September 1989, is one of the first to suggest the use of a complete, cushioned shell that supports a patient’s foot, as well as a support for the patient’s upper leg. This is an important development, as it accommodates for patients with joint or muscle disease, similar to those who will be served by this most recent proposed invention.

The assisted leg holding device was again improved in 1990 with patent 4958816. This proposal introduces a compact mechanism for adjusting the leg holding device both laterally and longitudinally. In this way, patients who are not within the normal leg size range can be...
accommodated for, again something that is being considered in the design of this most recent proposed invention.

Patent 5369827 was a unique contribution to the field because it suggests a leg holding device that can be adjusted in three dimensions. This patent, approved in December 1994, also includes a stopping mechanism, so that a patient’s leg will not be over extended to an uncomfortable position.

In September 1998, patent 5802641 became one of the first to suggest a leg holding device that can be adjusted to support a patient against gravity. This design uses a motorized system to oppose gravity and raise a patient’s legs.

Finally, approved in July 1999, patent 5918830 proposes an alternative gravity opposing, leg holding device. Instead of using a motor, this design incorporates a ratchet system for adjusting a patient’s legs for a procedure.

2. Project Description:

2.1 Objective

Proposed is a low-cost, reliable and user-friendly leg orthosis that is more comfortable than the existing models and will improve the patient’s experience during medical procedures. It should also assist the medical practitioner in positioning a patient’s legs, and then use lock-unlock mechanism to prevent movement or slipping during medical procedures, and also prevent hyper-extension of the patients’ limbs. This device should be adjustable over the average range of heights and weights for both men and women. We intend to use the principles of dynamics to design a device that opposes gravity, allowing for easy positioning of a patient’s legs for medical procedures. By incorporating adjustable springs, pulleys, hydraulics, or a motor, we should be able to accommodate for a wide range of heights and weights. We plan to design the device so it could accommodate people in between 4’10” to 6’ 5” and up to 500 lbs. We also intend to use medical soft-padding in order to make this device comfortable, especially for patients with serious physical disabilities. Overall, the device should have good fatigue strength and be able to reduce stress to both the practitioner and patient during the procedure. Thus, the device must be light-weight and compact, to allow easy movement by the practitioner and storage when it is not being used, and it should be easy to sterilize. Hence, the overall objective of this project is to build a leg holding device with anti-gravity and lock-unlock mechanism in order to assist the disabled community for medical purposes.

The main goal of the proposed device is to oppose gravity and lift a patient’s leg as he moves from a sitting to a supine position, so that a medical procedure can be performed. Allowing the patient to start in a sitting position is useful for those patients who cannot position themselves independently and require the help of the practitioner. Without assistance, this can cause difficulties for the practitioner, but these difficulties can be alleviated by the anti-gravity capabilities of the proposed device. The foundation of the device will be a solid metal bar, which will be attached to the operating table near the hip joint. Supports for the knee and foot will also be attached to the bar. These supports help to achieve another goal of the device: to make the
patient as comfortable as possible during what can be a lengthy medical procedure. Patients who are disabled and who have severe muscle weakness are very susceptible to this type of discomfort, as many of the current devices on the market lack sufficient support, and leg holding devices that lack a knee support isolate those patients who are amputees and cannot make use of the traditional foot support. To maximize comfort, each support will be well padded. The padding, as well as a sliding and locking capability for each support, also allows the device to be adjustable so that it can be customized to fit patients of nearly any size, a third objective to this project.

When completed, this device will be able to accommodate a large range of patients both with and without disabilities. In the methods section below, the features that will allow this device to work and achieve the project’s goals are described in further detail. Overall, this device is designed to be efficient and cost effective in order to be competitive in the field of medical technology.

2.2 Methods

There are many things to take into consideration before attempting the design of the assisted leg holders. Figure 2.1 diagrams the basic problem that must be solved:

![Diagram of leg holding device](image)

**Figure 2.1** The problem that must be solved in order to design an assisted leg holding device.
The most difficult hurdle is the following question: how should the device propel a patient’s legs from a comfortable position on the floor, where the patient or practitioner can easily secure feet and legs into it, to the placement and angle needed for a medical procedure?

Figure 2.2, below, proposes a solution to the problem described above.

Figure 2.2 Schematic for the proposed device, with parts labeled.

The device has several key features that will allow it to succeed for its purposes. First consider part A, a propelling device located near the patient’s hip joint, which will lift the patient’s leg to the proper height. This could be a spring, a hydraulic, or a motor. Each of these possibilities is feasible, and must be considered before building the final prototype. A spring would be simple and inexpensive, but would have to be adjusted depending on the patient’s weight. A hydraulic, which could be adjusted, may be slightly more expensive, and would give more difficulty in 3-D adjustment. Both the spring and the hydraulic will provide assistance, but may not position the leg precisely and may require some additional rearranging depending on the patient and procedure. A motor would be the most expensive option, and would also be the most difficult to install. However, this would be the most easily adjustable option, positioning the patient’s leg exactly where it is needed for surgery.

Regardless of the part chosen, A must also have a locking mechanism so that once the proper height and angle are reached, this position can be kept constant throughout the procedure. Ideally, the assisted leg holding device must be able to move in three directions: adduction/abduction, internal/external rotation, and flexion/extension, thus giving it a three dimensional range of motion (see figure 2.3 below).
Figure 2.3 The assisted leg holding device should be capable of abduction/adduction, internal/external rotation, and flexion/extension.

In this way, the assisted leg holding device can be used for a wide variety of surgeries. Ideally, there should be marks for particular angles, and the device should lock into position at these places.

Part D shows the bar that will be the foundation of the device. This type of design was chosen after much consideration of the different methods currently used and available. Part D will be used as an attachment for the other parts of the device, and will support the device. Making D a rigid bar will allow for fewer joints, which means that less of the device will be subjected to torques and stress concentrations. Therefore, as long as cautions are taken to strengthen joint A, the device to be more durable and sustainable, so that it can be used many times without failure.

It is very important to consider the materials selection for part D. Because it is the foundation of the device, it must be strong and sturdy to support other parts as well as the patient’s leg. It cannot bend or warp, even after being used for extensive periods of time. Metal, which is very strong and not prone to deformation, will therefore likely be the best choice. The metals that are most commonly used for medical equipment are stainless steel, titanium, and aluminum, because these are relatively cheap and easy to sterilize. Stainless steel is the strongest of these three metals, but it is also the heaviest and may be impractical for the leg holding device. Aluminum, on the other hand, is very light but may not be strong enough to support the device without warping with time. Titanium, which is much lighter than stainless steel but nearly as strong, may be the optimal choice, however, the prices of each type of metal must also be considered so as to make the device competitive on the market.

A handle, part F, will be attached to the end of part D. This handle will make it easy for the practitioner to move and adjust the leg holding device to the proper position. By pushing, pulling, or twisting the handle, the practitioner will be able to unlock the leg holding device from its original position, adjust it as necessary, and control the locking mechanism described for part A above.

Part E on figure 2.2 shows a boot that will be used as the foot support for the proposed device. In this way, the proposed device is similar to others already on the market, as this is a common type of foot support for leg holding devices. For this device, the boot should be hinged in order to mimic the motion of the ankle joint, which will increase the comfort of the patient during adjustment. Foam padding should also be incorporated into the boot’s design. This serves the dual purpose of increasing comfort to the patient, as well as making the boot adjustable for patients with different foot sizes.

One feature of the proposed device that is different from many on the market is part B of figure 2.2, the knee support. Most devices only support the patient’s leg at the foot. However, since a main consideration of this device is to make it accessible to people with disabilities or muscle weakness, more support is necessary. The knee support will have adjustable straps in order to prevent patients from moving during a procedure. Like part E, part B will also be
encased in foam padding. This will prevent discomfort or injury to the patient that may occur from being in the device during a lengthy procedure.

Aside from the handicap accessibility, another important consideration in the design of this device is to make it adjustable, so that it can be used for a wide variety of patients. The patients who use this device will have different upper and lower leg lengths, and will all be of different weights. With a proper design, this device will be able to accommodate a large range of patients.

Because each patient has unique dimensions, the distance between part A and both parts B and E should be adjustable. This can be accomplished by having part D be telescoping. In this way, the knee support will always be centered under the knee, and the patient can plant his heel firmly against the heel of the boot. Also, because a patient must go from sitting to a supine position while using this device, parts B and E together should be able to translate along part D. Both of these features allow for customization of the device for each patient, which will maximize comfort as positioning takes place.

The translational movement will also allow the practitioner to adjust the angles of the knee and ankle based on the protocol for any particular procedure. Standard measurements should be marked on the device corresponding to angles that would be used for certain procedures, so that no further angle measurement is required. Once the proper position has been reached, the practitioner should be able to lock the parts into place so that no further movement will occur during the procedure.

Part C of figure 2.2 incorporates one more feature of adjustability that has been incorporated into the design of this device. As a patient is moved into the proper position in the leg holders, it is likely that the height of his knee will change, and this height will be different for every patient. Therefore, part C describes a mechanism for raising or lowering the knee support so that it will provide support for the knee and surrounding leg of any patient in any position. This can be done either manually by the practitioner, or using a motor or hydraulic. Figure 2.4 shows a free body diagram of the forces that must be opposed in order to lift the leg at the knee:

![Figure 2.4 Free body diagram of parts B, C, and D of the leg holding device. For this system, the only force that must be opposed in order to lift the knee is the weight of the leg.](image)
Although the only force that must be opposed in order to lift the knee is the weight of the patient’s leg, for a heavier patient this could cause difficulties if the practitioner had to do it manually. Therefore, a hydraulic or motor would be a more practical choice.

In order to have a full understanding of the mechanics involved with the assisted leg holding device, the forces and torques that are applied to the system must be considered. A free body diagram of the proposed device is shown in figure 2.5 below. All of the forces are generally in the y-direction.

![Figure 2.5](image)

**Figure 2.5** Free body diagram of the proposed device, showing the forces and torques applied to the system.

When considering the motion of the system, the following equation can be derived:

\[
\sum F = -W_{\text{leg}} - W_{\text{device}} + F_{\text{app}} \quad (1)
\]

Equation one shows that the applied force must be greater than the total weight of the leg and device in order for the device to propel the patient’s leg upwards. This upwards force can be applied by either the physician, which is what happens with traditional stirrups, or it can come from an outside source such as those proposed for part A above. Clearly, the heavier the device and the patient’s leg, the more difficult it becomes for the physician to lift and adjust the stirrups independently.

Each of the applied forces creates a torque about the origin of the system, shown as point O in figure 2.2. This torque is equal to the force multiplied by the distance of the force from the origin. Thus, an object that is further from the origin will create a larger torque using the same force. Based on this observation, it is beneficial to make part B as long as possible in order to create a large torque without applying as much force. This way, if the practitioner must adjust the stirrups slightly, he will have an easier time overcoming the torque exerted by the weights of the device and legs and rotating the device upwards to the correct position. Equation two shows the calculations that support this reasoning:

\[
\sum T = \sum \mathbf{r} \times \mathbf{F} = -W_{\text{leg}} * d_{\text{CM}} - W_{\text{dev}} * l/2 + F_{\text{app}} * l \quad (2)
\]

This equation shows that the torques created by the weights of the leg and device, assumed to be concentrated at the center of mass of the leg and half of the length of the device respectively, oppose the torque that would be created by a force applied at the end of the bar, and must be
overcome in order to move the device upwards. Without assistance, this could require either a very large force or a very large device, justifying the design of an assisted device.

Another important free body diagram to consider shows the forces and torques applied to the clamp that will attach the device to an operating table, figure 2.6.

![Free body diagram of the forces and moments that the clamp must resist in order to keep the device mounted to the table.](image)

Figure 2.6  Free body diagram of the forces and moments that the clamp must resist in order to keep the device mounted to the table.

Depending on the motion required of the device, there may be forces and torques applied in all three directions x, y, and z. The clamp must be able to oppose all of these forces and torques in order to keep the device still and not disrupt medical procedures. Thus, the free body diagram must be taken into consideration when designing this clamp.

A rough timeline for the essential steps in the development of the assisted leg holding device is shown in figure 2.7 below. It is important to have a schedule for the design process, in order to have everything accomplished on time.
3. Budget

The budget allotted for this project is $2000.00. This money has been allotted as part of the RERC student design competition. Below, in Table 1, is a projected estimate cost for the raw and prefabricated materials that the assisted leg holding device requires. The projected total cost, must remain within the limits of the budget, as there is no additional money available. It is essential to not exceed the limit early on so back-up resources will be available for unforeseen issues that may occur.

<table>
<thead>
<tr>
<th>Material</th>
<th>Cost Range (U.S. dollars)</th>
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<tbody>
<tr>
<td>Lift Options:</td>
<td></td>
</tr>
<tr>
<td>- Hydraulic</td>
<td>200.00-350.00</td>
</tr>
<tr>
<td>- Springs</td>
<td>40.00-60.00</td>
</tr>
<tr>
<td>- Crank</td>
<td>60.00-120.00</td>
</tr>
<tr>
<td>- Electric Motor</td>
<td>100.00-250.00</td>
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<tr>
<td>Metal</td>
<td></td>
</tr>
<tr>
<td>Surgical Stainless Steel</td>
<td>70.00-200.00</td>
</tr>
<tr>
<td>Titanium</td>
<td>150.00-250.00</td>
</tr>
<tr>
<td>Surgical Form</td>
<td>20.00-60.00</td>
</tr>
<tr>
<td>Rotation Device</td>
<td></td>
</tr>
<tr>
<td>Clamps</td>
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<tr>
<td>Boot (pair)</td>
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<tr>
<td>with rod</td>
<td>275.00</td>
</tr>
<tr>
<td>Knee support (pair)</td>
<td>380.00</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Screw/Nuts/Bolts etc</td>
<td>100.00-150.00</td>
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<td>Medical vinyl</td>
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</tr>
<tr>
<td>Paint/aesthetics</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1175.00-1960.00</td>
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</table>

Table 1.1 Estimated Budget for Assisted Leg Holding Device for Medical Procedures

An additional consideration that is based upon calculations of the actual costs at time of ordering is whether or not to order a medical table. The lower end of a medical table is available and quoted in the budget. The benefit of having an actual medical table is in testing the device and correlating the table attachment pieces for use with currently used medical tables. However, since a crude table could be created from hardware the advantages must outweigh the cost to justify additional expense.
Ideally, the cost of the prototype is roughly 35% of the price of available, similar units currently on the market. Table 1.2 compares the estimated prototype cost with the prices of available leg holding devices currently on the market. It should also be noted that not all units currently available will include all the options that are proposed for the prototype, and this should be considered when comparing costs.

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Cost (U.S. dollars)</th>
<th>35 % of Cost (U.S. Dollars)</th>
<th>Difference between prototype and 35% of cost (U.S. Dollars)</th>
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<tbody>
<tr>
<td>Candy Cane Stirrups by CinTech</td>
<td>450</td>
<td>157.50</td>
<td>-1017.50</td>
</tr>
<tr>
<td>Leg Positioners by CinTech</td>
<td>990</td>
<td>346.00</td>
<td>-829.00</td>
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<tr>
<td>Assisted leg lifting device</td>
<td>4395</td>
<td>1538.25</td>
<td>363.25</td>
</tr>
</tbody>
</table>

4. Conclusion

According to U.S Census, the estimated percentage of the seniors will increase by 147% in between 2000 and 2050, about 86.7 million additional seniors. Medical devices with better functions and flexibility for the seniors and the disabled would be on high demand by the clinical society. Current medical devices such as the assistive leg holders for medical procedures are highly desired for those seniors and disabled with arthritis and muscular/bone degenerative diseases. In consideration to this, a leg assisting device that would help the disabled and senior citizens is proposed.

This design would be a low-cost, compact, reliable, user-friendly and more comfortable than the existing models for better service of the patient. More importantly, it would also assist the medical practitioner in positioning a patient’s legs, and use lock-unlock mechanism to prevent any injuries or discomfort during medical procedures. This device would be adjustable over the average range of heights and weights for both men and women. We intend to use the principles of dynamics to design the leg assisting device that opposes gravity, allowing for better positioning of a patient’s legs for medical procedures. The device should be able to accommodate for a wide range of heights and weights using springs or pulleys mechanism. We also plan to design the device so it could accommodate people in range of 4’10” to 6’ 5” height and up to 500 lbs weight. Hence, the purpose of this project is to design leg assisted holder for medical purposes for those disabled with muscular or bone disease and for wide range of people.

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2 [http://seniorliving.about.com/od/lawpolitics/a/senior_pop_demo.htm](http://seniorliving.about.com/od/lawpolitics/a/senior_pop_demo.htm)