

Redesign of a continuous passive motion machine for total knee replacement therapy

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Abstract

Purpose – After knee replacement surgery, rehabilitation is needed to recover to normal levels of mobility. A continuous passive motion (CPM) machine is usually introduced at this stage to aid rehabilitation. However, the redundant structure and complex mechanism of the existing machine has resulted in irregular use. The purpose of this paper is to redesign the current machine.

Design/methodology/approach – The mechanical and electrical systems of the current machine were studied alongside interviews with stakeholders. Problems with the existing machine were identified. Related information was gathered in both the engineering and medical aspects. The redesign concept of the equipment was specified following engineering analyses to develop the final model. Finite element analysis was performed to ensure the appropriate size and dimension of the equipment. The prototype of the redesigned CPM was manufactured in-house. Product testing was conducted with 40 volunteers including experienced therapists, nurses, university students and working-age people.

Findings – Compared to the previous machine, the newly designed model was improved in both functioning and manufacturing costs. The redesigned machine is more durable and consists of a less complex structure.

Originality/value – The redesigned machine introduces some new features and removes unnecessary functions. As a result, the model costs less and hence, is considered beneficial to the general public. More utilization is expected which could eventually reduce the therapists' workload at the hospital. This research provides well-defined processes of the product development starting from the users' requirement analysis to the prototype testing stage.

Keywords Rehabilitation, Continuous passive motion, Knee replacement, Machine design, Physical therapy

Paper type Research paper

Introduction

Total joint replacement is the removal and replacement of a damaged joint[1]. For example, knee replacement surgery involves replacing the diseased or damaged joint surfaces of the knee (or ends of the bones) with metal and plastic components which together are shaped to allow continuous motion of the knee[2]. In the last decades, total knee replacement (TKR) surgery procedures have continued to increase, with the most pronounced rate among younger patients[3, 4]. Generally, the average age of individuals undergoing TKR has declined. The underlying reason for this trend could be a combination of changes in medical practices as well as increased prevalence of an individuals' obesity[5, 6]. There is also a significant correlation between GDP and health expenditures with the utilization of the TKR[4]. Not only have the number of operations increased, but also the total cost charges for the procedure have also increased resulting in a significant economic impact on the overall healthcare system. In Thailand, a similar trend has been found. According to data from some national funds



(i.e. Government Welfare fund, National Health Security Fund and Social Security Fund), the total number of knee replacements have continually increased from 2006 to 2010[7]. The increased lifetime direct costs in the case of TKR procedures can be offset by societal savings from reduced indirect costs (i.e. increased employment and earnings, fewer missed workdays and lower disability payments) and eventually the total net benefit[8]. Nonetheless, to achieve such offset, effective recovery to gain full functional status after surgery is crucial.

After surgery, the orthopedic surgeons or therapists usually discuss the option of an exercise program pertinent to each individual patient. It is necessary for patients to take physical therapy seriously in order to return to their normal condition or as close as possible to it. According to our interview with the head therapist in the orthopedic department at Chulalongkorn hospital Bangkok, the effectiveness of the exercise is largely due to whether the correct posture is achieved during the training sessions. At the same time, from the time of pre-surgery to the recovery phase, patients were reported to have undergone difficult experiences and support from healthcare staff which resulted in negative emotions and discouragement[9]. Hence, patients usually need the help of therapists throughout the recovery process. Compared to the demand of bone and joint cases (i.e. more than 40,000 patients had bone and joint operations or treatments in a year[10]), shortages of physical therapists have become a consistent problem. Moreover, for some patients who use splints, high exertion force is continually required from physical therapists due to the splint weight. To ease such difficulties, the continuous passive motion (CPM) machine was introduced to the orthopedic department at the hospital.

The machine focuses mainly on range-of-motion exercise rather than resistance or functional training which requires different therapies[11]. Unfortunately, its redundant structure and complex mechanism make the existing machine difficult to fix or to perform regular maintenance. As a result, the machine is usually left unused. On the other hand, from the patient viewpoint, it is found that many patients preferred to undergo therapy sessions at home or in their own accommodation rather than visit the hospital. Visiting the healthcare unit on a daily basis undoubtedly requires large amounts of resources from a time and financial perspective. Hence, the situation has resulted in pressure on the medical system to provide more care on an outpatient basis. With professional competence, timeliness, and proper post-surgery care planning, the home healthcare physical therapy system (HHCPPT) was shown to be a successful choice when measured against the patient recovery status[12]. A review of over 2,400 patients from 2007 to 2011 also found no difference in terms of pain and knee function two years after surgery between patients who directly went home or those patients who utilized an inpatient rehabilitation facility[13]. Importantly, it is still important to address the patient's preparations during the discharging process. Five aspects were identified as key checkpoints to consider a patient's readiness for transferring from hospital to home including physiological and psychological experiences, coping ability, needs from the healthcare team and family support[14].

In light of the existing needs, the aim of this research was to redesign the current machine that involved the improvement of the mechanical and electrical systems. The newly redesigned machine is scoped to address knee movement in flexion and extension directions alone. The underlying reason not to design for a more flexible machine that could be used by various joints is to avoid possible human error. Once the machine is more flexible, it will require better understanding and more attention to operate the machine appropriately whereas operating error is not acceptable in the therapy tasks. For instance, when using a machine with three possible therapy postures, there is a chance that patients recovering from a hip replacement will accidentally do the knee replacement posture, which is extremely harmful. The highest proportion of medical errors was found to be treatment or operation related errors[15]. Possible human errors can be expected as a result of various factors such as caregiver's fatigue, emotional stress, multitasking demands and communication failure among individuals involved[16]. Therefore, design for only one posture in a machine is considered safer.

Materials and methods

The redesign process consists of three major steps including the study of knee replacement and current therapy, the machine redesign utilizing the engineering process, and prototype development and testing. Details for each step are as followed.

The study of knee replacement and current therapy

People may consider knee replacement surgery if one has a stiff, painful knee that makes it difficult to perform even the simplest of activities. In many cases, the pain is intense both during movement and during rest periods. Knee replacement is a viable solution when other treatments are no longer working and/or to avoid side effects from continuing use of painkillers[17]. Usually, a more affordable and less invasive procedure such as a weight loss program focusing on diet and exercise is preferred by the patient[18]. Although it may take up more than a year, the concrete prevention program overseen by a licensed personal trainer and skilled kinesiologist could successfully improve the TKR candidate's knee pain symptoms (i.e. reduced body weight, more quadriceps strength) to the point that the surgical intervention could be deferred[19]. Theoretically, the reduction in joint load may play a significant role even though there are no anatomical changes in the knee area. Also, with the advancement of smartphone technology, it is possible nowadays for a telephone-based tracking program to facilitate the patient's behavior changes[18]. Hence, preventive methods are suggested as an alternative treatment modality, particularly for younger adults. Of note, TKR surgery is typically reserved for people over 50 years of age.

When it is necessary, the surgical process begins with giving the patient a general or spinal/epidural anesthesia. The incision is made across the front of the patient's knee. The damaged bone and cartilage is then removed from the femur or thighbone. Then, the cut area is resurfaced to shape fit with the artificial joint; the femoral component in this case. Usually, the artificial component (either metal or plastic) gets attached to the bone using cement or a suitable special material. Similar processes are performed with the tibia or shinbone in order to attach the tibial tray. Finally, if necessary, an additional plastic piece will be attached to the patella or kneecap bone and depends on proper fitting of the entire implant. When fit together, the attached artificial parts serve as the new knee joint. The surgeon will bend and flex the knee to ensure proper alignment and position before stitching to close the incision.

The average hospital stay after knee joint replacement is usually three to five days. The pain caused by the damaged joint is usually relieved when the new gliding surface is constructed during surgery. A day after surgery, patients are usually encouraged to perform light physical activities including standing and exercise involving movement around the joint. At first, the patient may walk with the help of parallel bars. Then, a walking device such as a walker or cane will be introduced until the patient's knee is able to support his/her own body weight. During the recovery period, patients are usually sent home or sent to a rehabilitation facility, depending on the patient's condition at the time. If patients are sent to a facility, the average rehabilitation stay is approximately seven to ten days. If patients are sent directly home from the hospital, the doctor will usually have a physical therapist assigned to treat patients at home. The doctor also may have patients go to an outpatient physical therapy facility as the final stage of the rehabilitation. Outpatient therapy may last from one to two months, depending on the patient's.

During the first six weeks of physical therapy, patients should not pivot or twist the operated leg. Additionally, when lying in bed, patients should keep the involved knee as straight as possible. Kneeling and squatting should be avoided soon after knee joint replacement surgery. The physical therapist will provide patients with techniques and adaptive equipment that could help patients. Guidelines and precautions while performing daily activities are usually provided. All techniques are followed to avoid the dislocation of

the patient's newly replaced joint. Ideally, the patient should exercise two to three times a day, everyday, after surgery. Post-surgery exercise starts with knee bending movements by sliding the heel up toward the buttocks. The heel is kept on the bed. This is flexion movement. Then, the heel is slid back to the starting position for extension movement. A plastic bag can be added under the patient's heel to help make this sliding easier. Exercising both legs are recommended. Within about six weeks, most people are able to walk comfortably with minimal assistance. Once muscle strength is restored, people who have had knee joint replacement surgery can perform most activities[20].

Machine redesign

Machine redesign steps commenced with user requirement analysis to specify machine necessary functions, conceptual design to draft the machine body structure, 3D drawing to illustrate the redesigns, engineering calculations to specify detailed design and finite element analysis to verify the calculated dimension of the equipment. Details are as followed.

User requirement analysis. Interviewing and brainstorming with doctors, therapists and nurses were conducted. In general, ease of use is crucial to avoid operating error as much as possible. It is particularly important to note that main users are not only therapists but also a patient's relatives or caregivers. Therefore, it is most advisable that only two inputs are required from the operator to run the machine, which includes the degree of knee bending and lapse or number of repetitions. The degree of movement range is set up according to each patient's range-of-motion capability at that time. At the very first day of therapy, patients might not be able to move the joint much but by the last week of therapy, they should be able to bend their knee more than 90° and walk like normal.

After setting the movement range, the operator will be required to input the number of lapses needed (repetition times). Normally, the exercise is arranged in a set of thirty repetitions. Each set is followed by the other during the 30 session. Lastly, for any unpredictable events, an emergency stop button is added to the design. Note also that the emergency button was not available in the previous design.

Conceptual design. To specify the body size of the machine, the lower extremity anthropometric data (i.e. thigh length, lower leg length and foot length) is considered and translated into the design range. The design for adjustability concept is selected to accommodate various sizes of patients. Two major adjustable components which are designed in the new model include thigh and footpad ranges. The existing CPM machine is shown in Plate 1.



Plate 1.
Existing CPM
machine at
Chulalongkorn hospital

3D drawing. The 3D drawings composed of various machine parts were continually introduced. The drawings were essential for enabling effective communication between the design team and the healthcare personnel before making the final changes and refinements. The reverse engineering technique was utilized. This iterative development process was intended to improve the quality and functionality of the design. Eventually, three successive models were created as shown in Figure 1.

Engineering calculations. After the final conceptual design was completed, the important component has to be theoretically calculated by engineering principles and knowledge in order to find the required and verified dimension for the detailed design of all mechanical and electrical systems. Detailed calculations for this stage are explained below.

Knee joint structure

During actual usage, the weight from the patient's leg is applied directly to the knee joint structure of the CPM machine. This load can be considered as a compressive load onto the bar which has a high tendency of bending failure. Therefore, the mechanics of material principles were used to verify the appropriate bar cross section. The patient's total leg weight was estimated from 18.94 percent of the total body weight[21]. To ensure that the machine can withstand the extreme weight, the weight data is selected from a large male subject and multiplied by five to set the safety factor. The dimension of the pipe was later selected based on two conditions; the proper size related to its operating condition and whether the size withstands the applied load. Whether the pipe size and specification are available commercially or not was another crucial factor for pipe selection to allow for manufacturing possibility.

The calculation process started from performing force analysis on a simplified 2D free body diagram. The shear and bending moment along the bar were analyzed using a graphical method which results in shear force and bending moment diagrams. The maximum bending moment was then estimated from the diagram. Relevant formulas utilized in this step are Equations (1)–(4) as follows:

$$\frac{dV}{dx} = -q, \tag{1}$$

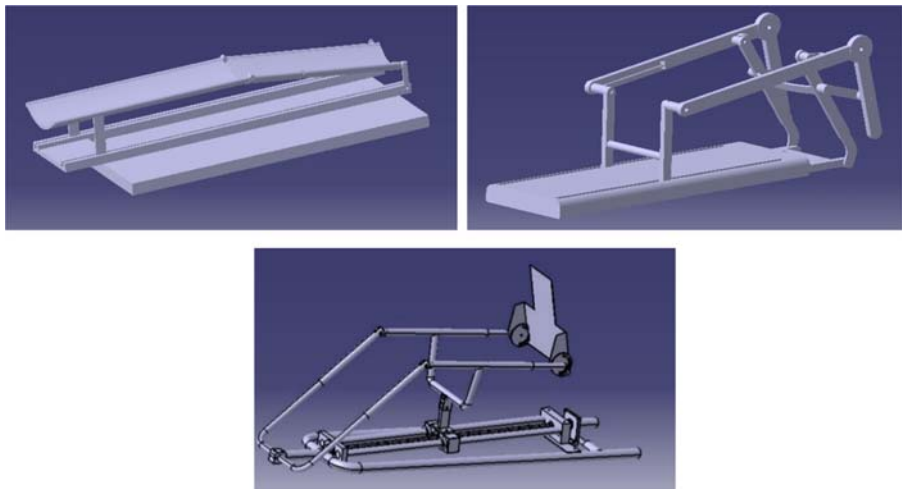


Figure 1.
First (above left),
second (above right),
and final conceptual
designs (below)

$$\Delta V = -F(F \downarrow \rightarrow \Delta W \downarrow), \quad (2)$$

$$\frac{dM}{dx} = V, \quad (3)$$

$$\Delta M = Mo(\text{Clockwise} \rightarrow \Delta M \uparrow), \quad (4)$$

where V is the shear force, q is load intensity, F is applied normal force, M is bending moment and x is distance.

After that, by knowing the maximum bending moment and moment of inertia for the selected stainless steel pipe, the maximum bending stress was calculated. Relevant formulas for this step include Equations (5) and (6) as follows:

$$I = \frac{\pi D^2}{4}, \quad (5)$$

$$\sigma_{\max} = \frac{M_{\max} C}{I}, \quad (6)$$

where I is the moment of inertia, D is diameter of the circular pipe cross-sectional area, σ_{\max} is maximum bending stress, M_{\max} is maximum bending moment and C is the radius of the circular pipe cross-sectional area.

Finally, maximum bending stress was compared with the allowable compressive strength of the selected material.

Connector

The connector is one of the most important components connecting with the movable slider. It is a moving component which is used not only to connect the upper and lower section together but also to carry all existing compressive loads when in use. The total compressive load from various parts (i.e. knee joint, patient's leg, doctor bar, footpad and movable support) is axially and directly applied on the connector. Then, using an Equation (7), the minimum cross-sectional area (and hence, its length) was calculated:

$$A = P_{\max} / \sigma_{\text{allowable}}, \quad (7)$$

where A is the minimum cross-sectional area, P_{\max} is total compressive loads and $\sigma_{\text{allowable}}$ is material compressive strength.

Finally, the following equation was used to verify the designated cross-sectional area and dimension of the connector by considering expected deformation from the applied load:

$$\delta = PL/AE, \quad (8)$$

where δ is the displacement due to loading force, P is the total compressive loads, L is the connector's length, A is the connector's cross-sectional area and E is the modulus of elasticity.

Calculation results show that the displacement is expected to be very low (able to be rounded into zero displacements). Therefore, there is no deformation on the bar.

Ball screw selection

In order to find an appropriate size of the ball screw, the axial load had to be identified. This load can be estimated by using the following equation:

$$\text{Axial load} = \mu Wg, \quad (9)$$

where μ is linear bearing friction coefficient, W is moving mass (i.e. patient's legs and machine components) and g is gravitational acceleration.

Then, the selection of the ball screw was made and several parameters were checked to confirm the safety factor. Evaluation utilizing information[22] showed that the machine is not performed under high external load and can be considered as acceptable. Equations (10)–(12) were used to confirm this particular step:

$$L_{10} = (C_a/F_m)^3, \quad (10)$$

where L_{10} is life performance, C_a is dynamic carrying capacity of the ball screw, F_m is mean load:

$$\eta_{cr} = (49 \times 10^6 f_1 d_2) / l^2 \quad (11)$$

where η_{cr} denotes the critical speed of the screw shaft, f_1 is the mounting correction factor, d_2 is the root diameter and l is the distance between support beams. Also, the speed limit ($\eta x d_0$) should not exceed 50,000 rpm:

$$F_c = (34 \times 10^3 f_3 d_2^4) / l^2 \quad (12)$$

where F_c is buckling strength, f_3 is the mounting correction factor, d_2 is the root diameter and l is the distance between support bearings.

Motor selection. In order to ascertain the suitable size of the motor and its gearhead, the motor is selected based on its application, the drive mechanism. The specification and operation conditions of the drive mechanism are determined from the previous selection of the ball screw. Next, the gear ratio of a gearhead and load torque are calculated. Calculation for this step utilized Equations (13) to (15):

$$N_G = (V \times 60) / C \quad (13)$$

where N_G is the speed at gearhead shaft, V is ball screw speed and C is the distance moved for one rotation of the ball screw:

$$T_L = \left(\frac{FP_B}{2\pi\eta} + \frac{\mu_0 F_0 P_B}{2\pi} \right) \times \frac{1}{i}, \quad (14)$$

where T_L is the load torque, F is axial load, P_B is ball screw lead, η is ball screw efficiency, μ_0 is internal friction coefficient of preload nut, $F_0 = (1/3)F$, i is the gear ratio of mechanism.

Finally, the motor was selected from the Suntech Motor catalogues [23,24] ensuring that it must produce more torque than the load requires:

$$T_M = \frac{T_L}{ix\eta_G}, \quad (15)$$

where T_M is motor torque, i is gear ratio of mechanism and η_G is gearhead efficiency.

Finite element analysis

Finite element analysis, a reliable computer-aided engineering (CAE) method, is performed to verify the calculated dimension in order to ascertain if it can withstand the expected applied load. The simulation program is used to compute and simulate the stress and displacement analysis of each part of the equipment to verify the structure. The total number of ten parts was tested using this method. Figure 2 illustrates an example of the finite element analysis results.

Prototype development and testing

A prototype of the redesigned CPM was fabricated in-house and used during the interview sessions. Interviews were conducted with 40 people consisting of 22 males and 18 females. Their age ranges varied from 19 to 41 years old. Volunteers for the evaluation sessions included university students, working-age group individuals, experienced therapists and nurses. Some examples from the sessions are shown in Plate 2.

During the session, the volunteer was given information regarding how to use the CPM machine. After allowing time for actual operation, discussion on their opinions toward the machine was held. Volunteers were asked to give their subjective rating on ten performance dimensions using a four-point scale ranging from excellent, good, fair and poor. The ten assessed indexes were aimed to measure the machine’s usability (i.e. ease of use, the level of understanding for pictorial instruction, appropriate and correct commanding), functionality (i.e. smooth operation, noise level, safety usage), and body structure (i.e. aesthetics, size). Overall satisfaction on the redesigned machine was included as the last index.

Results

Plate 3 shows the prototype of the CPM final redesign. The redesigned machine has a simpler structural design and fewer components than the previous model which results in

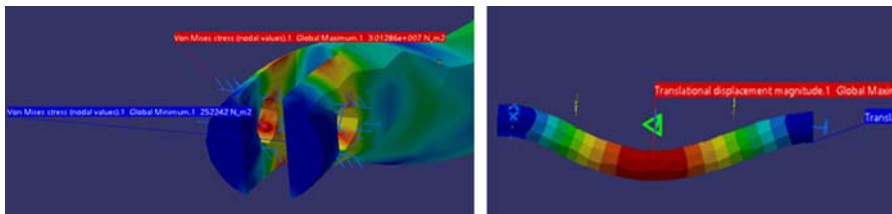


Figure 2.
Stress analysis (left)
and displacement
analysis (right)



Plate 2.
Evaluation sessions
with therapists
and nurses

easier operation and maintenance processes. By having stronger and more durable structures and mechanisms, the machine can be expected to also last longer.

Additions to this new model are shown in Figure 3 which include a double safety switch, a numerical keypad and counting program and an emergency stop. All these additions are not available in the existing model. The redesigned machine can automatically count lapse numbers and perform a self-stop function rather than stop upon the user's activation. Arduino IDE software was used for coding the electrical components.

Furthermore, vibration from the driving motor is reduced and the machine operates with lower noise. Production cost is also cheaper than the current machine. At present, the redesigned model sale price is estimated at 100,000 Baht compared to the previous 150,000 Baht.

For evaluation purposes, interviews with volunteers found that 47.5 percent of the responses considered the redesigned machine as "good" regarding performance, 43.3 percent reported "excellent," and 9.2 percent reported "fair". There were no "poor" performance ratings in any of the assessed dimensions. Subjective responses collected during the session are summarized in Table I.



Plate 3.
The final design of
CPM machine for
knee therapy

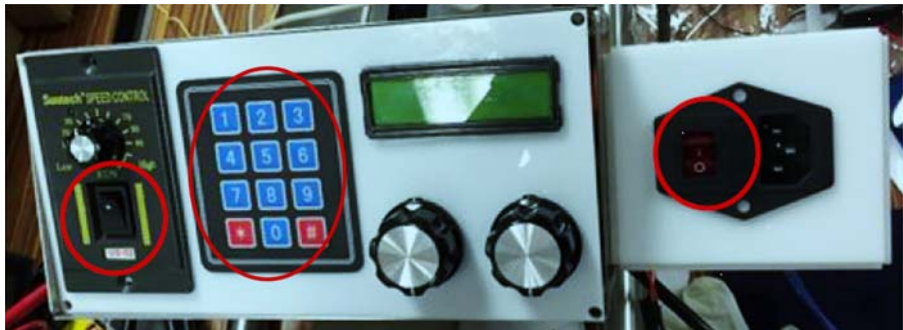


Figure 3.
New additions to the
CPM machine

	Excellent	No. of responses (%)		Poor
		Good	Fair	
<i>Usability dimensions</i>				
Ease of use	15 (37.5%)	22 (55.0%)	3 (7.5%)	0 (0%)
Pictorial instruction	8 (20.0%)	27 (67.5%)	5 (12.5%)	0 (0%)
Appropriate commanding	19 (47.5%)	19 (47.5%)	2 (5.0%)	0 (0%)
Correct commanding	24 (60.0%)	12 (30.0%)	4 (10.0%)	0 (0%)
<i>Functionality dimensions</i>				
Smooth operation	21 (52.5%)	17 (42.5%)	2 (5.0%)	0 (0%)
Noise level	18 (45.0%)	19 (47.5%)	3 (7.5%)	0 (0%)
Safety usage	21 (52.5%)	14 (35.0%)	5 (12.5%)	0 (0%)
<i>Body structure dimensions</i>				
Aesthetics	11 (27.5%)	21 (52.5%)	8 (20.0%)	0 (0%)
Size	17 (42.5%)	19 (47.5%)	4 (10.0%)	0 (0%)
Overall satisfaction	19 (47.5%)	20 (50.0%)	1 (2.5%)	0 (0%)
Average	43.30%	47.50%	9.20%	0%

Table I.
Subjective responses
on the performance of
the redesigned
CPM machine

Discussion

The redesigned machine is expected to result in more utilization at the hospital. Not only can the CPM machine be used after knee surgery, but the machine is also proposed as a possible movement therapy for early stroke recovery[25, 26]. The machine could also provide movement opportunities for otherwise immobile patients. Obviously, with increasing machine usage, the total workload of the therapists could expect to be reduced while fast progressing therapy for the patient is still possible.

Despite the success of the redesign, there is still room for further improvement as found during the interview sessions. Three major improvement points include pictorial instruction, aesthetics, and ease of use where there are much larger responses of “good” than “excellent,” respectively. As illustrated in Figure 3, the control panel is still lacking information transmission such as labels and symbols to indicate the functionality of each control. Future models deserve more attention on the machine interface design in particular. Providing information on the total operating time was also requested by some evaluators because some users may easily lose track of time while performing such a passive repetition of movement. Furthermore, auditory signals should be added when the emergency stop is pressed. From an esthetic point, modification of the machine exterior should be made. Most of the complaints were regarding messy wires that should be kept tidy. For ease of use, it was suggested that the location of the control box should be nearer to the patient to ensure an easier and comfortable reach. Finally, adding the leg’s supporter with thicker leg wraps while reducing the total weight of the machine was deemed preferable.

Among all the above suggestions, the machine interface is the most critical, especially if the machine is intended for the market. Once the user understands how to control the redesigned machine (given verbally during interviewing sessions), all functionality dimensions are satisfied. Balancing between interface design (for safety and usability) and aesthetics is a key success factor for medical devices[27] where misuse can result in harmful consequences. The published trending data analysis from the US Food and Drug Administration (FDA) on Medical Device Recalls between FY2010 and FY2015 pointed out that device design is the most prevalent cause of recalls and also the most likely to cause serious health problems to the end user[28]. Problems with design are usually categorized in various aspects such as the design component, label, packaging, etc.

With continued problems that have arisen, it is not surprising that usability related standards and codes are specifically given to the medical device design by various organizations such as Quality System Regulation 21 Code of Federal Regulations part 820 (21 CFR 820)[29], ISO:62366 Usability Engineering to Medical Device[30], and ANSI/AAM HE75:2009[31].

Eventually, with the appropriate design, administration of the redesigned CPM in the home setting could also be enhanced. In reality, not only is the machine design important, but various factors from the patients' perspective also play a crucial role in the patient's compliance with the home-based exercise regimen. These factors include the ability to accommodate exercise within everyday life, the opportunity to multi-task therapy with recreational activities, perceived severity of symptoms, attitude and self-motivation[32]. Therefore, a well-designed machine needs to be provided accompanied by person-specific advice from health-related personnel to ensure the overall effectiveness of the therapy session.

Conclusion

The redesigned machine has followed the product development process. Having no background in medical related knowledge, the design team had to spend some time gaining knowledge of knee replacement procedures and therapy. Thereafter, the redesign process was performed starting from user requirement analysis to specify current problems which assist in coming up with the conceptual design of the machine. The 3D drawing, engineering calculations, and finite element analysis were later carried out. After theoretical confirmation of the design had been made, the prototype was created and tested with volunteers. In conclusion, the redesigned model serves its objective to reduce complex and unnecessary functions. There are several advantages resulting from the simpler design of structure and mechanism which are as follows:

- (1) decreased weight owing to fewer included structures;
- (2) lower material and manufacturing costs;
- (3) reduced points of maintenance;
- (4) the machine's ability to automatically count the number of lapses and stops; and
- (5) reduced vibration from the driving motor.

The proposed improvement of the machine is summarized and discussed. The most critical shortcoming is the lack of visual information on the machine to allow decent usability. Standards and codes will need to be reviewed and followed accordingly when the machine is intended to be on the market.

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