Original Article

Design and development of safe gait prosthetic knee joint in India

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Abstract

Context: The prosthetic technology in recent years has grown by leap and bounds. The most advanced gadgets like microprocessors are available worldwide at exorbitant costs. Developing countries have issues with terrain, access to services, and cost. The new design of the prosthetic knee joint was planned to develop a cost-effective, sturdy, and easy to fit a universal system. **Methods and Material:** This exploratory design was undertaken to develop a prototype. The design was further developed and tested for its materialistic properties. Pilot study assessing functions using this joint is also underway. **Results and Conclusion:** The novelty of this knee joint is that locking and unlocking are made simple such that it can be done by the transfemoral amputee at will, with ease, on the spot, independent of the terrain he/she is traversing. The awareness of such a prosthetic joint is vital for family physicians.

Keywords: Gait analysis, microprocessor, a prosthetic knee joint, single-axis knee joint, transfemoral amputee

Introduction

The prosthetic technology in recent years has grown by leap and bounds. The mostadvanced prosthesis incorporates advanced gadgets like microprocessors[1-11] which are available at exorbitant costs. India is a developing country and the Indian Government endeavors to provide the aids and appliances to the disabled at the minimum costs.[12] Although the government has floated several schemes for the welfare of the disabled, these schemes are not enough. Moreover, these schemes are fraught with terms and conditions which make it very difficult for the patients to avail of the benefits.

There are grossly two types of lower limb prostheses endoskeletal and exoskeletal. Since, endoskeletal prosthetic components are modular, interchangeable, and easy to align anytime they are widely accepted. Most endoskeletal knee joints available in India are imported and are thus expensive.

As most institutions in India were fitting exoskeletal prostheses to all transfemoral amputation (TFA) using wooden shin attached to a constant friction wooden knee block, which is carved and assembled to the transfemoral socket (technically has a pivotable joint with a backstop at 180°). The fitting of the knee joint assembly has an elastic strap fixed on the anterior aspect of the knee assembly as an extension assist to those TFA who would prefer to walk with a free knee gait. This knee assembly also has a manual locking mechanism like a door latch which would slide down the shin to lock and maintain full knee extension of the prosthetic knee. This would help in the initial weight bearing learning and gait training of the TFA with above-knee (AK) prosthesis. The locking mechanism always added security to the TFA while using their prosthesis and to overcome the fear to stumble.

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The most common and economical prostheses in India is the "Jaipur foot"[4] prostheses which has an exoskeletal system with a pair of an orthotic drop lock externally fitted for all its prostheses and which requires both hands to lock and unlock the knee joint. All amputees fitted with Jaipur foot prostheses, therefore, walk with a stiff/locked knee, the reason being that the amputee wants to have the stability to negotiate on all terrains.[13]

In brief, knee joints of AK prosthesis are used for the stance phase for load-bearing stability and to have swing phase control. In recent years, worldwide, we have many kinds of knee joints developed providing control either with the use of hydraulic fluid mechanisms or pneumatic control mechanisms.[1,3-7,9,11] For the consumer, choice of knee joint and selection of knee joint is becoming problematic.

The single axis, constant friction artificial knee joints, power not needed in the passive endoskeletal prosthesis like OFM 2 of Medi, Endolite, Otto Bock, and Ossur, available today in India do not provide the amputee the freedom to lock or unlock at will. He has to take the help of a prosthetist to lock or unlock it or select the knee joint accordingly.

The new endoskeletal prosthetic knee joint (SAFE GAIT) was thus planned and designed with the main objective that

1. It will eliminate the services of a prosthetist to lock or unlock the prosthetic knee joint for TFA.
2. The locking and unlocking mechanism of the knee joint will be simple and easy to operate
3. The amputee should be able to walk with a free knee at will.

Procedure

Design considerations for Safe Gait Prosthetic Knee Joint

Stainless steel material was chosen for the manufacture of the knee joint due to the following reasons:

1. Titanium is costly and would take the cost too high.
2. Stainless steel would make knee joint rust-proof (free of corrosion) and durable.
3. An investment casting has been done on the joint to make it cost-effective manufacturing.
4. Since there are no standard tests on knee joint testing available in the country, the prototype was manufactured with Stainless Steel 304, and a compression load test was done at the Energy Research Development Agency (ERDA) – an authentic autonomous body in the field of testing.

Technical features

- The knee axis is behind (posterior) for stability
- Extension assist is done with an elastic cord which is easily interchangeable and tension can be adjusted for the swing phase.
- The lock mechanism works with a spring-loaded plunger, when the knob is shifted; itimmediately locks the knee (in full extension)

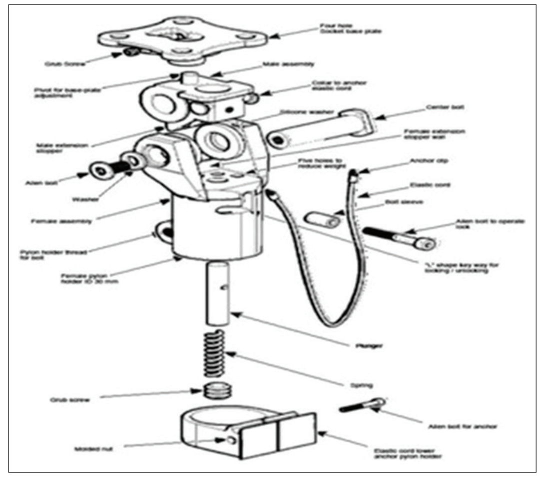

Figure 1: Various components of safe gait prosthetic knee joint

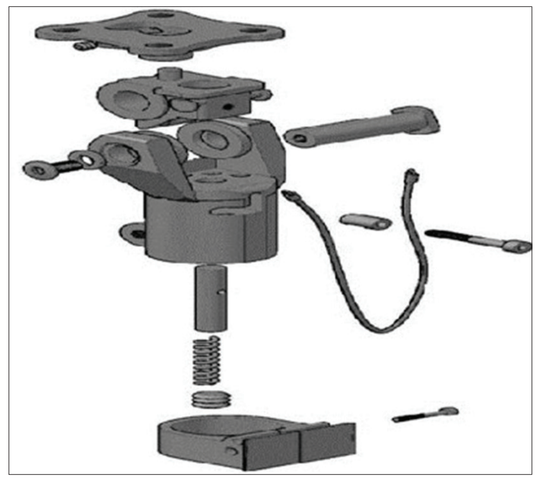

Figure 2: Assembly drawing of safe gait prosthetic knee joint

Figure 3: Final look of safe gait prosthetic knee joint

- Load Limit - 120 kg, UNB 12.9
- Knee Flexion Range – 125° (approx)
- Height (Knee center – upper edge) – 22 m
- Optional height (Knee center with special coupling) -12 mm
- Universal socket assembly features (which could be fitted to any prosthetic component manufacturer's assembly system)- 30 mm pylon tube fitting.

Description

Figures 1 and 2: The upper end or top end of the joint has a universal four-bolt baseplate which has a groove to accommodate the pin (part of the male component) with both sides grub screw so that desired rotation of the knee joint while assembling with socket could be achieved.

The middle/male component of the knee joint has an inbuilt pin which anchors on the base plate on the top. It has a look like that of a bobbin with an extension to be functioning as a stop. It also has two built-in pins on both sides in the front like a flat head rivet, this is to anchor the elastic cord which would help in extension (swing phase motion) the hole in the center of the male component acts as the hinge to the center bolt.

The center bolt is in conjunction with the female component which is machined with a spherical shape on one side, which settles in the spherical shaped groove of the female component (for firm anchor). The center bolt also has fine threading on the other end to get itself locked. There are silicon and metal washers that mimic free motion as a hinge. Overall, the male rests on the female body which has a flat surface like a wall on the rear side which makes the 180° stop. The bottom part of the female component is a double locking pipe holder for a 30 mm tube which is now universally used.

It also has a small tube in the center which acts like a barrel for the inserted plunger (which is inserted in the small hollow shank which is parallel to the 30 mm inner diameter tube clamp, the center body replicates a pipe within a pipe) where the inner pipe has respective threading for grub screw at the bottom to hold the spring-loaded plunger in its desired position, once the plunger is up it would lock the joint restricting/lock the male component in 180°.

To control the plunger movement there is an Alan bolt which is tightened in the middle shaft of the plunger pin, which passes through the L-shaped keyhole on the outer front part of the female body this controls the locking and unlocking of the joint. The operating Alan bolt has a soft sleeve that gives grip for easy operation by the amputee. The elastic cord for extension assist is like any other prosthetic knee joint universally available. The manufactured joints are as shown in Figure 3.

Discussion

Amputee functional level and their prosthetic components are classified universally as K levels[3]

- K0 – Non-ambulatory (cannot walk at all),
- K1 – Transfer activity (wheelchair to bed/commode seat),
- K2 – Household ambulatory (can walk only on even surface predominantly indoor),
- K3 – Community ambulatory (can walk outdoor on uneven surfaces/staircase/ramps etc.),
- K4 – High activity level ambulatory (sports, recreational activity).

In India, no prosthetic components have been categorized. Besides, soft sleeves are not manufactured and hence only a hard socket system with an EVA foam liner is fitted and distributed in the camps free of cost.

Prosthetic knee joints are categorized from K2 to K4 levels which meet the demands of stability and mobility during the gait cycle, also during activities like the stand to sit. Apart from closely resembling the biological knee, ideally, a knee prosthesis should not exceed the size and the weight of the missing limb.[3]

There are three major groups in which the TFA prosthesis have been classified, viz. passive, damping, and powered. No power is needed in the passive prosthesis while damping need power for variable damping and powered prosthetic knees can perform positive knee work[1-3,5-10]

The safe gait knee joint stands out giving the TFA ease to lock unlock at will and without anyone's assistance. This is possible because of the "plunger mechanism with a control knob" used. The operation of locking unlocking is possible with a very slight pressure of a single finger of the hand on the control knob.

In free knee gait mode, shortfalls are also applicable to this newly designed joint i.e., it is not capable of adapting to the changing speed during gait. Mechanical stance control (although the knee axis is kept posterior for stability) may still be unreliable, this increases the risk of stumbling in free knee joint ambulation.

Ideally, there is a protocol for a TFA to reach a stage where he can be fitted to a permanent prosthesis. Besides, following this he needs to undertake physiotherapy sessions of gait training, strengthening, balance, etc., apart from other education about donning, doffing, etc., However, most fittings of prostheses in India are done during camps, therefore, there may be minimal time given for gait training and very seldom under a qualified physical therapist.

In camp, on fitting prosthesis on the first day, the amputee is struggling to gain the confidence of stability, while standing and the easy locking mechanism is desired as only then will he attempt to ambulate with the prosthesis. The "safe gait" joint provides the locking mechanism with ease and at will thus providing initial confidence of stability required by TFA.

Conclusion

The novelty of this "prosthetic knee joint" is that it can be locked and unlocked by the patient himself on the spot depending on the terrain he is traversing, without having to go to the professional. This feature is hoped to help the amputee to negotiate even uneven terrain and crowded situations with confidence, apart from being economical and available at a very low cost. The awareness of such a prosthetic joint is vital for family physicians.

The pilot study comparing this novel knee joint to other imported knee joints available is completed and found to be satisfactorily compatible (under publication).

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Conflicts of interest

There are no conflicts of interest.

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