Clinical Appraisal of Indigenous Below Knee Endoskeletal Carbon Fibre Prosthesis

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Abstract

Background: Amputation is a catastrophe, which results in physical, social, psychological and economic handicap. Provision of suitable prosthesis (artificial limb) is a major step towards rehabilitation of these patients.

Method: With an aim to provide comfortable, prosthesis to these patients, Artificial Limb Centre (ALC) Pune, developed Below Knee Carbon Fibre Shaft Endo-Skeletal (BK ES CF) Prosthesis in collaboration with DEBEL, Bangalore, a DRDO establishment. 815 Below Knee Amputee patients have been provided with the newly developed Endo-skeletal prostheses at ALC Pune till 31 Dec 2003. New BK ESCF prosthesis was evaluated for its performance by feedback received from 500 patients.

Results: More than 86% patients were satisfied with the performance of new prosthesis and they achieved almost normal gait.

Conclusion: The performance of new BK ESCF prostheses was excellent and it achieved good clientele satisfaction.

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Key Words : Prosthesis; Endoskeletal; Rehabilitation; Performance; Clientele satisfaction

Introduction

Normal human locomotion is achieved by a complex mechanism of precise alignment of lower limb skeletal system, joint motion and coordinated muscle activity, which gives a smooth forward progression. Therefore loss of lower limb gives rise to problems of body support, balance as well as of locomotion [1].

Ratio of upper limb to lower limb amputation in USA is 1:4.9 [2]. Below Knee (Transtibial) amputation is the most important amputation in the lower limb because it is the most proximal level at which near normal function is still available to a lower limb amputee [3]. It is also most common level of amputation in lower limb as found in various studies and surveys [4,5,6].

Till recently, Below Knee amputee patients of armed forces used to be provided with conventional (Exo-skeletal) prosthesis made of wood or plastic. In Exo-Skeletal Prosthesis, walls of prosthesis provide shape to the limb and also perform the weight bearing function. These prostheses usually are heavy and cumbersome.

Keeping these facts in mind Artificial Limb Centre, Pune took up a project to develop state of art Below Knee Endo-Skeletal Prosthesis. In Endo-Skeletal prostheses a tube frame construction provides the weight bearing function. A flexible cosmetic foam cover provides the outer shape. As body weight is transmitted through a central shank, it is biomechanically and

functionally better than Exo-Skeletal prostheses.

Material and Method

The Below Knee Endo-Skeletal prostheses was conceptualized with following components:

- A central carbon fibre tube, which would work as central shank for transmission of body weight.
- Below Knee close contact socket, would work as interface between BK stump and prosthesis for transmission of weight from body to prosthesis.
- Stainless Steel upper coupling, having socket adopter and pyramid for fixing socket to central carbon fibre tube with provision to change alignment in all direction with help of screws.
- Stainless Steel lower coupling with Solid Ankle Cushioned Heel (SACH) foot adopter and pyramid, with provision to change alignment in all direction with help of screws.

Depending on this design proto-type below knee prosthesis was made (Fig. 1) and laboratory trials were conducted. On successful completion of lab trials at DEBEL Bangalore, the technology and design was transferred to 515 Army Base Workshop Bangalore for further production. These BK prostheses were tried on Below Knee amputee patients at ALC Pune.

During clinical trials following shortcomings were encountered:

- Socket adopter used to break at the junction of pyramid

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and square plate.

- b) Square plate of adopter used to break at the edge near area of screw fixation.
- c) SACH foot bolt, made up of mild steel used to break frequently.
- d) SACH foot used to rotate on SACH foot adopter.
- e) SACH foot adopter plate used to break frequently.
- f) There was play between carbon fibre tube and adopter.

These problems were discussed with engineers of 515 Army Base Workshop and following remedial measures were taken:

- a) Quality of material of socket adopter was improved and design changed, to have a wide contact area between plate and pyramid.
- b) Design of Square plate of socket adopter changed from flat plate base to curve with four steel extensions to have good grip on socket.
- c) Material used to manufacture bolt was changed to stainless steel.
- d) To arrest rotation of SACH foot adopter hole size increased to 3/16" diameter from 1/8".
- e) SACH foot adopter bolt thread length increased to 4.5cm from 3.5cm.

Fig. 1

Fig. 2

Fig. 1 : Prototype below knee endoskeletal carbon fibre shaft prosthesis

Fig. 2 : Improved version of new below knee endoskeletal carbon fibre shaft prosthesis after modification

- f) SACH foot adopter plate depth reduced to avoid the breakage.
- g) To avoid the play between carbon fibre tube and the adopter, the bolt size in adopter was increased to 2mm from 1.5mm (Fig. 2).

It was possible to overcome all the shortcomings in prostheses, with the changes made in design of prostheses as suggested above (Fig. 3). The prostheses were fitted to 815 Below Knee (BK) patients. Initially, the patients underwent evaluation of BK stump, followed by fabrication of close contact BK Plastic Laminated Sockets. The BK PTB prostheses were fabricated by assembling BK ESCF assembly kit to these sockets. After bench, static and dynamic alignment of BK prostheses, the patients underwent gait training to learn to walk with new prostheses (Figs. 4,5).

Results

815 Below Knee Amputee patients have been provided with the newly developed Endo-Skeletal prostheses at ALC Pune till 31 Dec 2003. New BK ESCF prostheses was evaluated for its performance by feedback received from 500 patients after a minimum 3 months of continuous use. Longest follow up has been for 2½ years and shortest 3 months. Patients were given questionnaire, asking about comfort, stance phase stability, sturdiness, performance on even and uneven surface, fabrication time and maintenance required for new BK Endoskeletal prostheses. More than 86% patients were satisfied with the performance of new prostheses (Table 1).

Patients were also asked to compare qualities of Endo-Skeletal prostheses with Exo-Skeletal prostheses. Majority preferred Endo-Skeletal prostheses due to a) comfort b) good cosmesis c) lightweight d) reduced fabrication time e) reduced gait training time f) good stability g) easy to don and doff

One patient complained about early breakage of SACH foot bolt. 6 prostheses had loosening of screws of Adopter. 11 patients replied that their socket has become loose, which was because of normal physiological response of stump, not

Fig. 3 : Below knee endoskeletal carbon fibre shaft prosthesis trial and finished product

Fig. 4 : Below knee amputation patient with trial stage endoskeletal carbon fibre shaft prosthesis

related to quality or sturdiness of prosthesis. 23 patients who replied that prosthesis was not very comfortable during standing, were those patients who had bad stump with skin grafted area/bony spurs/puckered scars. Patients who complained of poor stability on uneven surface/on staircase/ on ramp, were normally old debilitated patients with poor musculature and knee joint instability (Table 2). Table 3 shows comparative weight of below knee prostheses of different firms. It is clear from the table that weight of ALC BK CFES

Table 1

Feedback of endo skeletal prosthesis (total cases - 500)

Parameter	Good	Satisfactory	Unsatisfactory
Comfort in standing	81%	12%	3%
Comfort in sitting	77%	18%	5%
Stability on even surface	72%	24%	4%
Stability on uneven surface	73%	18%	9%
Stability on stair case	58%	28%	14%
Stability on ramp	58%	28%	14%
Easy to don and doff	81%	19%	0%
Gait Pattern	80%	14%	6%

Table 2

Clinical evaluation

Complaint	Number	Remarks
Early breakage of foot bolt	01	-
Loosening of screw of adopter	11	-
Uncomfortable socket	32	bad stump due to SSG/scar/bony spur
Poor stability on uneven surface	23	Old debilitated patients with poor muscle

Fig. 5 : Below knee amputation patient with trial stage endoskeletal carbon fibre shaft prosthesis

prostheses is almost same as that of prostheses of other standard firms. There is only a difference of 132 gm with lightest available prostheses. Table 3 also shows comparative cost of prostheses of different firms. ALC BKCFES prostheses is found to be very cost effective compared to BK Carbon Fibre prostheses of other firms.

Discussion

Rapid advances are taking place in the field of rehabilitation to improve the quality of life of disabled patients. Fabrication of artificial limb has also witnessed revolutionary changes in recent past. Artificial Limb Centre (ALC) Pune has kept itself abreast of ever changing techniques and technology to meet the aspiration of its clientele. As the maximum numbers of amputees of Armed Forces belong to Below Knee level

Table 3

Weight and cost of BK prostheses

Name of firm	Foot in gm	Shaft with Adopter	Assembly weight	Cost in Rs.
ALC carbon fibre endo skeletal	520	620 gm	1.140 kg	6,010/-
Endolite carbon fibre endo skeletal (UK)	400	620 gm	1.020 kg	30,000/-
Endolite aluminium alloy endo skeletal (UK)	400	612 gm	1.012 kg	13,800/-
Otto bock aluminium alloy	484	504 gm	1.008 kg	10,715/-
Tata auto Ltd solution Alluminium alloy endo skeletal	512	602 gm	1.114 kg	7,600/-

of amputation, it is mandatory to provide them with a comfortable and functionally efficient mobility aid.

In prosthetic management at the transtibial (Below Knee) level, there is general acceptance of biomechanical analysis of Radcliffe and almost all such amputees are fitted with "Patellar Tendon Bearing" prostheses of one design or another [7]. The total contact "Patellar Tendon Bearing" (PTB) socket is characterized by a bar in anterior wall designed to apply pressure to the patellar tendon. Pressure tolerant areas on below knee stump include the patellar tendon, the pretibial muscles, the gastrocnemius – soleus muscle the popliteal fossa, the lateral flat aspect of fibula and medial tibial flare. Pressure sensitive areas include the tibial crest, tubercle and condyle, the fibular head, the distal tibia and fibula, and the hamstring muscle. Despite the name "Patellar Tendon Bearing", the pressure should be equally distributed over pressure tolerant area and relieved over the pressure sensitive area [8].

While fabricating prostheses following principles are kept in mind:

- a) Only most important functions are duplicated.
- b) A reasonable and practical compromise is made between weight and strength of the prostheses.
- c) Amputee's gadget tolerance is not exceeded.
- d) Amputee's sound limb is not limited in any way [9].

The primary goal is to produce a prosthesis, which permits unhindered function of the knee on the amputated side. To achieve this a total contact socket, which helps in distribution of weight and control forces generated between stump and socket when amputee walks, is required [10].

In Endo-Skeletal prostheses weight is transmitted through a central shank from socket to foot and to ground. Therefore a central carbon fibre tube was designed, which could be attached to the socket above through a stainless steel upper coupling and lower coupling attaches it to foot. The upper coupling had a socket adopter with pyramid, which had provision to change the alignment of prostheses. Similarly lower coupling had SACH foot adopter with screws for alignment at lower level [11].

Provision of prostheses to amputees is aimed at making their gait as normal as possible in terms of function, cosmesis and energy consumption.

Development and provision of Below Knee Endo Skeletal Prostheses to Below Knee Amputees of Armed Forces by ALC Pune has achieved its aim as shown by patients feed back. The new Below Knee Endo Skeletal prostheses achieved good acceptability and high degree of clientele satisfaction among Below Knee amputees of armed forces.

Conflicts of Interest

None identified

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