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Comparative study of HDPE below knee prosthesis with Jaipur foot and Laminated below knee prosthesis with SACH foot - *Cost, efficacy and utility in rural setting*

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Abstract

There have been various claims about the ideal below-knee (BK) prosthesis for our rural amputees. However, to date we have not come across any comparative study. This study was undertaken in an attempt to compare the cost, efficacy and utility of High Density Polyethylene (HDPE) BK prosthesis with Jaipur foot and Laminated BK prosthesis with Solid Ankle Cushion Heel (SACH) foot. Twenty unilateral BK amputees belonging to the rural and urban slum areas in and around Delhi and using Laminated BK prosthesis with SACH foot for more than 6 months were studied as per inclusion/exclusion criteria. All the Laminated prostheses were replaced by High Density Polyethylne prostheses with Jaipur foot. A comparative difference in cost, efficacy and utility between the two prostheses was studied.

Majority of the amputees were male belonging to the age group of 26-35 years. Most of them were manual workers. Road Traffic accident (RTA) related amputation were the commonest cause. Laminated prosthesis with SACH foot was found almost 4 times costlier than HDPE prosthesis with Jaipur foot. Looseness and breakage was found more frequently with the HDPE prosthesis. No significant differences between the two prostheses were observed in negotiating architectural barriers or in the ease to carry out activities of daily living (ADL). However HDPE prosthesis was also found favourable in religious activity and in activities related to water. Therefore HDPE prosthesis was found superior in terms of lower cost, lighter weight and with better efficacy and utility in rural setting as compared to the Laminated prosthesis.

Key words : **Activities of daily living (ADL), Below knee (BK) amputee, High Density Polyethylene (HDPE), Jaipur foot, Laminated prosthesis, Solid Ankle Cushion Heel (SACH) foot.**

Introduction

Artificial limbs manufactured in different Limb fitting Centres in India are based on Western design and technology. These limbs are not found favourable by the rural amputees because they do not take into consideration the various geographical, socio-economic and cultural variations, existing in this Country. An appropriate lower limb prosthesis in India should be: a) low cost, b) locally available, c) capable of manual fabrication, d) adapt to local climate and working conditions, e) durable, f) simple to repair, g) as light as possible and h) psychologically as well as cosmetically acceptable.[1] Various authors had claimed Jaipur foot and HDPE prosthesis with Jaipur foot fulfills the above cited criteria.[2-6]

This study was conducted to compare the cost, efficacy and utility of HDPE BK prosthesis

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fitted with Jaipur foot and laminated BK prosthesis fitted with SACH foot in the rural set-up.

Material and methods

Twenty amputees using laminated BK prosthesis with SACH foot for more than 6 months were studied.

Inclusion criteria;

a. Unilateral, uncomplicated below knee amputees.

b. Age between 14-55 years.

c. Belonging to rural or urban slum areas.

Exclusion criteria;

a. Amputees with multiple associated problems.

b. Unmotivated patients.

All the laminated BK prostheses were replaced by HDPE BK prostheses with Jaipur foot. Patients were followed up in terms of cost, efficacy and utility of the HDPE prosthesis as compared with the laminated prosthesis at the end of 6 weeks and every 3 monthly thereafter for the duration of the study (2 years). Analysis was done using both descriptive and inferential statistics.

Observation and Results

Out of the 20 amputees studied, 16 were male. Majority of the patients (n=9) belonged to the age group of 26-35 years and were mostly laborers and farmers (n=10). The commonest cause of amputation was train and road traffic accident (n=11), followed by peripheral vascular disease (n=4). Mean length of the stump was 16.15 cm. Three patients had adherent scar and another two had painful stumps due to neuroma.

The overall cost of the laminated prosthesis inclusive of the cost of raw material, fabrication and patient's expenditure to procure the prosthesis was Rs. 4682 approximately whereas the cost of HDPE prosthesis was Rs. 1030. Breakage of prosthesis and looseness of the socket was common in HDPE prosthesis. Therefore, prosthesis related pain was more common with HDPE prosthesis. However the need of repairing for both the prostheses was statistically insignificant. Difference in weight between this two prostheses was significant [p<.001]. Mean weight of the laminated prosthesis was 3±0.4 kg. and 1.2±0.6 kg., for the HDPE prosthesis. Stability while performing ADL was comparable for both the prostheses. HDPE prosthesis was cosmetically more acceptable (n=12) than laminated prosthesis (n=7) though the finding was not statistically significant.

Architectural barriers such as threshold, steps/staircase, uneven roads and terrain, high basement of house were found disturbing day to day activities in 5 patients using laminated prosthesis and in 3 cases using HDPE prosthesis. Prosthesis related problems like heaviness, cumbersome, ill fitting, pain, skin reaction, excessive sweating, loosening etc., was noted in both the prostheses in variable degree. However, differences were insignificant. The differences between the two prostheses while performing important activities such as sitting, walking, dressing, cycling, toilet and recreational activities were found statistically insignificant. In activities involving water, HDPE prosthesis with Jaipur foot was found favourable and in religious activities the laminated prosthesis with footwear (leather shoes) was found restrictive.

Discussion

In the present study, male/female ratio was 4:1. This is comparable to other similar studies.[6-9] Males are mostly involved in outdoor activities and therefore, more prone to injuries and accidents. Commonest age group for amputation ranges from 21 to 40 years.[2,5,6] Maximum patients in this study were also in the age group of 26 to 35 years. As persons in this age group are more active with

increased family and social responsibilities and hence, more exposed to injury.

Train and road traffic accident caused the maximum amputation (57-74%) followed by peripheral vascular disease (PVD) (14-24%).[5,6] Straats[10] had reported 14,000 amputations every year in India due to train accidents. The present study also showed 55% and 20% of amputation due to RTA and PVD respectively. This may be explained by the non-existence and non-observance of proper traffic rules and regulation by the general population, coupled with reckless driving, overloaded buses, trucks and trains, assorted animal drawn carts, rickshaws, extremely crowded and inadequately maintained roads. Prevalence of PVD may be due to tobacco chewing and smoking habits in the rural areas.

Laminated below knee prosthesis was found more costly (Rs. 4682) than the HDPE below knee prosthesis (Rs. 1030.50). The actual cost of the prosthesis was worked out as follows;

a) Actual cost of the raw materials.
b) Cost of fabrication
c) Patients expenditure to procure the prosthesis.

The rural amputees are poor and when considering the cost of the prosthesis, which may represent a year's earning, may decide against owning a prosthesis to feed their family or to buy a cow.[10] Sometimes the cost of transportation and accommodation may be as great or grater than the prosthesis cost.[11]

The reasons for the lower cost of Jaipur HDPE prosthesis are a) the use of locally available materials, b) the wage bill for the locally trained limb makers are much lesser than that would be required by a qualified prosthetist.[6] This study also highlighted a few additional reasons such as; a) the time taken for fabrication was much less, b) prosthetic fitting and training took less time since most of the amputees were already trained with the laminated prosthesis.

In the present study 40% of the patients with HDPE needed some form of repair mostly for breakage and looseness of socket within 6 months of their use against 25% in case of laminated prosthesis. Sharma[5] reported that 84% of the patients needed new prosthesis due to breakage or loosened prosthesis and another 12% for change of foot-piece and straps. Goenka[6] reported that in 66% of HDPE prosthesis, the shank was broken-30% at the medial and 24% at the lateral hamstring release sites and remaining 12% at various sites. In this study, the incidence was lower (45%). The lower incidence maybe due to the modification done on these weaker areas, where an additional strip of HDPE have been used to reinforce the brim.

The use of plastic or other materials, which will neither rust nor rot is important in the community, where the amputee walks through mud and wading through water is a daily occurrence.[12] Limitation of laminated prosthesis due to rain, muddy road or field was noted in this study [$p<0.001$], because of the shoe. Jaipur HDPE prosthesis is claimed to be waterproof and many amputees work in their fields, wading through water and mud.[2-4] In the present study it was observed that HDPE prosthetic shank needed metal screw to join the prosthetic foot, breakage occurred mostly though the hole drilled to fix the screw.

Weight of the HDPE prosthesis (1.2 ± 0.6 kg.) was found significantly lighter than laminated prosthesis (3.0 ± 0.4 kg) [$p<0.001$]. Weight of the HDPE prosthesis was mostly due to the Jaipur foot. Whereas, weight of the laminated prosthesis comes from the shin block and the materials (polyster resin, catalyst, accelerator, etc.) used for laminating the socket and shin block. Footwears were included in the overall weight of the laminated prosthesis, as it is an integral parts of the prosthesis. Weight of the prosthesis is an important consideration while selecting an ideal prosthesis because energy consumption is directly proportional to the

prosthetic weight and in terms of minimum gait disturbance.

65% of the patients felt that the laminated prosthesis was cosmetically inferior to HDPE prosthesis (45%). Inability or difficulties in wearing shoes over the Jaipur foot is another problem. This point is relevant because due to the change of time, some of our rural amputees need to wear shoes occasionally depending on their vocation, occupation and social roles. Heaviness was complained by 30% in laminated prosthesis against 10% in HDPE prosthesis. The weight of the laminated prosthesis was heavier than the HDPE prosthesis [$p<0.001$] which depend upon the weight of the Jaipur foot piece of variable sizes. Jaipur foot is heavier than most other prosthetic feet.[13] However the overall weight of the HDPE prosthesis is light and as such walking is possible at a faster speed and for a longer distance.[5-6]

Excessive sweating from the stumps of HDPE users while walking long distances especially in summer occurred in 20% of cases.[6] Sharma[5] in his study did not come across perspiration even during the summer season. In the present study excessive sweating was observed in 10% of patients.

Therefore while comparing the comfort of the two prostheses, no statistically significant difference was observed except for the seasonal problem [$p<0.01$].

Meanley[12] had stated that many centres are seeking to ensure that the limbs they produce are appropriate to the culture in which they are situated. In many tropical countries, barefoot walking or the use of open toe sandals is common and footwear is removed when entering a home, place of work or religious sites. Religious activities were not possible with the laminated prosthesis because of the shoe. Some patients have stated that they would rather prefer to remove the laminated prosthesis while entering a temple or while eating food on the ground because even if they could remove the shoe from the prosthetic foot with difficulties, they do not feel comfortable walking barefoot and of course, donning on the shoe afterward is also another problem. The HDPE prosthesis does not have such problems and is ideal for the amputees in the rural areas, who have to adjust to their cultural need and habit.

Conclusion

HDPE prosthesis when compared with the laminated prosthesis was found lighter, cheaper, not affected by seasonal problems and religious restriction. However, in the other important factors like cosmesis, stability, comforts, ease in performing ADL and other activities, there were no statistically significant differences between the two types of prostheses.

Therefore, HDPE BK prosthesis with Jaipur foot was found superior in terms of low cost, lower weight, with a comparable better efficacy and utility in rural setting, as compared to the laminated prosthesis with SACH foot.

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