

Comparative Study of Laminated Exoskeletal versus Modular Endoskeletal Below Knee Prostheses

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Abstract

The purpose of this study was to compare the endoskeletal modular below knee prosthesis and the exoskeletal laminated below knee prosthesis for their acceptability, durability and cost effectiveness. Forty unilateral below knee amputees between 15-55 years using laminated below knee prosthesis (n=20) and endoskeletal modular prosthesis (n=20) for more than 6 months were interviewed regarding period of gait training, architectural barriers, need for repair, stability, comfort, cosmesis, ease with activities of daily living (ADL) and patient's satisfaction. It was found that modular below knee prosthesis was superior in terms of ease of fabrication, shorter hospital stay, less expensive, stable and comfortable as compared to the laminated below knee prosthesis

Key Words – Below Knee Prosthesis Endoskeletal, Exoskeletal, Modular.

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Introduction

The word Prosthesis, the proper name for an artificial limb derives from the Greek word which means "to place an addition". The earliest reference to lower extremity prosthesis is from the Rig Veda from the period 3500-1800 B.C. It gives the account of a militant queen who lost her leg in a battle, had it replaced with iron prosthesis and subsequently returned to combat¹. The prototype of modern prosthesis was finally developed in 16th century. The most significant prosthetic design of transtibial prosthesis was introduced by the Dutch surgeon Verduyn. This became the prototype for functional transtibial prosthesis until the introduction of the patellar tendon bearing (PTB) prosthesis in 1961 by Charles Radcliffe and James Forte at the University of California at Berkeley². The fabrication of this prosthesis is cumbersome and time taking. The Patient has to stay for a long time in the hospital or make repeated visits for complete fabrication and fitting. Over the years, an endoskeleton modular prosthesis was developed. The present study was done to compare the laminated exoskeletal and the modular endoskeletal prostheses for their ease of fabrication, cost effectiveness, durability and acceptability along with functional evaluation of amputees using these prostheses.

Material and Methods

Forty unilateral below knee amputees between 15-55 years using laminated exoskeletal below knee prosthesis (n=20) and endoskeletal modular prosthesis (n=20) for more than 6 months were selected for the study. Each group consists of 17 males and 3 females. Period of study was between Jan 2003 to June 2005 in Physical Medicine and Rehabilitation Department of the Swami Vivekananda National Institute of Rehabilitation Training and Research (SVNIRTAR), Cuttack. Consent of the amputees was obtained. They were clinically examined and interviewed regarding period of gait training, architectural barriers, need of repair, stability, comfort, cosmetics, ease with ADL and patient's satisfaction after using laminated prosthesis. Fabrication, cost and weight of both the fabricated prosthesis was ascertained. Examination at the end of six months was conducted in the out patient department and workplace of the patient.

Observations and Results

The socket of the prosthesis and its interface were made up of resin³ by pouring over the positive cast. It took 2 days for complete setting. In case of modular prosthesis, socket was prepared from 12 mm polypropylene sheet over positive mold by vacuum forming technique⁴. It took on an average three hours to prepare the polypropylene socket along with top plate.

Suspension mechanism and prosthetic foot was available as raw materials for both the prostheses.

Alignment for the laminated prosthesis was done by wooden block attachment to the socket. It took three days for proper alignment. In case of modular prosthesis alignment was done by prefabricated aluminum pylon with detachable aligner.

The average fabrication time was one working day for modular prosthesis and five working days for the laminated prosthesis. Gait training period and re-alignment adjustment took approximately 15 days in case of laminated below knee prosthesis and 7 days in case of modular below knee prosthesis .

Cost of both the prostheses was calculated from the cost raw materials, cost for the fabrication and patients' expenditure to procure the prosthesis. The cost of the raw materials were calculated as the fixed rate of Rs 2910 at SVNIRTAR for both the prostheses. Average daily pay of senior qualified prosthetics (government set up) in our hospital was Rs 275/day. The average time spent in fabricating the laminated exoskeletal below knee prosthesis by prosthetics was 5 working days. The cost of Fabrication of laminated PTB prosthesis was Rs 1375. The average period of gait training in case of laminated prosthesis was 15 days. The minimum wages were Rs 70/day in our state. Therefore in case of laminated prosthesis the average wages loss to a patient was Rs 1400. In case of modular endoskeletal prosthesis the average fabrication time was one day and gait training period was 7 days. Therefore the cost of fabrication of a modular PTB prosthesis was Rs.275 and average wages loss was Rs 560. Overall cost of fabrication of below knee laminated prosthesis and modular prosthesis was worked out as Rs 5685 and Rs 3745 respectively. Administrative and manufacturing overheads were not included .

Mean weight of the exoskeletal laminated prosthesis was 1.8±0.3 kg and the endoskeletal modular prosthesis was 1.5 ± 0.2 kg.

Functional evaluation was done for all the amputees subjectively. Thirteen amputees using laminated below knee prosthesis and 15 amputees with modular below

Index	Entity	No of patients	
		laminated	modular
Duration of fabrication	1-2 days	0	40
	3-5 days	2	0
	>5 days	38	0
Period of gait training	5-10 days	8	33
	11-15 days	28	7
	16-20 days	4	0
Cost of	Raw materials	Rs2910/-	Rs2910/-
	fabrication	Rs1375/-	Rs275/-
	Patient expenditure	Rs1400/-	Rs560/-
Weight of prosthesis	1-2 kg	34	40
	2-3 kg	6	0
Durability	0-6 month	0	0
	6-12month	12	6
	12-24 month	28	34
Functional Subjective evaluation by questionnaire			
Threshold in doorway	disturbed	6	2
	undisturbed	34	38
Performing stable ADL activity	Fully stable	26	30
	Stable with walking stick	12	9
	unstable	2	1
cosmetic	acceptable	20	32
	unacceptable	20	8
problems	heaviness	12	8
	cumbersome	8	2
	Ill fitting	4	2
	pain	8	4
	Skin reaction	1	2
	none	7	22

Table 1. Key differences between the prostheses.



Fig. A. Laminated Prosthesis. B. Laminated prosthesis with alignment blocks. C. Components of modular endoskeletal Prosthesis.

knee prosthesis performed ADL activities independently and walked without any ambulatory aid. Rest of the amputees took help of a walking stick or a pair of axillary crutches for walking. Modular below knee prosthesis was cosmetically acceptable to 16 amputees where as the laminated below knee prosthesis was acceptable to 10 amputees. Difficulty in negotiating the threshold at the door way was found in 3 amputees using the laminated exoskeletal prosthesis and 1 for amputees using the endoskeletal modular below knee prosthesis respectively. There was no problem found in 4 amputee using laminated below knee prosthesis and 11 amputee using modular prosthesis. No breakage was reported for any prosthesis during their six months of usage.

Discussion

In the present study there was substantial difference in the cost of the prosthesis. Laminated prosthesis was approximately Rs. 2000 costlier than the modular prosthesis. Pithawa⁵ reported that the carbon fiber endoskeletal prosthesis costed Rs 6010 at the Artificial Limbs Center, Pune. It was nearly equal to the amount of laminated below knee prosthesis. But in our endoskeletal model by using aluminum shank, the cost of the prosthesis reduced to half of the above. The cost of the prosthesis is an important parameter in the developing country like India for acceptability of prosthesis. Sapp⁶ cited that the overall gait training time for a transtibial amputee was 44.0+-26.5 days. However, in our study the gait training period was approximately 7 - 15 days in both types of below knee prosthesis. Unlike in western countries, amputees in our study did not want to spend more time to stay in hospital, despite its importance stressed by professionals. This was probably due to the loss of wages of the patients or their care-takers while being away from work and patients wanting to return home faster and continue their training unsupervised. Most of the amputees were satisfied to use the modular below knee prosthesis due to lesser period of gait training. In our study weight of modular prosthesis was found approximately 300gm less than the laminated prosthesis. Mathur⁷ reported that the mean weight of the Jaipur prosthesis was 1.6 kg. Energy consumption is directly proportional to the weight of the prosthesis, so heavier the prosthesis, more energy is consumed in the walking and lesser distance covered in the single stretch. Stability with Prosthesis was comparable for both the Prosthesis and there was no significant difference. Cosmetics of the Prosthesis have been an important factor for its acceptability. In the present study laminated prosthesis was cosmetically unacceptable in 50% and modular prosthesis in 20% of amputees. In 1999-2000, Kiba⁸ reported that 65% of patients felt that the laminated

prosthesis was cosmetically inferior compared those patients using high density polyethylene socket prosthesis. In our study Modular below knee Prosthesis (80%) was cosmetically more acceptable due to finishing by cosmetic stockinet. The discomforts like heaviness, cumbersome, ill-fitting, skin reaction were noted among the amputee using laminated below knee prosthesis. Nielson⁹ found that 52% of their patients fitted with lower limb prosthesis were concerned about comfort. In our study the amputees using modular below knee prosthesis were more comfortable than the amputees using laminated below knee prosthesis.

Conclusion

Modular endoskeletal below knee prosthesis was superior to the exoskeletal laminated below knee prosthesis in terms of ease of fabrication, shorter hospital stay and being less expensive. It was also found that the endoskeletal modular below knee prosthesis was functionally better accepted than the exoskeletal laminated below knee prosthesis.

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