



COMPARATIVE STUDY OF MANUFACTURE COST OF LAMINATED TRANSTIBIAL PROSTHESIS AND MODULAR TRANSTIBIAL PROSTHESIS

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ABSTRACT

Aim: To compare manufacturing cost of Laminated and Modular Transtibial (TT) Prosthesis for Below Knee amputation.

Methods: A prospective randomized controlled study was conducted for 30 unilateral Transtibial (Below Knee) amputees at Government run Rehabilitation Institute, Chennai between Jan 2017 to Dec 2017. 15 were randomly assigned to Laminated and 15 to Modular TT Prosthesis group and manufacturing cost of prostheses calculated. Cost analysis included fabrication time, material costs, wages lost by patient while procuring the prosthesis and wages of prosthetist.

Results: Total cost of Modular TT Prosthesis was Rs 11550 ±275.68 compared to laminated variety Rs 10908 ±843.22 ($p=0.02$). Even though this cost difference is statistically significant, modular variety is only 1/10th costlier than laminated variety. Production time for Modular TT Prosthesis was 1 day compared to 5.8 ±0.421 days ($p<0.01$) for Laminated variety.

Conclusion: Cost of Modular TT prosthesis is not very expensive and delivered faster compared to Laminated variety, hence economically viable in a government run artificial limb center.

KEYWORDS : Amputation, Prosthesis, Cost analysis

1. INTRODUCTION

Design of modular socket system transtibial prosthesis is an approach that targets the requirements to fabricate a prosthesis within 1 day with limited required tools where the socket is produced directly on the residual limb of the patient.¹ With the introduction of endoskeletal prosthesis the prosthetic design has dramatically improved, especially considering the weight and material selection but prosthetic cost of modular socket transtibial prosthesis is significantly higher than standard laminated socket.¹ Modular socket transtibial prosthesis is widely used in developed countries. Its use in developing countries and in a rural setting has also been studied but to a lesser extent and found to be feasible in terms of performance, patient satisfaction and manufacturing time.²

It is well accepted fact that the cost effectiveness is a key criterion for decision making in health care interventions³. In many low-income countries, only 5%–15% of the people who need assistive technology can afford it.⁴ So especially in developing countries, as we shift to newer technology in prosthesis field, there is a need for cost comparison with the older technology. There are several studies done to compare cost of the Laminated and Modular TT prosthesis but no such study was done in a government run institute in Tamilnadu, India and hence the need for this present study. Further only limited studies are available in which the societal costs such as wages lost by the patient while procuring the prosthesis and wages paid to the prosthetist for fabricating the prosthesis are considered when calculating cost of the prosthesis.

2. METHODS

Thirty patients with unilateral transtibial amputation about to receive a new prosthesis were recruited to participate in this study and randomly assigned to 2 groups 15 to receive modular TT prosthesis and 15 to receive laminated TT prosthesis. The inclusion criteria were age above 20 years, occupation daily laborer and with a unilateral transtibial amputation. Exclusion criteria were patients not willing to cooperate in the study. All prosthetists and patients gave written informed consent.

2a. *Cost analysis* : Cost data was collected by recording the time (in days) and raw material cost (in rupees) used to manufacture the prosthesis. Rates of raw materials procured by the institute was collected from the store manager logging book and quantity of the raw materials used were estimated with the help of a questionnaire answered by prosthetist. We defined the cost of raw materials (in

rupees) as all material costs made during fabrication of prosthesis. Prosthetist time was defined as the total days spent for fabricating the prosthesis. The time required for fabrication was then multiplied by daily wage for a prosthetist as paid by the state government to arrive at the fabrication cost. Delivery time was defined as the number of days taken to deliver the prosthesis which was calculated from the time of initial examination until the time of final fitment and ready for use. Even though the patients get the prosthesis free of cost, being a government institute, they do incur certain indirect expenses such as due to wages lost during their stay in the hospital to get the prosthesis which was defined as expenditure met by the patient to procure a prosthesis.

2b. Statistical analysis

Time and cost data were analyzed using independent samples t-test to identify differences between the two groups and p value found using SPSS version 21 computer software.

3. RESULTS

A total of 30 subjects were analyzed, all were daily laborer with average daily wages of Rs 300 which was kept same for both the groups. Patient characteristics in the two intervention groups were not specifically divergent except for the composition of sex (Table 1).

TABLE-1 DEMOGRAPHIC CHARACTERISTICS FOR THE STUDY GROUP

Variables	Laminated TT Prosthesis (n= 15)	Modular TT Prosthesis (n= 15)
Age in years mean± SD	40.07 ±9.76	45.2 ± 8.14
Sex male/female	14/1	13/2

Calculation of cost of Prosthesis:

The cost of the two types of prosthesis were calculated separately by adding cost of prosthesis raw materials, cost of fabrication and expenditure incurred by the patient to procure the prosthesis.

3a. Cost of Laminated TT Prosthesis

Raw material cost remained the same for all patients in the same group but the fabrication cost varied for each of the patients because of the differences in the fabrication time.

3a I. Cost of raw materials included :

Ankle block-1, Socket block(puff)-1, Stockinette, Thermoset resin, Additives, Pigments, PVC film,

Lever- 1.5 sq ft, Ethaflex/puff covering, Solid Ankle Cushion Heel foot , shin piece, Leather liner, POP bandage, POP powder and Vaseline.

Cost of the above raw materials was about Rs.5600.00 which was same for all patients in the Laminated prosthesis group.

3a II. Cost of fabrication:

Cost of fabrication was determined by calculating number of days spent manufacturing the Laminated TT prosthesis multiplied by per day salary of prosthetist. Basic monthly salary of prosthetist (govt.) is Rs 9300.00 (i.e. Rs 310.00/day). Mean fabrication time was 5.8 (SD 0.421) days. Therefore, cost of fabrication of Laminated TT prosthesis is Rs. 1798 ± 130.7.

3a III. Expenditure met by patient:

Mean delivery time of the prosthesis was 11.7(SD 2.45) days. Average wages lost /day by the patient during their stay in the hospital is Rs 300. Wages lost for 11.7± 2.45 days was Rs. 3510 ±735.53 which is the expenditure met by the patient to procure a prosthesis.

Overall cost of Laminated TT prosthesis was calculated by adding cost of raw materials + cost of fabrication + expenditure incurred by the patient which is Rs 10908 ±843.22.

3b. Cost of modular TT prosthesis:

3b I. Cost of raw materials included : TT rod kit, Polypropylene sheet(12mm)- 15 sq inch, Ethaflex/puff covering, suspension, outer covering socks, Solid Ankle Cushion Heel foot and Silicon liner.

Cost of the above raw materials was about Rs 10100.00 which was same for all patients in the same group.

3b II. Cost of Fabrication:

Average time to fabricate a modular TT prosthesis was 1 day. Therefore, cost of fabrication was Rs.310.00.

3b III. Expenditure met by patient:

Mean delivery time of the prosthesis was 3.8 (SD 0.92) days, average wages lost/day was Rs.300.00 and the expenditure met by the patient was Rs 300 x 3.8 ±0.92 =Rs.1140 ±275.68.

Overall fabrication cost of a modular T.T. prosthesis was Rs 11550 ±275.68 which was more and statistically significant (p=0.02) compared to laminated variety (Table 2).

Table-2. Economic Variables Of Prosthesis Manufacture

Variables	Laminated TT Prosthesis	Modular TT Prosthesis	p value
Fabrication time	5.8 ±0.421 days	1 day	0.001
Fabrication cost	Rs 1798± 130.7	Rs 310	0.001
Delivery time	11.7± 2.45 days	3.8 ±0.92 days	0.001
Patient expenditure	Rs 3510± 735.53	Rs 1140 ±275.68	0.01
Total cost	Rs 10908 ±843.22	Rs 11550 ±275.68	0.02

Note: Values are group mean ± SD. p values correspond to the t test comparing both groups.

4. DISCUSSION

In our study cost of raw materials was significantly higher in the modular prosthesis group costing Rs 10100.00 compared to Rs 5600.00 for the laminated variety which is similar to other studies.⁵ All modular TT prosthesis were manufactured in 1 day and the average delivery time was 3.8 ±0.92 days which was statistically significant (p<0.01) compared to the fabrication time of 5.8 ±0.421 days and delivery time of 11.7± 2.45 days for the laminated variety which is consistent with studies done even in western countries.^{1,5,6}

When analyzing the total cost, modular T.T. prosthesis was expensive costing Rs 11550 ±275.68 (p=0.02) compared to laminated variety costing Rs 10908 ±843.22 (Table 2). Even though this cost difference is statistically significant modular variety is only one tenth more costly than laminated variety. This is due to the less time required to fabricate and deliver the modular prosthesis which lowered the cost of fabrication as well as the expenditure met by the patient in spite of higher cost of raw materials utilized. T. B. Straats⁷ has stated that in developing countries, only limited financial or personal resources are available for amputee rehabilitation. In most of the western studies, expenditure met by the patient is not taken into consideration when calculating the cost of the prosthesis¹ but in our patient population this

is an important factor as evidenced in our study.

H.J.B. Dey⁸ cited that cost of prosthesis have to be divided into two parts, the actual cost of the prosthesis and the cost of transport and accommodation expenses of the patient at the prosthesis fitting centre. He further stated that there is lack of standardization in calculating the prosthesis cost and observed that the cost of transport and accommodation expenses of the patient may be as great as or greater than the prosthesis cost. According to Ennion L even though modular T.T. prosthesis is more costly than the traditional laminated variety, because of the less fabrication time it is suitable in rural areas also where there is limited number of prosthetists.⁹

5. CONCLUSION

Except for the prohibitive cost of raw materials for Modular TT prosthesis, it has various advantages over Laminated TT prosthesis which has already been established such as it is easy to manufacture, superior patient satisfaction,¹¹ less fabrication time, alignment can be done even after final finishing and components are available in prefabricated form except for the socket.¹⁰ From this study we have found that the cost of Modular TT prosthesis is not very expensive compared to Laminated TT prosthesis and hence we conclude that given its advantages Modular TT prosthesis is economically viable even in a government run artificial limb center.

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