

Comparative Study of User Satisfaction between Modular Transtibial and Laminated Transtibial Prosthesis

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ABSTRACT

BACKGROUND

Primary goal of amputee rehabilitation is restoring functional mobility and secondary goal is optimizing the person's quality of life and patient satisfaction with the prosthesis. The aim of this study was to analyse the two commonly used prosthesis namely the Laminated Exoskeletal Transtibial (TT) Prosthesis and the Modular Transtibial Prosthesis in terms of patient satisfaction with their prosthesis and also to identify the demographic profile in the study group.

METHODS

This is a cross-sectional questionnaire study conducted in the rehabilitation research department of a university hospital. Thirty unilateral transtibial amputees of whom fifteen using Laminated TT Prosthesis and fifteen using Modular TT Prosthesis for more than 1 year were selected for the study. Unpaired T test was used, and p value determined in the two groups for Trinity Amputation and Prosthesis Experience Scale Revised (TAPES-R) Aesthetic and Functional subscales using SPSS version 21 computer software.

RESULTS

66.7% of subjects in the modular prosthesis group were very satisfied with the appearance of the prosthesis compared to only 20% in the laminated prosthesis group and had a statistically significant p value (0.001). 46.7% in the laminated prosthesis group were not satisfied with the weight of the prosthesis as compared to none in the modular prosthesis group which was statistically significant (p value <0.05). The mean overall score in aesthetic subscale and functional subscale for modular prosthesis group was 2.49 ± 0.25 and 2.27 ± 0.34 respectively compared to 1.87 ± 0.07 and 2.01 ± 0.26 for the laminated prosthesis group which was statistically significant (p value <0.05).

CONCLUSIONS

Modular prosthesis is by far superior in terms of patient satisfaction of prosthesis weight and aesthetic appeal.

KEYWORDS

Amputation, Prosthesis, Transtibial, Satisfaction

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BACKGROUND

One of the most important factors which helps people with disabilities to integrate back in society is their accessibility to assistive technology. Prostheses and orthoses make up the majority of the devices which are required by people with physical disabilities.¹ Restoring functional mobility following lower limb amputation is generally considered a primary goal of amputee rehabilitation process.^{2,3} In addition to the restoration of functional mobility, secondary goal of optimizing the person's quality of life and patient satisfaction with the prosthesis also has to be given importance. It has also been reported that satisfaction with the prosthesis plays a key role in achieving the primary goal of regaining mobility in persons with amputation and thereby preventing their rejection of prosthesis.^{4,5}

In Laminated Transtibial Prosthesis, walls of prosthesis provide shape to the shank piece of the prosthesis which perform the weight bearing function and is usually heavy. In Modular Transtibial Prosthesis a tube frame construction provides the weight bearing function. A flexible cosmetic foam cover provides the outer shape. There are many outcome measures available to measure quality of life and general satisfaction, and many of these are more detailed and informative than Trinity Amputation and Prosthesis Experience Scale Revised (TAPES-R) questions. However, these instruments require considerable time to administer compared to the TAPES-R and thereby would decrease the administration rates of the outcome measure.

Although several studies have been conducted to determine user satisfaction with prosthesis, not many are available comparing Laminated Transtibial Prosthesis and Modular Transtibial Prosthesis. With this background, the current study was undertaken to find the satisfaction level with their prosthesis and comparison performed between the two groups namely the Laminated Transtibial Prosthesis and Modular Transtibial Prosthesis.

METHODS

30 Transtibial amputees of which 15 using Laminated Transtibial Prosthesis and 15 using Modular Transtibial Prosthesis for more than 1 year attending Government run Rehabilitation department, Chennai were selected for the study which was conducted between Jan 2018 to Dec 2018. Inclusion criteria were persons having a unilateral transtibial amputation, age between 20- 60 years, using either Laminated or Modular Transtibial Prosthesis for more than 1 year, willingness to cooperate in the study. Exclusion criteria were persons without prosthesis.

All subjects had a general health checkup and were explained about the harmlessness and non-invasiveness of the study. A case history format, questionnaire as per published TAPES-R (revised Trinity Amputation and Prosthesis Experience Scale) and consent form was filled for each of the selected cases. Since most subjects were non-English speaking, questionnaire was interviewer-

administered by prosthetists who were fluent in both English and the local language that the participants speak. Answers were also translated back to English. Ethics: The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975 that was revised in 2000. (http://www.wma.net/e/policy/17-c_e.html.)

Outcome Measure

Subject's satisfaction with the prosthesis was assessed by Trinity Amputation and Prosthesis Experience Scale Revised (TAPES-R)⁶ which is widely used to evaluate the effects on Transtibial amputees' prosthesis-related quality of life and its reliability and validity have previously been assessed and approved. The TAPES-R is a multidimensional assessment designed to facilitate examination of the psychosocial processes involved in adjusting to a prosthesis and the specific demands of wearing a prosthesis. The revised TAPES (TAPES-R) incorporated a Rasch analysis across several data sets to further strengthen its psychometric properties. The TAPES-R comprises a Psychosocial Scale with subscales consisting of five items each (general Adjustment, Social Adjustment, and Adjustment to Limitation). The second section consists of an Activity Restriction Scale incorporating 10 items. The third section concerns Satisfaction with the Prosthesis scale and comprises 8 items, which are subdivided into two scales, the Aesthetic and Functional characteristics of the prosthesis. The fourth section explores the experience of phantom limb pain, residual limb pain, and other medical conditions not related to the amputation. Each of the scales can be used individually. In this study we have administered and analysed the satisfaction with prosthesis scale. It consists of 3 questions in aesthetic subscale and 5 questions in functional subscale with a total of eight questions. It is rated by three-point scale (not satisfied, satisfied, and very satisfied). A higher score indicates higher level of satisfaction.

Statistical Methods

The TAPES-R scores for each subscale were summarized using descriptive statistics of mean, standard deviation, and percentages as appropriate. Statistical analysis performed using SPSS version 21 and p value calculated with unpaired T test and comparison performed between Laminated and Modular Transtibial Prosthesis groups. p value <0.05 was considered significant.

RESULTS

A total of 30 subjects were analysed. In our study group majority (i.e.) 63.4% (19 subjects) were daily laborers, followed by students 20% (06 subjects), unemployed 10% (03 subjects) and agriculturists 6.6% (02 subjects). The cause of amputation in 76.7% (23 subjects) was traumatic due to train and road traffic accidents, in 16.7% (05

subjects) due to peripheral vascular disease and osteomyelitis in 6.6% (02 subjects). Demographic characteristics for subjects using Laminated (n= 15) and Modular (n= 15) prosthesis is shown in Table 1.

| Variables | Laminated Prosthesis | Modular Prosthesis |
|----------------------|----------------------|--------------------|
| Age (yrs.) mean ± SD | 43.27 ± 12.03 | 40.6 ± 12.84 |
| Sex male/female | 12/3 | 13/2 |

Table 1. Demographic Characteristics of the Study Group

| TAPES-R Subscale | Modular Prosthesis (Mean ± SD) | Laminated Prosthesis (Mean ± SD) | p |
|-------------------|--------------------------------|----------------------------------|-------|
| Aesthetic | | | |
| Colour | 2.6 ± 0.51 | 1.93 ± 0.7 | 0.003 |
| Shape | 2.2 ± 0.56 | 1.87 ± 0.52 | NS |
| Appearance | 2.67 ± 0.46 | 1.8 ± 0.78 | 0.005 |
| Overall score | 2.49 ± 0.25 | 1.87 ± 0.7 | 0.001 |
| Functional | | | |
| Weight | 2.53 ± 0.52 | 1.67 ± 0.72 | 0.004 |
| Use | 2.27 ± 0.46 | 2 ± 0.53 | NS |
| Reliable | 1.73 ± 0.46 | 2.26 ± 0.7 | NS |
| Fit | 2.2 ± 0.77 | 1.8 ± 0.52 | NS |
| Comfort | 2.6 ± 0.51 | 2.27 ± 0.59 | NS |
| Overall Score | 2.27 ± 0.36 | 2.01 ± 0.26 | 0.007 |

Table 2. Comparison of Statistical Values between Modular and Laminated Prosthesis Group

TAPES-R Aesthetic Subscale

This subscale consists of 3 items, which are colour, appearance and shape of prosthesis. 60% of subjects in the modular prosthesis group were very satisfied with the colour of the prosthesis compared to only 20% in the laminated prosthesis group which was statistically significant. (p value = 0.003). 66.7% of subjects in the modular prosthesis group were very satisfied with the appearance of the prosthesis compared to only 20% in the laminated prosthesis group which again was statically significant. (p value = 0.001). As for the question regarding satisfaction with the shape of the prosthesis there was no significant statistical difference between the two groups. The mean overall score in Aesthetic subscale for modular prosthesis group was 2.49 ± 0.25 compared to 1.87 ± 0.07 for the laminated prosthesis group which was statistically significant. (p value = 0.001)

TAPES-R Functional Subscale

This subscale consists of 5 items, which are weight, usefulness, reliability, fit and comfort of the prosthesis 53.3% of subjects in the modular prosthesis group were very satisfied with the weight of the prosthesis as compared to only 13.3% in the laminated prosthesis group which was statically significant. (p value = 0.0004). 46.7% in the laminated prosthesis group considered that they are not satisfied with the weight of the prosthesis which meant that their prosthesis was heavy. On comparison none of the patients in the modular prosthesis group answered 'not satisfied' for this question which meant that their prosthesis was of optimal weight. 26.7% of subjects in the modular prosthesis group considered that their prosthesis is not reliable compared to only 13.3% in the laminated group which was statically significant. (p value = 0.01). The probable reason could be their frequent visits to the prosthetist for either alteration in the alignment of components or damage of the outer flexible cosmetic cover over the prosthesis. As for the questions regarding

satisfaction with the use, fit and comfort of the prosthesis there was no significant statistical difference between the two groups. The mean overall score in Functional subscale for modular prosthesis group was 2.27 ± 0.34 compared to 2.01 ± 0.26 for the laminated prosthesis group which was statistically significant. (p value = 0.007). Summary of statistical values of the two groups is shown in table 2.

DISCUSSION

While prosthetic rehabilitation has traditionally placed large emphasis on improving and maximizing mobility, more recently rehabilitation has started to focus on both the quality of life and general satisfaction of the affected individuals.⁷ Meanley S in 1995 had stated that the major objective of lower limb prosthesis is to restore the amputee to his original functional capacity as possible.⁸ The objective of this study was to analyse the satisfaction level of our subjects with their prosthesis and comparison performed between the two types namely the modular and laminated transtibial prosthesis and we were able to come to few important conclusions.

There is evidence in the literature that 40% to 60% of amputee patients are not satisfied with their prostheses and fifty-seven percent are dissatisfied with the comfort of their prostheses.^{9,10} The aesthetics of a prosthetic limb is important to amputees and can influence their acceptance of the prosthesis.¹¹⁻¹³ Therefore, improving prosthesis aesthetics may have a positive impact on an individual's body image and thereby enhance their psychological well-being. Prosthesis aesthetics are intrinsically linked to the cosmetic cover fitted over the mechanical limb. Harness and Pinzur found a positive association between overall satisfaction and appearance of the prosthesis.¹⁴ Several literature studies agree that prosthesis weight was the most important aspect for patient satisfaction and that patients were satisfied with the weight of modular prosthesis than with the laminated variety. Many researchers have shown that light weight transtibial prosthesis has reduced the energy consumption but also indicated the deviations in the gait parameters of the amputees.¹⁵ Modular prosthesis weigh lighter than laminated prosthesis hence has a higher satisfaction score than the laminated prosthesis and that was observed in our study also.

These findings are further substantiated in our study in which 53.3% of subjects in the modular prosthesis group were very satisfied with the weight of the prosthesis as compared to only 13.3% in the laminated prosthesis group. However, satisfaction levels were similar for all other features, including the use, fit and comfort of the prosthesis. This evidence is interesting given that the modular prosthesis aims to achieve a high-quality fit and comfort. An explanation for this variation could be satisfaction level with prosthesis use differs with activities performed. A person might be perfectly satisfied with the prosthesis while sitting but dissatisfied with the same prosthesis while walking on

uneven terrain and thus, satisfaction is also related to the kind of activity a person wants to do.¹⁴

Yet, the findings suggest that our subjects using laminated prosthesis have similar satisfaction levels as the more expensive modular prosthesis which is similar to the study by Selles RW, et al.¹⁶

CONCLUSIONS

Modular prosthesis is by far superior in terms patient satisfaction with regard to weight of the prosthesis and aesthetic appeal. Feedback from amputees about their satisfaction with the aesthetic and functional aspects of prostheses is valuable. Low satisfaction scores on appearance of the prosthesis indicate that there is a need for considerable improvement in prosthetic design which would have a significant impact on the future cosmesis research. At the same time, we must understand that satisfaction is a subjective evaluation influenced by several factors that might change and vary over time. Our ultimate objective with this study was to increase the awareness regarding the amputee rehabilitation programs to include such feedback responses from amputees that will go in a long way in ensuring their compliance with the prosthesis.

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