Comparison of Balance in Unilateral Transtibial Amputees Using Exoskeletal Prosthesis with Solid Ankle Foot with Two Different Cushion Variants

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ABSTRACT

Background: The process of rehabilitation is to restore function and to regain an acceptable level of functioning and social participation. In case of amputation, to reach this goal, prosthesis is used to compensate for the functional loss. Prosthetic feet are devices designed to replace one or more function of the biological human ankle-foot system. The prosthetic feet may influence the mechanics of gait, energy expenditure and balance.

Methods: 30 eligible subjects were included in the study as per random sampling. In group 1 subject with unilateral transtibial amputation were provided exoskeletal transtibial prosthesis having PTB socket with solid ankle foot with polyurethane cushion and cuff suspension, and in group 2 transtibial amputees were provided exoskeletal transtibial prosthesis having PTB socket with solid ankle foot with rubberized cushion and cuff suspension.

Results: The result of the present study shows there is no statistically significant difference between the two groups i.e. polyurethane cushion foot and rubberized cushion foot in terms balance. Balance in case of polyurethane cushion is higher than rubberized cushion. In results it was found that the comparisons were not significant for both the groups. (p>0.05)

Conclusions: This study concluded that although both the feet are reconcilable to the person with unilateral transtibial amputation but solid ankle foot with polyurethane cushion shows more effectiveness than solid ankle foot with rubberized cushion in terms of balance.

Keywords: Transtibial amputee, Exoskeletal Prosthesis, Traumatic amputation, Balance, Polyurethane cushion, Rubberized cushion.

INTRODUCTION

Amputation is the removal of whole or part of the limb. Lower extremity amputation is the most common amputation surgery. Limb amputation can be considered as both a life-saving procedure and a life changing event. According to World Health Organization, India has the highest number of road accidents in the world with 16.8 fatal injuries per 100,000 population and 38.9 non-fatal injuries per 100,000 populations as per the data from 2006. According to a survey on 1983, every year 23,500 amputees are added to the amputee population in India, of which 20,200 are males and 3,300 are females. Trauma was the leading cause of amputation in all age groups except for those in their 60s. In fact, in each of the younger groups from the teens to the 30s, amputation due to trauma accounted for more than 70% of all amputations.
The main purpose of the rehabilitation process is to restore function and to regain an acceptable level of functioning and participation. To reach this goal, prosthesis is used to compensate for the functional losses. [5, 6] Prosthetic rehabilitation in adults with lower limb amputation depends on different factors like amputation level, anatomic and functional condition of the amputated limb, weight, activity level, quality of prosthetic appliances and cardiorespiratory function. [7, 8]

The aim of providing a prosthetic foot is to maximize every patient’s rehabilitation potential so that they may return to their daily activities and work at a level comparable to their peers. Ideally, the function of a prosthetic foot should match that of an anatomical human foot. [9]

Balance plays an important role in transtibial amputee to do all ADL activities. For measuring balance there are a no of scales available. Berg balance scale is one of the important scale that is basically used in case of lower limb amputees. Lack of balance in case of lower limb amputations may lead to fall. Falls pose a significant risk to persons with lower-limb amputation (LLA) during and after the rehabilitation process. The Berg Balance Scale (BBS) is composed of 14 functional tasks, each of them ranking 0–4; the maximum total score of the index is 56. Major et al. demonstrated the high BBS validity and reliability for assessing balance in lower limb amputees. [10]

**MATERIALS AND METHODS**

Study was conducted on case to case basis of 30 participants unilateral transtibial amputee population attending outpatient, Inpatient Rehabilitation ward of N.I.L.D, Kolkata. All the subjects were selected based on inclusion criteria like age between 20-50 years, only traumatic amputees, stump length 40 to 60 percentage of normal limb etc, then allocated into two groups of 15 each according to random sampling of chit picking method. Transtibial subjects with solid ankle foot with polyurethane cushion were allocated in group 1 and Transtibial subjects with solid ankle foot with rubberized cushion were allocated in group 2.

Firstly, the participants were assessed and evaluated. The demographic data like age, gender, side of amputation, height and weight was taken. Most of the subjects participating in the study were using the prosthesis second time or more. In group “1” the subjects with unilateral transtibial amputation were provided exoskeletal transtibial prosthesis (Figure 1) having PTB socket with solid ankle foot with polyurethane cushion and leather cuff suspension and In group “2” the subjects with transtibial amputation were provided exoskeletal transtibial prosthesis (Figure 2) having PTB socket with solid ankle foot with rubberized cushion and leather cuff suspension. After the fitment of prosthesis, training for donning & doffing and a course of gait training for four week was given. After completion of gait training, Berg Balance Scale test was done (Fig 3 and 4). Comparison was done in between two groups. Finally patient was discharged from the department with advice of care and maintenance of final finished prosthesis.

**Statistical Analysis**

Data analysis was performed in SPSS version 21.0. The data were explored using appropriate descriptive and graphic techniques. Each data set was examined for a normal distribution prior to conducting any inferential analysis. Test of normality was done by using Shapiro Wilk test, which revealed data were normally distributed (p>0.05). Statistically Mann-Whitney U test was used to analyze the balance between transtibial amputee with solid ankle foot with polyurethane cushion and rubberized cushion. Statistical significance was taken at p≤0.05 with 95% confidence interval.
Comparison of balance in unilateral transtibial amputees using exoskeletal prosthesis with solid ankle foot with two different cushion variants

Demographic Details

Thirty subjects were evaluated for the study. In group 1 - 15 transtibial (9 male and 6 female) subjects with solid ankle foot with polyurethane cushion and in group 2 - 15 (8 male and 7 female) transtibial subjects with solid ankle foot with rubberized cushion age range from 21 to 50 years. Their heights, weight, side of amputation were recorded. Table 1 represents the mean and standard deviation of these scores. There was no drop out during the study. Data were collected after the completion of gait training session.

Table 1: Result of demographic data of group 1 and group 2

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Age (mean ± SD)</th>
<th>Height (mean ± SD)</th>
<th>Weight (mean ± SD)</th>
<th>Sex In %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>30.93 ± 3.84</td>
<td>161.62 ± 6.23</td>
<td>60.26 ± 4.04</td>
<td>male 60 / female 40</td>
</tr>
<tr>
<td>Group 2</td>
<td>32.33 ± 3.88</td>
<td>161.53 ± 7.88</td>
<td>58.4 ± 2.89</td>
<td>male 53 / female 47</td>
</tr>
</tbody>
</table>
RESULT

Data for Balance by Berg Balance Scale after completion of 4 weeks of intervention in Group 1 and Group 2 are given in Table 2 that represented graphically. The variable balance was compared using Mann Whitney U test. Data shows there is no significant difference between two groups. (p>0.05, Z= - 1.326)

Table 2: Comparison of Balance between Group 1 and Group 2

<table>
<thead>
<tr>
<th></th>
<th>BBS Score Mean ± SD</th>
<th>Z-value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>52.20 ± 2.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2</td>
<td>51.33 ± 1.71</td>
<td>-1.326</td>
<td>0.185</td>
</tr>
</tbody>
</table>

From above Graph it signifies the difference in Balance between unilateral transtibial amputee with solid ankle foot with polyurethane cushion and rubberized cushion. It showed that Balance for unilateral transtibial amputee with solid ankle foot with polyurethane cushion 2% higher than rubberized cushion.

DISCUSSION

Most of the previous studies explain and show effect of various types of endoskeletal prosthesis on metabolic process. [11,12] But in developing countries as India the patients are from rural area and low economic group. They are generally fitted with low cost exoskeletal prostheses. Limited number of studies and data are available to show the balance of amputee using exoskeletal prosthesis. So it was required to study on effect of different prosthetic feet on exoskeletal prosthesis on balance that will help the clinician to select the component like proper prosthetic feet and improve the quality of life of amputee in developing countries. Balance is also an important factor to determine the type of prosthetic foot. The result of the present study shows there is no statistically significant difference in balance in transtibial subjects using exoskeletal transtibial prosthesis with solid ankle foot with two different cushion variants. The average Balance of transtibial subjects with solid ankle foot with polyurethane cushion is 2% higher than solid ankle foot with rubberized cushion. The mean values of Balance in solid ankle foot with rubberized cushion have (51.33 ± 1.71) and the mean values of Balance in solid ankle foot with polyurethane cushion have (52.20 ± 2.14).

The findings of the present studies are in the agreement with the study of Nooranida Arifin et al in which 10 male unilateral below-knee amputees were taken and they were fitted with three prosthetic feet that were SACH, a single-axis foot, energy-saving and return (ESAR) foot Talux. The Berg Balance Score (BBS) for the amputees came 52.9± 4.9 which showed no statistical difference between the groups. [13] But this study contradicts with the study of Fracesco Paradisi et al in which they fitted two types of feet that were SACH and 1M10 (a multiaxial foot) and the result of the study was statistically significant in BBS score. [14] The result was probably due to the multi axial foot where as in the present study the prosthetic ankle is solid and there was no difference in balance between the groups. However the balance in case of solid ankle foot with polyurethane cushion is more as compared to rubberized cushion because of the superior load bearing capacity of the material which leads to greater balance.

CONCLUSION

This study concludes that although both the feet are reconcilable to the person with unilateral transtibial amputees, Solid ankle foot with polyurethane cushion is marginally more effective in maintaining
balance as compared to solid ankle foot with rubberized cushion. Thus it can be concluded that the solid ankle foot with polyurethane cushion is marginally better than solid ankle foot with rubberized cushion.

**Conflict Of Interest**

The author does not have any conflict of interest regarding research, authorship and publication of this article.

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