Prospective comparative study for the evaluation of prosthetic rehabilitation users with transtibial amputation

Abstract  Individuals with transtibial amputations have difficulties in performing march and stay in balance, directly affecting their quality of life. The use of prostheses can enable the rehabilitation of the individual, but we question how effective are for certain tasks and how they can still improve. To evaluate the prosthesis for transtibial amputation, a comparative study was conducted with two groups: Amputee and NOT Amputees. With the help of Motion Capture technology was held measuring the angles of static balance, walking speed and scores in the execution of daily activities. The results indicate that dispersions of larger static equilibrium angles belonging to the group amputees. In terms of average speed march and in scores of Daily Activities, there was better performance for the group of NOT amputees. From this it was also identified that the technical characteristics of transtibial prosthetic could impact rehabilitation of its members.

Key words  Prostheses, March, Technology, Motion capture
Introduction

Face with the need for correction, rehabilitation or modification of the structure or function of the human body for health purposes, are used products called medical devices. In addition, these can be used for the monitoring, diagnosis or therapy of disease.

In the scope of ergonomics, it is contemplated assistive technologies referring to any device that assists people with intellectual and developmental disabilities to perform daily activities; compensate their functional limitations; provide opportunities for learning, independence, mobility, cooperation, or communication; reduce the risk of secondary diseases; allow health professionals easily provide assistance; and avoid the need for nursing home care.

Nowadays the rehabilitation assistive technologies offer a wide range of services and medical products to promote health patients. The focus of the investigations of this research are the products used for the rehabilitation of amputees: the prostheses. To do so, we review the literature relating health problems with prosthesis when instructions for use it were made. Also, it was researched methods and tools to evaluate the ergonomy of these products by looking at the needs of amputees users and evaluating how the prostheses fulfill their function in terms of efficiency or performance.

Amputation, in general, is a traumatic process for any individual. Since the prosthesis is an artifact whose function psychologically and socially stabilize the amputee individual stand at a critical moment of his life. It is salutary that for an individual to make use of a prosthesis happen a process of rehabilitation and readaptation. And these processes favor of individual independence, promoting a balanced gait and performing daily activities with quality, reinserting it into the social life.

For an individual to gait is one of the factors that can be used to evaluate the balance, which in its broadest sense includes the capability to control the erect posture under a variety of conditions and situations, well as the capacity of this individual perceiving their stability limitations.

To maintain this balance, it is necessary integrity of the anatomical and functional elements, which comprise the vestibular system, vision, nerve centers, proprioceptive system and the musculoskeletal system. In order to maintain the balance of amputees, prostheses are products that seek to return the amputee integrity of the
Hypothesis 2: Rehabilitation of transtibial amputees followed by physiotherapy promotes functional health, considering the performance of the prostheses in terms of gait speed, angular variation of balance and daily activities.

Methods

This research was conducted as a prospective comparative data study, using a control group consisting of healthy people who do not need orthotics or prosthetics, and groups with users of prosthetics, divided as follows:

Control Group: Healthy individuals, NOT amputated and not using orthotics;

Group A: Amputees using transtibial prosthetics (below the knee).

In order to enter the Control group, individuals had to meet the following inclusion criteria: Ages ranging between 18 and 65 years; No pathology or recent pain in legs, arms, back and/or ribs; No musculoskeletal changes disabling orthostatism maintenance; No discrepancy of more than 1 cm between each lower limb; No hypertension.

In order to enter the Group A, individuals had to necessarily meet the following inclusion criteria: Ages ranging between 18 and 65 years; Well adapted to prosthetic or orthotic device (excluded if feeling pain or discomfort); Using prosthetics or orthotics between 1.5 and 5 years; Not musculoskeletal changes disabling orthostatism maintenance.

Once in a group, individuals were informed of the aims and procedures of the study, and requested to read and sign the Statement of Informed Consent to participate in the study, if so they wished.

Then, volunteers were weighed using a scale certified by the Brazilian institute of metrology, quality, and technology (Instituto Nacional de Metrologia, Qualidade e Tecnologia - INMETRO), their height was measured, and they filled identification and evaluation forms.

Each volunteer was invited to laboratory, where a Motion Capture System unit performed the balance measurement tests.

The team involved in conducting investigations and tests consists of researchers with multidisciplinary backgrounds and skills, covering areas such as Biomedical Engineering, Mechanical Engineering, Design, Physical Therapy, and Medicine. This setting comprises intellectual and operational skills necessary to obtain relevant findings for performance measurements of assistive technologies.

Instrumentation and Procedures

For categorize the performance of assistive rehabilitation technologies as prosthetics, the balance and gait of users will be measured according to procedures detailed in sequence.

Procedure A: Adapted Romberg test

This widely used procedure in scientific research is effective as a method to assess risk of falling. The Romberg Test is conducted with participants instructed to stand with their feet together and eyes closed for 1 minute. The adaptation made can be justified by results obtained by Presumido et al., who have demonstrated major oscillations in the first 30 seconds. The Motion Capture system will point out moments of great trunk oscillation, as well as quantify angles from the initial position (with eyes closed) and the moments of major oscillation, for comparison between individuals.

The Motion Capture system will provide the following data: Angle at the moment of Major Anterior Oscillation (MAO); Angle at the moment of Major Posterior Oscillation (MPO); Angle at the moment of Major lateral Oscillation to the Right (MOR); Angle at the moment of Major lateral Oscillation to the Left (MOL).

Procedure B: Berg Balance Scale Test

Procedure B comprises asking participants to perform everyday life tasks. Fourteen activities can be scored from zero to four points, with a maximum fifty six points. If participants score forty five points or less, it is considered that they have suffered balance change; a score of thirty six points or less indicates risk very close to 100% of falling.

The test is simple to perform; it takes approximately 15 minutes and also allows researchers to monitor the evaluation of older patients. It also has a high test-retest objectivity (ICC = 0.98), good reliability (0.96), and it is well established, correlated with other tests of balance and mobility, including the Tinetti Mobility Index (0.91) and the Test to Arise and Walk (0.76).
Procedure C: Tinetti Gait and Balance Test

The Tinetti Gait and Balance Test consists of two parts. The first has 9 aspects of static equilibrium scoring 0-16 points – 0 indicating poor balance, and 16 a good balance control. The second part of the test assesses 7 aspects of gait, initially with a walk with normal steps and then with quicker steps, scoring 0-12 – 0 meaning the inability to walk or perform any of the gait patterns performed, and 12 indicating an adequate standard of gait\textsuperscript{22}.

In this study, the Berg Balance Scale was used to measure static balance. Thus, the second part of the Tinetti Test is applied in order to compose a sample base of evidence for the healthy population and for users of prosthetics. With this data, it will be possible to achieve performance levels of assistive technologies in rehabilitation.

The Tinetti Gait Test aided by the Motion Capture system will provide the following data: (1) Gait speed in meters per second (m/s); (2) Cadence in steps per minute (step/m); (3) Step Size in meters (m); (4) Overall test score.

It is important to note that participants of the Control group have performed the tests with their bare feet; participants in Groups A have performed the tests using their prosthetics and unique shoes for prosthetic alignment during all procedures.

Additionally, the collection balance data and gait of all participants has been obtained through the Motion Capture System. After collecting data from the greatest possible number of participants, all parameters have been tabulated and processed by statistical models in order to identify balance and gait patterns. These will enable categorizing the performance of medical devices used by people with needs of rehabilitation or functional correctness.

Motion Capture System

The Motion Capture System is a means of providing three-dimensional coordinates of an object from a set of two-dimensional images captured by a set of cameras arranged around the captured actor\textsuperscript{23}. Primarily created for applications in Medicine, the Optical Motion Capture system consists of a set of at least 4 cameras controlled by a computer. Actors or objects having movements captured have markers fixed on their bodies which can be either opaque (passives) or reflective (active)\textsuperscript{10}.

At least 2 cameras must be used to capture the signal of an active or passive marker by the Optical Motion Capture System. However, it is recommended that each marker is visible for at least 3 cameras for greater accuracy\textsuperscript{10}.

The Motion Capture System used in this study is an optical system with passive markers and fourteen cameras. This camera has technical specifications allowing motion capture with real-time feedback. Each camera has 4.0 Megapixel resolution, recording up to 515 Frames Per Second (FPS) at full resolution. This model is also equipped with infrared vision, solving any lighting problem and ensuring data reliability\textsuperscript{24}.

In addition to the cameras, the system has two core Giganet units and a PC with the Blade Software installed. The Giganet devices are responsible for receiving and processing data from the cameras and sending it to the PC. Each Giganet can receive information from up to ten cameras simultaneously and send it to the PC\textsuperscript{24}.

Before using the Motion Capture System, calibrations are done in a sequence of two steps to take before capture in order to ensure data reliability. The first step is to calibrate the volume or dynamic calibration that checks camera coordinates with the help of a calibration device with markers attached to a fixed distance and known by the system. The calibration device is moved in the air to calibrate and adjust camera and lens settings. The second step of calibration is called source or static calibration, made to ensure that the X, Y, and Z axes of the capture environment are correctly determined\textsuperscript{10}.

The procedure of marker placement on volunteers follows a well-defined method called marker setting (Figure 1a), guided by the anatomical structure of participants\textsuperscript{10} and markers are allocated in the same bones and joints for each volunteer.

Data generation in the Optical Motion Capture System is made through a set of actions: the cameras capture image in black and white, reflecting light from the markers attached to the body of participants. Each camera sends two-dimensional information to the Giganet core units. They use images and coordinates of each camera and triangulate marker coordinates with data from different cameras.

This is necessary to identify positions in three-dimensional coordinates, linking markers that move in space, and thus calculate rotation of joints\textsuperscript{10,23}. Interpretation of coordinates is performed by the Blade software, reconstructing a
simplified human skeleton (Figure 1b) with the size proportions of the participant and allowing for data extraction and comparison of each individual.

**Data Treatment**

The focus of the investigation was to verify the hypotheses 1 and 2 produced and also build a database for the establishment of standards for transfibial prosthesis performance. For this, were applied to groups of Amputees and NOT Amputees the Adapted Romberg test, Berg Balance Scale and Tinetti Gait.

Regarding the application of adapted Romberg test were obtained at the time of angles bigger oscillation back, posterior, lateral right and lateral to the left of the trunk. These parameters have been extracted from the motion capture system which has implantable markers on the body of the participant, able to logically reconstruct the human skeleton. The observed time was two minutes.

The virtual human skeletal structure obtained contains several representative points of the bone joints. Specifically for the measurement of angles mentioned it was assumed to be representative point the CHEST Delivering trunk rotation angles of the axis x, y and z. The x-axis in the negative polarity is the anterior trunk oscillation. The same axis in the positive polarity results in posterior oscillation. Regarding the y axis can be obtained in a negative polarity right side oscillation, by reversing the polarity is obtained left side oscillation. The z-axis is represented twisting of the trunk.

For the Berg Balance Test participants perform fourteen simple daily tasks, such as getting up from a chair and pick up an object on the ground. Each task was scored from zero to four points, with zero for task not completed and four task performed completely. Intermediate values correspond to the participant’s level of difficulty to accomplish the proposed activity. The total score in the implementation of all activities varies between zero and fifty-six.

In Tinetti Gait and Balance Test were measured several parameters that allowed us to verify gait efficiency of the participants. In this configuration it was possible to compare the average speed of gait between transfibial amputees and NOT amputees.

In tabulation of data obtained by applying the methodological procedures balance assessment (procedures A, B and C) were employed valid statistical methods to the type of samples reached. The main relevance of the statistical processing is to test the capability to extrapolate the test results to other populations beyond the investigated samples. For example, averages with deviations of gait speed patterns, rotation angles, time to accomplish a task, among other parameters of samples of amputees and NOT amputees. So to estimate the performance of the tested prostheses, and therefore the scope of the rehabilitation of existing and future users of the assistive technologies.

**Results**

**Participation rates**

For the overall study, 58 people were invited to participate and 28 provided informed consent for a participation rate of 48.28%. Study participant demographic and epidemiological characteristics have been described previously: the mean age amputated and NOT amputated was 43.73 and 26.89, respectively; 68% of the participants were male. Table 1 presents the breakdown by group for those who participated. The sample size for the control group was n=14 and amputated group n = 14. There was no significant difference regarding the drop out rates among the groups, and there was a high level of retention (92%). The project was submitted to
the Research Ethics Committee in Humans of the university where the research was conducted, approval was obtained.

**Collected Data**

The information collected in this study may come to assist in the development and improvement of prostheses, and can be used to promote technological advancement in this area, providing better rehabilitation of users of these devices and increasing their quality of life.

Through the several data collected in the application of the tests in groups, is expected to compose evidence that can assist in shaping representative of an individual with borderline values of balance and gait patterns. The model developed may allow the understanding of the performance of the evaluated medical devices.

The results of the study are presented in Table 2, indicating the average angle related to the balance of individuals by applying the adapted test Romberg Tinetti Gait and Berg Balance Test.

The results presented in Table 2 demonstrate that there are differences between MAO angles, MPO, and MOR MOL compared to Amputates group and NOT Amputates (adapted Romberg test). Is possible to notice that the larger standard deviation values (SD) are in Amputates group. However, t-student parameters and p-value (> 0.05) denote that it is not possible to ensure statistical validity in static equilibrium tests of the participants at this stage of the research.

As contrasted to the evidence of Gait Speed (Tinetti Gait Test) and Daily Activities (Berg Balance Test) the best results were achieved in NOT Amputates group. This is confirmed by their higher average with smaller SD and variances. It highlights the magnitude of the dispersion obtained in amputees group concerning daily activities. The statistical validity of the samples were obtained and tested by the Student t values (> 3) and p-value (< 0.05).

Still regarding Daily Activities, magnitude and dispersion of scores can be seen in Graph 1. The graph shows the results of the Berg Balance Scale Tests comparing the values obtained in groups of Amputates and NOT Amputates with reference fifty-six points. It is observed that the highest dispersions compared with reference correspond to Amputates group.

Regarding the technical characteristics of the prostheses were grouped into five categories: type, hard socket, flexible socket, material and foot technology. With that aimed to identify the effectiveness of these devices as a relevant factor in the rehabilitation process of users. Table 3 presents the technical characteristics of the prosthesis associated with the individual performances of users. These characteristics are related to individual performances of the users in terms of Gait Speed, score of Daily and physiotherapy activities.

**Discussions**

The results compiled in Table 2 denote values for the groups assessed in relation to the balance. In addition, these differ between amputees groups and NOT amputees, however, still no statistical validity at this stage of the study (p > 0.05). In contrast, the mean and standard deviation of daily gait speed and activity have clear differences among the groups and with statistical validity (p < 0.05).

The average Gait Speed were 0.6793 ± 0.0992 for amputees groups and 0.7844 ± 0.0736 for non-amputees. The difference between means implies that the rehabilitation actions promoted to amputees may not have been satisfactory. The results show the difficulties of amputees in maintaining a speed in gait, and performing daily activities close to not amputees group. In scores of Daily Activities the averages were 50.7857 ± 0.0000

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**Table 1. Demographic and epidemiological characteristics of the participants.**

<table>
<thead>
<tr>
<th></th>
<th>Amputees n = 14</th>
<th>NOT Amputees n = 14</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>M (DP)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>43.79 (13.22)</td>
<td>27.78 (5.92)</td>
</tr>
<tr>
<td>Women</td>
<td>41.00 (8.49)</td>
<td>25.54 (5.04)</td>
</tr>
<tr>
<td>Men</td>
<td>44.25 (14.08)</td>
<td>29.02 (6.28)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>85.357 (19.445)</td>
<td>70.54 (11.29)</td>
</tr>
<tr>
<td>Women</td>
<td>81.000 (16.971)</td>
<td>57.75 (3.5)</td>
</tr>
<tr>
<td>Men</td>
<td>86.083 (20.411)</td>
<td>76.22 (8.27)</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.731 (0.082)</td>
<td>1.72 (0.07)</td>
</tr>
<tr>
<td>Women</td>
<td>1.615 (0.0354)</td>
<td>1.66 (0.06)</td>
</tr>
<tr>
<td>Men</td>
<td>1.751 (0.070)</td>
<td>1.75 (0.06)</td>
</tr>
<tr>
<td><strong>N</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Leg Amputation</td>
<td>8</td>
<td>-</td>
</tr>
<tr>
<td>Left Leg Amputation</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Functional therapy/physical activity</td>
<td>5</td>
<td>5</td>
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</table>
5.0258 and 55.4615 ± 1.1266 for the group of amputees and not amputees, respectively. Again, the performance in the group of amputees was significantly lower. The data suggest that these results may be related to the technical characteristics of the prostheses and physiotherapy rehabilitation of amputees.

The results shown in Table 3 allow to verify the performance of the prosthesis used by volunteers in terms of Gait Speed Daily Activities and associated technical features of these devices. Likewise, observed in this table is suggested that a relationship between the highest scores Activities of Daily Speed Gait with the highest values (correlation 0.6641). Additionally, it was noted that volunteers who scored lower performances reported in pain or discomfort in the use of their prosthesis, and in some cases were identified wounds caused by mechanical abrasion of the prosthesis.

Such evidence strengthens the hypothesis 1 which seeks to ascertain whether there is any relation between performance of the prosthesis and performing daily tasks. This performance is measured in terms of the angular variation of balance and gait speed of the users of the prostheses.

However, with a possible enlargement in voluntary samples will be possible to reduce error and increase the statistical validity, the angular variation, by comparing the amputees groups and NOT amputees. Also a higher correlation is expected, close to 1, between Gait Speed and Daily Activities presented in Table 3. In addition, with larger samples seeks to homogeneity in the epidemiological characteristics of the participants, in particular, the average age of volunteers between groups investigated.

Regarding the technical characteristics of the prostheses used by volunteers, Table 3 indicates that the configuration of the prosthesis 7, 8, 9 and 13 showed the best values of Gait Speed and Daily Activities (based on averages, c / SD, group of no amputees). It can be observed in Table 3 that the prosthesis 7, 9 and 13 have the same characteristics and the prosthesis 8 makes use of special materials such as titanium and carbon fiber. In contrast, the prosthesis 10 is associated with a lower performance Gait Speed Daily Activities and having a differential of the other, the use of Aluminum.

According to Table 3, amputees who perform or performed physiotherapy achieved performances close to the mean of the group of non-amputees (0.7844 ± 0.0736 and 55.4615 ± 1.1266 for Gait Speed and Daily Activities,
respectively, see Table 2). With these features include users of the prosthesis 1, 8, 13 and 14 shown in Table 3. It was also observed that those who scored lower performances did not realize physiotherapy for lack of access to the same or information about it.

With these findings it is plausible to evidence to Hypothesis 2, which seeks to determine whether the rehabilitation of transtibial amputees followed by physiotherapy promotes functional health assimilated to non-amputees, considering the performance of the prostheses in terms of gait speed, angular variation of balance and daily activities.

The demographic and epidemiological characteristics of the studied groups were obtained wide intervals regarding the average. In the static balance differences were identified between the groups investigated. The largest dispersions performances occurred in the amputee group.

The main difficulty corresponds to availability of volunteers, a factor that influences preponderantly in the statistical validity of the research. Another aspect to be highlighted in the research method used was the application of Motion Capture technology as an evaluation tool, which allowed observation and detailed comparison between individuals in order to precisely identify the limitations that hinder the domain of static balance.

During the research it was verified that, of the way the rehabilitation centers is proceeding, is low the integration of the amputated individual in society. One of the difficulties identified during the research was the recurrence of discomfort in the fitting system and suspension when the individual does not have a system with vacuum to prevent mechanical friction with the body. It is noteworthy that there are indications that special materials such as titanium and carbon fiber can provide an improvement to the balance of end-user when compared with simpler materials such as aluminum.

### Table 3. Technical specifications of the prostheses of participants in tests.

<table>
<thead>
<tr>
<th>Nº</th>
<th>Type</th>
<th>Hard Socket</th>
<th>Soft Socket</th>
<th>Material</th>
<th>Foot Technology</th>
<th>Gait Speed (m/s)</th>
<th>Daily Activities (score)</th>
<th>Physio.</th>
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<tr>
<td>1</td>
<td>Exo.</td>
<td>KBM</td>
<td>Synthetic Foam</td>
<td>Steel</td>
<td>Sach</td>
<td>0,8125</td>
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<tr>
<td>2</td>
<td>Exo.</td>
<td>KBM</td>
<td>Synthetic Foam</td>
<td>Steel</td>
<td>Sach</td>
<td>0,8000</td>
<td>52</td>
<td>Yes</td>
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<tr>
<td>3</td>
<td>Exo.</td>
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<td>Synthetic Foam</td>
<td>Steel</td>
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<td>0,8335</td>
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<td>Steel</td>
<td>Dynamic</td>
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<td>5</td>
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<td>Dynamic</td>
<td>0,5880</td>
<td>48</td>
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<td>Steel</td>
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<td>Dynamic</td>
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<tr>
<td>8</td>
<td>Endo.</td>
<td>TSWB</td>
<td>Silicone</td>
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<td>Carbon Fiber</td>
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<td>Endo.</td>
<td>KBM</td>
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<tr>
<td>10</td>
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<td>Silicone</td>
<td>Aluminum</td>
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<td>Sach</td>
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<td>51</td>
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</table>

### Conclusions

This article aimed to present the reviews of performances of transtibial amputees group and NOT amputees group. Therefore, performance evaluations were conducted in transtibial amputees groups and NOT amputees. In this configuration, data were collected static balance, gait speed and capacity of volunteers perform everyday tasks.

Two hypotheses were tested. Hypothesis 1: The ease of transtibial amputees perform daily tasks is related to the performance of the prosthesis. This in terms of angular variation of balance and gait speed of the users of these assistive technologies. Hypothesis 2: Rehabilitation of transtibial amputees accompanied by physiotherapy promotes functional health assimilated to non-amputees, considering the performance of the prostheses in terms of gait speed, angular variation of balance and daily activities.
Thus, it is suggested that improvements be made in the rehabilitation process, including an appropriate selection of the materials that comprise the prostheses and effective physiotherapy. These findings indicate the existence of a connection between the performances achieved in the tests, with the ability of amputees perform daily tasks. The rehabilitation of transtibial amputees accompanied by physiotherapy can promote functional health. This evidence corroborates the hypothesis tested.

The evidences originated by the tests can contribute to the scientific community not only in the purposes of this research, but highlighting the importance of producing primary evidence in developing countries. These countries with their own economic, geographic and cultural characteristics, differing from the developed countries that stand out in the production of evidence in health. In this context, new initiatives are expected and encouragements that enable primary studies for other conditions amputations and functional limitations.

Finally, it is recommended that health policy makers implement efforts in improving the amputee rehabilitation, allowing users prostheses social activities, quality of life and productivity.

Collaborations

G Prim, FAS Santos, M Vieira and V Nassar contributed equally in all stages of drafting of the article.
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