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CONCORDIA UNIVERSITY, ST. PAUL

ST. PAUL, MINNESOTA

COLLEGE OF KINESIOLOGY

An Outcome Comparison of Osseointegrated and Traditional Socket-Fit Prostheses

A GRADUATE PROJECT

SUBMITTED TO THE GRADUATE FACULTY

in partial fulfillment of the requirements

for the degree of

Master of Science in Orthotics & Prosthetics

by

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St. Paul, Minnesota

June 2023

Abstract

This is one of the first studies to report on the comparison of walking ability between socket-based and osseointegrated bone-anchored prostheses of the trans-femoral amputee. Each participant's hip active and passive range of motion was assessed. The Timed Up-and-Go test (TUG), 10-meter walk test (10MWT), and 6-minute walk test (6MWT) were administered to all participants with the addition of the Amputee Mobility Predictor with a Prosthesis (AMPPro). The study consists of unilateral transfemoral amputees with an activity level of K3-4. The current prosthetic users were divided into two groups based on their current intervention, socket prosthesis (S) and osseointegrated prosthesis (OI). The average completion times of each functional outcome measure is taken, recorded and compared between groups. The study provides valuable information on the impact osseointegration may have on an individual's ability to ambulate when compared to their socket-based counterpart. The information gleaned from this study provides valuable information in determining appropriate care and outcome expectations of those undergoing the procedure.

Keywords: *Osseointegration, tran-femoral prostheses, outcome measures*

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Introduction

The common method of rehabilitating amputees involves fabricating a custom-fit rigid socket around the individual's residual limb. This socket serves as the foundation for the prosthetic components which restores the appendage. In trans-femoral amputees, this socket attempts to contain the large volume of soft tissue which surrounds a single bone, the femur. One of the main problems involved with a socket-based prosthesis is the fluid-like characteristic of the soft tissue. The soft tissue constantly wants to move which can cause serious problems when being contained by the rigid socket. Movement of the tissue is necessary for a residuum to remain healthy. A socket which provides too little movement causes the breakdown of soft tissue and results in the form of pressure sores or ulcerations (Hachisuka, 1998). A socket which provides too much movement of the soft tissue can allow friction or loss of control of the prosthetic device (Brodie, 2022). Multiple socket designs are available for providers to solve the problems of containing soft tissue. Some designs utilize the bones of the pelvis to maintain their positions and restrict motion around the residuum. Whereas others implement compression of the soft tissue itself. No socket design currently available is able to continually provide superior prosthetic control without risking damage to the soft tissues contained within the socket. The reason for this is because an amputee's residuum will experience volume fluctuations throughout their day-to-day life. Naturally, with the volume being contained within a socket, pressure placed on the soft tissue will fluctuate as well. This increases the aforementioned risks of tissue breakdown and loss of control.

Recently, methods of direct attachment of a prosthetic device to an individual's bone, known as osseointegration, have been developed. Osseointegration serves to eliminate some of the common problems associated with socket-fit prostheses (Atallah, 2018). Due to the direct

attachment of the prosthetic component to the individual's bone there is no longer a need for a socket. Without a socket, the tissue of the residuum is allowed to move freely and unrestricted. Volume fluctuations and pressure sores caused by the device no longer pose a problem to these amputees. Osseointegrated devices are also thought to provide increased prosthetic control due to their direct attachment and increased feedback (Häagström, 2013).

The research surrounding osseointegrated prostheses has limited clinical application within the field of orthotics and prosthetics. The vast majority of the available information is reports on the complications, outcomes, and rehabilitation of the implant procedures themselves. This is understandable, due to the infancy of the procedures with the first appendicular involvement being performed a little more than 30 years ago. The procedure is highly involved and the qualification criteria remain restricted, significantly reducing the number of individuals who may undergo the procedure. However, despite the small population which has undergone an osseointegration procedure, there are a handful of studies observing some of the clinical applications. Atallah et. al (2020), Hagberg et. al (2001) Pospiech et. al (2020), & Van de Meent et. al (2013) observe the impact on the quality of life an osseointegrated prosthesis may have on an individual. Häggström et. al (2013) evaluates the vibrotactile sensation socket and osseointegrated patients experience. This study suggests patients with an osseointegrated prosthesis experience increased feedback and therefore have greater control over their device. Hagberg et. al (2005) analyzes range of motion of the hip and sitting comfort in both socket and osseointegrated individuals. The results suggest that osseointegrated users may have greater range of motion capabilities which increases sitting comfort and gait efficiency. The lack of socket trimlines in osseointegrated users further contributes to improved sitting comfort. Van de Meent et. al (2013) further analyzes and compares a cohorts walking ability with a socket-based

prosthesis and an osseointegrated prostheses after the implantation procedure. The results of this study indicate patients involved with a poor socket experience may improve their functional capacity and quality of life if their prosthesis is directly attached to their bone rather than to a socket.

While the available research is continually growing, to this author's knowledge, there is no study available which directly compares the walking ability of well established socket-based prosthetic users with osseointegrated prosthetic users. A study of this nature would help bridge the gap of available data between these two groups. Realistic expectations and abilities of this patient population can be established with the data attained. Thus, providing orthotic and prosthetic professionals with the valuable information regarding appropriate clinical outcomes. The data would ultimately serve to expand the orthotic and profession as a whole. The primary purpose of this study is to determine whether osseointegrated prosthesis users have increased walking ability and range of motion when compared to their socket-based counterparts.

Methodology

Participants

Total participants of the study will number 50, which will be divided into two groups; Socket (S) group and Osseointegration (OI) group. Each will number around 25 participants. Inclusion criteria for the study are. Have a unilateral trans-femoral amputation, utilizing their socket-based or an osseointegrated prosthesis for 2+ years, achieved skeletal maturity, have a K-level of 3 or higher, have no wounds of on the residuum or contralateral side that would impede walking ability within the last 3 months. Unilateral amputees are the target population based possibility that bilateral amputees would likely incorporate uncontrolled variables into the study. Bilateral amputees have an established slower walking speed and decreased ability when compared to their unilateral counter-parts. There also includes the additional variable of different amputation levels which may also influence an individual's walking ability. A bilateral amputee may also possess both a socket-fit and osseointegrated prosthesis which can introduce an additional inconsistency of walking ability. Participants are required to be utilizing their type device for 2+ years because a well-established user is desired. A participant utilizing a device they have only been familiar with for a few months or a year may not have developed gait patterns to which they are entirely comfortable with. The tests being used require a natural gait at a comfortable walking speed. New users may introduce unwanted gait deviations, thereby influencing the results of the study. Skeletal maternity is included as a requirement because it is a requirement to undergo the osseointegration procedure. While trans-femoral amputees who have not achieved skeletal maturity may utilize a socket-based prostheses; they are currently not allowed to undergo an osseointegration procedure due to the effect growth may have at the implant site. This requirement is an attempt to eliminate socket-fit participants which do not

currently appear in the osseointegration population. A K3 or greater level of activity is preferred to ensure completion of tests as well as representing a large portion of the trans-femoral population. Individuals undergoing the osseointegration procedure are also more likely to be classified as K3 or above due the required bone density of accepting the transplant. The no wound requirement on either the residuum or contralateral side reduces the likelihood that a temporary gait deviation be introduced into the data. Socket users may experience tissue break-down while currently utilizing their device, possibly influencing the time necessary to complete the tests. A similar experience may affect the osseointegration users. These users are more prone to infection at the surgical site which may or may not affect walking ability. Both groups are subject to injury and wound development on the contralateral side as well. An attempt is being made to eliminate these possibilities and attain a balance between groups.

Procedures & Measurements

The participant of the study will self-report demographic information including cause, year of amputation and/or implantation. Data about the prosthesis, height, weight, and residual limb length will be collected and reported. Measurement will be reported utilizing the metric system and BMI will be recorded utilizing the measurements taken.

Active and passive range of motion of the hip joint will be obtained and recorded utilizing goniometry. Hip Flexion, Extension, abduction, adduction, internal rotation, and external rotation will all be measured. The subjects of each group will then be administered the following tests in the respective order: Amputee Mobility Predictor (AMPPro), Timed Up-and-Go (TUG), 10 Meter Walk Test (10MWT), and 6-Minute Walk Test (6MWT). All of

these tests are widely accepted and commonly used in the assessment of walking ability and mobility by rehabilitation professionals.

Manual goniometer testing is reported to have good validity and high test-retest reliability in measuring joint range of motion. For the purposes of this study hip flexion/extension will be taken with the patient lying flat on a table. The axisreferences the lateral aspect of the greater trochanter, the stationary arm referencing lateral midline of the pelvis and moving arm referencing the lateral midline of the femur. Hip adduction/abduction will be taken with the patient lying flat on the table. The axis referencing the anterior superior iliac spine (ASIS), the stationary arm extends from ASIS to ASIS, and the moving arm references the anterior midline of the femur through patella midline. Rotation of the hip is taken with the patient in a seated position with the feet hanging off of the table. With the prosthesis donned, the axis is positioned over the anterior knee center, the stationary arm is perpendicular to the floor, and the moving arm references the midline of the lower leg.

The Amputee Mobility Predictor (AMP) is an instrument designed to measure walking potential of lower limb amputees. In this study the AMPPro (with the use of a prosthesis) will be used. The AMP is a valid and reliable method of assessing an amputee's potential for ambulation (Gailey, 2002). The AMPPro is a 21 item assessment protocol aimed to analyze the static, and dynamic sitting as well as transfer and gait skills of individuals in a progressive manner. This assessment tool may provide a closer look at some of the nuances that may appear between the S and OI groups.

The TUG test is used to assess a patient’s lower limb function as well as their fall risk. The test consists of the patient sitting in an armed chair with their hands on the chair. When the instructor says “Go” the patient is to rise, walk to a line marked 10ft in front of the chair, turn,

walk back to the chair and sit down again. This test will be conducted twice where the recorded speeds will be averaged.

The 10MWT is used to assess walking speed over a short distance. A line on the floor is marked at 0, 2, 8 & 10 meters. The patient starts at the 0m mark and is instructed to walk to the end mark (10m). Timing is initiated when any part of the lead foot crosses the 2m line and ends when any part of the lead foot crosses the 8m line. The participants will be instructed to perform the test at both comfortable walking speed and at a fast walking speed. Each test will be conducted twice where the record speeds will be averaged.

The 6MWT is used to assess walking over a long distance in both endurance and aerobic capacity. The participants will continuously walk for 6 minutes. A preset distance on a flat surface of at least 12 meters will be marked and the participants will be instructed to walk as far as possible within these 6 minutes but not to run or jog. This test will be conducted only once for each participant and the distance walked by the participant will be recorded in meters.

Design & Statistical Analysis

This study will conduct a pre-experiment utilizing an alternative treatment posttest-only with nonequivalent groups design. Population sampling will be a multi-stage convenience sample in which Orthotic and Prosthetic locations are identified in treating osseointegrated and socket-fit transfemoral patients. These patients are subsequently contacted with a request for participation within the study. The study will focus on the effect that the prosthetic intervention has on the timing and score of the aforementioned outcome measures. While an osseointegrated or a socket-fit prosthesis is the manipulated variable there are other factors which may introduce statistical noise into the results. Individual components of the participants will not be accounted

for however, categorization of these components may be recorded and subsequently analyzed. The means of each outcome measure will be compared between each group. When comparing the groups, all tests will be two-tailed and conducted with an α-value equal to 0.05 to allow for type 1 errors.

Ethical Considerations

Patients will be contacted via the identified orthotic and prosthetic location about the study. Whereby participants will receive information regarding the study and enrollment details. Participants will receive a disclosure laying out the protocols of the outcome measures. A consent form will be provided and signed explaining that they are participating in the study of their own volition and will be able to withdraw from the study at any point in time should they wish. Participants will also sign an acknowledgment form indicating that personal identifying information may be gathered throughout the study which may include: name, date of birth, contact information for future/followup studies. The participants will be informed and will acknowledge that this identifying information will not be shared or released without the written consent of the individual. This information will be kept in a secured file of the surveyors until the time for eradication of this information is appropriate.

The participant will be asked to perform various physical activities. As with any physical activity there is the risk of injury. Participants will be informed that if at any point they feel they are unable to complete a task for safety or personal reasons they are permitted to withdraw. Assistance to the extent allowed per the outcome measures will be allowed and advised including walking aids and resting periods. Participants who have known cardiovascular or pulmonary

complications may be advised to withdraw from the study due to the physical demands of the sub-maximal 6MWT to which these are contraindications of administering the outcome measure.

Discussion

There are a handful of studies which compare socket-fit and osseointegrated prostheses in various categories. Quality of life studies are somewhat common and functional outcome reports following the osseointegration procedure are beginning to surface. These reports predominantly focus upon the participant's functional abilities post procedure without comparison to a separate group. This study would be one of the first to compare the functional abilities of separate well-established osseointegration and socket-fit amputees.

Practical applications

The data provided from the results of this study would primarily serve to expand the orthotic and prosthetic profession as a whole. This ultimate goal would be achieved in several ways. Firstly, the data provided could be utilized to determine whether or not osseointegration further supports an improved patient experience. The current available research suggests osseointegration may increase the quality of life a patient may have compared to their previous socket-based prosthetic experiences (Hagberg, 2013 & Van de Meent, 2013). The results of this study have the potential to indicate individuals who receive an osseointegrated prosthesis may have increased function over their socket-based counterparts. An increase in function could additionally arguably improve the patient experience and therefore the quality of life.

Currently, the osseointegration procedure is limited to a select group of individuals. Those receiving the procedure typically must have a documented history of poor skin conditions or low socket success rate. This restriction is understandable due to the infancy of the procedure to which there is limited outcome data. The results of these studies could serve to increase the support of an osseointegration procedure. If participants are able to function at a similar or even

increased level experienced by the standards of a socket-fit prosthesis, the intervention will be reinforced as a viable option for amputees experiencing difficulties due to socket use. The implant procedure could eventually lead to support the expansion of the indication criteria to the general amputee population rather than being limited to poor socket success. This application of the results would be presented as a patient's right to autonomy. By having the data available, a patient and their care team are able to make a well-informed decision about the best course of treatment for the patient.

Lastly, there is limited information regarding the functional outcomes of the osseointegration procedures. As a result, the expectations of the procedure are ill-defined. A wide variety of outcomes are present in the minds of potential patients and professionals alike. Although the outcome of any one individual cannot be foretold, the results of this study will begin to provide some answers to what can be expected and how they will be able to function and interact with their environment.

Limitations of the Study

Orthotic and prosthetic treatment plans are inherently individualistic. As such not every variable can be accounted for in any one study. Some of the largest limitations of this study are due to this individuality. For example, there are many different types of sockets available for treating a transfemoral amputee. Some utilize a bony-lock concept while others implement compression of the soft tissue in various configurations. Each of these methods may have their implications on an individual's ability to ambulate which may have a significant impact on the outcomes of the study. This variety is compounded by the different types of suspension found within socket-based prosthese. Some methods of suspension provide better control over a

prosthesis increasing gait efficiency. Similarly, there are a variety of osseointegration procedures, each of which may impact an individual's gait and therefore impact their performance on the outcome measures. Further complications arise when prosthetic components such as feet and knees are considered. The wide variety of componentry and customization of the prosthesis itself makes controlling all possible variables impossible. Attempting to do so would severely limit the application of the results to only those involved with the study. Generalization to a population would likely not be possible. As such, an attempt was made to include patient characteristics of a population that may be generalized to a small degree, until such a time that a larger sampling pool could be utilized.

Another limitation to this study is the small number of patients undergoing the osseointegration procedure. The indication criteria for the procedure is restricted until potential harm to the patient can be properly assessed. As such the community undergoing the procedures are typically in good health and have proven their compliance throughout their rehabilitation journey. It is possible osseointegration patients are more likely to be involved in an active exercise regiment or lead an active lifestyle which may not be properly reflected in the socket-based group. The K3-4 inclusion criteria attempts to address this potential incongruence however, there remains a large variety of individuals which would qualify as K3-4 users.

Recommendations for future research

This study looks at the simple functional outcome comparison of the osseointegration procedure. Perhaps some of the most useful information would be derived from a biomechanical evaluation and comparison of these two groups. As orthotic and prosthetic professionals, the goal is to provide the most efficient gait pattern to the patient as possible. Amputation involving two

joints is inherently inefficient when replacing anatomic joints with artificial ones. A study analyzing osseointegration prosthetics and comparing them to socket-based or even anatomic gait may provide valuable information regarding the patient experience and proper treatment. A study such as this may support the idea that a more efficient gait pattern is achievable through direct attachment and thereby reducing the risk of overuse injury on the contralateral side or of the ipsilateral hip.

Conclusion

The relatively new practice of direct attachment of a prosthetic devices provides many questions for further exploration. The investigation of comparing the functional outcome of socket-based users and direct attachment provides information which further supplements the available resources pertaining to the modality. With this information patients and medical professionals are better able to determine the appropriate course of action that is available to those that qualify. With the information provided within this study, investigators are additionally better able to discern valuable areas of investigation.

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