Design of a Corrective Hip Orthosis for Patients With Abnormal Flexor Pattern After Transfemoral Amputation

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ABSTRACT

Transfemoral amputation is a surgical procedure to remove part of the lower limb above the knee due to severe damage from trauma, disease, or congenital defects. Once the amputation is completed, it's very important to warranty muscle stabilization and to apply biomechanical principles to improve the quality of life after the procedure; in addition to this, one of the main goals is to preserve the adductor magnus muscle and perform myodesis to achieve a functional stump. The shape of the residual limb is a crucial factor in prosthetic fitting process and rehabilitation. However, there is a gap in information regarding the significance of the adductor magnus in preserving the anatomical femur axis post-amputation. Dysfunction of the adductor magnus and other adductor muscles can lead to abnormal abduction and flexion of the femoral stump, changing the posture of the person, especially during sitting or crutch-assisted walking. As a result, the modification of the center of gravity affects prosthetic suspension and handling. The project aims to develop a hip orthosis to maintain the stump in a more anatomical position after the amputation and during rehabilitation process. For the design of this device, it was necessary to define specific anthropometric criteria, with the purpose to adapt the measurements for an optimal fit and function. Finally, the materials had to be flexible and comfortable to ensure extended use without discomfort. The orthosis incorporates a harness system to modify flexor and abductor patterns, aligning the amputated stump in a vertical axis.

Keywords: Transfemoral, Amputation, Orthosis, Flexor pattern

INTRODUCTION

The term "amputāre", of Latin origin, suggests the notion of amputation (RAE, 2023), the definition of amputation refers to a medical technique that involves the separation of a limb or a portion of the body (Hagan et al., 2018). This intervention is performed in response to various medical conditions, such as vascular complications, diabetes, trauma or oncological reasons. The classification of amputations is based on the anatomical level of the bone or joint that has been removed during surgery.

In the context of lower limb amputations, two common variants are transtibial and transfemoral, designated by the specific location of the surgical procedure (Espinoza et al., 2014). According to the American Academy of Orthopaedic Surgeons, transfemoral amputation involves a transverse cut at the level of the thigh (Espinoza et al., 2014), removing significant anatomical structures such as the knee, tibia, fibula, ankle and foot. The resulting stump can be classified as proximal, medial or distal, according to the cut level.

The length of the femur has a direct influence on the prosthesis fitting due to the loss of musculature and a reduced lever arm (Bacallao et al., 2017). Moreover, optimal residual limb facilitates ideal conditions for prosthesis fitting by meeting the following specific criteria: adequate sensitivity for physical and psychological responses to stimuli and pain management of the phantom limb syndrome, a tapered shape, an appropriate length for socket adaptation, good range of motion, adequate tone, balance and muscle contraction, good blood circulation, optimal temperature and adequate anatomical alignment (Choo et al., 2022).

Although transfemoral amputation is necessary in some cases, there are several challenges for healthcare professionals and patients, especially during the post-surgical stage. Some of the undesirable conditions after surgical procedure may include scar adhesion or pain, loss of sensation, muscle weakness and atrophy, and phantom pain syndrome, among others. Hip flexion is another a common complication of transfemoral amputation that influences gait biomechanics and can lead to significant deviations. The presence of these pathological patterns has direct influence in the rehabilitation of the lower limb. Hence, it's crucial to understand and address these conditions to ensure effective rehabilitation and successful prosthetic fitting (Isaacs-Itua & Sedki, 2018). In this sense, post-surgical rehabilitation focuses on various aspects, including residual limb bandaging and specific exercises for joint strengthening and mobility (Devinuwara et al., 2018).

Therefore, the objective of this work is to design a corrective hip orthosis that helps to keep residual limb in an adequate anatomical position after amputation and during their rehabilitation treatment.

METHOD

Participants

A 28-year-old male with right transfemoral amputation performed 8 years ago due to trauma. The participant's met the ideal criteria for the study, such as having received physiotherapeutic treatment after surgery, lacking a prosthesis, and presenting parameters within an adequate functional structure. It's important to mention that anthropometric measurements were taken with previous authorization and consent of the participant's and under supervision from the healthcare staff.

The residual limb had a length of 29 cm (from the greater trochanter of the femur to the distal part of the residual limb), this is the most common length in cases of transfemoral amputation. In addition, the participant had an appropriate lever arm; also presented adequate sensibility and healing, joint range of motion, with optimal skin conditions.

Physiotherapeutic Evaluation and Assessment

The first stage of the project consisted in the physiotherapeutic evaluation which was carried out at the physical therapy clinic of the University Centre of Tlajomulco; this process included the anamnesis, exploration and assessment of residual limb; as well as postural, muscular and goniometric evaluation. As a result of this procedure, it was possible to identify a hip flexion of 25 degrees and an abduction of 10 degrees, these parameters confirmed the presence of abnormal postural patterns. These data were crucial to define the type of orthosis and design criteria.

Anthropometric and Angular Measurements

Anthropometric measurements included the length and circumferences of the residual limb, fundamental for the design of a device that fit securely and comfortably and very important, non-invasive. Anthropometric measurements provided detailed information about the residual limb, ensuring a more accurate design. Angular measurements complemented this analysis, confirming the flexor pattern and, for instance, the need to develop a hip abduction corrective brace. Because the selection of the amputation level plays a crucial role in the participant's future functional competencies, the closest amputations have the worst functional prognosis. The Table 1 shows the anthropometric criteria for the orthosis design.

Anthropometric Criteria	Objective of the Anthropometric Criterion
Residual limb length	Determines if the residual limb is long enough for its fitting.
Diameter of the residual limb	Establishes dimensional tolerance to meet design and accuracy requirements.
Residual limb width	Crucial for prosthesis design, ensuring a secure and comfortable fit to the residual limb.
Distal Thigh Circumference	Allows precise orthosis design for a comfortable and secure fit to the residual limb.
Medial Thigh circumference	Evenly distributes load on the residual limb, avoiding uneven pressures.
Proximal Thigh circumference	Essential for designing orthoses that allow the user to lead an active life.
Waist circumference	Considered for waist adjustment, maintaining adequate mobility for the participant's.

Table 1. Anthropometric criteria for the device

Material Selection and Orthosis Design

The choice of materials for the orthosis focused on textile neoprene, polypropylene, nylon, and Velcro, considering specific properties of flexibility, rigidity, and durability (Table 2). The design included a graphic sketch with Velcro girdle-belt adjustments, Velcro pants-type closure, and shorts-type adjustment on the right leg.

Materials	Description
Neoprene (textile)	Flexible and resistant material, suitable for areas requiring mobility and support (Edwardchen, 2019).
Polypropylene (plastic)	Light-weight and rigid material, used for the structure of the orthosis, providing stability and strength(NINGBO MH Polypropylene tape (PP) rigid tape, for backpacks belts and straps., 2024).
Nylon (composite)	Durable and versatile material, suitable for areas experiencing friction and tension (Conceptualia-Adm, 2023b).
Velcro (textile)	Adjustable closure system, facilitating placement and removal of the orthosis (Fernandez, 2022a).
D-ring	To connect the mechanism and other components, especially in systems that fulfill a safety function, used in harnesses, backpacks or safety carabiner connectors (Bunney et al., 2021).

For the fabrication, a detailed sketch was made considering the anthropometric dimensions. The orthosis consists of two parts:

Anterior Part

- Velcro girdle-belt adjustment for hip and waist support.
- Velcro pants-type closure for ease of use.
- Right leg adjustment for comfort.

Back

- Flexor pattern correction mechanism with polypropylene strap and safety buckle.
- Diagonal abduction correction mechanism towards the hip.

Fabrication Process and Sketch Visualization

The fabrication of the orthosis began with the visualization of a graphic sketch. The measurements obtained from the anthropometric assessment were considered, ensuring that the orthosis would fit comfortably and securely to the participant's residual limb. The design included a Velcro waist-band adjustment, Velcro pants-type closure, shorts-type adjustment on the right leg and two hip correction mechanisms.

This integrated approach to evaluation, design and fabrication ensures a customized and functional orthosis for the participant. In addition, orthopedic and biomedical guidelines have been followed to ensure the effectiveness of the device.

Material Considerations

The choice of materials for the orthosis was crucial, considering the specific function of correcting the flexor pattern. The combination of textile neoprene, polypropylene, nylon and Velcro ensures a balance between flexibility, rigidity and durability, complying with orthopedic and biomedical standards. This methodological approach was necessary to adapt the device to the unique needs of the participant's

PROPOSAL

The design proposal considered several aspects to provide a solid structure and support that corrects hip position, improving anatomical alignment for a more efficient gait. With the addition of biomechanical and anthropometric elements, the corrective orthosis seeks to prevent the tendency towards hip flexion, allowing the extension of the residual limb.

The proposal focused not only on correcting hip abduction and flexor pattern, but also improving quality of life for user, by the facilitation of mobility, and reducing the limitations associated with amputation. This comprehensive approach is supported by the collaboration between biomedical engineers and healthcare professionals.

RESULTS

The final orthosis prototype was based on a comprehensive approach that considered anthropometric criteria, physiotherapeutic analysis and evaluation, as well as biomechanical aspects to effectively address the flexor pattern. The implementation of this design includes the following features:

- Adjustable Hip Girdle: To provide a precise fit in the hip area. The design of this element, which uses Velcro material, allows for a customized fit to the user size, thus ensuring optimal support.
- Orthosis with shorts design for optimal mobility: The shorts design orthosis is presented as a particularly beneficial solution for people, in this case for the participant. This design seeks to maximize user mobility and addresses specific needs. By providing adequate structural support and facilitating natural biomechanical movements, this orthosis significantly improves the quality of life and comfort of the participant by allowing greater movement.
- Flexor Pattern Corrective Adjustments with Tension Mechanism: The adjustments incorporated into the orthosis were harnesses that have a tension mechanism to positionate the residual limb in a biomechanically correct manner. This functionality helps to effectively correct the flexor pattern under tension.
- Ergonomic limb holster: An ergonomic residual limb sleeve has been integrated and is attached in conjunction with the orthosis. This sleeve uses soft material, such as neoprene, to ensure that the participant's experiences comfort when wearing the orthosis and mobilizing with it on, thus avoiding any discomfort or pain.

The results met the established objectives and managed to demonstrate the corrective function of the device. This gives us a perspective that focuses on helping the individual's future mobility and contributing positively to their quality of life through this type of assistive device.

CONCLUSION

In rehabilitation there are different techniques such as auxiliary devices for the treatment of people with amputations. Among transfemoral amputation methods to prevent post-surgical hip flexion and contracture, it's possible to identify the use of a prosthesis immediately after amputation, rigid dressings, silicone liners, pneumatic postoperative prostheses, and others (Poonsiri et al., 2021).

Proper alignment of the residual stump is important for the functional prognosis of the lower limb. Physical therapy addresses the correct the position of the residual limb to facilitate daily activities including walking, sitting, or recumbency (Devinuwara et al., 2018). On the other hand, fitting a transfemoral prosthesis in people with abnormal hip abduction and flexor patterns is complex because of the anatomical and biomechanical modifications after the amputation process. For that reason, the use of other type of devices is desirable, especially during the pre-prosthetic period (Poonsiri et al., 2021).

Hence, this project aimed to design of a low-cost corrective hip orthosis for people with transfemoral amputation in response to the need of having a device that helps to keep a more anatomical position of residual limb during pre-prosthetic period. Also, this orthosis is intended to correct common pathologies following transfemoral amputation, such as hip abduction and flexor pattern.

Finally, it's important to mention the device is still in development phase and, key areas of improvement are identified. These improvements include the implementation of more breathable textiles to improve user comfort. In addition, optimization or change in the use of the D-ring to improve the fit of the residual limb and correct the flexor pattern more effectively.

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