Current overview of the state of disabled population, regarding the use of transtibial prosthesis

Una mirada actual al estado de la población en condición de discapacidad frente al uso de prótesis de miembro inferior a nivel transtibial

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Abstract

The Center of Design and Metrology of SENA-CDM (Centro de Diseño y Metrología del SENA–CDM) has found that the population with disability of lower limbs represents a technical-technological challenge, regarding locomotion recovery, since this group requires very expensive surgeries or devices, such as canes, crutches, wheel chairs or other items to help them move freely. It is important to take into account that there are doubts as to whether prosthesis on the market satisfy patients' economical and functionality needs. Through this project, we intend to solve this inconvenience and generate a solution with local technology in the Center of Design and Metrology of SENA. In Colombia, there are not many companies that design and manufacture the elements composing a prosthesis; for this reason, the CDM has been working for approximately five years on the design and adaptation of prosthesis and orthosis with imported components. Thus, we intend to design and implement a 100%-SENA-manufactured ankle articulation for transtibial amputation, which meets the ergonomic and functional needs for patients. This original scientific article gathers the most relevant information regarding a topic affecting our society. Here, we analyze different bibliographic sources described in the existing literature. Using this knowledge, we have created the stages required to write this article, defining revision objectives and making the most relevant bibliographical search, and organizing information according to mind maps in order to write this paper.

Keywords: Foot; transtibial prosthesis; articulation; ankle.

Resumen

En el Centro de Diseño y Metrología del SENA–CDM se ha detectado que la población en condición de discapacidad de miembros inferiores representa un desafío técnico y tecnológico en la recuperación de las condiciones normales de la marcha, puesto que se requieren intervenciones costosas o elementos que ayuden al desplazamiento de estas personas, como bastones, sillas de ruedas, muletas u otros implementos que sirvan de soporte y faciliten la rehabilitación del paciente. Es importante tener en cuenta que hay dudas acerca de si las prótesis existentes en el mercado suplen las necesidades económicas y de funcionalidad de cada paciente. Con esta investigación se pretende implementar una prótesis transtibial, a fin de mejorar algunas condiciones de la marcha del paciente. Colombia no cuenta con muchas entidades que diseñen y fabriquen los elementos que componen una prótesis. Por tal razón y porque en el SENA, específicamente en el Centro de Diseño y Metrología- CDM, hace aproximadamente cinco años se viene trabajando en el diseño y adaptación de ortesis y prótesis, pero con componentes importados, se quiere diseñar e implementar una articulación de tobillo para amputación transtibial, haciendo uso del recurso humano y tecnológico disponible en el país, y así, poder desarrollar un sistema con manufactura propia y 100 % SENA, que cumpla con las características de funcionalidad y ergonomía para los pacientes con dicha discapacidad. Este artículo científico original recopila la Información más relevante sobre un tema que afecta nuestra sociedad. Aquí se analizan diferentes fuentes bibliográficas descritas en la literatura existente. Con ellas creamos las etapas necesarias para la redacción del artículo definiendo los objetivos de la revisión, haciendo la búsqueda más relevante de la bibliografía y organizando la información de acuerdo con mapas mentales para redactar el artículo.

Palabras clave: Pie; prótesis transtibial; articulación; tobillo.

Introduction

All human beings possess an intrinsic, natural characteristic in our bodies that is movement; however, in some cases, this natural attribute is lost due to different circumstances. Most frequent factors are associated to situations such as violence, high accidentally rates, and medical causes which directly compromise the person. For the specific case of violence, some areas of the world have suffered the serious consequences of land mines, a worldwide issue that affects societies' public policies, according to the Red Cross international commission (CIRC, 2016). Countries where this issue is particularly serious are Cambodia, Angola, Bosnia-Herzegovina, Afghanistan, El Salvador, Nicaragua and Colombia, with a high number of active landmines, due to the armed conflicts in these nations.

For the specific case of Colombia, some distressing statistics have been retrieved; according to the Observatorio De Minas Antipersonas de la Presidencia de la Republica (Contraloria General de la República, 2012; Reyes, 2011), by 2011, around 1080 people had died due to landmines (Reyes, 2011). On the other hand, in most cases, the patient does not die, but loses one or both lower limbs, thus rendering landmines as one of the main causes for disability. Unofficial figures from the medic Thomas Küchenmeister indicate that, by 2011, the armed conflict in Colombia has left 20.000 victims counting deceased and disabled.

As one of the most affected countries by this situation, Colombia has a high percentage of disabled population (Nation general comptroller's office), who require medical and psychological aid on a daily basis (Álvarez and Ospina, 2013).

Thus, retrieving locomotion of population with lower-limb disability represents quite a challenge, since it requires expensive surgery, which, depending on specific needs, may require prosthesis, orthosis or devices which help them move freely, such as canes, crutches, wheel chairs or other items that generate the static balance of the person.

For Colombia, it becomes necessary generating around 4000 new prosthetics a year to cover the needs produced by the armed conflict (Ministerio de Posconflicto, Derechos Humanos y Seguridad, 2016) and amputations due to diabetes and accident tolls. Therefore, it is necessary to implement a bank of medical prosthetics which covers said need. Likewise, it is also important to consider if existing prosthetics meet the economic and functional needs of each patient. It is important to be aware that these elements represent a high investment and must be imported from other countries, since there is no local production.

By carrying out this research, it is sought to improve use, whether fixed or moderate, of aiding elements in order to reenable march, by implementing an electromechanical element, along with appropriate physical rehabilitation, which improves patient locomotion.

Method

Bibliography of this document complies with the following characteristics:

- Up-to-date revision or basic references.
- Both global and specific state of the art.
- Bibliographic Revision of the four work areas of the Project.

References are oriented under professional bibliographic supervision.

General state of the art in the field of orthopedic technology

An amputated patient experiences a loss in life quality, due to the difficulties in mobility or aesthetic changes (Molero-Sánchez, Molina-Rueda, Alguacil-Diego, Cano-De la Cuerda and Miangolarra-Page, 2015; Zhou *et al*., 2015). This condition generates psychological sequels (Sagawa *et al*., 2011) which lead to changes in personality and affect rehabilitation and loss acceptance (Lewis, 2008). Other psychological conditions derive in an intense sensation, originated in the location of the severed limb; this symptom is known as "phantom limb" (Lewis, 2008).

Mobility deprivation due to the loss of a limb makes many patients become a burden for their families and society, since they are unable to perform an economic activity due to their condition (Sinitski, Hansen and Wilken, 2012).

Treatments are the first tool to aid patients with physical sequels (Sinitski *et al*., 2012; Morgenroth *et al*., 2011). In treatments, the patient is subjected to physical tests, in order to determine the extent to which their mobility has been compromised (Colombo, Marchesin, Vergani, Boccafogli and Verni, 2011). Some injuries require the patient to wear supporting devices and others limit them to a wheel chair (Yuan, Wang, Zhu, and Wang, 2014; Zheng and Shen, 2013). For the latter case, patients have few options to improve their conditions (Molero-Sánchez *et al*., 2015).

The first line of help for these diagnoses are prosthesis (Colombo *et al*., 2011; Wang, Yuan, Zhu and Wang, 2015). At first, prosthesis was a solution to physical sequels (Sinitski *et al*., 2012) as patients covered the inexistence of a limb. Other types of prosthesis help the patient recover part of their lost mobility (Au *et al*., 2015; Bellman, Holgate and Sugar, 2008; Casallas, Garzón and Luengas, 2011; Chen and Wang, 2015).

Au, Herr, Weber and Martínez-Villalpando (2007); Mancinelli *et al*. (2011); Lemoyne, Mastroianni, Hessel y Nishikawa (2015) define prosthesis as help devices for the people under disability conditions, configured as a set of mechanic, electro mechanic, orthotic and prosthetic pieces. Prosthesis design is carried out from pre-amputation, amputation and post amputation analysis (Ministerio de Salud de Colombia, 2015), thus achieving design suited to physical and personal conditions of each (Dillon and Fatone, 2013; Murdoch, 1967; Rubiano, 2012).

The mechanical principles of each limb are studied for design, in order to obtain an approximate model of the biomechanics of the limb to be replaced with the prosthesis (Au *et al*., 2015; Casallas *et al*., 2011; Cherelle, Grosu, Matthys, Vanderborght and Lefeber, 2014; Huang, Wensman and Ferris, 2016; Shultz, Lawson and Goldfarb, 2016; Sinitski *et al*., 2012; Yuan *et al*., 2014).

The approximate model of the limb is a mathematical representation, which allows characterizing the acting forces and the position of each part of the limb (Wang, Yuan, Zhu and Wang, 2014; Yuan, Wang and Wang, 2015; Zheng and Shen, 2013). This information is used in the design of a prosthesis with an approximate functionality, degree of Liberty and forces exerted on the limb (Adebayo *et al*., 2011; Au *et al*., 2015; Bellman *et al*., 2008; Casallas *et al*., 2011; Cherelle *et al*., 2014; Sagawa *et al*., 2011;).

The main inconvenience with mechanical and electro mechanical designs of prosthesis is centered on how to obtain a device which behaves similarly to muscles (Zheng and Shen, 2013). Muscles behave as both active and passive elements within the model of the limb (Bravo and Rengifo, 2014). In one moment, they exert lever force to produce the movement of the limb and in a second moment, they absorb impact or excess energy produced by other muscles (Lee Childers, Prilutsky and Gregor, 2014; Zheng and Shen, 2013).

Simulating muscle behavior is essential for the design of more functional prosthesis, which offer the patient a more natural experience (Bravo and Rengifo, 2014; Silverman and Neptune, 2012; Zheng and Shen, 2013). Achieving behavior similar to that of the muscles requires the use of several mechanic elements combined (Mancinelli *et al*., 2011; Shultz *et al*., 2016; Yuan *et al*., 2015, 2014; Zheng and Shen, 2013); however, the system is subjected to effects proper to the mechanical elements used, thus altering the dynamics intended to be simulated (Bravo and Rengifo, 2014; Fang, Jia, Wang and Suo, 2009; Gabriel *et al*., 2008; Mancinelli *et al*., 2011).

Lee *et al*.(2014), Silverman and Neptune (2012), Wang and Brown (2016) state that a mechanical system formed by a spring, and an engine exerting compression force on it, as well as contention of spring elongation simulate the behavior of a muscle (Au *et al*., 2007; Brasil and Rosa, 2011; Chen, Wang, and Wang, 2015; Cherelle *et al*., 2014; Hill and Herr, 2013; Huang *et al*., 2016). More accurate studies on the biomechanics of certain limbs have proven that with the system previously described, it is possible to fully model them and even producing functional protoypes of prosthesis (Chen *et al*., 2015; Chen and Wang, 2015; Cherelle *et al*., 2014; Cherelle, Matthys, Grosu, Vanderborght, and Lefeber, 2012; Eilenberg, Geyer and Herr, 2010).

Linear pneumatic cylinders are another alternative to simulate muscle behavior (Zheng and Shen, 2013). In their internal structure, cylinders have a spring which is compressed using a piston and pressurized air. The spring becomes an actuator which incorporates cylinder insertion within the pneumatic muscle, thus generating piston displacement, resembling the active part of the muscles in a lower limb (Zheng and Shen, 2013).

A clear example of the application of this mechanism is provided by Masum, Bhaumik and Ray (2014); Yuan, Zhu, Wang and Wang (2011), in the development of the prototype for a prosthesis for cases of transtibial amputation. They use the mechanical system to simulate the effect of compensation forces necessary for the patient to maintain balance as s/he moves (Adebayo *et al*., 2011; Arotaritei, Turnea, Filep, Ilea and Rotariu, 2015; Casallas *et al*., 2011; Chen and Wang, 2015; Wang *et al*., 2015). The prototype is able to absorb the force generated when the prosthesis comes into contact with a surface, avoiding bounce effects, and it also compensates the angle between the basis of the prosthesis and the coupling axis, thus allowing the user to walk on steep surfaces (Bravo and Rengifo, 2014; Morgenroth *et al*., 2011; Yuan *et al*., 2014; Zheng and Wang, 2016; Zhu, Wang, Li, Sun and She, 2015; Zhu, Wang and Wang, 2014).

In the prototype by Yuan *et al*.(2011) a digital control system is implemented to calculate the magnitude of the force necessary for the patient to maintain balance from its own weight; the angle between the components of the prosthesis regarding the ground and the part of the prosthesis coming into contact with the floor (Adebayo *et al*., 2011; Bellman *et al*., 2008; Cherelle *et al*., 2014, 2012; Yuan *et al*., 2011; Yuan *et al*., 2014; Zheng and Wang, 2016; Zhu *et al*., 2015, 2014). There is only one parameter left to the patient, the other ones are calculated by sensors located in diffrent parts of the prostesis. With these characteristics, it is possible to obtain a prosthesis which compensates changes in patients' steps (Cherelle *et al*., 2014, 2012; Yuan *et al*., 2015).

Previously cited prototypes only use the stages of the walking sequence to control actuators on the prosthesis (Shultz *et al*., 2015; Wang *et al*., 2014), requiring constant adjustments in each design, and their functionality is limited to a single use (Cherelle *et al*., 2014). Prosthesis are adjusted to walk or run, not both options, by changing the timing in the walking sequence (Wang *et al*., 2014).

The use of electromyography will enable the development of prosthesis which adjust to the patient's walking pace without previous adjustment required (Chen, Wang and Wang, 2014; Chen *et al*., 2015; Kannape, Member, Herr and Member, 2014). Placement of electrodes on certain muscles of the limb will deliver useful signals to determine the natural position of the limb (Chen *et al*., 2014, 2015; Kannape *et al*., 2014). This response from the limb to changes in the muscles will help patients to adapt to the prosthesis (Kannape *et al*., 2014).

Prosthesis with these adaptation characteristics can be used in different patients by only adjusting the parameters of weight and physical length of the prosthesis (Ferris, Aldridge, Rábago, and Wilken, 2012; Laferrier and Gailey, 2010; Zhou *et al*., 2015). Other prosthesis technologies require personal study of each patient, which consumes a considerable amount of time and does not guarantee patient's comfort with the result (Ferris *et al*., 2012; Laferrier and Gailey, 2010; Molero-Sánchez *et al*., 2015; Zhou *et al*., 2015).

Patients' rejection to the use of prosthesis propels the study of new techniques to make their use more natural (Ferris *et al*., 2012; Laferrier and Gailey, 2010; Rusaw and Ramstrand, 2010; Sanders, Zachariah, Baker, Greve and Clinton, 2000; Zhou *et al*., 2015). Changes in design, type of actuators, sensors and control techniques enable the improvement of commodities and functionality of prosthesis (Cherelle *et al*., 2014, 2012; Shultz *et al*., 2016; Zheng and Shen, 2013).

Follow-up on the prosthesis using the principles described by Masum *et al*.(2014); Yuan *et al*.(2011), have achieved several military-use versions, thanks to their resistance, and modular structure (Fergason, Keeling and Bluman, 2010). The modular approach of prosthesis allows swift replacement of defective parts without jeopardizing patient's health every time reparations are required.

On the other side, glancing at the local, Latin-American perspective, specifically in Colombia, several developments have been achieved in the field of orthopedic technology (Hernández-Castillo, Álvarez-Camacho and Sánchez-Arévalo, 2013; Valladares, 2015), although many of them are patented, but not under production. Developments have been relevant, since they provided conditioning of costume-made prosthesis, component conditioning and, in turn, applied research (Estupiñán, Garzón and Suárez, 2007).

This type of development has been achieved from different fields of action; meaning, advances in applied technology are occurring due to research in universities with costume-made laboratories. A good example is the ankle movement march analysis laboratory, where foot movement can be recreated (Borrás, Gómez Serrano and Pinto, 2011; Raschke *et al*., 2015). This laboratory displays the mechanical and mathematical process of said movement, all the way to the design of a prosthesis. Another example (Díaz and Cely, 2009) consists on a transtibial prosthesis, based on a CAT scan and validating design, through the method of analysis by finite elements. It is worth noting the use of this technique for prosthesis design. In 2015, Universidad San Buenaventura (Romero, 2012) designed and built a transtibial prosthesis, which takes electrical signals from the muscles and generates movement through it, using control technique for movement compensation.

Discussion

Along the information analysis, the different variables surrounding prosthesis use have been observed. Having said that, these variables increase and grow to a higher number of variables if we change height and condition of the amputation. Therefore, and considering the information reviewed, we can provide the corresponding technical recommendations for the implementation of prosthesis to be used in case of amputation. Technical parameters are as follow:

Technical or engineering parameters

- Patient's weight, height and biotype.
- Prosthesis must be similar in weight and length to the original limb.
- The system must offer great power and torque output during push.
- The system must be able to change rigidity.
- Prosthesis must be able to control articulation in the impulse phase.
- Prosthesis must be impact resistant to avoid damage.
- Prosthesis must generate low energetic expense, since it is strictly linked to battery use.

Materials

- The material used on prosthesis depends on the type of physical activity of the patient, but it is directly connected to his/her economic condition, since, depending on the level of resistance and low weight, the type of components may have a higher cost.
- Another important aspect in material management is life span of the components, since all these elements have pieces which wear out. Depending on the selection of components vs material characterization, it is possible obtaining a greater cost-weight benefit.
- Currently, ultralight materials are preferred, along with morphology similar to that of a normal leg, so that a patient with lower-limb disability is not excluded from practicing any sport or everyday activity and, on the other hand, his/her disability may go unnoticed by the rest of the community.

Psychosocial parameters

Although the ideal purpose of a prosthesis is reincorporating patients to their old social environment, with the same characteristics prior to amputation of lower limb, it becomes necessary, through different classes of rehabilitation and therapy, to minimize the impact of the missing limb, since the patient may be prone to future behavior, such as:

- Depression.
- Social dependence for routine activities.
- Social exclusion.

All these factors influence and are immerse in the proper treatment and rehabilitation to be provided for a patient.

Conclusions

- As the patient's degree of disability increases, along with the degree of liberty of the prosthetic component, the complexity index of the challenge increases proportionally, as kinetic and cinematic control vary accordingly.

- In order to implement an appropriate prosthetic component, which functioning depends on the acquisition and posterior control of electromyographic signals of the stump, experimental results in such practice must be excellent, as they are directly linked to the efficiency of the component as well as proper transmission of movement to the prosthetic device.

- Information analysis shows different transmission mechanisms, but the one reflecting the highest degree of efficiency and performance is the device composed by a ball screw, which has the main characteristic of increasing lineal displacement at very low speed and, surprisingly, with a minimum energetic consumption, thus making the mechanism easy to elaborate in a compact, lower-consumption manner.

- For proper implementation of the prosthetic component, the relation between the stump and the socket must generate minimum pressure, since it produces a sense of stability and confidence on the patient during march.

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