

Análisis biomecánico del pie protésico Bioc-dm2

Biomechanical Analysis of a prosthetic foot Bioc-dm2

Jhon Hernandez Martin^{1*}, Oscar Heli Bejarano¹, Edwin Yamith Martínez¹, Luis A. Parra Piñeros¹, Jairo Alberto Romero¹, Fran Eduard Perez¹, Phillipe Meziat Castro¹

¹Centro de Diseño y Metrología, Servicio Nacional de Aprendizaje, Colombia

*Autor de correspondencia: jhonmartin56@gmail.com

ABSTRACT– Walking is one of the aspects directly compromising human wellbeing, as it has a physical and emotional impact in daily life. For this study, we delve into the challenge of improving some walking conditions in a patient suffering lower limb loss, specifically at transtibial or transfemoral levels. Given that our purpose was the analysis, design and manufacture of a lower-limb prosthetic component, which fills the needs for functionality, it became necessary to build a foot with all the quality standards associated to each and all movements required to form the complex fundamental pattern of walking. Besides, this foot should also easily endure weight, daily use and physical characteristics of the patient object of this study. When performing physical validation and during human walk, a proper response is observed in terms of mechanics, materials and dynamics of the component, thus making evident proper construction and assembly. On the other hand, it is feasible that design and verification of the component provided a competitive element, as compared to existing elements currently in the market. The previous situation generated the need for verification from the National Institute for Medications and Food (INVIMA), as well as the revision of the use replying device, for component verification, in accordance with ISO 10328.

Keywords– *Biomechanical, gait analysis, foot, prosthesis, transfemoral.*

RESUMEN– La marcha humana es uno de los aspectos que comprometen directamente el nivel de bienestar del ser humano, además de impactar de manera emocional y física, también en el cotidiano vivir. Para este estudio nos encontramos inmersos en el reto de poder mejorar algunas condiciones de la marcha en un paciente que haya sufrido pérdida de miembros inferiores, específicamente a nivel transtibial o transfemoral. Dado que nuestro propósito fue el análisis, diseño y manufactura de un componente protésico de miembro inferior que supla las necesidades propias y de funcionalidad, es necesario construir un pie con todos los estándares de calidad que constituya todos y cada uno de los movimientos requeridos para formar el complejo patrón fundamental de la marcha; además que pueda soportar el peso fácilmente y el uso cotidiano además de las características físicas de nuestro paciente objeto de estudio. Al realizar la validación física y en la marcha humana, se observa una respuesta adecuada en términos mecánicos, de material de construcción y el dinamismo del componente, evidenciando la adecuada construcción y ensamble del componente. Por otro lado, podemos evidenciar que el diseño y la verificación del componente nos muestra un elemento competitivo, comparado con los elementos existentes en el mercado; Haciendo necesario la verificación ante Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, y la puesta en marcha del dispositivo replicador de uso, para la verificación del componente frente a la norma ISO 10328.

Palabras clave– *Biomecánico, análisis de marcha, pie, prótesis, transfemoral.*

1. Introduction

Human walk, configured as biped motion is one of the aspects emerging as a result of joining together a number of little physiological processes which, enable human body movement. For this particular case, the aforementioned function has been lost due to the amputation of a lower limb.

Along this research, it has been noted that prior to the implementation of any prosthetic component, it is necessary to assess the patient thoroughly both quantitatively and qualitatively. This will generate more

accurate diagnosis for the implementation of each component. Proper decision- making for the patient will increase the level of motor agility, stability and comfort, which are the characteristics for a proper walking pattern [1].

The most relevant factors which may, somehow affect walking function can be described as follows:

- Pathologic: injuries, trauma, amputation, and some type of neurological anomaly. For this case study we deal with lower limb amputation.

Citación: J. Martín, O. Bejarano, E. Martínez, L. Parra, J. Romero, F. Perez y P. Castro, “Análisis biomecánico del pie protésico Bioc-dm2”, *Revista de I+D Tecnológico*, vol. 15, no. 1, pp. (80-86), 2019.

Tipo de artículo: Original. **Recibido:** 17 de septiembre de 2018. **Recibido con correcciones:** 16 de octubre de 2018. **Aceptado:** 29 de enero de 2019.

DOI <https://doi.org/10.33412/iddt.v15.1.2102>

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- Physical intrinsic to the person: it is the most relevant factor when designing and implementing a prosthetic component, which corresponds to activity level, age and weight. For this case study it is a 1,75 m; 85-kilogram male, with a moderate level of activity, corresponding to level 3 [2].

Due to the research complexity posed by human walk, it is necessary that a group of professional staff performs an assessment of the patient. For this study, the group was formed by eight experts on orthosis and prosthetics areas, as well as physical therapists, who provide an ideal assessment of patient and his physical alterations [3].

Since there are several areas of work, as well as professionals in these areas, involved in this research, it becomes necessary for the whole work team to establish terms and concepts. For this reason, the first step consisted on the implementation of initial technical parameters which will be used for the manufacturing and assembly of the prosthesis and further adaptation to the patient.

Along this article we will show the development in manufacture of the foot, its analysis and validation, presenting a final product with high levels of acceptance from the patient. We will also observe the levels of proximity to normal patterns of walk for each of the measurements performed in component analysis.

2. General analysis of prosthetics

An interdisciplinary group of engineers, orthotists, prosthetists, physical therapists and some users was conformed for the design, manufacture and validation of the product. Using physical and biomechanical measurements, and with the help of patients, this team designed several solutions to select the prototype that best biomechanically and physically reproduces the behavior of walking, regarding balance and mass center, during biped walk under reasonable conditions [4, 5].

The prototype begins with the simulation and verification of walk under normal conditions of an average person with similar physical and behavioral conditions the those of the patient case of study. Hence the specific design parameters for prototype construction.



Figure 1. Support stage.



Figure 2. Gait analysis in balance stage.

After the walk analysis [6], and considering the physical parameters of the patient, reference parameters were extracted to implement the prosthetic component. Design parameters are shown below:

Table 1. Design parameters

PARAMETER	MEASUREMENT
Age	30-35 years
Foot size (wearing cosmesis)	34
Weight	85Kg (Max value)
Height	1,75 m
Activity level	3
Length of the stump	Medium third
Muscular strength	4
Length of the articulation	15 cm
Suggested weight for the whole component	1 kg (Max value)
Dorsiflexion	Normal up to 20°
Plantarflexion	Normal up to 50°

These prototype parameters were fully described in prior articles, as mentioned in [7, 8], so the analysis stage will be overlooked and we will proceed directly to the implementation stage [8].

Prior to the analysis of the prosthetic component, it was necessary to include a previous market research. In the field of applied research, several prototypes are available for prosthetic foot components, a number of which are currently under technical and commercial validation. Some of the cases for international reference are available in German universities and companies, who stand out for their technological advances.

Next, we describe some prosthetic components:

Fillauer's component presents a design incorporating a third carbon-compound spring and emphasizes on its higher quality due to their innovation on material science. The design is comfortable and smooth in each stage of the step cycle.



Figure 3. Fillauer's external foot prosthesis with impact buffer/ Dynamic reaction [9].

Another reference is the one built by Mercurius Company, a technological (spin-off) branch of the University of Munich (fig. 3). Their NextStep proposal implements CAD digital adaptation technology, through their Mercuris (beta) platform, along with 3D printing, supplied by a certified German dealer. Another relevant aspect in this model is the speed of costume-made assembly and validation, which aims at having a completely finished product within 48 hours.



Figure 4. 3D printed foot prosthesis [10].

3. Full articulation assembling

Assembly was carried out following the required protocols for each material and bearing as an objective that the prototype was not designed to be an exhibition model, but a functional one, as proven in the biomechanical analysis in the "findings" section.

Prototype building and construction was clearly described in previous articles, therefore, this topic will not be addressed in order to show the final result, which was used for the biomechanical verification of the component [11]. It is worth noting that there was a validation process along the design stage, by using the analysis through finite elements was carried out in the SolidWorks software, in which static and dynamic studies were carried out with similar parameters to our patient object of study, On the other hand, acrylic resin was chosen as coating, due to the crew's experience with its use and its compliance with the required characteristics of resistance; adding, using the analysis through finite elements was carried out in the SolidWorks software, in which static and dynamic studies were carried out with similar parameters to our patient object of study [12].

The layout of the raw material and the geometric orientation of the layers of carbon fiber for each of the pieces is given as follows:

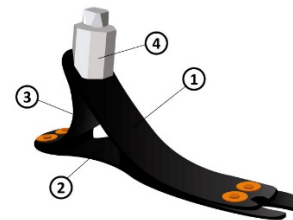


Figure 5. Foot design (1 instep; 2 sole; 3 keel; 4 adapter).

The layout of the material and its geometric orientation are described in the following table. 100 grams of acrylic resin were used for pieces manufacturing.

Table 2. Construction and geometric layout of the component; FC90: Carbon Fiber at 90°; FC45: Carbon fiber at 45°

Piece/procedure	1	2	3	4	5	6
Instep	FC45	FC45	FC90	FC90	FC45	FC90
Sole	FC45	FC45	FC90	FC90	FC45	FC90

Anterior spring	FC45	FC45	FC90	FC90	FC45	FC90
Adapter	Duralumin					

After the molding and manufacture, the final result is a functional component that meets the needs for the patient object of this study.



Figure 6. BIOC-DM2.

Next, we present the results of the bio-mechanic analysis performed on the component.

4. Analysis and results by using biomechanics analysis

The information presented was acquired experimentally at the gait laboratory of the Center for Design and Metrology (Centro de Diseño y Metrología), affiliated to the School of Orthopedic Technology. The laboratory was calibrated using Auto-Calc, which validates the information supplied by both; gauge and cameras.

Two studies were performed to describe the component performance. First corresponds to physical analysis consisting on platform measurement of forces, which will determine forces, gain, angle, and spatiotemporal parameters, for each of the morphological parts of the body influencing biped walk for the patient.

Results after the analysis are shown in table 3. It is worth noting that the prototype is accurately aligned, since it properly generates load vectors associated to each body part and the movements in each stage of gait.

Clarifying, only the most relevant results are presented, since the whole analysis is too deep and thoroughly covers each of the articulations in the body; for this reason, we only include the articulations relevant for the use of the prosthesis object of this study

Table 3. Construction and geometrical layout of the component

Parameters to be measured	Right leg	Left leg
Balance time (s)	0,45 ± ,02	0,45 ± ,02
Support time (s)	0,93 ± ,01	0,89 ± ,03
Support stage (%)	67,16 ± ,45	66,2 ± ,6
Balance stage (%)	32,84 ± 1,45	33,68 ± ,61
Step duration (s)	1,38 ± ,01	1,35± ,05
Knee Flex-extension (degrees)	4,3 ± ,2	12,9± ,4
Ankle Dors-plantiflexion (degrees)	-4,6 ± ,1	-4,2 ± ,2
Foot progression (degrees)	-6,1 ± ,2	-12 ± ,1

4.1 Discussion

Analyzing the results obtained, it is feasible that values do not correspond to exact numbers, but a range, since the walking function varies depending on several physical and behavioral factors, proper to each patient.

From the results, we see that the figures in both the amputated leg and the whole leg are quite near. Likewise, range variations are also within the functional parameters for the patient.

The parameters obtained are based on the results generated in the software, they are not presented in a percentage way but in a quantitative way so as not to damage and alter the study.

The difference in the flexion - extension angle is generated due to the dynamism of the construction materials of the prototype.

The results shown graphically and numerically, are reflected in the figures [8, 9, 10] in the same way as that shown in the table [3].

The second performance analysis, corresponds to kinematic validation, which is based on the acquisition of data using retro reflecting sensors, strategically located in the patient's articulations. Sensor layout is shown in the image.

After performing the required captures of patient walk, we see an appropriate response from the prosthetic component regarding manufacture and functionality.



Figure 7. Retro reflecting markers attached to patient object of study.

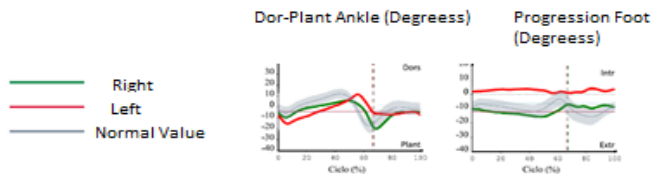


Figure 8. Cinematic analysis for ankle and foot.



Figure 9. Kinematic analysis for ankle and foot.

The ankle and foot will be specifically assessed for this analysis; all other articulations have movements rather approximate to proper walk, so the analysis will be based exclusively on the aforementioned ones.

The first image of figure 9 shows a high value in the force vector received by the prosthesis. This value corresponds to an energy return in the compound material and the dynamics of the component itself [13], as the material used for manufacturing poses energy return properties; however, this level is not too high because there are not any muscles to generate the ideal force.

The first image of figure 11 corresponds to muscular potential of the hip, which is in turn correlated to the muscular potential of the whole lower limb. This figure shows total muscular activation of the leg, generating proper extension and contraction.

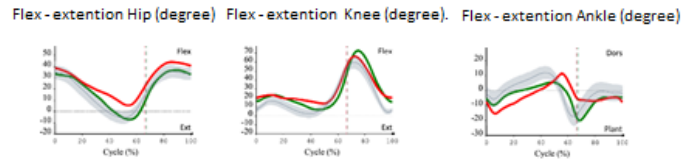


Figure 10. Kinematic analysis for hip and ankle.

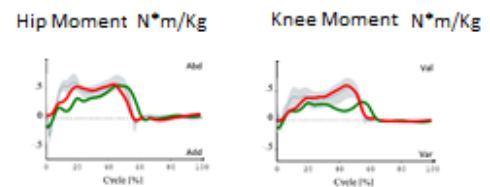


Figure 11. Kinematic analysis for hip and knee momentum.

Out of a general analysis, it is possible to conclude that prosthetic limb performance is rather same to that of a sound limb, and in some of the charts there even is a lineal graph, rather than a curve. This occurs because the manufacturing material makes the component stiff without any methods for direct dispel, as the individual muscles conforming the foot would provide.

Finally, the balance phase of the prosthesis behaves ideally. However, the inability for movement on the negative axis of the instep, due to the lack of extensor muscles on the foot, maintains the whole load on the leg, rather than the foot. For this reason, it is necessary to implement higher rigidity values in the anterior spring to dispel this effect and distribute the load.

Another relevant factor is the proper alignment of the component in the patient, since this setting enables efficient load distribution and the consequent reflection in the walking function.

5. Legal Framework

The legal frame is given by the possibility of validating the product by INVIMA (National Institute for Medications and Food) standards, the revision of the product with ISO 10328 and the possibility to build a device which validates all 30.000 use cycles of the component.

The implementation of new technologies for manufacturing, adapting and installing prosthesis and

orthosis in patients is somehow limited by Colombian regulations from manufacturing to the final user of these components. The General System of Social Security and Health, with Bill 5592, 2015 regulates technical assistance requiring the implementation of prosthesis or orthosis for users affiliated to Health Promoting Entities (EPS). This bill grants the users to receive prosthesis or orthosis complying with low process, and therefore lower quality and resistance, without determining the possible variables for adaptability of the user and appropriate functioning of the element; for this reason, this bill restricts innovation and implementation of new technologies by directing the market to the manufacture of prosthesis and orthosis compliant with the technical characteristics required by the EPS.

In view of the previous, new regulations are required to allow the implementation of new technologies, oriented to innovation and new forms of adaptability for people who require prosthesis or orthosis, working hand in hand with users. This joint work should enable inclusion and the elimination of the word “disability”, thus determining that this item in healthcare is not another line in the business of Colombian health emporiums. It would also facilitate compliance with all technical and legal regulations to receive the INVIMA approval on our component.

6. Conclusions

- The final element complies with all initial functionality protocols, it fully solves both physical and movement parameters for the patient case of this study.
- The follow up on this analysis is providing the element with the 30.000 use cycles required to validate the prototype commercially and industrially, in accordance with ISO 10328, and thus implement the component massively.
- Regardless of the static and dynamic analysis of the component, it becomes necessary to implement test specimens for each of the materials used (ASTM E8). This test is justified in that the component must ensure a lifespan of around three years, so it must be subject to tension and compression stress analysis, which will provide a level of certainty and quality closer to that of the actual use.
- After the construction and assembly of the component, exhaustive training is required from the patient, as dynamic behavior makes it difficult to

recognize and this may lead to a difference with components frequently used.

7. Funding

Scientific research article, derived from the research project entitled: “Design and construction of a system for collecting and adapting myoelectric signals for electro-mechanic ankle control in transfemoral prosthesis (“Diseño y Construcción de sistema de recolección adaptación de señales Mioelectricas para control de tobillo Electromecánico en prótesis Transfemoral”), financed do by National Learning Service - SENA-Center for design and metrology SENNOVA (“Servicio Nacional de Aprendizaje – SENA- Centro de Diseño y Metrología - SENNOVA”). Starting year: 2018.

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