SOMIB Sociedad Mexicana de Ingeniería Biomédica
43° CNIB 2020

A case study on measurement of comfort factor from metabolic rate and heart rate of a transtibial amputee while using novel prosthetic sockets

M. Acosta B.[1], L.A. Páramo F.[1], D. Rosales G.[1], R.Q.Fuentes-Aguilar[1], and B.Alemón[1]

[1] Tecnológico de Monterrey, Escuela de Ingeniería y Ciencias, Campus Guadalajara
macostab96@hotmail.com

Abstract

An individual that experiences right lower limb amputation was recruited to a study that proposes the use of diverse measurements to calculate a comfort factor in order to compare the functional performance of two prosthetic sockets. The comfort factor includes the assessment of the lower limb symmetry, the calculation of the metabolic rate and peak heart rate values, plus the results of a satisfaction survey. The data was collected during different stages. At the beginning of the performance evaluation, the participant was asked to be in anatomical position, and then a photo was taken for the symmetry analysis. Respiratory gas exchange, which is the maximum amount of oxygen (VO_2) consumption and carbon dioxide (CO_2) expenditure, for the calculation of the metabolic rate and heart rate in beats per minute (BPM) were done at the rest state test, and during a ten-minute hike on a treadmill. Finally, the volunteer answered a satisfaction survey regarding the comfort of the tested prosthetic device. The results showed differences between both prosthetic sockets used, regarding the metabolic rate and peak heart rate during the gait. The comfort factor quantitatively shows the level of satisfaction, as well as the perceived problems with the prosthetic socket, and by extension, the prosthesis in general. The proposed calculation of the comfort factor could help prosthetists, physical therapists, amputation care centers, and rehabilitation centers to evaluate and recommend the correct and personalized type of socket for a transtibial amputee.

Keywords: Metabolic rate, prosthetic socket, transtibial amputee.

1 Introduction

Lower extremity amputees, using conventional prostheses, experience many problems, one of these, is the affectation of the transtibial amputee mobility due to the discomfort that the amputee feels between the socket and the residuum. To feel comfort in the daily use, the prosthetic socket has a significant effect on the transtibial amputee mobility and level of satisfaction with the overall prosthesis. The socket is considered the main part of the lower limb prosthesis, because it receives and transmits loads to the residuum during the daily activities of the subject. The type of the socket, as well as the design, play an important role in the feeling of comfort of the lower limb amputee. The measurement of the Metabolic Rate (MR) and Heart Rate (HR) provide a quantitative way to evaluate the level of comfort that a transtibial amputee experiences using a prosthetic socket.

Clinical studies indicate that some of the problems during locomotion are non-symmetric gait and higher gait metabolic rates as compared to the values for non-amputee persons. For example, transtibial amputees expend 20–30% more metabolic power to walk at the same speed as a non-amputee [1].Adjusting the symmetry of the lower limbs and reducing the energy expenditure of the amputee gait may therefore be beneficial for the comfort of the amputee person [2].

dx.doi.org/10.24254/CNIB.20.29

1.1 Energetic expense

The human body utilizes energy in many different ways. Obtaining estimates of instantaneous metabolic cost is difficult because of the measurements of metabolic cost, collected from state-of-the-art systems, are significantly delayed from the instantaneous metabolic demands of the body. To date, indirect calorimetry has been the method of choice because it allows the subjects to move freely about the laboratory environment while the system measures their respiratory gas exchange. Nevertheless, the measurements obtained through this method show high noise, low sampling rate, and it requires the user to wear a bulky rubber mask that covers his or her nose and mouth, what make it unsuitable for real-world applications [3]. Although this, our research group decided to use it because it allows the volunteers to feel confident in a friendly environment.

The average energy spent by a male between 20-50 years of age, who consumes the three main macromolecules, carbohydrates, proteins and fats, is 4.825kcal per liter of oxygen (O_2) consumed. Basal metabolic rate (BMR) is measured under some specific standard conditions, such as, no food ingested by the volunteer for at least 12 hours prior to the test, the volunteer must be mentally and physically relaxed, and the volunteers body temperature must be normal [4]. These conditions minimize all factors that might alter the measurements. The MR can be calculated using (1):

$$MR = \frac{kV_{O_2}T}{A} \tag{1}$$

where, MR is the metabolic rate, VO_2 is the expired volume of oxygen, k is the energy equivalent of consumed oxygen, whose constant value is 4.825 kilocalories, T is the time in seconds which is calculated by integrating the data from the air flux. Finally, as given in (2), A is the superficial area of the body, calculated using the height, H, and the weight, W, of the volunteer, as well as a constant x whose value is 3600,

$$A = \sqrt{\frac{HW}{x}}. \tag{2}$$

1.2 Heart rate

In addition to metabolic rate, heart activity is also related to the body's energetic expense.

The cardiac output is the amount of blood that is pumped from each ventricle per minute, it depends on the stroke volume or volume of blood that is expelled per beat, and the heart rate (HR), which is the number of beats per minute [5]. A register of the heart electrical activity is possible with an electrocardiogram (ECG), which is a graphical record of the electrical activity of the heart. The ECG signal is made up of three sections, a P wave, a QRS complex and a T wave. The Holter monitor is a portable electrocardiograph capable of continuously recording the ECG signal for up to 24 Hrs [6], allowing to carry out long-lasting, moving tests.

According to Butler, the relationship between HR, MR and energy expenditure, can be used to estimate V_{O_2}. This method starts from Fick's convection equation for the cardiovascular system [7] (3).

$$V_{O_2} = H_R S_v (C_a O_2 - C_V O_2) \tag{3}$$

Where H_R is heart rate, S_v is the stroke volume, C_aO_2 is the amount of oxygen in arterial blood and C_VO_2 is the amount of oxygen in mixed venous blood [7]. From this concept it is obtained that H_R and V_{O_2} are linearly related. Therefore we know that the HR can be used to estimate V_{O_2}, which will give a reflection of the intensity of the work being done [6]. In a laboratory, the HR can be measured to approximate metabolic expenditure during one or various exercises, if the exercise conditions are the same [6], as is the case of this study.

1.3 Symmetry assessment

Anisomelia or lower limb length discrepancy is present in at least 80% of the global population, where 6% to 8% has a lower limb discrepancy more than 20 mm. When an individual has a lower limb discrepancy more than or equal to 20 mm, he or she may experience irregular gait, joint overload and wear, as well as muscle contraction, elements that can alter the comfort factor [8]. Among the people who suffer a discrepancy more than 1.9 cm, are the individuals who experience a lower limb amputation, where at least 97.3% suffer from anisomelia, where 92% had a femur or tibial shortening surgery [9]. Hisham et al. explored the biomechanics of motion related to human walking gait using a motion capture-analysis system combining a High Definition Digital Single Lens Reflex (HD DSLR) Camera and $Kinovea^{®}$, a software that permits the measurement of angles and distances of any object of interest. This article was useful to validate the software as a reliable system, convenient to understand the biomechanics of the waling gait cycle [10]. Due to the role that symmetry plays during the gait cycle, this article, proposes symmetry as an important element to determine the comfort factor that an individual, one that suffers from transtibial amputation, may experience while using a novel prosthetic socket.

1.4 Satisfaction Survey

The satisfaction survey is a qualitative way to study the perceived impact of socket fit by the person with lower limb amputation. According to Turner [11], the survey must contain variables such as demographics (age, sex, educational level, marital status, weight, height), cause and side of the amputation, and time elapsed since the last prosthesis adoption.

1.5 The proposal: Comfort Factor (Cf)

The comfort factor proposed herein represents a quantitative way to evaluate the socket design and the components of a lower limb prosthesis basically from the measurement of the metabolic rate and heart rate. According to Jaegers et al. the relationship between comfortable and most metabolically efficient walking speed of persons with a limb amputation is relevant to an optimal design of the prostheses used by those persons. It is well known that in non-amputee subjects the most comfortable walking speed is very close to the most metabolically efficient i.e. the speed with the least metabolic rate per distance covered [12]. The proposed comfort factor (Cf), takes into account the symmetry assessment factor (Sf) of the lower limbs, ranging from 0.95 to 1.0, a satisfaction survey (S_s), whose total points where calculated, the metabolic rate (MR), and the peaks that show the heart rate (HR) of the amputee, both measurements, HR and MR, were obtained during the gait at a constant and defined speed (1.4 m/s). The proposed formula to obtain the Cf is given as (4) :

$$Cf = Sf(S_s - MR - HR) \tag{4}$$

Thus, the purpose of this study is to obtain the symmetry assessment factor of the lower limbs, obtained by dividing the lowest humerus length by the highest humerus length, as well as acquiring both, the metabolic rate and the heart rate of the volunteer while using different prosthetic devices, taking into consideration the satisfaction survey made to the participant, in order for us to calculate the comfort factor, so that prosthetists, physical therapists, amputation care centers, and rehabilitation centers can be able to evaluate and recommend the correct and personalized type of socket for a transtibial amputee.

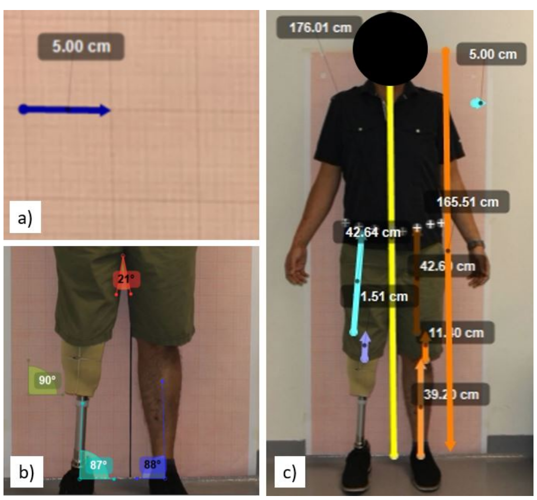
2 Methodology

Although the overall study will recruit 16 volunteers, and it has been approved by an Ethics Committee (PR2018-17Huegel), the current pilot trial study only has one participant. The 29-year-old volunteer, is a unilateral transtibial amputee, with at least one year since the amputation procedure. He has not any other musculoskeletal condition, nor cardiovascular, pulmonary or neurological disorders. During the test the participant wore two types of patellar tendon bearing prostheses (PTB). One of them had a socket which was designed and manufactured by conventional hand made process, whereas the other socket was designed using TAC images, finite element analysis (FEA) and 3D printing technology. The development of this protocol consisted in the application of a test to register data, and it also consisted in a data post-processing and analysis to calculate metabolic and heart rate.

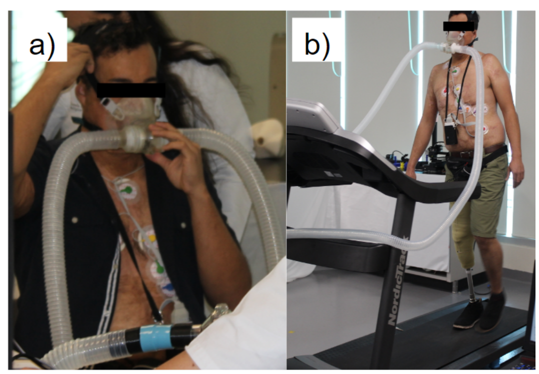
2.1 Preparation for the test

This protocol requires the volunteer not to ingest food for at least 6 hours prior to the test; the night before the test, the volunteer must sleep at least eight hours and he or she must not do any kind of intense physical activity on the day the test is done.

Firstly, the length of both lower limbs, are measured, for this to be possible it is necessary to take a picture with a digital camera, with a graph paper background, of the subject in standard anatomical position, with the body standing up straight and facing forward, with arms by the sides of the body and palms facing forward as well. The legs are straight, and the feet are slightly apart from one another and turned outward slightly. Once the picture was taken, it was uploaded to the software *Kinovea*®, where the measurement was calibrated, this was possible due to the graph paper background, where it was known that a square measured 5 cm. To calculate the error, it was necessary to measure the length of the graph paper and compare it to the actual length, the height of volunteer was measured as well as the length of each lower limb. Finally the standing legs angles were measured. The calibration and measurements are shown in Fig. 1a **b** and Fig. 1a **c**.



(a) Measurement calibration using *Kinovea*®.



(b) Voluntary test.

Fig. 1. (a) **a**: Escalated image of one of the squares of the graph paper with the calibration line. **b**: Angles formed by the lower limbs referenced to the floor while the volunteer is standing. **c**: Measurements of interest. Figure 1: (b) **a**: The volunteer is performing the Test at rest. **b**: The volunteer is performing the Test in motion.

Before the test starts, the volunteer is asked to take off all metal accessories, chest skin is cleaned with 95% alcohol, and electrodes are placed in precordial configuration, those electrodes are connected to the Hölter for ECG register. After that, a face mask is collocated to measure oxygen and carbon dioxide exhalation. The Fig. 1b shows a volunteer performing the test.

2.2 Test procedure: Resting and Motion

The tests were divided into two phases: the first at rest and the second in motion. In both stages ECG and Metabolic rate were measured at the same time, using the equipment described previously. The next paragraphs contain a detailed description of each phase.

The resting test has a duration of five minutes, in which the volunteer is in a sitting position, it is necessary to carry out continuous inspirations and expirations through the mouth, without using the nose at all.

In the motion test, the volunteer is asked to perform a walk on the treadmill for 10 minutes. The treadmill is programmed at a constant speed of $1.4m/s$.

ECG register and heart rate calculation The heart rate measurement is performed by analyzing the volunteer's ECG signals; these signals are recorded with a TLC5000 Hölter (by CONTECT®) during the test procedure. The TLC5000 is a small, lightweight, portable ECG system, capable of obtaining and storing data from precordial leads at a 200 Hz sample rate. Once the ECG is stored in the Hölter memory, it is downloaded and exported to Matlab®for its processing and analysis. First, a 0.5 Hz to 100 Hz bandpass filter is applied to decrease the noise of the signal. Then HR is determined by identifying the peak R and calculating its mean frequency of occurrence over time (the inverse of the R-R period).

2.2.1 O_2 and CO_2 register and metabolic rate calculation

The metabolic rate is obtained from the processing of the data registered with the $GASSYS2$. In order to record both, oxygen (O_2) and carbon dioxide (CO_2), firstly it is necessary to calibrate the $GASSYS2$ in the $BIOPAC^{®}$ software; the signal samples are registered at 100 Hz. Once it is all calibrated, a breathing mask is placed on the face of the volunteer; the breathing mask is connected to the $GASSYS2$ through plastic tubes from the same equipment. Taking the breathing frequency (BF) gives us an idea of how the volunteer is during the test, to know if he does not have difficulties during breathing and this may affect the data recorded in the test. According to Alexardenson, the RR at rest is 12 to 20 breaths per minute, but during exercise it can reach 35-45 breaths per minute [13].

The data obtained is then analyzed with the $Matlab^{®}$ software to find the metabolic rate. First, the airflow signal is filtered with a moving average, which is a calculation used to analyze the data obtained in the form of points and create an average of the signal, to smoothen the airflow curve. Subsequently, an integration method known as the trapezoid rule is applied to obtain the expired volume. Furthermore, the percentage data of O_2 and CO_2 is obtained with the same process. The value of V_{O2} is obtained through the registration of the V_{O2} curve captured by GASSYS2. The MR is finally obtained using the Eq. 1.

2.3 Satisfaction Survey

The satisfaction survey that was applied to the volunteers consisted of 12 questions. The responses ranged on a scale from 0, indicating that the volunteer was "unsatisfied", to 100, indicating that the volunteer was "completely satisfied", and they were used to score overall satisfaction with the socket.

On the next section, the results obtained after applying the mentioned methodology, are displayed.

3 Results and Discussion

3.1 Symmetry Assessment

As mentioned in the methodology section, the real measurements were compared to the ones obtained using $Kinovea^{®}$, the errors between these are shown in table 1, where the resultant errors are below the accepted 5%, with this into consideration, it was established that the software can be reliable, and that the measures obtained can determine the symmetry or asymmetry between the lower limbs lengths.

Tabla 1: Comparison between the real measurements and the obtained measurements in *Kinovea*® from the volunteer.

Measured object	Real measurement	*Kinovea*® measurement	Error
Graph paper height	165.00 cm	165.51 cm	0.3333
Height of the volunteer	176.00 cm	176.01 cm	0.0056

Earlier, it was established, that the comfort factor depended on the symmetry factor, to calculate this, a division must be made, where the numerator is the lowest lower limb length and the denominator the largest one. The right femur of the volunteer has a length of 50.17 cm, while the left femur length is 50.43 cm, so the symmetry factor is 0.9948.

3.2 Resting and Motion

For the resting test, the results of both, the respiratory and heart rate, were taken into account. The calculated mean heart and respiratory rate are shown in the Table 2. As it can be noticed, both variables exist in the normal rest interval. As it have been mentioned in the course of this document, HR, RR and MR were taken into account for the gait test. In the following section the results for this test are presented.

3.2.1 Heart Rate and Respiratory Rate

Heart rate and respiratory rate were obtained and calculated as it was explained in the methodology section. Table 2 shows the mean heart rate in beats per minute and the respiratory rate in breaths per minute; both were presented by the volunteer in the gait and rest tests.

Tabla 2: Mean heart and respiratory rate during gait and rest.

Phase	Volunteer	Socket	Heart Rate (Beats per minute)	Respiratory Rate (Breaths per minute)
Rest	1	Conventional	66.60	19.45
		Novel	71.80	11.53
Gait	1	Conventional	76.70	31.33
		Novel	81.20	23.98

3.2.2 Metabolic Rate

According to (1) that is used for the metabolic rate it is necessary to obtain VO_2 in the gait phase as shown in Figure 2 , it is important to mention that since the GASSYS2 sensor has a delay of approximately 80 seconds, the delay was taken into account for the following graphs, where the results of the volunteer with the different sockets that were tested will be shown.

The results obtained from VO_2 and the data of the volunteer are shown in table 3. With the data obtained from VO_2 and the superficial area body (A), it is possible to calculate the MR according to (1) in each of the volunteers sockets.

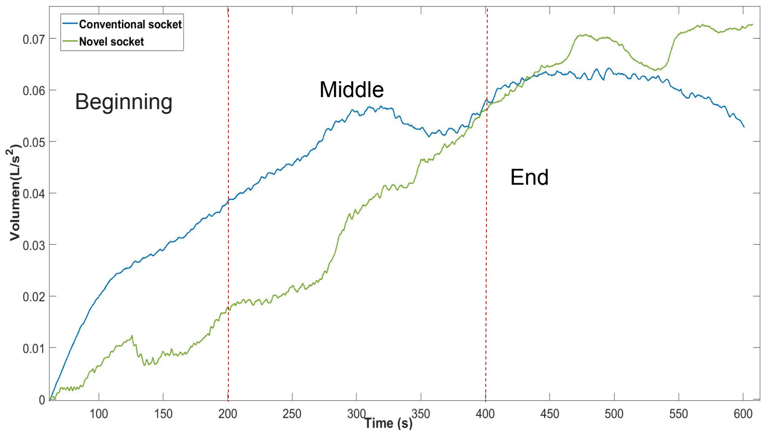


Fig. 2. VO_2 waves of the volunteer. The blue line corresponds to the conventional socket and the green line to the novel socket. The parallel lines divide the test time in phases , and each phase denotes the effort the volunteer has to make while using each type of socket.

Tabla 3: Results of VO_2 and Metabolic Rate.

Socket	Body superficial area (cm/kg)	VO_2 $(l/s^2)^2$	MR $(kcal/m^2/h)$
Conventional	2.06	0.31	42.39
Novel	2.06	0.24	33.92

3.3 Satisfaction Survey and comfort factor

The results of the satisfaction survey that was applied to the volunteer at the end of the test were obtained by adding the points of each of the multiple choice questions corresponding to each type of socket used by the volunteer during the gait, these are shown in table 4, the bigger the Cf, the better the comfort.

Tabla 4: Results of comfort factor.

Socket	Metabolic Rate $(kcal/m^2/h)$	Heart Rate (bpm)	Satisfaction Survey	Symmetry Factor	Comfort Factor
Conventional	42.39	96.1	501	0.9948	360.62
Novel	33.92	88.5	350	0.9948	226.40

4 Conclusions

From the results obtained from the comfort factor for the volunteer who participated in the test and who used both, a conventional socket and a novel socket, it could be concluded that Cf could represent a quantitative measure of the functional performance of the socket because it takes into consideration the lower limbs symmetry, physical perception and the measurement of HR and MR of the transtibial amputee. The results of the comfort factor for the volunteer show that he feels more comfortable with the conventional socket rather than the novel, and this result is confirmed by the VO_2 waves shown in Fig.2 in the tendency of the Novel socket curve to get up during the time consuming more VO_2, as well as it can be observed in the table 4, where the conventional socket has a higher Cf (360.62) than the novel (226.40).Finally, due to CoVid-19 contingency, it was not possible to recruit more participants and to obtain each of the elements proposed in order to obtain the comfort factor.

Declaration of conflicts of interest

The authors declare that they have no conflict of interest for this work.

References

[1] S. K. Au, J. Weber, and H. Herr, "Biomechanical design of a powered ankle-foot prosthesis," in *2007 IEEE 10th International conference on rehabilitation robotics*, pp. 298–303, IEEE, 2007.

[2] R. E. Quesada, J. M. Caputo, and S. H. Collins, "Increasing ankle push-off work with a powered prosthesis does not necessarily reduce metabolic rate for transtibial amputees," *Journal of Biomechanics*, vol. 49, no. 14, pp. 3452–3459, 2016.

[3] K. Ingraham, E. Rouse, and C. D. Remy, "Accelerating the estimation of metabolic cost using signal derivatives: implications for optimization and evaluation of wearable robots," *IEEE Robotics & Automation Magazine*, 2019.

[4] I. BIOPAC Systems, *Basal Metabolic Rate (BSL PRO Lesson H29)*, 2018.

[5] D. Mohrman and L. Heller, "Cardiovascular responses to physiological stresses," *Cardiovascular physiology. McGraw Hill*, p. 193, 2014.

[6] J. Achten and A. E. Jeukendrup, "Heart rate monitoring," *Sports medicine*, vol. 33, no. 7, pp. 517–538, 2003.

[7] P. J. Butler, J. A. Green, I. Boyd, and J. Speakman, "Measuring metabolic rate in the field: the pros and cons of the doubly labelled water and heart rate methods," *Functional ecology*, vol. 18, no. 2, pp. 168–183, 2004.

[8] L. Broche Vázquez, M. Torres Quezada, C. Díaz Novo, P. Pérez Bonne, and R. Sagaró Zamora, "Influencia de la asimetría de la marcha en el comportamiento biomecánico de las articulaciones de cadera en pacientes con prótesis transfemorales," *Ingeniare. Revista chilena de ingeniería*, vol. 23, no. 2, pp. 312–322, 2015.

[9] V. Sanchís, F. Vaquero, and F. León, "Las diferencias en longitud de las extremidades inferiores y su tratamiento," in *IX Congreso Nacional de la Sociedad Española de Cirugía Ortopédica y Traumatología*, pp. 19–30, Sociedad Española de Cirugía Ortopédica y Traumatología, 1962.

[10] N. A. H. Hisham, A. F. A. Nazri, J. Madete, L. Herawati, and J. Mahmud, "Measuring ankle angle and analysis of walking gait using kinovea," in *International Medical Device and Technology Conference*, pp. 247–250, 2017.

[11] S. Turner and A. H. McGregor, "Perceived impact of socket fit on major lower limb prosthetic rehabilitation: a clinician and amputee perspective," *Archives of Rehabilitation Research and Clinical Translation*, p. 100059, 2020.

[12] S. M. Jaegers, L. D. Vos, P. Rispens, and A. L. Hof, "The relationship between comfortable and most metabolically efficient walking speed in persons with unilateral above-knee amputation," *Archives of physical medicine and rehabilitation*, vol. 74, no. 5, pp. 521–525, 1993.

[13] E. A. Rosas and G. G. Ayala, *Fisiología cardiovascular, renal y respiratoria.* Editorial El Manual Moderno, 2014.