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Novel computational protocol to support transfemoral prosthetic alignment procedure using machine learning techniques

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ABSTRACT

Background: The prosthetic alignment procedure considers biomechanical, anatomical and comfort characteristics of the amputee to achieve an acceptable gait. Prosthetic malalignment induces long-term disease. The assessment of alignment is highly variable and subjective to the experience of the prosthetist, so the use of machine learning could assist the prosthetist during the judgment of optimal alignment.
Research objective: To assist the prosthetist during the assessment of prosthetic alignment using a new computational protocol based on machine learning.
Methods: Sixteen transfemoral amputees were recruited for training and validation of the alignment protocol. Four misalignments and one nominal alignment were performed. Eleven prosthetic limb ground reaction force parameters were recorded. A support vector machine with a Gaussian kernel radial basis function and a Bayesian regularization neural network were trained to predict the alignment condition, as well as the magnitude and angle of required to align the prosthesis correctly. The alignment protocol was validated by one junior and one senior prosthetist during the prosthetic alignment of two transfemoral amputees.
Results: The support vector machine-based model detected the nominal alignment 92.6 % of the time. The neural network recovered 94.11 % of the angles needed to correct the prosthetic misalignment with a fitting error of 0.51°. During the validation of the alignment protocol, the computational models and the prosthetists agreed on the alignment assessment. The gait quality evaluated by the prosthetists reached a satisfaction level of 8/10 for the first amputee and 9.6/10 for the second amputee.
Importance: The new computational prosthetic alignment protocol is a tool that helps the prosthetist during the prosthetic alignment procedure thereby decreasing the likelihood of gait deviations and musculoskeletal diseases associated with misalignments and consequently improving the amputees-prosthesis adherence.

1. Introduction

The goal of prosthetic alignment of the lower extremity is to match the prosthetic load lines with the anatomical and biomechanical ones of the amputee [1], to provide stability, an efficient gait, and movement functionality [2]. Prosthetic mismatches induce gait deviations that result in injury to the musculoskeletal system and affect the amputee's quality of life [3]. To avoid prosthetic misalignment, different technological tools such as biaxial tilt sensors [4–6], goniometers [7,8], comfort surveys, inertial and postural systems [9,10] are used as to help the prosthetist to assess the amputee's gait and identify the optimal or nominal alignment. The skills of the prosthetist to detect a gait deviation

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caused by prosthetic misalignment, their ability to simultaneously interpret biomechanical parameters, anatomical parameters, amputee feedback, among others, make the judgment of optimal or nominal alignment a complex, iterative and subjective procedure.

The use of computational modeling techniques could assist the prosthetist during the judgment of nominal alignment [11–13]. However, few authors have used computational models as tools to assist during the assessment of prosthetic alignment. Luengas et al. proposed a decision rule model to predict the center of pressure (COP) and joint angles of the hip, knee and ankle during flexion-extension prosthetic alignment variations of transtibial prostheses during standing [14]. For the same purpose, Camargo et al. used Generalized Regression Neural Networks (GRNN) reaching a maximum error of 6.25 % in the estimation of COP and joint angles of hip, knee and ankle [15]. In [16] they trained a Support Vector Machine (SVM) based classifier to differentiate correctly aligned and misaligned transtibial prostheses from the components of the Ground Reaction Force (GRF). The SVM achieved a detection accuracy of 96.67 % within the same subject and 88.89 % for inter-subject. Luengas et al. used neural networks (NN), decision trees (DT), and SVM to identify the best prosthetic alignment during the standing of transtibial amputees [17,18]. They used center-of-pressure (COP) parameters in the mediolateral and anteroposterior directions. The nominal alignment matched in 96.22 % of the cases with the NN method and in 100 % with the SVM and DT algorithms.

The literature search did not find any articles that provided information on the use of machine learning techniques to evaluate the quality of alignment of transfemoral prostheses. Considering the gap for transfemoral prosthetic alignment, this article proposes a novel protocol to assist prosthetists during the analysis of biomechanical parameters and the selection of the ideal prosthetic alignment for transfemoral amputees during the dynamic alignment procedure. The alignment protocol consists of a SVM model with a Gaussian radial basis function to detect prosthetic misalignments. In addition, a Bayesian Regularization Neural Network (BRNN) is used to predict the magnitude and angle required to correct the socket and prosthetic foot misalignment from the GRF parameters [19]. The computational models were evaluated, trained and tested with a population of sixteen transfemoral amputees and the effectiveness of the protocol was validated with two volunteers.

2. Methods

2.1. Subjects and experimental equipment

The Ethics Committee of the Institute of Medical Research of the Universidad de Antioquia (Medellín, Colombia) approved this research study. The computational models were trained using a population of sixteen transfemoral amputees, two women, and fourteen men. The volunteers were unilateral non-contracted transfemoral amputees, with a functional level K> =2, at least six months of experience in the use of transfemoral prostheses, older than eighteen years and had no other diagnosed musculoskeletal limitations. Two female and fourteen male below-knee amputees were recruited. Nine of them had left-sided amputation and seven had right-sided amputation. The main cause of amputation was traumatic. The population characteristic was 35.4($\pm$ 11.1) years old, weighted 65.8($\pm$ 10.3) kg, 166.7($\pm$7.7) cm tall, and a body mass index of 23.7($\pm$ 3.0). The prosthetic devices were assembled by Mahavir Kmina Artificial Limb Center in Medellín, Colombia. A quadrilateral socket, an unidirectional vacuum valve for suspension, prosthetic knee ReMotion (D-Rev V3, USA), and Jaipur foot (BMVSS, Jaipur, India) were used to assemble the prosthesis.

Bench and static alignment of the prostheses was performed by two prosthetists following the location of the trochanter-knee-ankle (TKA). Nominal or optimal dynamic alignment was achieved by two prosthetists by assessing the amputee's standing and walking. Four prosthetic misalignments were performed for each amputee, considering alterations of the socket and prosthetic foot angles. The prosthetic knee and shank were the reference elements for the alignment variations for the socket and foot respectively. All volunteers were blinded on the alignment tests. The misalignment experiments followed three stages: (1) Random variations between -18.0° and 28.0° of the sockets were performed in flexion-extension, adduction-abduction, and internal-external rotation. In parallel, random variations of the prosthetic foot were made between -13.0° and 11.0° in dorsal-plantar flexion, eversion-inversion, and internal-external rotation. Excessive changes in misalignment angles were avoided because they increased the mechanical stress on the pyramidal adapter screws, increasing the likelihood of amputee falls. (2) The amputees walked for fifteen minutes along a ten-meter walkway using their self-selected walking speed. During the final five minutes of the test, three records of the ground reaction force of the prosthetic member were averaged. (3) The amputees were asked about the level of walking satisfaction with the previously performed alignment and then allowed to rest for twenty minutes.

The remaining four repetitions were referred to as misalignments. The GRF raw data were filtered using a Butterworth second-order low pass filter with a cutoff frequency of 20 Hz to eliminate the electromagnetic noise of the GRF measurements.

The ground reaction force was recorded with the force platform P6000 (BTS Bioengineering, Italy) with a sampling rate of 120 Hz and processed using the Smart Clinic and Smart Analyzer software (BTS Bioengineering, Italy). MATLAB (MathWorks, USA) was used to analyze the signals and train the computational models. Alignment variations were recorded with a goniometer, a protractor ruler, and verified by image analysis with Geogebra software (International Geogebra Institute, Austria). For the calculation of the angles using GeoGebra, reference points and laser line projections were used. With the double check we could ensure errors in the angles of about 0.1°.

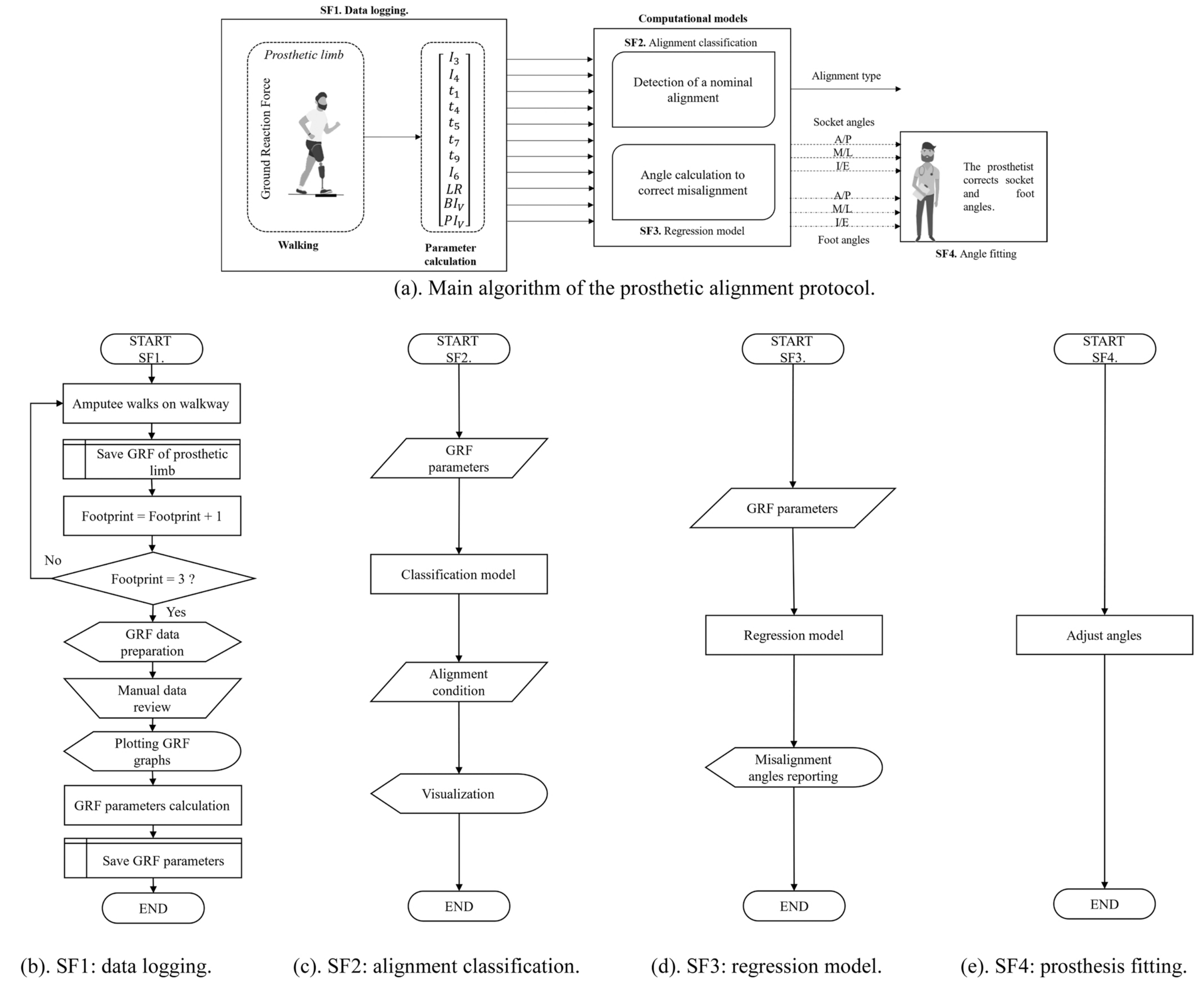
The force platform records the Ground Reaction Forces while the volunteer stepping on it (stance phase). A set of GRF parameters were selected due to their effectiveness in prosthetic gait analysis [15,16] and particularly those that showed statistically significant differences between nominal alignment and misalignments for transfemoral amputees [19]: the braking force impulse (I_3), propulsion force impulse (I_4), duration of the stance phase (t_1), duration of the braking phase (t_4), duration of the propulsion phase (t_5), time to propulsion peak (t_7), time to midstance valley (t_9), the impulse of terminal stance and pre-swing (I_6), the loading rate (LR), and the vertical braking impulse (BI_V) and propulsion impulse (PI_V).

2.2. Transfemoral prosthetic alignment protocol and validation

The block diagram of Fig. 1.a shows the computational alignment protocol. The subfunctions of the protocol are developed in Fig. 1.b-e. Subfunction SF1 describes the data collection and processing procedure. SF2 shows the process performed by the classification model and function SF3 defines the computational regression model process. Finally, SF4 describes the prosthetic alignment adjustment performed by the prosthetist using the angles suggested by the computational alignment protocol.

The alignment protocol was limited to three iterations to achieve convergence on nominal alignment. For each iteration, the prosthetist was asked about the diagnosis of the resulting alignment, nominal or misaligned. The results of the computational protocol were compared with the prosthetist's alignment trial to evaluate the success of the protocol. Two prosthetists, one junior and one senior performed and evaluated the alignments suggested by the protocol. The prosthetists in isolation observed the amputee's gait in the sagittal, coronal, and transverse planes without any time restrictions and moved freely along the gait walkway during the observation. Then, according to their experience, they evaluated the quality of the gait achieved with the alignment proposed by the automatic alignment protocol. A score from 1 to 10 was used for the evaluation.

Mahavir Kmina Prosthetic Center supplied the prostheses for the



(a). Main algorithm of the prosthetic alignment protocol.

(b). SF1: data logging. (c). SF2: alignment classification. (d). SF3: regression model. (e). SF4: prosthesis fitting.

Fig. 1. Architecture of computational prosthetic alignment protocol.

volunteers. Two transfemoral volunteers were recruited with a mean age of 37.0 ± 11.3 years, an average weight of 59.9 ± 1.6 kg, an average height of 166 ± 0.0 cm, and a body mass index of 25.4 ± 0.6. A completely new prosthesis was fabricated for each patient to avoid any bias associated with prosthesis wear or biomechanical gait adjustment due to the adaptation of the amputee to the prosthesis.

At the end of the test, the prosthetists were asked for the following information: (1) According to your alignment experience, rate the alignment suggested by the computational protocol (between 1 and 10). (2) Regardless of the effectiveness of this new protocol, do you consider that this type of initiative should be further developed? Please rate the importance from 1 to 10. (3) Has the alignment protocol allowed you to make a better alignment? Rate the importance from 1 to 10. (4) Did it take you longer to do your work with this new protocol? How long did it take (in minutes)?

2.3. Computational models design and validation methods

The alignment protocol proposed in this article involved the design of two computational models. A Bayesian regularization neural network (BRNN) was trained using thirty hidden layers, an input vector composed by the ground reaction force indices I_3, I_4, t_1, t_4, t_5, t_7, t_9, I_6, LR, BI_V, and PI_V. The output vector was formed by the magnitude and direction of the socket and foot that the prosthetist had to correct to achieve the nominal alignment (Eq. 1). The BRNN was trained on 70.0 % of the dataset, 15.0 % was used in validation and 15.0 % for computational model testing. The cross-validation technique was used defining thirty folds (k = 30).

$$\underbrace{\begin{bmatrix} ME_{S_{AP}} \\ ME_{S_{ML}} \\ ME_{S_{IE}} \\ ME_{F_{AP}} \\ ME_{F_{ML}} \\ ME_{F_{IE}} \end{bmatrix}}_{\text{Angle to correct misalignment}} = \underbrace{\begin{bmatrix} s_{M_{AP}} \\ s_{M_{ML}} \\ S_{M_{IE}} \\ F_{M_{AP}} \\ F_{M_{ML}} \\ F_{M_{IE}} \end{bmatrix}}_{\text{Nominal alignment}} - \underbrace{\begin{bmatrix} s_{N_{AP}} \\ s_{N_{ML}} \\ S_{N_{IE}} \\ F_{N_{AP}} \\ F_{N_{ML}} \\ F_{N_{IE}} \end{bmatrix}}_{\text{Misalignment}} \tag{1}$$

The Support Vector Machines (SVMs) considering the Gaussian radial basis function Kernel were used to classify the GRF parameters of amputees walking with a nominally aligned and misaligned prosthesis [20]. The SVM outputs were two classes, nominal aligned or misaligned prosthesis. The SVM used the same inputs used in the BRNN [19]. The training, validation, and testing dataset were 70.0 %, 15.0 %, and 15.0 % respectively. The K-Fold cross-validation used 30 folds. Finally, the best model was chosen according to the estimation error, model performance, accuracy, sensitivity, and specificity [21]. Confusion matrices and receiver operating characteristic (ROC) curves were used to evaluate the performance of the SVM computational model [22,23].

3. Results

3.1. Alignment classification model

The SVM model output during validation was able to classify 95.5 % of the dataset, misclassifying four alignments. The inter-subject classification accuracy was 96.4 %, the sensitivity 98.2 %, and the specificity 94.5 %. The confusion matrix in Fig. 2.a shows that three of the prosthetic misalignments were classified as nominal alignments (5.5 %), and only one nominal-type alignment was classified as a misalignment (1.8 %). Fig. 2.c shows with a spaced line the experiments that were misclassified. The misclassified alignments corresponded to four amputees. Fig. 2.b and Fig. 2.d show the receiver operating characteristics (ROC curve). The classification model tested with unknown data achieved an accuracy of 92.6 %, misclassifying two misalignments as nominal alignments.

3.2. Alignment regression model

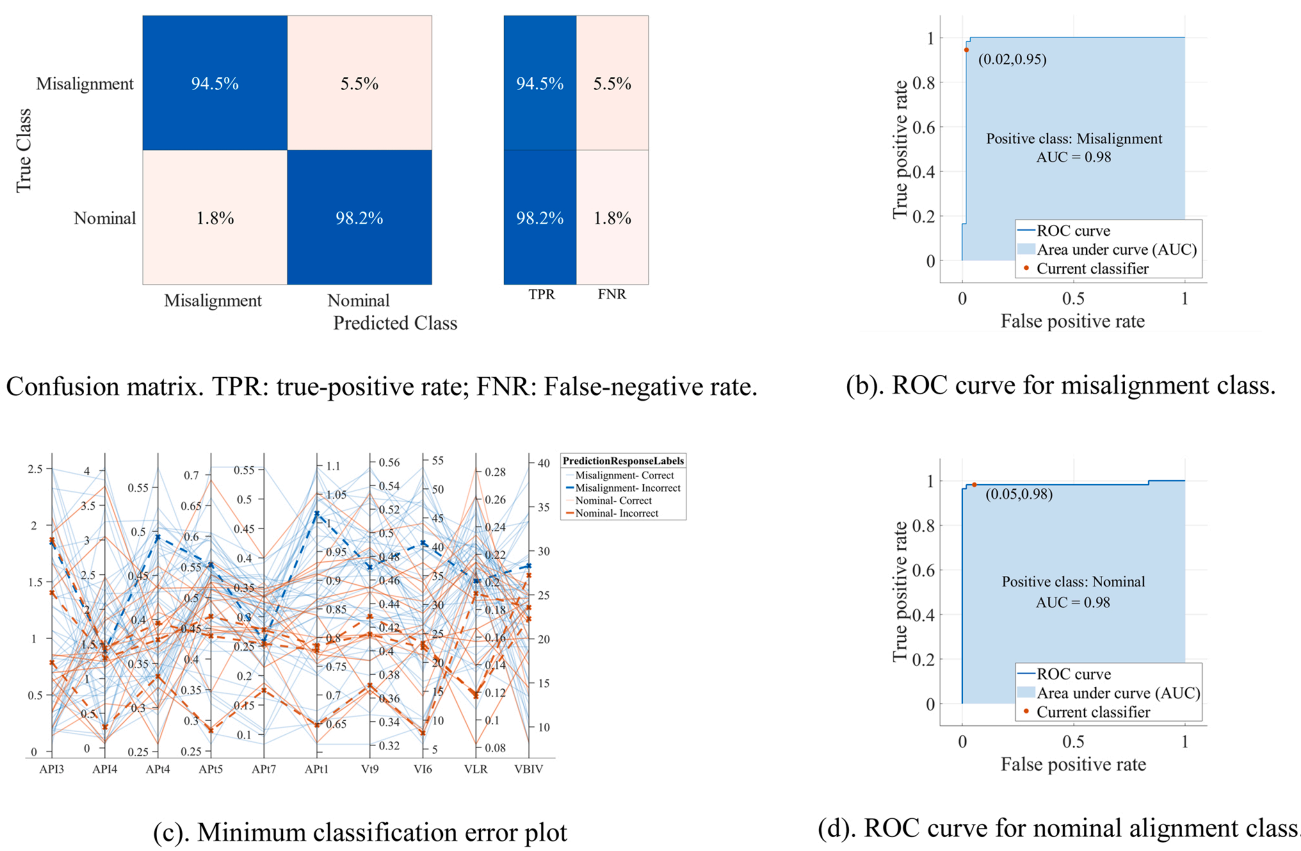
The best model fitting was achieved for thirty hidden layers and the result is shown in Fig. 3. The computational model recovered the 100 % data during the training process. The validation (Fig. 3.a) and (Fig. 3.b) testing procedure recovered the 94.11 % and 77.27 % of the alignment dataset, respectively. The error histogram plot (Fig. 3.c) shows that the error is concentrated in values close to 0.51°, so this value was considered the accuracy of the regression model.

3.3. Validation of the prosthetic alignment protocol

The alignment protocol was validated with two volunteers randomly selected from the initial set of amputees. The prosthetic alignment protocol was performed at the Mahavir Kmina Prosthetic Center for two days. The validation results are presented for each amputee in Table 1.

Results for amputee 1. During the first iteration the computational protocol and the prosthetists indicated that the prosthesis was misaligned. Prosthetists rated the amputee's gait with an average score of 3.9. During the second iteration, the computational protocol and the prosthesis again indicated that the prosthesis was misaligned, and the gait was rated 5.7. At the last iteration, the prosthetists and protocol indicated that the prosthesis was misaligned but rated the gait an 8.0. Throughout all experiments, the protocol and prosthetists agreed on the prosthetic alignment trial. The prosthetic adjustments suggested by the protocol improved the amputee's gait performance from 5.4 to 8.0. The amputee reported no difficulties during the execution of the protocol. The prosthetists had difficulty adjusting the angles in the first iteration; however, they quickly learned to perform the angulations. Results for amputee 2. During the first iteration, the prosthetists and the computational protocol agreed in judging the prosthesis as misaligned, rating the gait with an average score of 6.7. In the second iteration, the alignment computational protocol and the prosthetists assessed the alignment as nominal, and the prosthetists rated the amputee's gait with an average score of 9.6. This meant that the adjustment angles suggested by the protocol allowed the nominal alignment to be achieved. At the end of each alignment procedure, prosthetists were consulted about the procedure.

Fig. 4 shows the result of questions one to three. The prosthetists gave an average score of 8.18 to the prosthetic gait after applying the computational alignment protocol. The prosthetists rated this type of computational assistance of prosthetic alignment at 8.52 and stated that the alignment protocol allowed them to do a better job, rating it at 8.58.



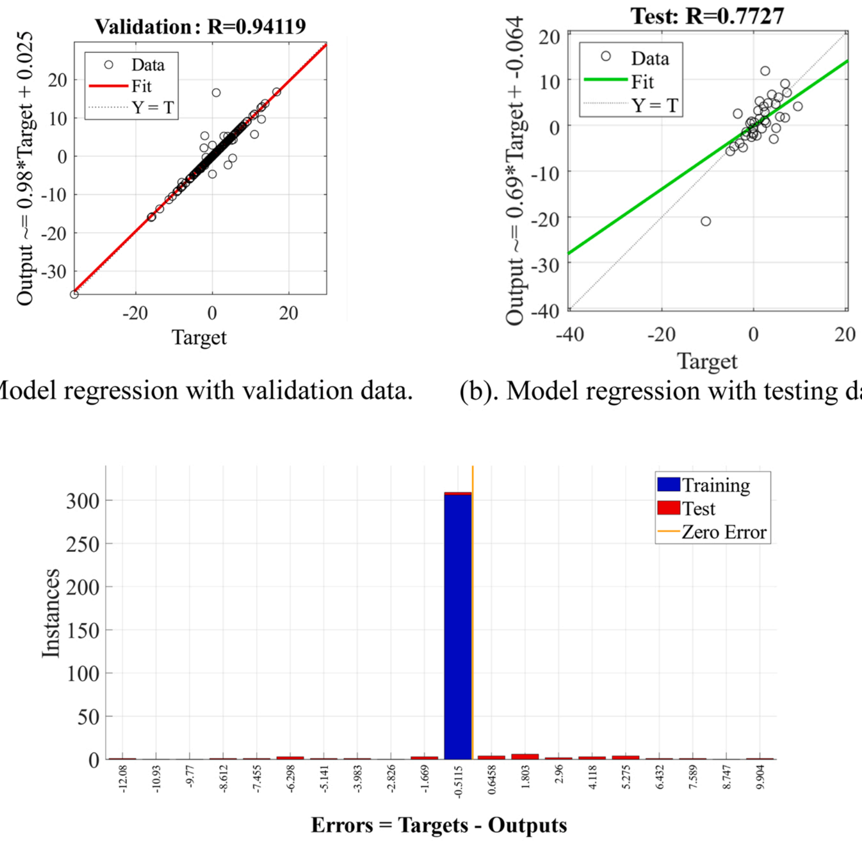
(a). Confusion matrix. TPR: true-positive rate; FNR: False-negative rate.

(b). ROC curve for misalignment class.

(c). Minimum classification error plot

(d). ROC curve for nominal alignment class.

Fig. 2. Validation charts of the classification model performance for the support vector machines.



(a). Model regression with validation data. (b). Model regression with testing data.

(c). Error histogram.

Fig. 3. Results of the neural network trained.

Table 1
Performance of prosthetic alignment protocol. Meaning of acronyms: Flexion (F), extension (E), adduction (Add), external-rotation (ER), internal-rotation (IR), plantar-flexion (PF), Dorsi-flexion (DF), and Eversion (Ev). This table describes the score evaluated by junior and senior prosthetists for each iteration of the protocol. Also included is the prosthetists' judgment of the type of prosthesis alignment according to the amputee's gait, as well as the type of alignment according to the computed protocol.

No.	It.	Prosthetist's score		Proposed alignment angles	Alignment assessment according to gait analysis		
		Junior	Senior		Junior prosthetist	Senior prosthetist	Computational alignment protocol
1	1	4.3	3.4	Socket: | 1.8° F | 8.3° Add | 5.9° ER | Foot: | 4.4° PF | 2.7° Ev | 5.9° IR |	Misalignment	Misalignment	Misalignment
	2	5.2	6.2	Socket: | 1.2° F | 1.3° Add | 1.3° ER | Foot: | 4.1° PF | 1.0° Ev | 1.7° IR |	Misalignment	Misalignment	Misalignment
	3	7.6	8.4	Socket: | 0.4° F | 0.8° Add | 0.7° IR | Foot: | 1.2° PF | 0.8° Ev | 1.1° IR |	Misalignment	Misalignment	Misalignment
2	1	5.9	7.5	Socket: | 1.4° F | 0.8° Add | 0.3° ER | Foot: | 0.6° PF | 2.0° Ev | 0.1° IR |	Misalignment	Misalignment	Misalignment
	2	9.8	9.4	Socket: | 0.7° E | 0.7° Add | 0.2° IR | Foot: | 0.1° DF | 1.2° Ev | 0.8° IR |	Nominal alignment	Nominal alignment	Nominal alignment
	3	-	-	-	-	-	-

In the question four, the senior prosthetist took 37 min longer using the computational protocol than the normal alignment procedure, while for the junior prosthetist it took no longer than usual.

3.4. Discussion

The aim of this work was to propose an alignment protocol to support the prosthetist during the evaluation of the prosthetic alignment of transfemoral prostheses. Two computational models were proposed, one to predict the nominal alignment from the prosthetic limb ground reaction force parameters, and another to provide the socket and foot setting angles to achieve the nominal alignment. Our protocol presents a significant advance with respect to the work presented in the literature. The most relevant works were proposed by Luengas et al., Camargo et al., and Zhang et al., in which they developed classifiers and regression models to assist prosthetic alignment of transtibial amputees [15–17]. Zhang et al. proposed a classification model using SVM with a Radial Basis Function (RBF) kernel to automatically detect transtibial prosthetic misalignment through ground reaction force (GRF), achieving 88.89 % accuracy [16]. Luengas et al. used the SVM, Neural Networks (NN), and Decision Trees (DT) to classify the alignment between nominal and misalignment based on the center of pressure during standing [17,18]. SVM and DT models differentiated the standing gait of transtibial amputees during the use of misaligned and nominally aligned

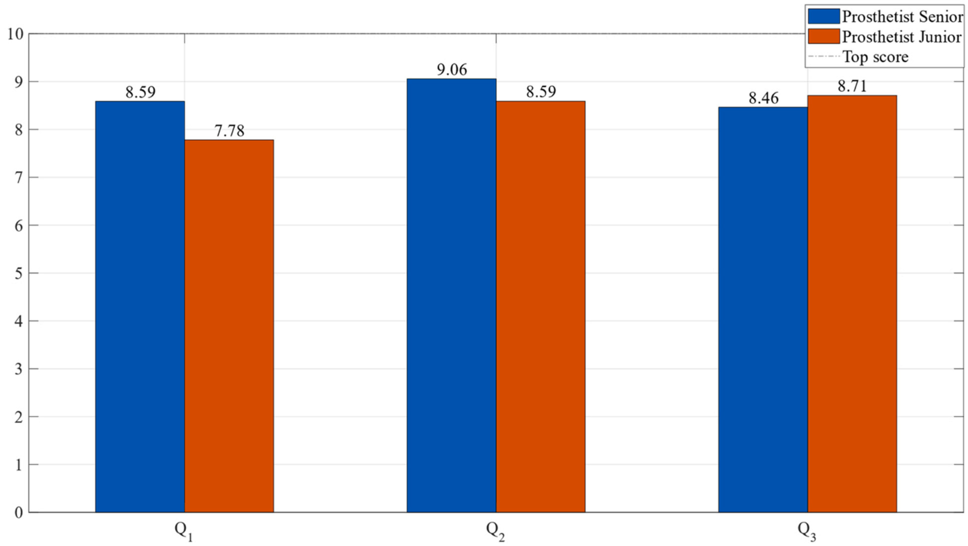


Fig. 4. Opinion survey of the prosthetic alignment computational protocol. The Q_1, Q_2, and Q_3 labels refer to questions of the survey. The scale of Q_1, Q_2, and Q_3 are between zero to ten.

prostheses with accuracies of at least 96.2 %. Our classification model using SVM with a Gaussian kernel achieved 95.5 % accuracy in classifying nominal and misaligned gait of transfemoral amputees. This result is an advance over that achieved with transtibial amputees. Regarding the regression models, Luengas et al. used decision rules to predict the effect of prosthetic socket location on joint ranges, the center of pressure and weight distribution of transtibial amputees during standing in which the models reached accuracy levels greater than 98.0 % [14]. Camargo et al. used Generalized Regression Neural Networks (GRNN) to estimate joint ranges and center of pressure in ipsilateral and contralateral sides using socket flexion-extension alignment angles in a transtibial prosthesis [15]. Their prediction model exhibited approximation errors of 6.25 %. The neural network trained in our work achieved errors of less than 5.8 % and was able to estimate the angle of adjustment of the socket and prosthetic foot to achieve the nominal alignment of the prosthesis.

To our knowledge, there are no computational models in the literature focused on assisting the alignment of transfemoral prostheses. Therefore, the result of our work is an important contribution in the prosthetic fitting of transfemoral amputees, since it guides the prosthetist during the alignment procedure, gives information about the angles needed to align the prosthesis correctly and assists the prosthetist during the evaluation of the quality of the alignment of transfemoral prostheses.

During the training and validation process of the classification model using support vector machines, the alignment was correctly classified except for four trials. To find an explanation for this fact, we assessed the satisfaction levels of volunteers during misclassified alignments. The level of satisfaction reported by amputees during alignment variations was a confounding factor, since in some cases amputee satisfaction with walking with a misclassified prosthesis was close to or higher than that of the nominal alignment. Under this consideration, it is possible that the prosthetist did not understand the cause of the gait deviation, confusing the biomechanical effect of the misalignment with the gait deviations previously adapted by these amputees [24].

The use of specific types of prosthetic foot (Jaipur foot), socket (ischial retention) and polyaxial knee (automatic locking, D-Rev), among other specificities, could limit the scope of the protocol for these types of prostheses, so future studies should include different prosthetic devices. However, some modifications could be implemented to the protocol to be used with other mechanical devices with translation and rotational movements The ability of amputees to adapt their gait patterns to accommodate prosthetic misalignments [25,26] and the amputee's previously acquired gait deviations could mask the effects of prosthetic misalignment [24] so that the judgment of the nominal alignment could have been distorted; however, we tried to minimize this effect by allowing adaptation times to alignment changes of less than 10 min.

Finally, the alignment protocol proved to be effective during validation, successfully identifying the type of prosthesis alignment in all experiments. It converged to nominal alignment in one of the subjects and in all cases the alignment variations suggested by the protocol succeeded in improving the amputee's gait. The applicability of the protocol in prosthetic centers is high, as there is no restriction on the ability of the prosthetist to perform the alignment procedure. The computational cost is low, so it can be performed on any computer. Only one force platform needs to be used, so there is no need for large investments to use the protocol. The use of statistically calculated force descriptors allows a higher degree of objectivity in the alignment procedure.

Declaration of Competing Interest

Authors Juliana Uribe, Josep M. Font-Llagunes, Alher M. Hernández, and Jesus A. Plata certify that they have no affiliations or involvement with any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript. Andrés Mauricio Cárdenas Torres is the beneficiary of a grant by the Administrative Department of Science, Technology and Innovation (Colciencias) of the Republic of Colombia "727 - Colciencias National Doctorate Scholarship Program 2015". However, this does not imply any limitation for the publication of the article.

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