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Fusion of Variables and Processes. Optimization in Prosthetics using Regression Models

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Abstract
In this paper, we propose a new objective method for estimating the comfort in prosthetics involving a stump-cuff-cup optimisation, a linear correlation and fusion of measurement variables. The basic idea is that the person with prosthesis feels better (has a greater comfort and satisfaction) if a combination of personal sensory perceptions relative to comfort / discomfort are perceived with varying degrees of acceptability.The aim of this paper is to find an effective method to select an optimal combination for socket-cup material (the same type of prosthesis) of a proper choose for one type of prosthesis using customized on a specific patient. For modelling and simulation, the stump-prosthesis-cuff assembly is scanned and it is determined the set of points for each element. The elements are re-assembled into a 3D spatial reconstruction. The patient’s perception on the handicap of prosthetics functionally and sensorially is determined by the method of the questionnaire. We propose a linear regression model in the first phase, which takes into account all the variables that influence the patient’s comfort with transtibial prosthesis. It is considered that different combinations of cuff-cup materials can produce various levels of satisfaction. This assertion is validated experimentally and specified in this article when different patients, depending on the person, feel comfortable at the maximum level with different types of cuffs and different materials. It is noticeable that in the fusion of non-optimised variables, the coincidence values are at least as good as the best ones for the individual variable. We proposed a method and application for objective evaluation of the patient’s satisfaction in transtibial prosthetics using fusion of variables. The questionnaire technique is used to validate our assertion. The results were very good, but the weighting coefficients were determined empirically.

Keywords: Comfort/Discomfort, transtibial prosthesis, Fusion of variabiles, multivariate regression

Introduction
The neuroreceptors of lower limbs transmit to the subject basic feelings including pain, touch (pressure and vibration), tensions of muscles, tensions of tendon and temperature (Neumann: 2001). Generally speaking, the term of comfort / discomfort refers to the problems that arise at the interface of the cup or cuff with the tegument of the patient’s stump, therefore, it is not basically a basic feeling of the human body. The perception / feeling of discomfort are as such a combination of two or more feelings that lead to a negative valence of the patient’s condition. Note that the feeling of discomfort is not always association with pain, but the pain will always cause a feeling of discomfort. The age, geographical area, genetic factors, and obviously the prosthetic materials, as well as the chosen prosthesis, respectively or / and cuff influence the comfort of the patient. The assessment of the comfort status is usually made on the basis of some medical validation questionnaires (Legro: 1998 and Van de Weg: 2005), but the questionnaire’s construction is clearly subjective and dependent on personal sensory perception, with personalised aspects according to the profile of those preparing the questionnaire, including the answers to the questionnaires. A numerical scale ranging from 0 to 10 of qualitative assessment is usually used, with 10 as the highest for satisfaction (Van de Weg: 2005). As a result, the assessment of discomfort feeling is subjective, and several methods are presented in the literature that deals with this subject using different measurement scales: the interval scale, the categorical scale, and the categorical ratio scale of Borg. Among these, the most commonly used in hospitals and clinics is VAS

(visual analogue scale), but there are also reports that this scale is not sensitive to verbal descriptors that separate the pain intensity from painful discomfort. The methods of quality assessment of prosthesis in terms of patient satisfaction can be divided into two: subjective methods (satisfaction questionnaires) based on subjective answers of patients and objective methods, based on the assessment of values of physical quantities, without consent feedback from patients. An objective method of quality assessment of prosthesis may be a measure of deviation from normal movement calculated by a method that takes into account the motion cycle and the kinematics values of some points on the human body (and prosthesis) that are qualitative characteristics of movement. The methods using kinematics indices of the movement have as their primary objective the assessment of a (possibly pathological) situation compared to a normal situation (given by a reference group or person). There are many papers dealing with the quantification of kinetic deviation from normal walking, but to the knowledge of the author, there is only one paper dealing with the applicability of the motion cycle measurement summaries for transtibial amputations (unilateral, single limb) (Kark: 2012).The most used indexes are: the Gillete index (Gillette Gait index -GGI), Gait Profile Score - GPS, and the Movement Analyse Profile (MAP). A summary of the medical measurements including questionnaire-based techniques and assessment of the quality of life of the patient with prosthesis is presented (Condie: 2006). In most cases, the authors record and calculate the kinematics using the Plug-In-Gait (Vicon, Oxford Metrics) model and place markers in line with the Helen Hayer set of markers. The markers are devices that emit light or reflect light in a dark background, and it is possible to determine the trajectory of the luminous point using video processing. Each method has advantages and disadvantages. What we propose in this paper is a semi-empirical method to combine the effects of several methods and optimise their weight in a (linear or non-linear) fusion function to maximise the effects of each method and minimise the global disadvantages

Materials and methods

For modelling and simulation, the stump-prosthesis-cuff assembly is scanned and then, using contour detection routines, it is determined the set of points for each element (stump, tibia, fibula, skin, cuff, cup) for the spatial reconstruction using NURBS (Non-uniform rational Basis spline) curves - mathematical model for curved lines and surfaces, implemented in the CAD/CAE SolidWorks 2012 Premium package (Figure 1 and Figure 2). The elements are re-assembled into a 3D spatial reconstruction

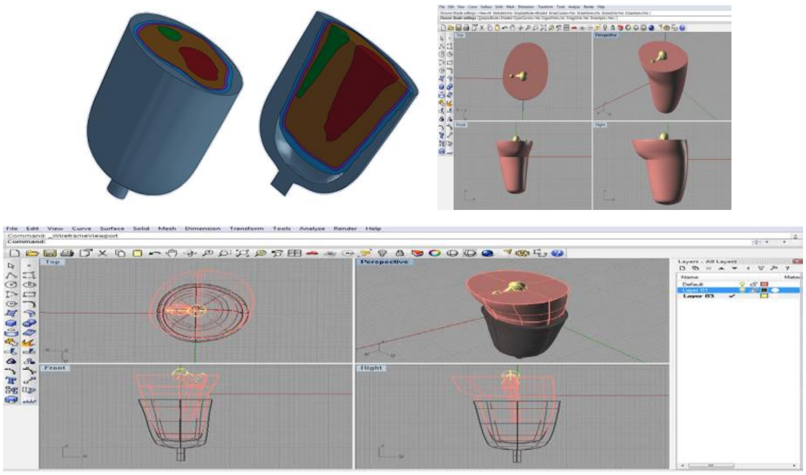

Fig. 1: Spatial reconstruction (3D) of the stump-prosthesis-cuff assembly and section in this assembly

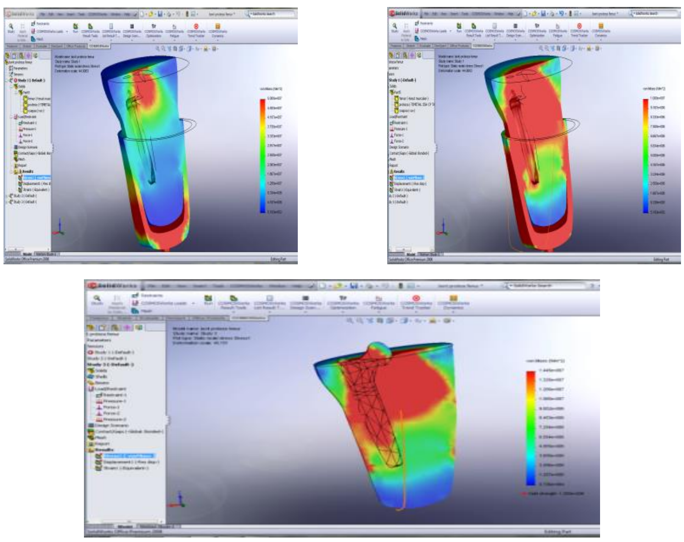

Fig. 2: Section at the blunt-prosthesis ensemble and section at the blunt-prosthesis ensemble (highlighting the influence over the bone) and blunt section

In order for surfaces to have only contact and not to intersect, manual corrections are made to CT (computerised tomography) scans, the output of which provides sections in the form of dots forming closed curved, and then the 3D reconstruction shall be made in SolidWorks 2012 with the option in this software instrument (use of NURBS curves). If the approximation with these curves generates bodies that have areas that enter each other (it is not possible in our case that, for example, the stump and cuff have common 3D areas), the points that create problems are manually corrected, moving spatially with infinitesimal distances until the modelling requirements in SolidWoks are fulfilled (Condie:2006).The patient's perception on the handicap of prosthetics functionally and sensorially is determined in the medical practice by the method of the questionnaire. A complex evaluation formula was used by the Study Group of Prostheses and comprises 82 questions, which have an analogue-linear format, with 42 elements sorted on 9 scales: walking, appearance, frustration elements, level of perception of the prosthesis' answer to requests, health of the stump, social issues of discomfort, utility, well-being, sound level of the prosthesis in operation (Kadaba: 1989 and Legro:1999).The use of the kinetic index for postural analysis is present in several papers and is based on the quantification of kinetic deviation from normal walking (Rozumalski : 2011 and Schwartz: 2008). To the author's knowledge, there is only one paper dealing with the applicability of the motion cycle measurement summaries for transtibial amputations (unilateral, single limb) (Kark: 2012). A summary of the medical measurements including questionnaire-based techniques and assessment of the quality of life of the patient with prosthesis is presented in (Condie: 2006).In previous papers, we proposed the use of the GDI index as an objective measure of the prosthesis performance centred on the needs of a patient (Rozumalski : 2011). The results were encouraging, so we propose the use of other objective methods, in the same range of approaches, of functional scores that take into account the effects of the patient's effort in wearing prostheses from combinations of materials (cup and cuff), for optimisation. The Physiological Cost Index (PCI) was introduced by MacGregor to estimate the energy consumption while walking (MacGregor: 1981). The assumed principle is that a higher energy consumption, indicating greater effort, involves a decrease in comfort and vice versa, a low energy consumption leads to an increase in comfort. The method proposes a linear relationship between the amount of oxygen consumed by the person and the heart rate and defines the PCI coefficient as:

$$PCI = \frac{FC_W - FC_R}{V_{walking}\,(m/\min)} \qquad (1)$$

In formula (1), FC_W is the heart rate during exercise (normal walking), FC_R is the heart rate during rest, and $V_{walking}$ is the walking speed and is measured in m/min. The veracity of the average PCI for healthy adults has been validated by several medical studies since 1993, with an average value of between 0.23 and 0.42. The literature is extremely reduced with regard to people with amputations; practically three papers have been discovered, of which only two make comparisons between healthy people and people with amputations.

One of the problems identified was that any method gives 100% results only if it is applied to small batches of patients. If the number of patients is high, each method that uses variable resulting from a particular type of process has its advantages and disadvantages. Most of the processes that have the highest weight (based on the papers in the medical and technique-prosthetics literature) were analysed in the estimation of the comfort of unilateral prosthesis of calf. After studying the process of interaction between elements, aiming at patient's comfort, the diagram of interaction in Figure 3 resulted.

We propose a fusion of variables that include more scores using different variables and processes. The fusion of variables is used in many applications, especially when information from multiple sensors needs to be considered (Hall:1997 and Khaleghi : 2013).We extend these techniques to the practical case of optimising combinations of materials used for transtibial prosthetics, centred on the personalised needs of the patient.

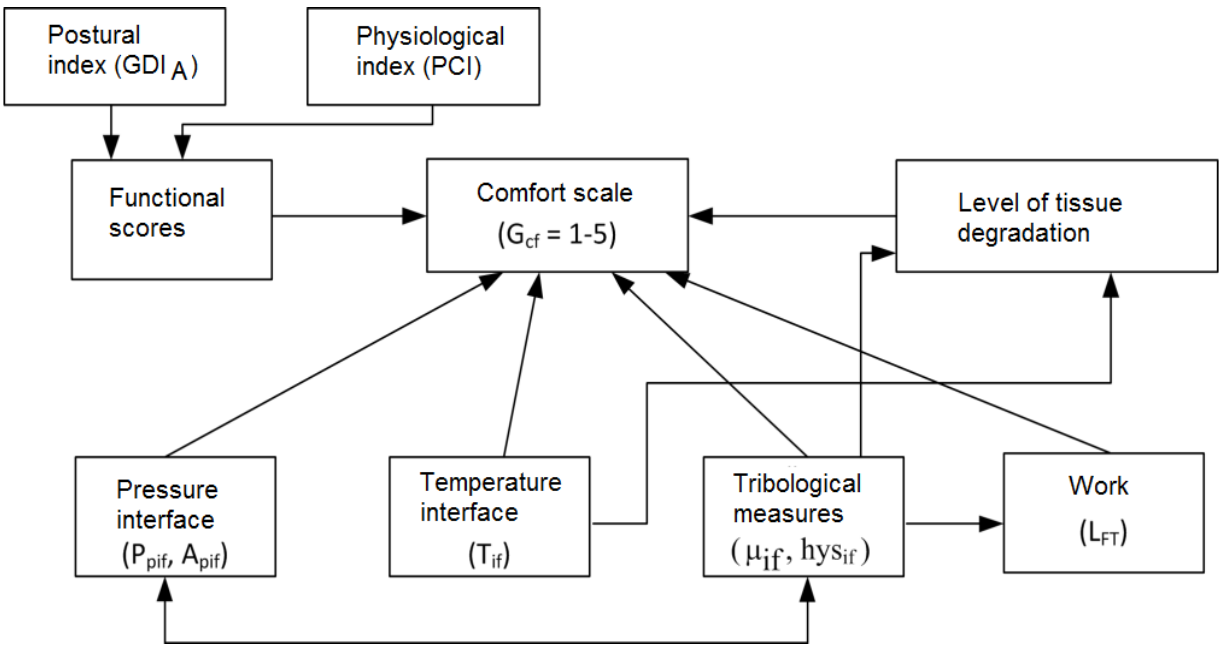

Fig. 3: Processes and process variables that influence the patient's comfort with transtibial prosthesis (calf)

We propose a linear regression model in the first phase, which takes into account all the variables in Figure 3. For normalisation, we considered that the sum of the weights is 1.0, and the values of the variables are also normalised by division to their maximum value, values obtained from the experiments.

$$CF_{fuz} = \sum_{k=1}^{n} w_k M_k , \quad \sum_{k=1}^{n} w_k = 1 \qquad (2)$$

$$CF_{fuz} = w_p M_p + w_t M_t + w_{tb} M_{tb} + w_L M_L + w_s M_s + w_d M_d \qquad (3)$$

The big problem is how we define the variables and how we quantify them. For example, it is clear that the temperature at the surface of the stump influences the comfort, but what is important needs further discussion: the areas with the highest temperature, the total surface of exposed areas, each with its temperature, etc.In the first instance, we consider a single area, the most exposed one with its parameters: temperature-surface, pressure-surface, hysteresis-area, etc. We will consider a relation of the type M=g(V, A), where M is the measure which intervenes and needs to be specified, V is the variable (temperature, pressure, coefficient - if it is hysteresis, etc.) and A the area or surface in the case of hysteresis. The significance of the process variables is: M_p, pressure / surface; M_t, temperature / surface, a gradient shape; M_{tb}, tribological size, F_μ - generally, a shape modelled by the power function given by friction and / or hysteresis, M_L, L_{FT} – Moment or mechanical work due to the force on an area of the tegument; M_s, GDI_A or PCI – kinetic or functional indexes, M_d index of the presence of tegument degradation, of binary value: 0 – healthy tegument and 1 tegument that has developed a tegument fissure.In the next phase of the research, we will also identify the best combinations of two, three or more variables for an optimum between performance and the computational minimum for the final formula.

Results & Discussion

In Table 1 we synthesised the experimental results according to the proposed methodology on a group of 11 patients with transtibial amputation and a control group of 9 healthy patients. The patients aged 16 to 47, male, without medical complications (e.g., diabetes) to avoid as much as possible the influence of other factors, few controllable in outcomes. Besides, in most of the specialised papers, it is recommended a homogeneous group, without individual pathology, and from the same geographical area.

Table 1: Comparison of patient satisfaction (patient comfort) using two indices: GDI_A and PCI, where M_1 represent Soft Pelite, M_2 represent Urethan, C_1 represent Polypropylene homopolymer, and C_2 represent polypropylene.

Combinations of materials	Mean GDI_A	Mean PCI	Percentage coincidence of satisfaction compared to questionnaire response GDI_A	Percentage coincidence of satisfaction compared to questionnaire response PCI	Conclusions
M_1+C_1	87.5	0.39	72%	90%	PCI has a higher accuracy, 3 patients preferred this type of prosthesis
M_1+C_2	90.5	0.44	72%	100%	PCI has a higher accuracy, 4 patients preferred this type of prosthesis of which 1 patient declared the same comfort as M_1+C_1.
M_2+C_1	91.3	0.59	81%	81%	PCI approximately equal, 1 patient preferred this type of prosthesis and declared the same comfort as M_2+C_2
M_2+C_2	85.4	0.55	63%	72%	PCI has a higher accuracy, 3 patients preferred this type of prosthesis

In Table 2, we apply the basic approach, which is the central topic of the paper, fusion of variables for an objective optimal score as close as possible to reality. There are five terms, five weights and a first attempt is to assign equal values, w_i = 1/5=0.2, i={p, t, tb, s, d}. An optimisation is possible first as a rough approach, variations in weights from 0.02 to 0.02 for each and testing all possible combinations, that is 50^5=312500000, which is easy to simulate on the computer. The results are given in the table below, on the test group and the associated walking protocols. It is noticeable that in the fusion of non-optimised variables, the coincidence values are at least as good as the best ones for the individual variable, and for the weight optimisation situation, the results are close to 100% (Table 2).

Table2: Comparison of patient satisfaction (patient comfort) using fusion of variables, 11 patients with calf transtibial prosthesis where M_1 represent Soft Pelite, M_2 represent Urethan, C_1 represent Polypropylene homopolymer, and C_2 represent polypropylene. Note $W=\{w_p, w_t, w_{tb}, w_s, w_d\}$,and W_1= {0.2, 0.2, 0.2, 0.2, 0.2, 0.2}, and W_2= {0.18, 0.20, 0.12, 0.06, 0.24, 0.2}.

	Percentage coincidence of satisfaction compared to questionnaire response (reference marker)						
Combinations of materials	M_p	M_t	M_{tb}	M_L	PCI	CF_{fuz} W_1	CF_{fuz} W_2
M_1+C_1	90%	27%	45%	54%	90%	90%	100%
M_1+C_2	90%	63%	45%	72%	100%	100%	100%
M_2+C_1	81%	54%	72%	72%	81%	81%	100%
M_2+C_2	45%	36%	72%	81%	72%	90%	90%

A systematic multi-patient study with medical validation is required, which can be done only at national level, as it is very difficult to find a large number of patients (at least 62, of which at least 31 with prosthetics and the rest healthy - for statistical validation, metical protocols, transportation to centres, testing all under the same conditions) and very high costs, possibly to be borne only if substantial grants are obtained.

Conclusions

In this paper, we proposed a method and application for objective evaluation of the patient's satisfaction in transtibial prosthetics using fusion of variables. The most common method to evaluate the comfort of one prosthesis using objective measure is based on single variable. Some of them are more suitable for different applications meanwhile some of them are less suitable in the sense of clearly discrimination of different levels of comfort. A combination of variables is expected to offer the advantages of each method. If a variable is less advantageous, a weighted coefficient will reduce the influence of this variable. In medical practice, the comfort measure is based on questionnaire, with subjective qualitative measure of sensations. The sensations are usually hard to quantify in numerical values and much more, the non-interdependence among them is hard to evaluate. The questionnaire technique is used to validate our assertion. The results were very good, but the weighting coefficients were determined empirically. In future research, we propose to determine these coefficients by a systematic method, namely optimisation with generic algorithms. We also propose to investigate the possibility of a non-linear formula, and if the selections of two or three parameters produce the same results and which are the most suitable combinations of variables.

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