Assisted analysis of the behavior of light unconventional structures, as biomaterials with applications in prosthetic biomechanics

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Summary: There is present a synthesis of an assisted analysis on the behavior of light, unconventional materials, intended in the biomechanics of prosthesis, both in terms of biocompatibility and in terms of mechanical behavior. In a first stage, a detailed comparative study was carried out on the advantages and disadvantages of several types of light, unconventional materials in order to use them in hip prostheses. A second stage consisted in the development, testing and use of a software application for the behavioral analytical study of different types of materials subjected to different static and dynamic loads in the case of wearing a hip prosthesis. Based on the two analytical and simulation studies, it has been shown that light, unconventional materials such as TEKA PEEK carbon fiber can be a safe and effective solution when used in combination with epoxy gluing resins. Thus, a prototype hip stent with a high level of biocompatibility could be made, but at the same time with a low mass.

1. Lightweight materials for hip prosthesis. Overview

Accidents, traumas, degenerations that occur with age are multiple causes that can lead to locomotor problems and stability of the human body, dramatically affecting the quality of life. For this reason, the problem of prosthesis of the upper and lower limbs and not only has experienced a continuous development and diversification. One of the most suggestive examples refers to the prosthesis of the hip joint, this being one of the most requested joints, especially when walking, running, sports, but also in orthostatism. Along with the problem of biocompatibility, the reduction of the mass of endo-prosthesis elements, especially in the case of the hip joint, has been and is of great concern to many researchers and orthopedic doctors in the field. For this reason, in recent years, great interest has been focused on fiber-reinforced polymeric materials for orthopedic prostheses designed to avoid bone loss around metal prostheses due to the protective effects of stress [1], [2]. For economic reasons, but also to significantly reduce the mass of an endo-prosthesis, especially in the case of the hip, in recent years for prototyping have been used high-density plastics, such as ABS plastic [3], [4]. But due to the fact that this material does not ensure a very good biocompatibility, it is still not widely used. In this context, in recent years, research has focused on identifying ultra-light materials, but also with a higher degree of biocompatibility. Among them can be mentioned polymeric materials, but also materials based on different textures of fiber or carbon foam [5].

2. Assisted comparative study on the choice of optimal unconventional materials for hip prostheses

Among the main categories of materials that can be used in stents, especially for the hip ones, the following can be identified: metallic, ceramic, plastic and based on carbon fiber materials.

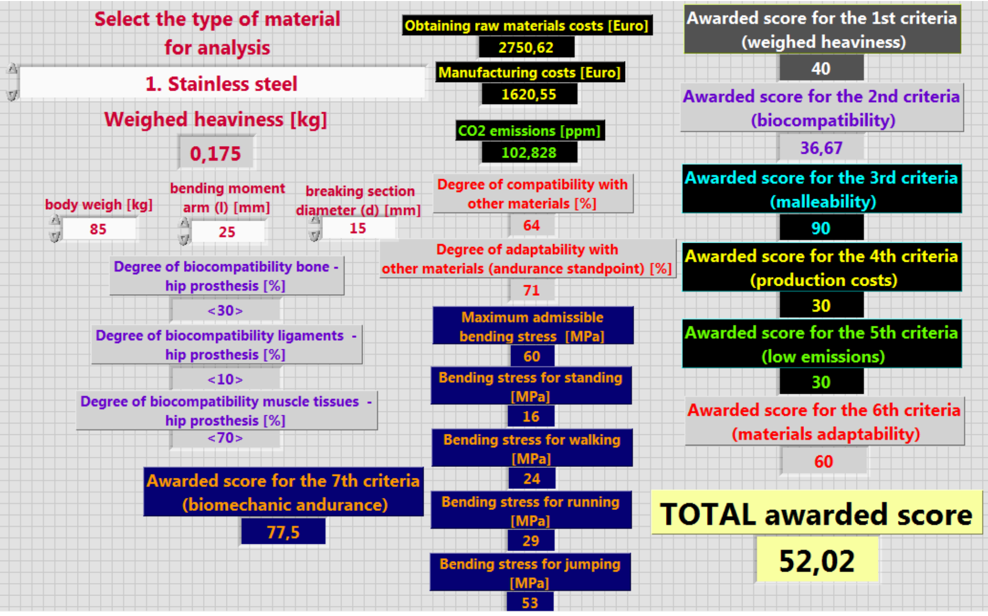
Metallic materials such as stainless steel, cobalt-based alloys, titanium and its alloys have been and still are widely used in orthopedic surgery. Some of the physical and mechanical properties can be obtained through heat and mechanical treatment for medical use. One of the most serious disadvantages of stainless steels, but also of alloys used in medicine are related to the low degree of biocompatibility. This fact is proven by statistics that reveal multiple side effects in the body, caused by the presence of chemical alloying elements (Al, V, Ni, Co, Cr). A second disadvantage of metallic materials is the existence of a discrepancy between the implant and the surrounding bone tissue caused by the difference between the elastic modulus of the bone and the metal implant [1], [6].

Ceramic materials can generally be considered refractory materials, due to their ionic or covalent bonds. Apart from their ability to withstand high temperatures, ceramic has many other advantages, such as: resistance to oxidation, chemical attacks, erosion, it is a lighter material than metal. For these reasons, they can be successfully used in medicine but also in aeronautics, also having a low coefficient of friction [7], [8]. Among the main disadvantages of ceramic materials can be mentioned (as in the case of metallic materials) the following two: low degree of elasticity (meleability) (in terms of adaptation to bone structures) and relatively high mass.

Plastic materials, due to their low weight, are currently used on a relatively large scale in the field of prosthetics. Among them can be identified biological, synthetic polymers and hybrids for various medical applications and processes. A wide range of polymers is available, the main advantage of which is the ability to modify their physical, chemical and biological properties to suit the requirements of medical prostheses [1]. The basic principle of polymers is to make assemblies of simple structural units to form a three-dimensional (3D) structure and can have a wide distribution in all biological systems [9]. Among the main types of polymers can be mentioned polyesters, poly-ethers, polyamides or polyurethanes, these ensuring a relatively high mechanical strength, due to the etheric bonds are bio-stable [1], [9]. A very accessible plastic material according to the prototyping would be the ABS type plastic, but this, being a relatively cheap and very light material, but its mechanical resistance is much weaker than in the case of polymers [10].

Carbon fiber-based materials have a multitude of unique physical, chemical and biological characteristics that can be used and exploited for various applications [1], [11]. The physical and chemical properties of carbon fiber are also determined by their microstructure. This is especially important in the case of carbon fiber used in medicine. One of the first medical uses of CF was the replacement or repair of ligaments and tendons. Moreover, carbon fiber induces significantly more tissue growth than polypropylene mesh at 6-12 months postoperatively. A likely mechanism of removal by erosion of carbon particles and their retention in the fibrous capsule surrounding the implant. In recent years, polyether ether ketone (PEEK polyether ether ketone) has been widely investigated for use in cranio-maxillofacial surgery. Possible applications are dental implants, osteosynthesis plaques and nasal, maxillary bone replacement material or mandibular reconstructions. Mechanical results indicated that pure PEEK showed low tensile strength, bending, and compression testing. However, the addition of 5% carbon fiber to the PEEK matrix improved the mechanical strength, showing values similar to those of human cortical bone [1], [11], [12]. TEKA PEEK carbon fiber is a state-of-the-art material and can be used with great success especially for the repair of cranio-maxillo-facial defects related to tumors, traumas, infections or congenital deformities. When bone loss is too severe for the human body's routine mechanisms to regenerate, autologous grafts are the first considerations due simultaneously to osteogenic, osteoinductive and osteoconductive properties [1], [12].

In order to make the most efficient and objective choice of ideal materials in terms of weight, production costs, production, energy consumption, mass, etc., the paper presents a solution in this regard. It is an assisted comparative analysis of different types of materials in terms of all the aspects mentioned above. For this, as a research stage, it was developed a software application, using LabVIEW software environment that can objectively and efficiently simulate the generation of scores on the behavior of several categories of materials for hip implants, in terms of the following criteria: weighed heaviness, biocompatibility, malleability, production costs, CO_2 emissions via based on carbon energy consumption and bio-mechanic endurance. The materials for which the simulation was performed are the following: stainless steel, hard aluminum, titanium, ceramic materials, ABS plastic and three types of carbon fiber-based materials among which TEKA PEEK polyether ether ketene invoked maximum interest. For each criterion, the score was set to be between 0 and 100. Figure 1 presents an example of software application using for stainless steel:



Select the type of material for analysis
1. Stainless steel
Weighed heaviness [kg]
0,175
body weigh [kg]
85
bending moment arm (l) [mm]
25
breaking section diameter (d) [mm]
15
Degree of biocompatibility bone - hip prosthesis [%]
<30>
Degree of biocompatibility ligaments - hip prosthesis [%]
<10>
Degree of biocompatibility muscle tissues - hip prosthesis [%]
<70>
Awarded score for the 7th criteria (biomechanic andurance)
77,5

Obtaining raw materials costs [Euro]
2750,62
Manufacturing costs [Euro]
1620,55
CO2 emissions [ppm]
102,828
Degree of compatibility with other materials [%]
64
Degree of adaptability with other materials (andurance standpoint) [%]
71
Maximum admissible bending stress [MPa]
60
Bending stress for standing [MPa]
16
Bending stress for walking [MPa]
24
Bending stress for running [MPa]
29
Bending stress for jumping [MPa]
53

Awarded score for the 1st criteria (weighed heaviness)
40
Awarded score for the 2nd criteria (biocompatibility)
36,67
Awarded score for the 3rd criteria (malleability)
90
Awarded score for the 4th criteria (production costs)
30
Awarded score for the 5th criteria (low emissions)
30
Awarded score for the 6th criteria (materials adaptability)
60
TOTAL awarded score
52,02

Figure 1. Example of simulation of the overall score and the score obtained for each criterion for the case of stainless steel, used as a material for a hip stent in the case of an adult, with a body weight of 85 kg

The application programming involved to define a type selector text ring variable and several numeric input variables, through which the user can easily and efficiently interface. The selector type variable was defined in order to be able to choose the type of material for which to perform the assisted critical analysis, in terms of all established criteria. Its relationship in the graphical programming window was made through a *Switch Case* programming structure, having a number of iterations equal to the number of types of materials identified to be analyzed. An example of this selector using, but also the context in which the variable was programmed can be seen in Figure 2:

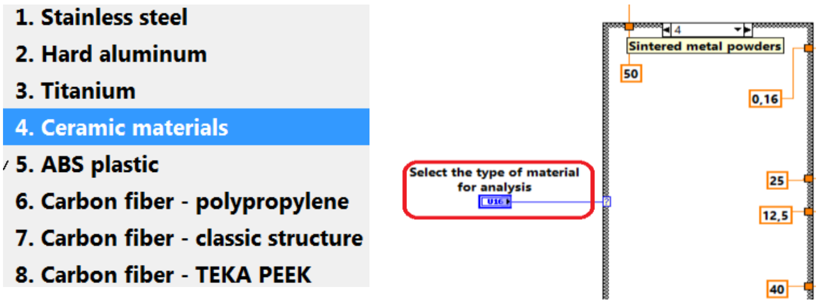


Figure 2. Switch Case structure using and programming

The numerical input variables have been defined in order to be able to enter all the necessary information on the conditions under which the testing of endo-prosthesis prototyping materials is simulated. The most important numerical variable is the one that refers to the body mass of the subject for which an implant would be made with a hip prosthesis. Of interest are, however, 2 other variables, specific to simulating the testing of materials in terms of mechanical strength. It is about the length of the arm specific to the bending moment of the prosthesis and the diameter of the cross section of the rod in the area most exposed to rupture at static and dynamic stresses. In addition, a numerical output variable, specifying (by automatic generation) what is the mass of the stent, for the specified dimensions and the type of material was defined, in order to be able to simulate the weight evaluation. An example of the completed and generated values for all numeric input variables as well as for the numeric output variable is shown in Figure 3:

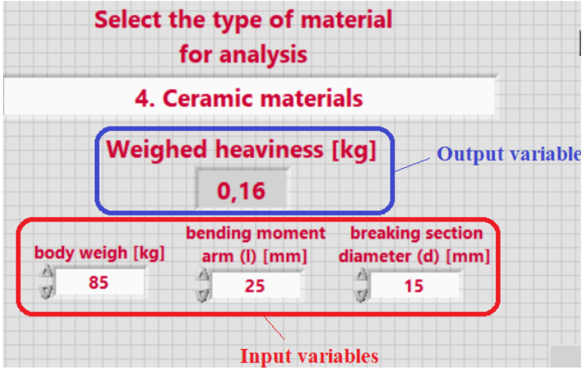

Select the type of material for analysis
4. Ceramic materials
Weighed heaviness [kg] 0,16
body weigh [kg] 85
bending moment arm (l) [mm] 25
breaking section diameter (d) [mm] 15

Figure 3. Input and output numeric variables numeric values for ceramic materials and 85 kg body weight

The numerical values of the input variables assume their input depending on the given situation. The value generated for the output variable (ie the weight of the endo-prostheses) involved a calculation algorithm based on the equivalent volume and density of materials from which the hip prosthesis would be made. Corresponding to the determined value of the endo-prosthesis mass, an algorithm was designed and programmed to give a partial score on the first analysis criterion (hip implant weight criterion). In this regard, it was considered that the lighter the implant, the higher the score. Specifically, based on theoretical considerations regarding hip biomechanics, the following scoring algorithm was established: If the mass of the implant is less than 50 g, then the score for this criterion should be maximum (100 points). If the mass of the implant is between 50 and 70 g, then 90 points should be awarded. If the mass of the implant is between 70 and 80 g, then 80 points should be awarded. If the mass of the implant is between 80 and 100 g, then give 70 points. If the mass of the implant is between 100 and 125 g, then 60 points should be awarded. If the mass of the implant is between 125 and 150 g, then 50 points should be awarded. If the mass of the implant is between 150 and 180 g, then 40 points should be awarded. If the mass of the implant is between 180 and 200 g, then 30 points should be awarded. If the mass of the implant is between 200 and 250 g, then 20 points should be awarded. If the implant mass is between 250 and 500 g, then only 10 points should be awarded, and if the implant mass is greater than 0.5 kg then 0 points should be awarded. The transposition of this algorithm was done by programming in the window - diagram of the LabVIEW interface, by associating some numerical constants for each iteration of a Boolean type structure, as can be seen in figure 4.

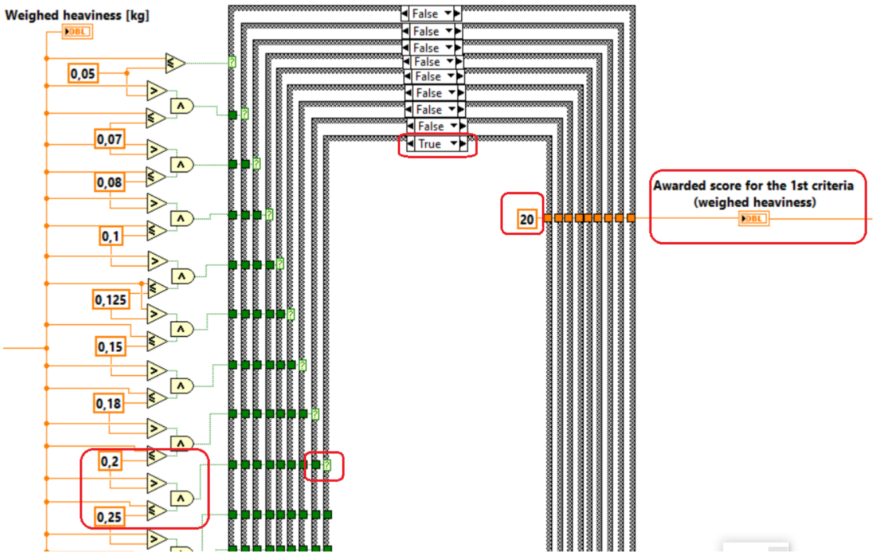


Figure 4. Programming algorithm for partial score awarding related to the implant weight criteria

For instance, for an adult wearing 85 kg, 1.85 m height, a hip implant prototyped using ceramic materials, it would obtain a score of 40 points.

Regarding the biocompatibility of materials, 3 aspects were considered: biocompatibility in relation to the bone structure of the tibia (on which the implant stem is fixed), biocompatibility in relation to the ligaments in the hip joint and biocompatibility in relation to muscle tissues that support the joint. A difference from the first criterion was that, in order to apply the programming algorithm, a function was first defined to determine the arithmetic mean of the value generated for all 3 aspects mentioned above, as shown in figure 5:

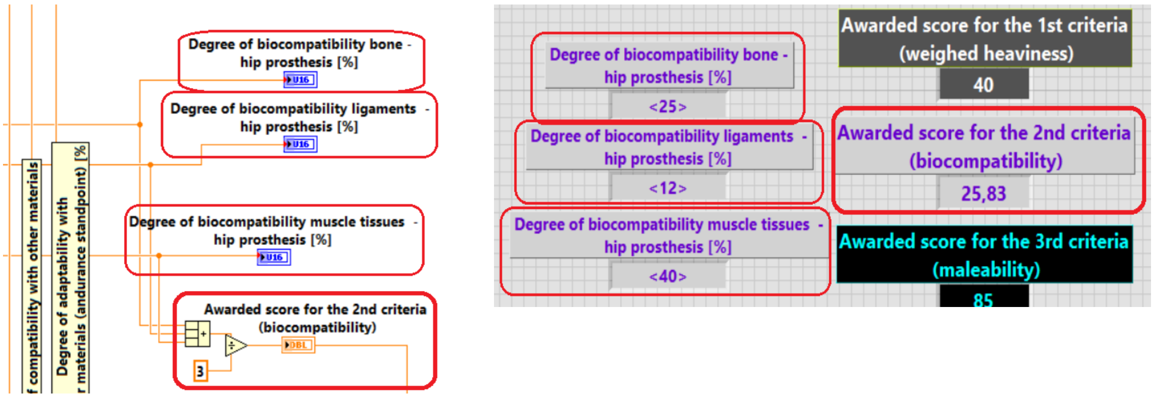


Figure 5. Programming algorithm for partial score awarding related to biocompatibility

As an example, for the same conditions (hip implant made of ceramic material for a subject weighing 85 kg) it was simulated to obtain a score of 25.83 out of 100, for the criterion of biocompatibility.

Another criterion for which we proceeded to program the algorithm for granting the partial score referred to the malleability of the materials, in terms of elasticity in order to mold them on bone structures in order to get the best implant. For this, in accordance with the modulus of elasticity of the materials, scores were given, by defining numerical constants, associated with each type of material. For instance, in case of ceramic material, the simulations generated a score equal to 85/100 regarding the criterion of malleability.

The cost criterion for obtaining implants involved an algorithm that involves the sum of two categories of costs: costs of obtaining raw materials (as materials for prototyping) and production costs. In turn, the costs of obtaining raw materials involved a calculation algorithm that would take into account the following costs: necessary machinery for primary and secondary materials costs (Euro), costs for energy consumption for extraction (Euro / hour), no. of hours for necessary primary materials extraction, primary materials - labor costs (Euro / hour), no. of work hours for necessary primary materials extraction, no. of work hours for necessary primary materials processing, secondary materials - labor costs (Euro / hour), no of work hours for necessary secondary materials extraction and no. of work hours for necessary secondary materials processing. The programming of the calculation algorithm with the costs for obtaining the raw materials that are the basis for obtaining the prototyping materials is exemplified in figure 6.

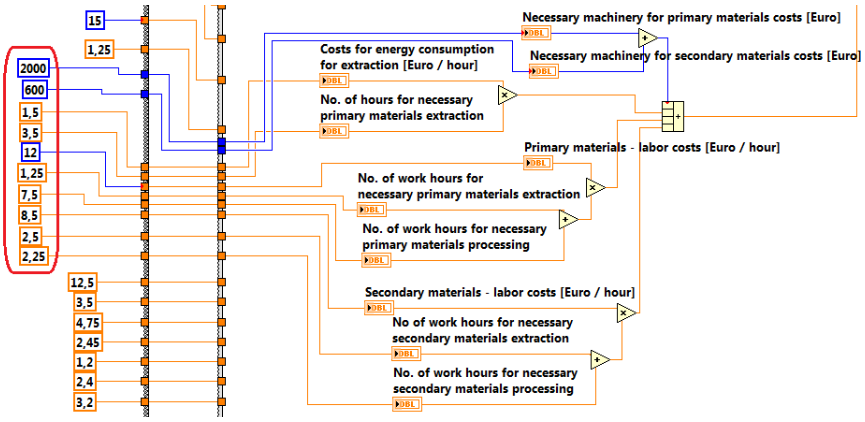


Figure 6. Programming algorithm for obtaining raw materials costs

For the purpose of the simulations, numerical constants have been defined for assigning cost values, based on general statistical information on the required costs. Production costs involved another calculation algorithm, involving: costs for primary material (Euro), necessary specific matrix costs (Euro), costs for energy consumption for manufacturing (Euro / hour), no. of hours for manufacturing, manufacturing - labor costs (Euro / hour) and no. of work hours for manufacturing and rectification. Figure 7 shows a sequence of programming the algorithm for calculating production costs.

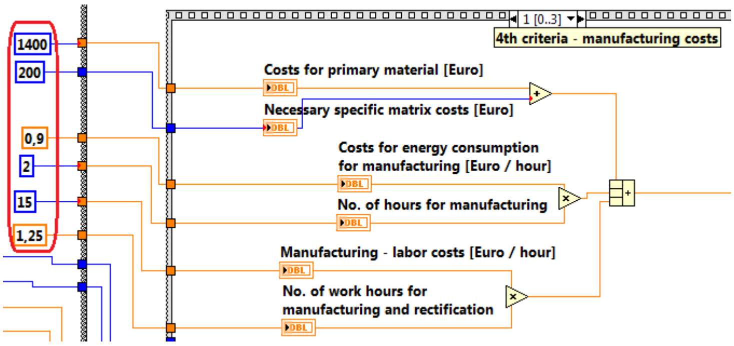


Figure 7. Programming algorithm for manufacturing costs simulation

For example, in the case of obtaining stainless steel as a prototyping material, under the conditions of simulating the prototyping of a hip endosthesis for a person weighing 85 kg, the estimated cost values would be approximately 2750 Euro for raw materials obtaining and 1620 Euro for production, respectively. thus meaning a total cost of 4730 Euro. Such a cost is currently assigned a score of 30/100, according to the scoring / costing algorithm, described below: if the total cost is below 1000 Euro, then the score given to this criterion is 100/100, if the total cost is between 1000 and 1500 Euro, then the score will be 90/100, if the total cost is between 1500 and 2000 Euro, then the score will be 80/100, if the total cost is between 2000 and 2500 Euro, then the score will be 70/100, if the total cost is between 2500 and 3000 Euro, then the score will be 60 / 100, if the total cost is between 3000 and 3500 Euro, then the score will be 50/100, if the cost is between 3500 and 4000 Euro, then the score will be 40/100, if the cost is between 4000 and 4500 Euro , then the score will be 30/100, if the cost is between 4500 and 5000 Euro, then the score will be 20/100, if the cost is between 5000 and 5500 Euro, then the score will be 10/100, and if the cost is higher than 5500 Euro, then score l granted will be 0/100. The graphical programming of this algorithm for simulating the awarding of points on the criterion of obtaining prototyping materials is illustrated in Figure 8, requiring the use of a multiple Boolean structure, including a number of iterations equal to the number of possible cases of simulation.

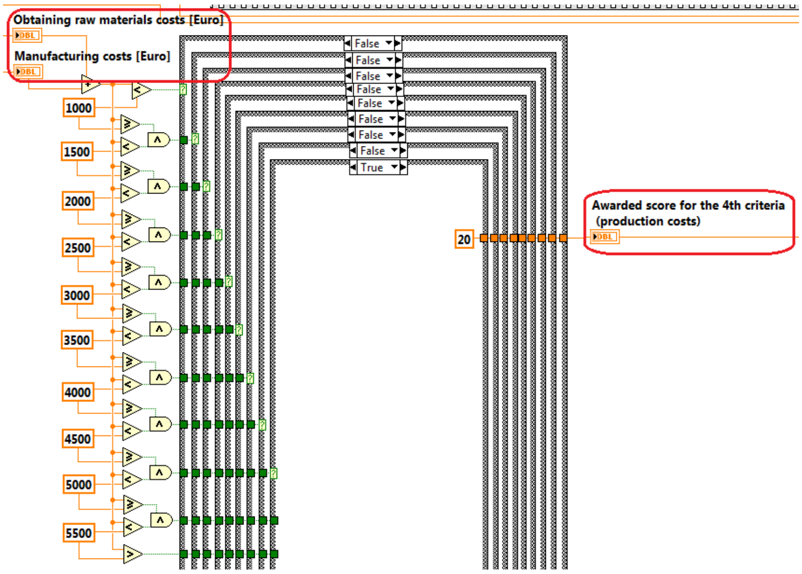


Figure 8. Programming algorithm for scores awarding for simulating on the cost criteria for obtaining prototyping materials for a hip endo-prosthesis

Another criterion for simulating the testing of materials has been established to be one of a very topical issue, namely the amount of CO_2 emissions, due to the energy consumption required to obtain the materials. For this, all the operations necessary to obtain materials involving energy consumption were taken into account: energy consumption for primary materials extraction (kWh), no. of hours for necessary primary materials extraction, energy consumption for secondary materials extraction (kWh), energy consumption for secondary materials extraction (kWh), no. of work hours for necessary secondary materials processing, energy consumption for necessary specific matrix (kWh), energy consumption for manufacturing (kWh), no. of hours for manufacturing. For the simulation, the calculation algorithm assumed the value of 1.6 CO_2 ppm for each consumed kWh. Thus, for example, a value of approximately 103 ppm CO2 was simulated for obtaining stainless steel, while a value of approximately 82 ppm CO_2 was simulated for obtaining materials based on ABS plastic, the score given to this criterion in the case of plastic being obviously a better one. The programming of the scoring simulation algorithm for this criterion is described below: if CO_2 emissions are zero, then the score is maximum, if CO_2 emissions are between 0 and 15 ppm (parts per million), then the score is 90/100, if CO_2 emissions are between 15 and 30 ppm (parts per million), then the score is 80/100, if CO_2 emissions are between 30 and 45 ppm, then the score is 70/100, if CO_2 emissions are between 45 and 60 ppm, then the score is 60 / 100, if CO_2 emissions are between 60 and 75 ppm, then the score is 50/100, if CO_2 emissions are between 75 and 90 ppm, then the score is 40/100, if CO_2 emissions are between 90 and 105 ppm, then the score is 30/100, if CO_2 emissions are between 105 and 120 ppm, then the score is 20/100, if CO_2 emissions are between 120 and 135 ppm, then the score is 10/100, and if CO_2 emissions are higher than 135 ppm, then the needle score the order is zero. The programming of the algorithm described above is shown in figure 9.

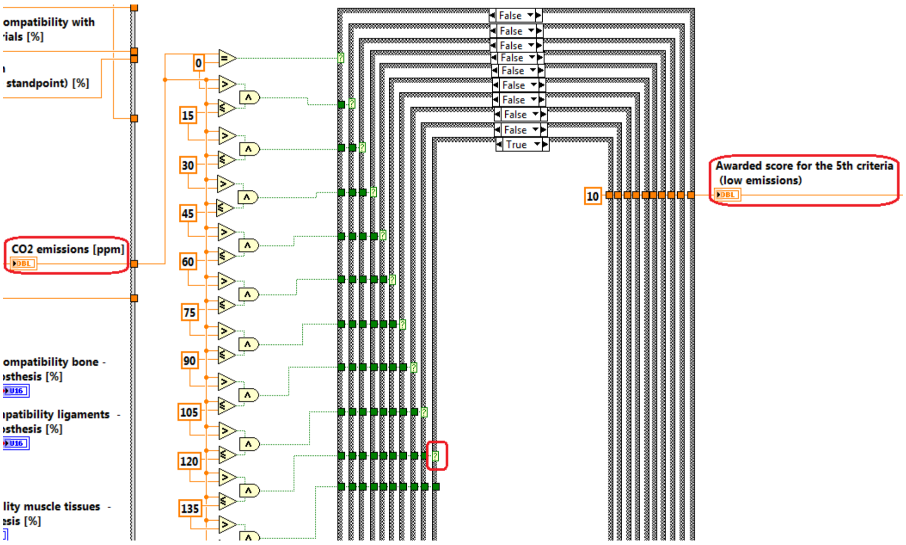


Figure 9. Programming algorithm for scores awarding for CO_2 emission simulating for necessary materials obtaining

The degree of adaptability with other materials in the case of prototyping models involving several types of materials was considered as another particularly important criterion in programming the simulator for comparative analysis of materials. This, in turn, involved 2 sub-criteria: compatibility (in terms of assembly) with other materials and adaptability in terms of the mechanical strength of the entire assembly formed, for example from 2 categories of materials. For this reason, regarding both sub-criteria, a calculation algorithm was established and programmed regarding the granting of some percentage values (as numerical constants), based on statistical information specific to the chemical and mechanical behavior of the materials. For example, in the case of ABS plastic as the main material for prototyping, in terms of compatibility with other materials (metallic, ceramic, etc.) it was possible to simulate obtaining a score of 50/100.

One of the most important criteria of assisted analysis referred to the endurance of static and dynamic mechanical stresses of materials. This criterion took into account the following aspects: maximum allowable bending stress (MPa), bending stress for standing, walking, running and jumping (MPa). When programming the calculation algorithms for determining the values of the bending stress (in the maximum risk area according to the rupture in the area of the prosthesis rod), the calculation relations specific to the strength of the materials were taken into account. More specifically, the ratio between the bending moment of the rod given by the static or dynamic stress and the strength of the cross section of the rod in the area of maximum risk of breakage was taken into account [13]. An example of a programming sequence for calculating the bending stress for different situations (orthostatism, gait, etc.) is shown in Figure 10.

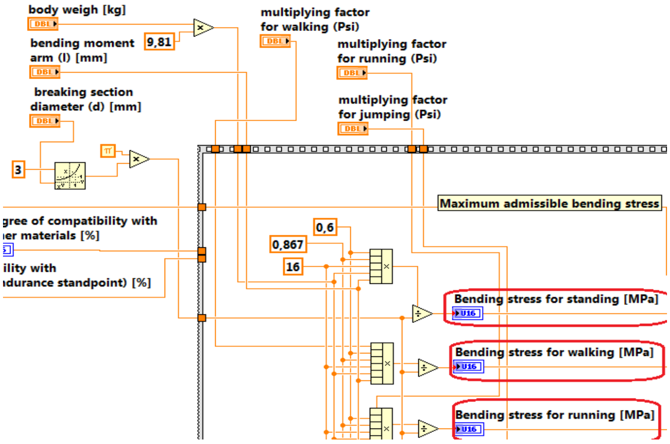


Figure 10. Example of algorithm programming for bending stress calculation

For each of the possible situations presented, the algorithm for awarding scores to this criterion was established based on the numerical values obtained as a ratio between the determined bending stress and its maximum allowable value (which differs for each type of material). Thus, if the ratio is less than 0.2 then the score given (for orthostatism, walking, running or jumping) is maximum, if the ratio is between 0.2 and 0.3, then the partial score is 90/100, if the ratio is between 0.3 and 0.4, then the partial score is 80/100, if the ratio is between 0.4 and 0.5, then the partial score is 70/100, if the ratio is between 0.5 and 0.7, then the partial score is 60 / 100, if the ratio is between 0.7 and 0.75, then the partial score is 50/100, if the ratio is between 0.75 and 0.8, then the partial score is 40/100, if the ratio is between 0.8 and 0.85, then the partial score is 30/100, if the ratio is between 0.85 and 0.9, then the partial score is 20/100, if the ratio is between 0.9 and 1, then the partial score is 10/100, and if the ratio the tulle is greater than 1 (meaning that the material would yield) then the partial score given is 0. An example of the transposition of this algorithm into a graphical programming sequence is shown in Figure 11, specific to the case of wearing a hip endo-prosthesis while walking.

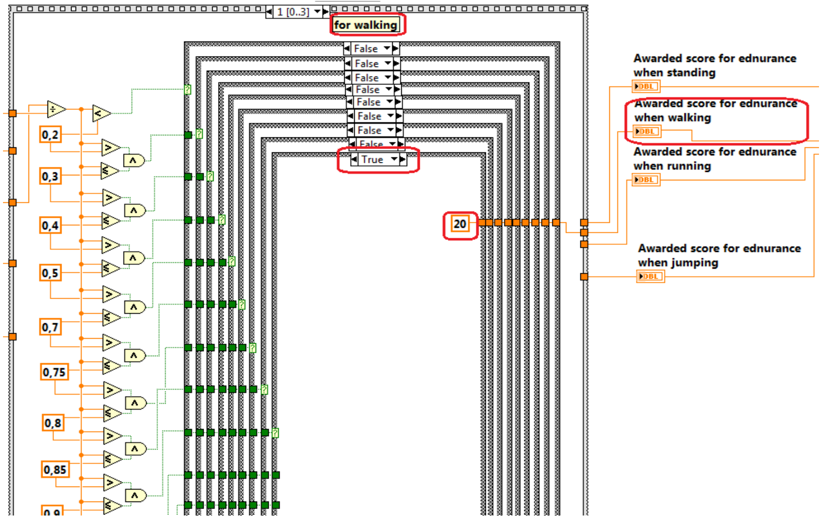
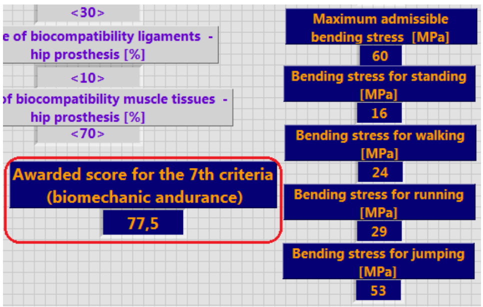


Figure 11. Example of algorithm programming for partial score awarding in case of walking

To determine the final score for this criterion, a programming algorithm was considered for calculating the arithmetic mean of the partial scores generated for the 4 situations (orthostatism, walking, running and jumping) [14]. In the case of a stainless steel endo-prosthesis that would be worn by a person weighing 85 kg, the score obtained by simulation for all 4 situations mentioned above would be 77.5 / 100, shown in figure 12.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e of biocompatibility ligaments - hip prosthesis [%]
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of biocompatibility muscle tissues - hip prosthesis [%]
<70>
Awarded score for the 7th criteria (biomechanic andurance)
77,5
Maximum admissible bending stress [MPa]
60
Bending stress for standing [MPa]
16
Bending stress for walking [MPa]
24
Bending stress for running [MPa]
29
Bending stress for jumping [MPa]
53

Figure 12. Example of obtained score for simulation in case of stainless steel

After running the application for all categories of materials it was possible to simulate different total scores, which were subsequently summarized in Table 1. The final scores generated took into account all the criteria described above, in the case of hip endo-prosthesis wearing by three persons, the 1st one having 65 kg weight, the 2nd having 85 kg weight an having 65 kg weight the 3rd having 105 kg weight, these being the most frequent situations.

Table 1. Obtained results in simulation using the software application for all types of prototyping materials

Obtained score for stainless steel	Obtained score for hard aluminum	Obtained score for Titanium	Obtained score for ceramic materials	Obtained score for ABS plastic	Obtained score for carbon fiber - polypropylene	Obtained score for carbon fiber – classic structure	Obtained score for carbon fiber – TEKA PEEK
for the 1st person (65 kg weight)							
53.1/100	50.6/100	68.57/100	44.05/100	47.86/100	74.76/100	73.33/100	77.98/100
for the 2nd person (85 kg weight)							
52.02/100	48.1/100	67.86/100	41.0/100	45.36/100	72.62/100	71.19/100	75.83/100
for the 3rd person (105 kg weight)							
49.52/100	45.95/100	66.79/100	39.4/100	44.29/100	70.48/100	69.05/100	74.05/100

3. Application of the solution regarding the use of ultra-light carbon fiber type TEKA PEEK for the realization of a prototype of hip prosthesis

Obtaining the results from the 3 simulations for all types of materials, it was found that the best solution in terms of all selection criteria would be that for the prototyping of a hip endo-prosthesis would use carbon fiber TEKA-PEEK [1].

From an experimental point of view, the next stage of the research focused on the prototyping of such a hip endo-prosthesis, but, in this experimental phase, the means of the department's endowment were taken into account. Thus, it was possible to prototype a model based on an ABS plastic core, which was subsequently wrapped in a layer of approximately 1.5 mm of TEKA PEEK type carbon fiber. For this, in the first stage, the CAD-CAM modeling of the core was performed, by scaling and starting from other similar models of hip stents.

Figure 13. Hip endo-prosthesis after gluing the carbon fiber over the ABS plastic core [1].

Subsequently, by applying a special adhesive, of epoxy resin type, the carbon fiber coating was arranged, obtaining the final prototype of the hip implant, as can be seen in figure 13 [1].

3. Conclusion

Based on the research done both as an analytical and simulation part, as well as as an experimental part, it was possible to prove the validation of an innovative and efficient solution for establishing methodologies for prototyping hip implants as efficient as possible from all points of view. Moreover, this methodology could be applied in the future for other types of implants, such as those for the ankle joint, elbow joint, etc.

This solution could be practical and sustainable in the future in terms of its use in hospitals and orthopedic clinics.

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