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Virtual simulation of an osseointegrated trans-humeral prosthesis: A falling scenario

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ABSTRACT

Introduction: Traditional prosthetic solutions expose the amputee to numerous problems that limit his ability to safely perform the normal activities of daily life. In order to eliminate the problems related to the use of the traditional prosthesis with socket, a new technique was developed for fixing the prosthesis to the amputees based on the principle of osseointegration. The aim of this paper is to study and analyze the stress distribution on the interface between a trans-humeral osseointegrated prosthetic implant and the residual bone, identifying the most stressed areas and thus foreseeing possible failure phenomena of the entire prosthetic system and, after, to compare the stress distribution on three different prosthetic designs that differ from each other for some geometric characteristics.
Materials and methods: A healthy individual mimics two fall scenarios of which the trans-humeral amputees can most likely be victims: Static fall and Dynamic fall. A force platform (P-6000, BTS Bioengineering) is required for load data acquisition. The CAD model of the trans-humeral osseointegrated implant was created following the guidelines of the OPRA implant. The bone model was created starting from the CAT scan of a left humerus. The FEM simulation was conducted throught a linear analysis.
Results: Both during static fall and dynamic fall, similar trends have been observed for the reaction force Fz, the torque moment Tz, the bending moments Mx and My. From the analysis of the von Mises stress distribution it was found that the stress distribution is more homogeneous in the case where the thread of the *fixture* is made by a triangular profile with height of the thread equal to 0.5 mm. However, it can be seen that, when passing from a thread with height of 0.5 mm to a 1 mm, there is a slight decrease in the stress on the whole contact zone between the *fixture* and the humerus. The same improvement can also be seen in the case of trapezoidal threading.
Conclusion: By modifying the height and/or by varying the thread profile, are obtained slightly better results with respect to the case with a 0.5 mm height triangular thread.

Introduction

Amputation of anatomical extremities may occur due to physical trauma or surgery. In the latter case, the choice of amputation stems from the need to stop the process of a disease, such as in cases of cancer and gangrene. Very often, moreover, undergoing an amputation involves several problems on those who suffer it, related to the functional, motor, aesthetic and psychological aspects. These problems that are greatly accentuated if the amputation is performed at the trans femoral, trans humeral and trans radial levels.

The purpose of the prosthesis is to reduce these problems as much as possible and restore the patient to a next-to-normal life.

Nowadays, prosthetic solutions for amputees can be divided into traditional solutions (external prosthesis) and innovative solutions (internal and external prostheses). In particular, the innovative ones are based on the concept of osseointegration, defined by Per-Ingvar Branemark as a state in which "*there is no relative progressive movement between the implant and the bone with it is directly attached*" [1].

Traditional prosthetic solutions, despite being the least invasive do not require surgery by protocol, expose the amputee to

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numerous problems that limit his ability to safely perform the normal activities of daily life.

In a study carried out by Maulenbelt et al. [2], performed on 872 lower limb amputees, it was found that about 63% of the participants showed 1 or more skin problems, with a high percentage of eczema (50%) and problems caused by occlusion (51%) such as excessive sweating, warm skin, pimples, excessive skin sensitivity and itching.

Furthermore, one of the main aspects that negatively characterizes the use of the traditional prosthesis is the pressure on the interface between the residual limb and the socket, which has a significant effect on the comfort of the amputee. In this regard, in fact, Razak et al. [3] conducted a study in which the pressure on the interface between the stump and the socket is analyzed by using a prosthesis equipped with an "air splint system" and a pressure sensor, to determine the size and assembling requirements to use the socket. It was concluded that the use of a prosthesis equipped with an "air splint" could reduce the pressure on the interface, with considerable advantages for the patient during normal daily activities.

In order to eliminate the problems related to the use of the traditional prosthesis with socket, at the beginning of the 90 s a new technique was developed for fixing the prosthesis to the amputees based on the principle of osseointegration.

In the study conducted by Lundeberg et al. [4] it is analyzed the quality of life of 13 Swedish patients, victims of amputation, comparing the cases with use of the traditional prosthesis with the one with the osseointegrated prosthesis. The results of this study showed that all participants described their life with an osseointegrated implant as a revolutionary change.

This technique, "Osseointegrated Prosthesis for Rehabilitation Amputees" (OPRA), allows the direct anchoring of the prosthesis to the bone by means of a titanium implant, called *fixture*. The *fixture* is surgically inserted into the residual bone during a first surgery. In a second surgery, a further titanium component called *abutment* is inserted into the *fixture* and secured with a screw, also in titanium, called *abutment screw*. The *abutment* penetrates the soft tissues present in the distal part of the stump and acts as a point of anchorage for the prosthetic limb [5].

The inclusion criteria to be able to use OPRA, and any other osseointegrated device, are to have previously used a conventional prosthesis, be less than 70 years of age and weight less than 100 kg [6].

The OPRA technique is mostly used for the treatment and rehabilitation of femoral amputees. This technique has also been used on a small group of humeral and radial amputates, although there are no published studies that analyze trans-humeral or trans-radial osteointegrated implants from the point of view of applied loads [1].

The aim of this paper is to study and analyze the stress distribution on the interface between a trans-humeral osseointegrated prosthetic implant and the residual bone, identifying the most stressed areas and thus foreseeing possible failure phenomena of the entire prosthetic system. Specifically, this paper is going to compare the stress levels on three different prosthetic designs realized on the basis of the OPRA technique, that differ from each other for some geometric characteristics. The fundamental focus of this paper is precisely the morphological aspect of the *fixture*. In particular, it is questioned whether to vary the height of the thread and/or the thread profile (from triangular to trapezoidal) may reduce the loads acting on the area of contact between the bone and the prosthesis, thus reducing the possibility of some adverse events characteristic of the osseointegrated implants, such as loosening and periprosthetic fractures.

The finite elements method (FEM) was used to study the stress distribution in osseointegrated prosthetic implants for trans-femoral amputees [7–10]. In the literature, FEM analysis was used to identify the forces transmitted during normal activities of daily life and to study how they could contribute to complications related to an osseointegrated implant, such as a sub-optimal bone remodeling and/or a high inflammatory response [8]. In some cases, the study was carried out as a comparison between two different implants [9,10]. In other cases, however, the FE (Finite Element) model was used to analyze the influence of the load application direction during the rehabilitation phase [7].

The main originality of this study lies in having carried out a finite element analysis for a trans-humeral osseointegrated implant, focusing on the influence of geometric variations of the *fixture*, such as helix height and profile of the threading, on the stress distribution at the implant/bone interface.

Materials and methods

This work can be divided into 3 phases: load acquisition, CAD modeling and FEM analysis.

Load acquisition

A healthy individual (male, weight 76 kg, height 1.77 m, age 25 years), equipped with appropriate protections (Fig. 1), mimics two fall scenarios of which the trans-humeral amputees can most likely be victims:

- Static fall: forward fall from a standstill;
- Dynamic fall: forward fall, during walk, caused by an interruption of the step.

The subject has carried out all the tests on a wooden walkway made by 3 parts, joined together and marked with bands to indicate the reference distances necessary for the execution of the tests (Fig. 2). In the last part of the walkway there is the force platform (P-6000, BTS Bioengineering) required for data acquisition (Fig. 3).

The studied scenarios are:

- The first is to fall forward from a standstill, a situation that can be compared to that being subjected to a moderate push from behind. The individual, during the fall, falls on both knees starting from a position of quiet 135 cm away from the center of gravity of the platform; subsequently, he hits the right hand against the force platform and the left hand against the surrounding wooden platform;
- The second consists in a fall forward during the course of a cycle of walking: a situation very similar to a stumble on an obstacle. The subject starts from a distance of 240 cm from the center of gravity of the platform, begins a step that is interrupted by an obstacle placed at a distance of 160 cm, always measured from the center of gravity of the platform. Once the fall phase has begun, the individual first falls on both knees simultaneously and then hits the right arm against the force platform and the left arm against the surrounding wooden platform.

During both scenarios, at the time of impact, the subject is focused as much as possible to keep his arm rigid and perpendicular to the platform in order to minimize dampening from the soft tissues and joints.

The force platform (P-6000, BTS Bioengineering, Milan, Italy) allowed to acquire the coordinates (x, y, z) of the point of impact, the values of the forces Fx, Fy and Fz and the twisting moment Tz.

Subsequently, the values of the bending moments produced by the direct forces along the x and y axes, respectively Fx and Fy, were obtained; multiplying the latter for the distance between the point