BBE 156 1-8

ARTICLE IN PRESS

BIOCYBERNETICS AND BIOMEDICAL ENGINEERING XXX (2017) XXX-XXX



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Finite element analysis of stresses generated in cortical bone during implantation of a novel Limb Prosthesis Osseointegrated Fixation System

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ARTICLE INFO

Article history: Received 13 October 2016 Received in revised form 18 December 2016 Accepted 22 December 2016 Available online xxx

Keywords: Cementless implantation Direct skeletal attachment Prosthesis

ABSTRACT

The aim of this study was a biomechanical evaluation of the stresses generated in bone during implantation of the implant designed for direct skeletal attachment of limb prosthesis and a typical interference-fit implant of the reference. Using the finite element method implantation processes of both implants were modelled. The influence of two factors on stresses generated in bone was analysed: first - the radial interference between the implant and reamed marrow cavity (0.05 mm up to 0.25 mm) and second - the three types of implant's surfaces: polished, beaded and flaked. Obtained results show that in the case of the smallest value of radial interference (0.05 mm), stresses generated in cortical bone are more appropriate for the reference implant than for the designed one. With the increase of both analysed factors generated stresses are in favour of the designed implant especially in longitudinal direction for both, implant-adjacent and deep cortical tissue (even 18 times lower) alike. Stresses patterns also present that stresses values are lower in overall volume of analysed bone's part, during implantation of the designed implant. Presented characteristics and patterns confirm that the implantation method of presented implant is safer than a method for typical interference-fit implants for direct skeletal attachment of limb prosthesis.

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1. Introduction

DSA implantation of limb prosthesis is a modern method used in today's medicine. DSA is based on cementless (usually) implantation of an implant into the reamed bone's marrow cavity. The part of the implant to which an exoprosthesis is attached penetrates the soft tissue. These solutions are used to avoid the disadvantages of sockets, e.g. skin abrasions and sliding prosthesis off a stump. Additionally, DSA provides more appropriate prosthesis control during gait [1,7,9,10, 12,16].

Please cite this article in press as: Prochor P. Finite element analysis of stresses generated in cortical bone during implantation of a novel Limb Prosthesis Osseointegrated Fixation System. Biocybern Biomed Eng (2017), http://dx.doi.org/10.1016/j.bbe.2016.12.001

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Biocybernetics

and Biomedical Engineering

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http://dx.doi.org/10.1016/j.bbe.2016.12.001

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BIOCYBERNETICS AND BIOMEDICAL ENGINEERING XXX (2017) XXX-XXX

There are many types of implants for direct skeletal attachment of limb prosthesis. The most commonly used involve an application of an interference fit between the cylindrical implant (with appropriate anchoring/anti-rotation elements and surface's roughness) and bone, e.g. the ITAP [15]. After around 6 months of osseointegration, a stable implantbone connection is obtained [5,6,11,20].

Due to the fact that implants for direct skeletal attachment 32 33 of limb prosthesis are a constantly developing and innovative 34 method, numerous studies are carried out. Most of them try to 35 determine DSA's functionality in relation to other solutions used to achieve the same purpose [4,5,7,9,11,12,16-19]. One of 36 Bishop's studies describes an evaluation of bone damage and 37 its influence on implant-bone connection's stability. However, 38 it does not specify the stresses generated during implantation 39 of an implant into marrow cavity [5]. They create the areas of 40 damage and microcracks leading to lowering bone strength, 41 which directly affects the stability of the implant-bone 42 connection and the safety of implantation [8]. 43

44 The aim of this study was an evaluation of the stresses 45 generated in the femur during implantation of the LPOFS. Its 46 long-term effectiveness was already proved by Prochor et al. 47 [15]. The results were compared with the results obtained for the implant with commonly used cylindrical shape, similar to 48 49 the ITAP [14]. The conducted analyses considered the influence of two factors: first - the radial interference between the 50 implant and reamed marrow cavity and second - the 52 roughness of implant's surface (modelled as changes in the coefficient of friction between the implant and bone). 53

2. Materials and methods

2.1. Implantation method and analysed factors

56 The analyses took into account the anatomical femur's cortical 57 tissue model of an adult human. The bone was cut about 58 halfway to keep enough space for the implantation of the 59 implant into the marrow cavity (reamed to the right diameter). 60 Two implants were analysed. First, the LPOFS and the second, a cylindrical-shaped REF, similar to the ITAP. This shape is one 61 of the most frequently used in implants for direct skeletal 62 attachment of limb prosthesis [14]. The detailed description of 63 the LPOFS is presented in Fig. 1. Its effectiveness was proved by 64 Prochor et al. in comparison with the two chosen implants in a 65 previous study [15]. However, its thread for cortical bone 66 placed on a cylindrical segment of the fixture (Fig. 1i) was 67 neglected in analyses. Its use is primarily limited to obtain a 68 proper coaxial position of the fixture to bone's axis before 69 placing the abutment. 70

71 Overall dimensions of both implants were similar in order 72 to reduce factors influencing stresses' generation. Implants 73 were coaxially set to the reamed marrow cavity. Then, in case 74 of the LPOFS, its conical, triple notched segment B is expanded 75 resulting in teeth thrusting into the cortical tissue (Fig. 2a). Considering the thread (neglected in presented analyses, as it 76 77 does not significantly affects the generated stresses during 78 implantation), a short, initial part of the LPOFS should be screwed into the reamed marrow cavity before the previously 79 80 described step. The REF is displaced by a predetermined value



Fig. 1 - The LPOFS's structure: W1 - the fixture (view): (A) cylindrical segment A; (B) conical, triple notched segment B; (a) blocking cap; (b) the implant thread for cortical bone; (c) helically cut teeth with an outer diameter equal to the outer diameter (Ø1) of segment A (bottom of the thread's notches); (d) Ti-coating; W2 - the fixture (cross-section): (e) metric thread for attaching the abutment; L - abutment (view): (C) cylindrical segment C; (D) conical segment D; (f) head; (g) head's shaft with a porous layer; (h) abutment's blocking cap; (i) metric thread for fixture attachment; (j) closure cap [15].

equal to the length of the implanted part of the implant (Fig. 2b). Presented implantation processes indicate that in opposition to the LPOFS, the REF requires dangerous hammering the implant in, which creates the possibility of creating damages in bone tissues. The correctness of the adopted analysis method has been determined in experimental conditions [5].

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The first analysed factor affecting the stresses generated in the bone during the studied implantation was a radial interference between the implant and a reamed marrow cavity (δ_r) . For this reason 5 cases of interference-fit connections were considered: $\delta_{r1} = 0.05 \text{ mm}$, $\delta_{r2} = 0.10 \text{ mm}$, $\delta_{r3} = 0.15 \text{ mm}$, δ_{r4} = 0.20 mm, δ_{r5} = 0.25 mm. The scheme of an implant-bone interference-fit connection is shown in Fig. 3 [15].



Fig. 2 - The analysed methods of the implantation: (a) the LPOFS' implantation method; (b) the REF's implantation method.

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