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Load-shift—numerical evaluation of a new design philosophy for uncemented hip prostheses

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Abstract

All hip replacement prostheses alter the load transfer from the hip joint into the femur by changing the mechanical loading of the proximal femur from an externally to an internally loaded system. This alteration of the load transfer causes stress shielding and might lead to severe bone loss, especially with uncemented prostheses. To minimize these effects, load transfer to the femur should occur as proximal as possible. In order to support sufficient primary stability, however, directly post operative (PO) distal stabilization is reasonable. Consequently, the prostheses have to alter its mechanical characteristics after implantation. This concept is referred to as load-shift concept. Primary stability during the early PO state is provided by a prosthesis shaft, which is widened at the tip by a biodegradable pin. After resorption of the pin load transfer occurs no longer distally. The objective of this study was the numerical evaluation of the load-shift concept. The analysis was performed with a finite element model. Three-dimensional non-linear dynamic gait analyses data were used to evaluate whether the load transfer during walking can be altered effectively by insertion and resorption of a distal pin. Directly PO 38% of the transverse load is transferred through the prosthesis shaft and micromotion of the proximal prostheses tip is below 55 μm. After resorption of the pin, no transverse loads are transferred through the prosthesis shaft. Therefore, the loading of the proximal bone tissue is far more pronounced than in the case of a standard prosthesis, demonstrating the feasibility of the load-shift concept. A balanced degradation of the pin simultaneously with the ingrowth of the prosthesis is expected to reduce hip replacement complications.

Keywords: Prosthesis; Stress shielding; Biodegradable; Micromotion; Finite element analysis

1. Introduction

The basic function of the hip joint is to allow motion and load transfer between the pelvis and the femur. The natural load transfer occurs from the acetabulum to the head and the neck of the femur. The specialised arrangement of trabeculae within the proximal region of the femur guarantees a continuous load transfer into the epiphyseal femoral cortices. One of the problems of artificial hip replacement is the alteration of this load transfer by inserting a prosthesis into the femural canal (Aamondt et al., 2001). The mechanical loading of the proximal femur is such changed from an externally loaded into an internally loaded system (Stauffer and Chao, 1991). The smooth stress gradient along the metaphyseal to diaphyseal direction is severely disturbed. The implanted inert prosthesis is surrounded by bone, which is a biologically "active material", capable of adaptive response to the altered stress state. In a matter of time the bone will remodel until a new equilibrium is reached. This can be a stable state in the case of a successful integration of the device or it can become instable, which would correspond to the failure of the system. The more the design of the femoral prosthesis enables the natural physiologic load transfer, the less changes to the bone during remodelling is to be expected, especially for uncemented prostheses. However, still one of the most important reason for femoral bone loss is non-physiologic load transfer and associated stress-shielding (Pritchett, 1995; Bryan et al., 1996; Sumner et al., 1998).

The philosophy of uncemented femoral prostheses is the enduring implant fixation by bone ingrowth (Engh et al., 1990; Breusch et al., 2000), which includes all

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kinds of rigid bonding between the bone tissue and implant surface. To achieve successful bone fixation of the implant, several requirements have to be fulfilled (Kienapfel et al., 1999): physiological load transfer, biocompatibility of the implant material, characteristic surface geometry, implant stability, small micromotions between bone and implant, and prevention of an interface gap. Two of these requirements are mostly mechanical: sufficient initial and long-term stability guaranteeing successful bony ingrowth and fixation, and a load transfer as similar as possible to the untreated femur.

Several attempts have been made to achieve the goal of minimum alteration of the physiologic load transfer with more or less successful results. Examples are the "isoelastic" prosthesis (Au, 1994; Niinimäki et al., 1995; Ali and Kumar, 2002), the "McMinn" prosthesis (McMinn et al., 1996; Eisler et al., 2001), and proximal fixed prosthesis (Niinimäki et al., 2001).

Many authors like Engh and Bobyn (1988), Huiskes (1990), Laine et al. (2000), and van Rietbergen and Huiskes (2001) have shown the impact of the shape, length, and surface characteristic of the prosthesis shaft on the stress-shielding effect and bone resorption. Munting and Verhelpen (1995) and Munting et al. (1997) demonstrated also the possibility for a stemless femoral prosthesis and analyzed its influence on the bone remodelling of the proximal femur.

Being aware of the importance of the prosthesis shaft a new design philosophy was developed. The result is a prosthesis with time varying mechanical characteristics post-operatively, which is referred to as the "load-shift" concept. Directly post-operative (PO) a stable initial fixation is achieved by a press-fitted prosthesis cone and enhanced by the stabilizing prosthesis shaft, which is widened at the tip by a biodegradable pin. This allows the applied loads to be transferred partly through the cone and partly through the prosthesis shaft. Simultaneously to the process of bony ingrowth of the prosthesis the pin is resorbed. The amount of load that is transferred through the prosthesis shaft continuously decreased until it vanishes completely. At the long-term PO state all loads are transferred through the prosthesis cone into the proximal femur—establishing a more physiological stress state and reducing side effects like stress shielding and femoral bone loss.

The purpose of this study was the numerical evaluation of this concept and the comparison of the load-shift hip prosthesis to a standard design hip prosthesis of similar shape.

2. Material and methods

The main interest in this study was focused on the analysis of the loading of the bone tissue in the proximal femur, the load-transfer from the implant to the bone, and the interfacial micromotion between implant and surrounding bone.

2.1. Prostheses

The load-shift prosthesis is a modular system made from titanium (AL6V4) composed of a neck, proximal cone, shaft, and a biodegradable pin (Fig. 1). All components are available in standardized sizes and angels allowing an adaptation to the patient's femur. The neck and prosthesis shaft are inserted into the cone, aligned, and locked. The cone has a special surface texture (sand blasted) to support bone ingrowth whereas the surface of the prosthesis shaft is polished to suppress local ingrowth (Cameron, 1997). The major section of the prosthesis shaft is quartered into four wedge shaped legs (Fig. 1). Its diameter is tapered into the distal direction. Initially the distally inserted biodegradable pin (PDLA—poly(D-lactic) acid) pushes the four legs apart and a nearly constant diameter (16 mm) is achieved along the prosthesis shaft. The expanded distal tip of the prosthesis shaft is in direct contact with the endosteal surface of the femur.

The analyzed load-shift prosthesis was composed of a neck with an angle of 135°, a large sized cone with proximal/distal width of 27/25 mm and a large sized prosthesis shaft with a tip diameter of 14 mm (pin not inserted). The inserted pin generates a radial enlargement of 1 mm at the distal tip leading to a diameter of 16 mm. The load-shift prosthesis was compared with a standard prosthesis having similar shape except for the prosthesis shaft, which for the standard prosthesis is solid with a constant diameter ($\varnothing$ 16 mm) without biodegradable pin. All the other components were identical. Seven simplified cases (three for the load-shift, four for the standard prosthesis) representing different time-points and histories post-operatively were investigated (Table 1).

Case I: The load-shift prosthesis at the immediate PO state. The proximal femur is pre-stressed due to the press-fitted prosthesis. The inserted pin brings the distal prosthesis shaft into contact with the endosteal surface of the femur.

Case II: The load-shift prosthesis at a long-term PO state. Complete bony ingrowth has occurred at the cone surface and the pin is completely biodegraded leading to a gap between prosthesis shaft and bone. The pre-stress effect has vanished due to stress relaxation and bone remodelling within the proximal femur.

Case III: The load-shift prosthesis at a long-term PO state but with total failure of bony ingrowth at the cone surface. The pin has degraded and the pre-stress is absent.

Case IV: The standard prosthesis at the immediate PO state. Conditions as in Case I.