Pre-clinical development of a new osseointegrated fixation implant for amputated patients designed to reduce bone failure risk and periprosthetic bone loss

Tomaszewski, P K; Verdonschot, N; van Diest, M; Lasnier, B; Bulstra, S K; Verkerke, G J

INTRODUCTION:

For amputated patients, direct attachment of upper leg prostheses to the skeletal system by a percutaneous implant is an alternative solution to the traditional socket fixation. Currently available implants, the OPRA system (Integrum AB, Göteborg, Sweden) and the ISP Endo/Exo prosthesis (ESKA Implants AG, Lübeck, Germany) allow overcoming common soft tissue problems of conventional socket fixation and provide better control of the prosthetic limb, higher mobility and comfort. However, restraining issues such as soft-tissue infections, peri-prosthetic bone fractures and considerable bone loss around the stem limit functional behavior. Moreover, a long residual limb segment is required for implant fitting, which limits the applicability of the system.

In order to overcome the limiting biomechanical issues of the current designs, a new concept of the direct intramedullary fixation was developed. The aim was to restore the natural load transfer in the femur and allow implantations in short femur remnants. We hypothesize that the new design will reduce the peri-prosthetic bone failure risk and adverse bone remodeling. To verify this hypothesis, the new design was tested both in finite element (FE) simulations and in cadaver experiments.

METHODS:

For the FE analyses (MSC Software Corporation, Santa Ana, CA, USA) generic CT-based models of an intact femoral bone and amputated bones implanted with 5 analyzed implants were created for the study. Models were loaded with two loading cases from a normal walking obtained from the experimental measurements with the OPRA device. Periprosthetic bone failure risk was evaluated by considering the von Mises stress criterion. Subsequently the strain adaptive bone remodeling theory was used to predict long-term changes in bone mineral density (BMD) around the implants and the results were visualized in the form of DXA scans. The cadaver experiments comprised periprosthetic strain measurements with 7 femoral bones, first intact and afterwards implanted with a model of standard titanium screw fixation implant and prototypes of the new design. The unidirectional strain gauges (YFLA-5, Tokyo Sokki Kenkyujo, Japan) were positioned at three different levels along the implants on lateral, medial, anterior and posterior side of the femora. Two static loads representing single-leg stance and toe-off phase of a normal walking cycle were applied to the specimens mounted in a tensile testing rig (MTS Systems Corporation, den Prairie, Minnesota, USA) (Fig.3). Strain measurements were expressed as a percentage of the strains in the intact femora and to evaluate differences between the standard and the new design a two way repeated measurement ANOVA analysis was performed.

RESULTS:

The FE simulations for the OPRA and the ISP implants showed high stress concentration in the proximal region decreasing in the distal direction to values below physiological levels as compared with the intact bone. The stresses around the new design were more uniformly distributed along the cortex and resembled better the intact case. Consequently, the bone failure risk was reduced as compared to the OPRA implants. The adaptive bone remodeling simulations showed high bone resorption around distal parts of the OPRA and the ISP implants in the distal end of the femur – zones 1 and 7 (on average - 42% ISP to -51% OPRA after 60 months) (Fig.4). The experimental measurements showed overall changes in cortical strains after insertion of the standard titanium screw fixation compared with the new designed implant for single-leg stance and toe-off (ANOVA, p<0.03). The strains measured for the new design were much closer to the values obtained for the intact bones, as compared to the standard screw implant (Fig.5).

DISCUSSION:

The FE analysis showed much better bone maintenance and lower failure probability for the new design in comparison to the current osseointegrated trans-femoral prostheses. The cortical strain measurement supported these predictions, as significantly more physiological cortical strains were obtained for the new designed implant in comparison to the standard screw fixation. Obviously the presented studies embedded several limitations such as the use of a generic model rather than a subject-specific model, as well as relatively poor cadaver bone quality due to high age of the donors. Nevertheless we believe that the performed analyzes were suitable for comparisons of the influence of the different types of the direct fixation implants on the periprosthetic bone. The positive outcomes encourage further developments of the presented concept, which is currently studied in an in-vivo model. With these running experiments we expect to complete the pre-clinical development of the new implant.

SIGNIFICANCE:

The new implant is expected to improve safety of the rehabilitation of amputees with the direct fixation implants and allow treatment of the patients with the short stumps.

ACKNOWLEDGEMENTS:

This project was supported by the Fonds NutsOhra.

REFERENCES: