INTRODUCTION

In vivo loading of orthopedic implants during activities of daily living is still not well known in total knee arthroplasty (TKA). Recently, the first implantation of an instrumented tibial baseplate for measuring the axial force in one patient was reported [1]. To overcome the limitation of uniaxial measurements, two prostheses capable of measuring all 6 load components in TKA were proposed [2, 3] (Fig. 1). The design principle is based on two plates (distal and proximal) separated by a given distance from each other. The plates are connected with a central hollow stem [4]. Loading of the implant forces the central stem to bend, which is measured by strain gages. However, this design allows the immediate postoperative ingrowth of soft tissue, which most likely decreases the measuring accuracy.

The aim of the study was to determine the accuracy of our telemetrized measuring accuracy.

METHODS

A custom made tibial baseplate based on the INNEX™ Fix Knee (Zimmer GmbH) was equipped with 6 semiconductor strain gages and a custom-made telemetry chip [5]. Semiconductor strain gages instead of conventional ones were chosen because of their stable zero signals and the higher resolution. The telemetry chip is powered by inductive coupling and has 9 channels for additional measurements of the implant’s temperature, power supply and data synchronization. The power consumption of the telemetry is 5 mW and data transfer rate is 125 Hz. The antenna is placed outside the metal cavity and connected via a ceramic feedthrough to the telemetry circuit. A polyethylene cap protects the antenna against mechanical damage.

Calibration was performed using a uniaxial materials testing machine and load cell. The prosthesis was placed in water at 37 °C with a coil for telemetric power supply and an antenna for data transfer. Different orientations of the prosthesis resulted in a combination of both forces and moments at each calibration point. Twenty load combinations were used covering the whole range of estimated points of load incidence in a TKA. The matrix method [6] was used to calculate the calibration coefficients. Deviations between the applied and measured loads were calculated.

The influence of connective tissue invading the gap between the proximal and distal plate was investigated using silicone stripes with a thickness of 0.5 mm. The Young’s modulus of connective tissue fibers can be up to approx. 54 MPa [7]. Silicone has a Young’s modulus of approx. 3 MPa and represents very soft connective tissue. The stripes were inserted at different positions and the progressive motion of the two plates resulted in an average absolute error of 0.8, 0.8 and 2.6 % for the antero-posterior (AP), medio-lateral (ML) and axial force, respectively. The moments were accurate within an average absolute error of 0.8, 0.8 and 2.6 % for the frontal, sagittal and transversal plane, respectively. The peak error is below 10 % for forces and below 2.5 % for moments.

RESULTS

The calibration of the implant without silicone stripes between the plates resulted in an average absolute error for simultaneously applied forces and moments of 1.2, 8.3 and 0.8 % for the antero-posterior (AP), medio-lateral (ML) and axial force, respectively. Before the experiment the pros thesis was placed in water at 37 °C with a coil for telemetric power supply and an antenna for data transfer. The accuracy dramatically. The maximum insertion depth of the silicone stripe of 2.5 cm from the posterior aspect resulted in an absolute measurement error of more than 1000 N between the applied and measured vertical force (Fig. 3). Without any silicone between the two plates the maximum error at this loading point of the prosthetic stem was below 20 N, i.e. better than 1 %.

In Fig. 3 the force readings from 3 loading cycles with and without silicone between the plates is shown.

DISCUSSION

The accuracy in ML-direction is lower compared to the AP-direction. The clamping of the calibration frame on top of the instrumented prosthesis is not the same in both directions and led to some micromotion primarily in ML-direction. Modification of the calibration frame and prosthesis will overcome this issue.

The results with the silicone stripes clearly showed that connective tissue ingrowth has to be avoided absolutely. A complete loss of the implants measuring function will occur, if the whole volume between the two plates is filled. The adverse effects of bone particles, cement or biological tissue ingrowth were also discussed in a comparable study [2]. Therefore, we develop a molded sealing, which protects the gap from any ingrowth or any other third body.

REFERENCES


Acknowledgements

This project was supported by Zimmer GmbH, Winterthur, Switzerland.