IN VITRO EVALUATION OF A FORCE- SENSING DEVICE FOR LIGAMENT BALANCING IN TKA

+*·**Crottet, D; ***Maeder, T; *Sarfert, S A; ****Fritschy, D; **Bleuler, H; *Nolte, L P; *Pappas, I P
+*M.E. Müller Research Center for Orthopaedic Surgery, University of Bern, Switzerland
**Laboratoire de Systèmes Robotiques, Ecole Polytechnique Fédérale de Lausanne, Switzerland
***Laboratoire de Production Microtechnique, Ecole Polytechnique Fédérale de Lausanne, Switzerland
****Policlinique des Services de Chirurgie, Hôpitaux Universitaires de Genève, Switzerland

INTRODUCTION

Component loosening and instability are common causes of dysfunction after Total Knee Arthroplasty (TKA) and it is generally assumed that such complications are due to tibio-femoral misalignment or ligamentous imbalance. During the surgery, the ligamentous force balance is currently qualitatively assessed by the surgeon through manual trial movements of the limb. In order to improve this procedure, we developed a force-sensing device to intraoperatively measure knee joint forces and moments. The aim of this device is twofold: a) using tibio-femoral forces and moments make quantifiable measurements of what surgeons describe as a balanced knee joint b) help surgeons during TKA to reach this balance state.

METHOD

The developed force-sensing device consists of two sensitive plates, one for each condyle, and a tibial base plate, which is fixed by customized surgical pins. Due to its small size and thickness (6 mm), the device entirely fits inside the tibio-femoral gap with the patella in its anatomical place after an initial tibial precut. Lateral and medial wedges are used to adjust the device thickness to the tibio-femoral gap. Each sensitive plate contains three deformable bridges, which are instrumented with thick-film piezoresistive sensors (Fig. 1). Applying a load in the sensitive area generates a vertical reaction force and a deformation in each bridge, which is measured by the piezoresistive sensors. The bridges are designed for a maximal total load of 500 N. The amplitude and location of the applied load is determined from the static equilibrium conditions. Based on the measurements of force amplitude and on the contact location of each condyle, the net varus-valgus moment of the tibio-femoral forces, which we assume to be the parameter characterizing the ligament balance, can be computed. Teflon insulation cables and medical connectors are used to ensure the device's autoclavability. Furthermore, the sensitive plates are coated with a 10 µm parylene layer which makes the device operational in an aqueous

Figure 1: Sensitive plates of the force sensing device

environment and fully biocompatible.

Intrinsic accuracy: The intrinsic accuracy of the device was evaluated by loading the sensitive area with weights ranging from 0 to 100 N applied at 20 evenly distributed locations.

Plastic Bones: A control experiment was performed with plastic bones equipped with adjustable springs, which represented the collateral ligaments. The tension of the springs was tuned to simulate ten different degrees of ligamentous imbalance.

Cadaver Experiments: To make quantifiable measurements of what surgeons describe as a balanced knee joint, we measured the tibio-femoral forces and moments in a balanced and an unbalanced condition.

Furthermore, we performed five 90° knee flexions with two different degrees of ligamentous balance, which were realized using (a) a 3 mm lateral and medial wedge and (b) a 6 mm lateral wedge and a 3 mm medial wedge. According to the surgeon's judgment the second condition was better balanced than the first.

RESULTS

Intrinsic accuracy: The accuracy study for the device yielded a maximum force amplitude and location error of 1.4 N and 0.6 mm respectively.

Plastic Bones: The forces and moments measured by the device reflected the imbalance imposed by the adjustable springs. The measured net varus-valgus moments were proportional to the applied spring force differences. The proportionality factor corresponded with an error of 13% to the total lever arm of the spring forces. This deviation is explained by the cumulative effect of the intrinsic measurement error, the adjustment uncertainty of the spring tension and the play in the mechanical fixation.

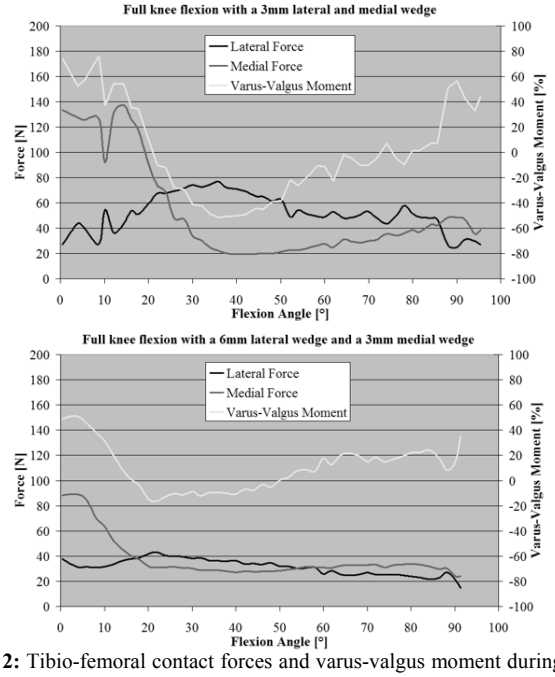

Figure 2: Tibio-femoral contact forces and varus-valgus moment during full knee flexions with two different degrees of ligamentous balance

Cadaver Experiments: In the balanced knee condition, we measured a lateral and a medial force amplitude of 24 N and 22 N. The relative difference of the respective varus-valgus moments was 6%. In the unbalanced condition, the lateral and medial force amplitudes were 36 N and 9 N, and the relative difference of the respective varus-valgus moments was 60%. These results indicate that device's measurements reflect the surgeon's perception.

The averaged forces and moments measured during the flexion experiments are shown in Fig. 2. In agreement to the surgeon's opinion, the second condition exhibits a relative varus-valgus moment significantly closer to 0.

DISCUSSION

The proposed force-sensing device for ligament balancing in TKA provides not only the amplitude of the tibio-femoral contact forces but also their net varus-valgus moment. The intrinsic accuracy of 1.4 N and 0.6 mm, as well as the measurement range of 0-500 N seems to be appropriate for this application. The plastic bone experiment showed the device's suitability for the purpose of ligament balancing. The data acquired during the cadaver experiment demonstrated the consistency between the device measurements and the surgeon's perception. In addition to measurements in discrete positions, the device allows continuous measurement during full knee flexions. Thanks to its quantitative and precise measurements, the developed force-sensing device has the potential to improve the quality and repeatability of the ligament balancing procedure in TKA. Further cadaver experiments will be performed to confirm these results and to quantify the benefit of using such a device compared to the manual approach.