A FORCE-SENSING DEVICE FOR LIGAMENT BALANCING IN TOTAL KNEE ARTHROPLASTY

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Introduction: Common causes of dysfunction after Total Knee Arthroplasty (TKA) are component loosening and instability, which are mainly due to a tibio-femoral misalignment or a ligamentous imbalance. While current surgical tools and navigation systems help to achieve a precise alignment and placement of the prosthesis, the ligamentous force balance is still qualitatively assessed by the surgeon through manual trial movements of the limb. An objective and quantitative measurement of the forces acting within the knee would help the surgeon to improve the accuracy of the ligament balancing procedure, thus ensuring a good joint stability and an increased prosthesis lifetime. Within this framework, we developed a force-sensing device for TKA that provides precise, real-time, quantitative measurements, while permitting the patella to be kept at its anatomical place and ensuring a small bone resection.

Materials and Methods: The developed force-sensing device consists of two sensitive plates, one for each condyle, a tibial base plate, which is fixed by customized surgical pins, and a set of lateral and medial wedges, which allow varying the tibio-femoral gap. Due to its small thickness (6mm), the device entirely fits inside the knee joint in the tibio-femoral gap with the patella in its anatomical place after an initial tibial precut. Each sensitive plate contains three deformable bridges instrumented with thick-film piezoresistive sensors, which have been designed to reach their yield point at a load of 500N. Applying a load in the sensitive area generates three vertical reaction forces, whose amplitudes are measured by the piezoresistive sensors and allow determining the amplitude and location of the applied load from the static equilibrium conditions. Knowing the force amplitude and the medial-lateral location of each condyle, the net varus-valgus moment of the contact forces, which is regarded as the parameter characterizing the ligament balance/imbalance, can be computed. Following a calibration, the intrinsic accuracy of the device was evaluated by loading the sensitive area with weights ranging from 0 to 100N applied at 20 evenly distributed

locations. To validate that the device is suitable for the purpose of ligament balancing, a control experiment was performed with a plastic knee joint model equipped with adjustable springs, which played the role of the collateral ligaments. Different spring tensions were applied representing ten levels of medial and lateral imbalance. According to laws of mechanics, a linear relationship between the spring tension and the net varus-valgus moment of the femoral contact forces should exist with the proportionality factor being the lever arm of the spring forces. Finally, the device was tested in a cadaver experiment by an experienced surgeon. After a standard opening of the knee, a tibial precut of about 6mm was performed and the device installed. The amplitude and location of the contact forces of the femoral condyles were measured in full extension before and after a ligament balancing.

Results: During the accuracy study, which validated the system's calibration and functioning, the maximum force amplitude and location measurement error, i.e. the maximum deviation from the given weights and locations, were 1.4N and 0.6mm. In the plastic bone experiment, the expected linear relationship between the spring forces and the net varus-valgus moment was experimentally verified and the slope corresponded to the measured lever arms within 12%. This deviation is due to the cumulative effect of the intrinsic measurement error of the device, the adjustment uncertainty of the spring tension as well as the play in the mechanical fixation of the springs. During the cadaver experiment, the contact forces of each condyle ranged from 40N to 70N when no external forces were applied. When the surgeon manually applied varus-valgus loads, the maximal contact force reached 350-400N. Consequently, the design specification of 500N maximal loading seems appropriate. In a second step, the surgeon released the medial collateral ligament guided by the measurements of the device leading to a reduction of the initial imbalance of 1.25±0.12Nm to 0.15±0.12Nm. The ligamentous balance thus achieved was consistent with the surgeon's manual perception of a balanced knee.

Discussion: The proposed force-sensing device for ligament balancing in TKA provides not only the tibio-femoral contact forces but also their resultant varus-valgus moment, which describes the ligament balance. Furthermore, the device offers the advantages of real-time measurements, of keeping the patella in its anatomical place during the measurement and of a minimal bone resection, which helps to preserve the joint line. The intrinsic accuracy of 1.4N and 0.6mm should be sufficient for this application. The plastic bone experiment affirmed the device's suitability for the purpose of ligament balancing. The data acquired during the cadaver experiment demonstrated the suitability of the designed measurement scale. The agreement between these preliminary in-vitro measurements and the surgeon's perception tends to confirm the soundness of the balance measurement principle. In conclusion, the design of the force-sensing device has been experimentally validated and shows a strong potential to provide useful quantitative information and effective assistance during the ligament balancing procedure in TKA.

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