A FORCE-SENSING DEVICE FOR ASSISTANCE IN SOFT-TISSUE BALANCING DURING KNEE ARTHROPLASTY

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Nowadays, the large majority of the instrumentation for orthopaedic surgery consists of more or less complex mechanical tools. To increase the accuracy and the safety of orthopaedic interventions, sensors and computers were recently introduced in the operating room. Computer Assisted Orthopaedic Surgery (CAOS) uses a navigation system that tracks in real-time the movements of surgical instruments and displays their exact location in relation to the operative area. Such technology improved the quality of orthopaedic arthroplasties, but it is still limited to the measurement of kinematic parameters such as axial alignments, position and angle measurements. In Total Knee Arthroplasty (TKA) for example, the ligament balance, which is crucial for the stability and lifetime of implants, is currently only qualitatively assessed with manual trial movements or basic mechanical tools. The goal of this thesis was therefore to demonstrate the importance of the intraoperative measurement of musculoskeletal forces through the development of a force-sensing device designed to improve the ligament balancing procedure during TKA.

The device consists of two sensitive plates, one for each condyle, a tibial base plate and a set of spacers to adapt the device thickness to the patient-specific tibiofemoral gaps. Each sensitive plate is equipped with three deformable bridges instrumented with thick-film piezoresistive sensors, which allow accurate measurements of the amplitude and location of the tibiofemoral contact forces. The net varus-valgus moment is then computed to characterize the ligament imbalance. The developed device has a measurement range of 0-500 N and an intrinsic accuracy of 0.5 % full scale. The first experimental trials on a plastic knee joint model and on a cadaver specimen demonstrated the proper in-situ functioning of the device.

The performance and surgical advantages of the device were then evaluated with six cadaver specimens mounted on a knee joint loading apparatus allowing unconstrained knee motion as well as compression and varus-valgus loading. Four different experiments were performed on each specimen: 1) Knee joints were axially loaded. Comparison between applied and measured compressive forces demonstrated the accuracy and reliability of in-situ measurements. 2) To estimate the importance of keeping the patella in its anatomical place during imbalance assessment, the effect of patellar eversion on the mediolateral distribution of tibiofemoral contact forces was measured. One fourth of the patellar load was shifted to the lateral compartment. 3) Assessment of knee stability based on condyle contact forces or varus-valgus moments were compared to the current surgical method (difference of varus-valgus loads causing condyle lift-off). The force-based approach was equivalent to the surgical while the moment-based, which is considered optimal, showed a tendency of lateral imbalance. 4) The effect of minor and major medial collateral ligament releases was biomechanically quantified. On average, the medial contact force was reduced by 20% and 46% respectively. Large variation among specimens reflected the difficulty of ligament release and the need for intraoperative force monitoring.

Finally, an in-vivo trial was carried out to evaluate how the device performs in a surgical environment. After the tibial cut, the medial and lateral tibiofemoral gaps ensuring a stable knee were determined according to the device measurements and compared to the femoral cuts performed on the basis of standard instrumentation. Both approaches agreed in full extension but not in 90° flexion. However, an imbalance in flexion could be measured after the cuts with the femoral component in place, thus demonstrating the consistency between the measurements. Moreover, the surgeon also estimated at that point of the surgery that the knee was not correctly balanced and that a ligament release would be required.

In conclusion, the proposed force-sensing device for assistance in ligament balancing during TKA provides accurate, reliable and useful measurement. In addition to the precise imbalance assessment based on the measurement of forces and moments, important clinical advantages, such as the possibility to keep the patella in its anatomical place during the measurement or the real-time force monitoring during the delicate phase of ligament release, were demonstrated. The encouraging results of the in-vivo trial proved the usability of the device in a surgical environment and opened the way for larger clinical studies. The developed device has thus shown potential to improve the ligament balancing procedure and the survivorship of TKA.