A COMPUTER-ASSISTED CONTROLLED DISTRACTION DEVICE TO GUIDE LIGAMENT BALANCING DURING KNEE ARTHROPLASTY

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Introduction: In knee replacement surgery, it is difficult to quantify the ligament system prior to making the bone cuts, at which point the surgeon can only try to correct for ligament imbalance (i.e., tautness or looseness in the ligaments during flexion) rather than explicitly making a compromise between alignment and balance. This inability is significant because revision procedures are often performed because of instability [4], which is primarily attributable to incorrect ligament balancing. To address this need, devices known as tensors are sometimes used to assess ligament balance; they are typically used after the tibial cut is made to distract the bones until the ligaments are tight and indicate the shape and size of the gaps (e.g. Insall, Freeman, Cores systems). A major problem with these tensors is that they require eversion of the patella, which distorts the soft tissue envelope of the knee. To avoid this problem, Muratsu [3] developed a tensor which leaves the patella in place, thus reproducing the normal condition of the knee and improving the measurements, especially in flexion. It is used once the femoral cuts are done, and ligament balancing is performed by releasing the appropriate ligaments. Other systems (e.g. Balansys, PiSystem [5]) control the distraction force, thereby improving the consistency of the measurement. The Centerpulse tensor is used in parallel with a navigation system and the external rotation of the femoral component is monitored. These measurements are biased in flexion because they are used with the patella upturned. Other navigation devices (e.g. Surgetics) measure the laxity without a tensor using quick manipulations of the limb after the tibial cut is made. We propose a system [2] which improves on these others by (1) being used after making only the tibial cut, (2) leaving the patella in its normal position, (3) applying a consistent distraction force throughout the range of motion of the knee, and (4) tracking the distraction with a computer-assisted navigation system. Our objective is to use only a few intraoperative measurements to characterize the ligaments and simulate their behaviors for different proposed implant positions. We combine two different approaches to determine the ligament insertions and lengths more robustly and use this information to predict the prosthesis size and position which optimally satisfies balance and alignment goals.
**Materials and Methods:** Our device is based on hydraulic technology. The system has a base plate carrying two independent superior trays placed under the two femoral condyles. Distraction is applied between the base and each superior plate through two rubber bladders which can be inflated until they apply 100N each. The back of the base plate is shaped to fit around the posterior cruciate ligament if it exists. The bladders are inflated with water via a screw mechanism (currently manually operated, but easily motorized). The height of the distractor can range from 6 to 16 mm, and additional blocks of 1, 3 and 5 mm can be added if necessary. The system is placed manually on the tibial surface and centered on mechanical axis with the superior plates below the condyles. The bladders are inflated, and the resulting force computed from pressure sensors. A computer-assisted navigation system is used to find the bone gap and display on a monitor the articular space and the transepicondylar line, which are used in positioning the femoral component in flexion.

Because there is not yet unanimity regarding how to optimally measure or implement soft tissue balance, we provide means to acquire a variety of measurements. In addition to the distraction measurements described above, we allow the surgeon to digitize each ligament insertion (the anatomic insertions). The surgeon also digitizes various points on each bone which are used in a bone-morphing procedure. The insertion locations are identified on the model and morphed to the current bone too. In addition to these two anatomic modeling approaches, we also used a model-based algorithm to estimate the insertions of equivalent single-fibre ligaments that best model the constraints between the two bones during a rapid manual manipulation technique of the limb [1]. This algorithm selects the points around anatomic insertions on the femur and tibia that have the smallest change of distance throughout the recorded movements. The estimate distances are taken to be the initial lengths of the single-fibre models and during the distraction step the current lengths are displayed and compared to them. According to the surgical technique the ligament balancing is then performed with reference to the monitored distances. Our device could be used to measure the distraction forces at different flexions of the knee from which the stiffness of each single-fibre model can then be calculated and the optimal prosthesis size and position can be predicted.

**Results:** We tested our first prototype of the distraction device on two cadavers. The cadaveric knees were nonpathological and in very good condition. The bodies weighed 40 kg and 90 kg. The acquisition of the articular centers and the bone-morphing procedure were performed successfully. The tibial cuts were both 10 mm deep. On the first cadaver, the distraction was applied during manual manipulations of the leg and unfortunately the applied torsion tore a silicone joint between the right superior plates; this problem was solved with minor mechanical modifications. On the second cadaver, we found that the distraction was more difficult due to the heavy weight of the leg, and the surgeon had to initiate and help the distraction manually during the manipulations. We also found that manipulation of the foot produced variations in the measured forces and it was difficult to manually control these forces. Despite the difficulties, several trials were carried out in which we tracked the articular space, the ligament lengths and the distraction forces and the surgeon felt that the information we gathered would be useful if it were easier to obtain. We therefore decided to develop a second more powerful prototype. While the first device was based on a parallelogram linkage, the second employed the rubber bladders described above. Postoperatively, the insertion locations defined by one position on the statistical
model then matched with the recorded data, and on the matched model by the operator have been compared. The approximate difference was under 0.5 mm (1 triangle of the model). We also compared them to each average of the measured anatomic insertions and the approximate differences were between 1 and 2 cm in the first two experiments.

**Conclusions / Discussion:** Our initial cadaver trials were for the most part successful. The surgeon was able to assess soft tissue balance but judged the device not powerful enough. The first prototype was limited to 100 N, so we have designed a new more powerful prototype to apply larger loads of 200 N during the ligament balancing. In contrast to most existing soft tissue assessment devices, the measurements can be made after a preliminary tibial cut, but prior to any femoral bone cuts and with the patella in its normal anatomical position. Before being tested in the clinical setting, we need to complete the calibration procedure and test the robustness and durability of the device. We are also addressing technical issues of sterilizability, storage and manufacturing cost, and are currently planning to test it clinically in the near future. We anticipate that this tool will be more versatile and easy to use than existing options and can be adapted to a wide variety of prostheses and surgical techniques. Although numerous approaches have been proposed to address ligament balancing intraoperatively, imbalance remains an important clinical problem and comprehensive soft tissue assessment is key to finding the optimal approach. The ligament models derived from various associated insertion location techniques can be coupled with approaches such as the ones developed by Martelli to assess and predict ligament balance throughout the functional range of knee motion. In a future study, we will assess intra- and interoperator repeatability as well as cross-specimen repeatability and the relation of the effective attachment sites to the corresponding anatomic locations. We will also consider the significance of assuming that the ligaments behave as inextensible strings. Using the force measurement capability of our new prototype, we will be able to characterize the stiffness of the ligaments along the knee flexion. This information can replace for each patient the estimates used in models such as Chen’s to assess ligament balance throughout the knee’s flexion range.

**References**


