Sensor integrated tibial inlay for soft-tissue balancing

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Abstract

A tibial inlay with integrated force sensors for a total knee arthroplasty was developed. It is inserted after the bone resection together with the trial components of the prosthesis intraoperatively to measure the tension in the collateral ligaments to carry out ligament balancing. Forces on the medial and lateral condyle of the knee can be measured separately. Three force sensors per condyle are used to determine the magnitude of the force and the point of force application for the respective condyle. In contrast to the methods used in clinical practice it is possible to measure the ligament tension over the whole range of motion of the joint. Moreover the results are not dependent on the surgeon. First tests in an automated load system showed good agreement between calibration data of single force sensors and load applied on the inlay.

Keywords: knee arthroplasty; force sensor; tibial inlay; soft tissue management

1. Introduction

With the increase of life expectancy an augmented need of arthroplasties becomes necessary. The prolonged use of joints often leads to failure and a replacement is needed. Arthrosis, especially in the hip and the knee joint, is the major indication for the replacement of the affected joint. Artificial joints offer pain relief and a better quality of life for the patients and have become a standard intervention today. In Germany, more than 136,000 total knee arthroplasties have been performed in 2007 and the case numbers are constantly increasing.

Nevertheless post-operative complications are not uncommon. In total knee arthroplasty the misalignment of tibial and femoral components and an incorrect soft tissue balancing are main reasons for premature implant failure or persistent knee instabilities. Tibiofemoral misalignment can be minimized with navigated surgical techniques. On the other hand soft tissue balancing means the right adjustment of the ligament tensions. The intraoperative measurement of ligament tension is carried out manually or with basic mechanical tools. The most common methods include laminar spreaders or spacer blocks: after the bone cuts are carried out femur and tibia are distracted until a sufficient tension in the lateral ligaments is reached. Then the joint gap is measured and a suitable bearing is chosen according to the manufacturers guidelines and is inserted.

Equalization of collateral ligament tension can be reached by release of the ligaments. The ligaments are cut until the forces acting on the condyles are equalized. During the procedure the surgeon measures the forces from time to time by pulling the joint apart. It is obvious that this measurement method is not quantitative, reproducible and dependent on the surgeon. With the presented tibial inlay it is possible to get a precise intraoperational measurement of the forces acting on the condyles created by collateral ligament tension. Moreover the procedure can be fully integrated into the existing operation procedure since the presented tibial implant replaces a sensorless trial inlay that has to be inserted during the operation. Hence the time needed for the procedure should not be prolonged. Another big advantage is the possibility to measure the ligament tension over the whole range of knee motion. The surgeon can adjust the ligament tension more accurately.

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2. Methods

2.1. Modeling

The knee joint allows bending of the leg. Several ligaments hold tibia and femur together and stabilize the knee. While the collateral ligaments provide stability in the direction of the leg axis the patellar tendon and the cruciate ligaments stabilize the knee in the transverse plane. For soft tissue management, the collateral ligaments are adjusted during the knee arthroplasty operation. So a simplified mechanical knee model, which shows the forces on the two condyles of the tibia, can be derived: only tension in the collateral ligaments cause forces on the tibial condyles.

![Mechanical model of the femur](image)

The role of the other ligaments and tendons can be neglected. Additional forces from the body weight are omitted because the do not act on the joint during the measurement. The model for the femoral part of the knee can be seen in Fig 1. The point of force application for $F_{c,\text{lat}}$ and $F_{c,\text{med}}$ is dependent on the contact points of the femur with the tibial condyles. The direction of these forces is defined normal to the surface of the plateau of the tibial stem. On the basis of this model the tibial inlay was designed: a tibial trial inlay consisting of two independent halves for the medial and the lateral condyle was created. The geometry of the inlay is identical to a trial inlay of the Columbus implant from Aesculap AG. Three load cells were inserted into each part of the inlay. They enable to measure the magnitude of the force and the point of force application on the respective condyle.

2.2. Force Sensors

For the measurement of the force on the condyles piezoresistive pressure sensors were used in a load cell. SM 5102 sensor dies from Silicon Microstructures Inc. were used as pressure sensors. The silicon dies were contacted via a flexible polyimide foil with conductive tracks of electroplated gold in a flipchip process. On the other end of that foil, a micro-cable was attached by resistive welding. The sensor was then placed in to a housing of stainless steel which consists of a base plate where the pressure sensor is mounted and fixed with epoxy glue. A ring was then mounted with adhesive on the base plate. Because of the small thickness of the flexible polyimide of only 12 µm, the foil can be lead through the adhesive bond between base and ring. The steel housing is then filled with silicone and a cap made from PEEK is placed on the silicone before curing. A cross-section through a load cell can be seen in Fig 2b). Forces acting on the cap create a pressure in the silicone and can so be measured with the pressure sensor. A force of 100 N creates a theoretical pressure of 1.894 MPa. The sensor is capable to measure pressures up to 300 psi, which equates to 2.068 MPa. But moderate overloading will not destroy the sensors, because the manufacturer guaranties a proof pressure of three times the nominal maximal pressure.

![Backside view on the complete tibial inlay and cross-section through a load cell](image)
2.3. Tibial Inlay

As mentioned, the tibial inlay is based on a test inlay of an implant from Aesculap AG, Germany from the Columbus knee arthroplasty suite and can be seen in Fig. 2. The inlay is separated into halves to measure the forces on the lateral and medial condyle independently. Three cavities for the take-up of the load cells are inserted in each half of the inlay. To conduct the six microcables to a central point, channels are built in the test inlay. A flexible joint serves as a strain relief between the two halves and prevents the rupture of the microcables that lead from one half to the other connects the halves of the inlay.

Three load cells per condyle are needed to calculate the point of force application and the magnitude. The values can be calculated by solving the mechanical equilibrium equations:

\[ \sum F_i = -F_{\text{condyle}} \]
\[ \sum M_{x,i} = 0 \]
\[ \sum M_{y,i} = 0 \]

Since the load cells can only measure compressive forces the point of force application has to be inside the triangle spanned by the force load cells of one condyle. Otherwise wrong readings will occur because one sensor will lift off.

3. Results

The piezoresistive pressure sensors were characterized in a pressure chamber. A pneumatic pressure controller Druck DPI 520 was used to regulate the pressure from ambient pressure to 200 kPa. Hence, the following characterization is limited to this range of pressure. Furthermore the pressure chamber was placed into a climatic chamber Weiss SB 220 to change the ambient temperature from 0°C to 80°C. The sensor was supplied with a constant voltage of 5 V by a precision voltage source. The output voltage of the sensors was measured with a digital multimeter from Keithley. Fig. 3 shows the measured data of one load cell: Fig. 3a) depicts the sensor output at a constant temperature of 25°C. The sensor shows a linear output behavior over the available range of pressure. At other temperatures the sensor shows the same sensitivity but differs by a temperature dependent offset. Fig. 3b) shows this strong temperature dependence of the output signal at a constant pressure, which cannot be neglected. Therefore the ambient temperature was also measured at all subsequent calibration and characterization measurements. For a temperature range up to 50°C linear temperature compensation can be assumed in good approximation. For compensation over a larger temperature range polynomials of higher order are needed to receive a good fit. A polynomial of fifth order is needed to fit the complete curve shown in Fig 3b).

![Fig 3a: Pressure dependence](image1)
![Fig 3b: Temperature dependence](image2)

Fig 3: Characterization of Silicon Microstructures pressure Sensors SM5102

![Fig 4: Calibration curve for a complete load cell over a force range of 100 N](image3)
The load cells were calibrated using a spring-loaded piston, which applies a normal force on the PEEK cap of a load cell. The force of the spring can be adjusted manually and the spring inside the piston can be exchanged to cover a larger range of forces without losing accuracy in the adjustment. The applied force was measured with a reference force sensor from Schunk. Temperature is measured with a digital thermometer in the vicinity of the load cell.

Fig. 4 shows that the sensor output is still linear for a fully assembled force load cell and forces up to 100 N can be measured. 80% of the nominal span of the output voltage is used in this case. This shows a good agreement with the design but the measured pressure in the silicone is a little bit lower than expected. We explain this because the silicone is also adheres to the walls of the housing and the PEEK cap is deformed elastically. These factors cause damping of the created pressure in the silicone.

With the described setup a complete inlay was calibrated and characterized in a compression test machine. The inlay was mounted on a base plate of stainless steel and a femoral component of a matching implant was pressed on the inlay. Fig. 5 shows the result of this test. After a preloading phase the force was increased gradually up to 250 N. The measured forces of each sensor and the sum of forces are shown in the graph. It can be seen that the point of force application is near the connection line between sensor 2 and 3 because sensor 1 measures only little force. Moreover it can be seen that the applied force was measured correctly.

Fig 5: Load test of one condyle in an automated compression load cycle

4. Conclusion

A tibial inlay for measurement of condylar forces was designed and characterized. The utilized sensors are able to measure forces up to 100 N with a linear sensor output. Temperature compensation is needed for the sensors and is realized by a digital thermometer and an offset compensation. We could show that compressive forces can be measured on a testing machine accurately and reproducibly. First tests in a knee simulator showed, that refinement of the attachment between base plate and inlay is needed in rotational motion of the femoral component on the inlay. This is currently under investigation.

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References