Effects of a surface matching articular resurfacing device on tibiofemoral contact pressure: results from continuous dynamic flexion–extension cycles

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Received: 7 October 2009 © Springer-Verlag 2010

Abstract
Introduction The application of a defect-size metal implant for the treatment of focal articular cartilage lesions of the femoral condyle is of potential concern resulting in cartilage damage to opposing biological structures. This in vitro study aims to determine the tibiofemoral contact pressure with a contoured articular partial femoral resurfacing device under continuous dynamic pressure loads.

Methods Peak and area contact pressures were determined in eight fresh-frozen cadaveric specimens using a pressure-sensitive sensor placed in the medial compartment above the menisci. All knees were tested in the untreated condition and after implantation of the prosthetic device in the weight-bearing area of the medial femoral condyle. A robotic knee simulator was used to test each knee under continuous pressure load for 400 s during 40 dynamic knee bending cycles (5°–45° flexion) with body weight ground reaction force (GRF). The GRF was adjusted to the living body weight of the cadaver donor and maintained throughout all cycles.

Results Comparison of the untreated condition to focal inlay resurfacing showed no statistically significant differences (P ≤ 0.05) between all testing conditions. The average maximum peak contact pressure across all 40 flexion cycles increased by 5.1% after resurfacing compared to the untreated knees. The average area contact pressure essentially stayed the same (+0.9%).

Conclusion The data suggest that resurfacing with the contoured articular prosthetic device does not pose any immediate deleterious effects to the opposing surfaces based on peak and area contact pressure in a continuous dynamic in vitro application. However, long-term in vivo effects remain to be evaluated.

Keywords Knee · Articular cartilage defect · Tibiofemoral joint · Articular prosthetic device · Contact pressure · Dynamic loading

Introduction

Full thickness articular cartilage defects are commonly found in symptomatic knees and are associated with disability and symptoms such as joint pain and reduced or disturbed function [9, 18]. Furthermore, these defects may result in progressive articular degeneration and predispose to the development of osteoarthritis [8, 19, 31]. Biological repair techniques, such as autologous chondrocyte transplantation [6], osteochondral transplantation (OATS, Mosaicplasty) [5, 16] and microfracture [28] are primarily used for surgical treatment. However, although these techniques have shown promising results in younger patients [15, 23, 24, 27], the repair appears to be less effective with increasing age [21, 23].

A metallic inlay resurfacing prosthesis (HemiCAP®, Arthrosurface Inc., Franklin, MA, USA) was developed to precisely match the surface of a metal implant to the contour of the patient’s articular cartilage surface, thus
filling the defect and restoring a smooth and continuous articulating surface (Fig. 1). The rationale of the device is to provide an additional treatment layer in the management of focal defects after biological measures have been exhausted or are deemed unsuitable for middle-aged or active elderly patients. Healthy cartilage, bone and soft tissue structures are preserved until conventional joint arthroplasty may become necessary.

The use of a defect-size metal implant, however, is of concern resulting in cartilage damage to the opposing articulating structures due to rigid fixation of the resurfacing prosthesis in the underlying bone. Although the magnitude of physiological tibiofemoral articular cartilage deformation during functional joint loading remains widely unclear, in vivo high-resolution MRI investigations showed marked decrease in cartilage volume during or after knee bending exercises [4, 13]. We could demonstrate in a previous biomechanical study that flush implantation of a 20 mm HemiCAP\textsuperscript{®} implant did not appear to be a biomechanical disadvantage under static loading followed by a short dynamic knee bending cycle, whereas increased peak contact pressure was observed with prone position of the device to the adjacent articular cartilage [2]. The objective of this in vitro investigation was to determine the effect of continuous dynamic knee-flexion–extension cycles on the tibiofemoral contact pressure using the prosthetic device implanted in the medial femoral condyle.

Materials and methods

Eight fresh-frozen knee cadaver specimens (4 pairs, all male), transected 25 cm proximal and distal to the knee joint line, were used for data collection. The specimens were obtained from donors, who consented in writing during their lifetime to the use of their body for research and education. A longitudinal incision was made over the medial compartment to gain access for joint inspection. Specimens were only used if tibiofemoral cartilage, meniscus, cruciate and collateral ligaments were intact. Skin, subcutaneous tissue, articular capsule, ligaments, and tendons were preserved. The proximal and distal ends of the specimen were freed from all soft tissues for fixation into a 5 cm by 7 cm tall steel cup using a low melting alloy (Cerro Bend Alloy 158F, Cerro Alloys Co, Pittsburgh, PA, USA). A 0.1-mm thin 33 × 22 mm electronic pressure sensitive film (K-Scan 4000, Tekscan, Boston, USA) was placed in the medial compartment above the menisci and fixed with sutures in a manner that no displacement was possible. The sensor consists of load-sensing regions oriented in a grid with 1.27 mm spacing between rows and columns. Each region is referred to a sensel with piezo-resistive pigments to determine the total compressive load within that region. The K-scan sensor was successfully used in our previous studies in the same application [2] and comparable setup [1, 14, 22].

The specimens were mounted in a specially designed knee simulator (Fig. 2) [2, 30]. Similar to in vivo conditions, the main system forms a closed loop and is composed of artificial muscle, force transducer sensor, joint angle detection, and the ground reacting force. The ground reaction force (GRF) is adjusted according to the donor’s weight. The knee simulator consists of a loading frame (MTS 858 Bionix, MTS Systems, Eden Prairie, MN, USA) with a long stroke main actuator driven by a hydraulic pump (MTS 505.11 silent flow) to simulate body weight and the vertical hip displacement in the mechanical axis of the lower limb. Ankle joint simulation is performed with a hinge joint that provides one free axis in motion. The possible rotation during the movement occurs in the artificial hip joint as if standing with fixed shoe contact. A load transducer is fixed between the mounting plate and ankle joint to detect the vertical ground reacting force (U3 load cell, Hottinger-Baldwin, Darmstadt, Germany). Two smaller actuators apply loads which simulate the quadriceps force. The tendons of the quadriceps muscle are attached to customized curved cryo-clamps which avoid patella tilting. These cryo-clamps are connected to a waterproof force transducer (SSM-AJ 500, Interface, Scottsdale, AZ, USA) and connected to an artificial muscle (Fluidic muscle MAS, Festo, Esslingen, Germany). The mathematical models have

![Fig. 1 HemiCAP\textsuperscript{®} implant for the femoral condyle composed of a cannulated tapered titanium alloy anchoring screw (fixation component) and attached Co–Cr alloy resurfacing implant (articular component). The CAP\textsuperscript{®} system is intended to precisely match the surface of the implant to the contour of the patient’s articular cartilage surface (gray arrows)](image-url)
shown that the properties of this fluidic muscle are comparable to skeletal muscle [29].

All specimens were positioned using a fixed laser beam to achieve correct alignment in the mechanical axis of the lower limb. The mechanical axis was defined as a line through the center of the head of the artificial hip joint, the center of the knee joint and the center of the hinge joint representing the artificial ankle. For calibration of the intra-articular sensor, the ankle hinge joint was secured with two aluminum plates perpendicular to the ground and the knee was fixed in full extension. The sensor was placed in a fashion to ensure complete transmission of load in the respective compartment through the sensor. Prior to testing of each specimen, a new sensor was preconditioned individually performing five knee bending cycles from 5° to 45° flexion and calibrated in the joint with a two-point calibration method at 700 and 1,500 N according to manufacturer guidelines. Definitions of the correct angles of the actual knee position were adjusted with a custom-made goniometer and verified by the displacement controlled main rod. During the test cycles the specimens were sprayed with saline solution to prevent dehydration.

For implantation of the 20 mm HemiCAP® implant, the specimens were released at their femoral fixation. The exact position was marked and recorded to maintain exact specimen position in the knee simulator across all testing conditions. The position of the sensor did not change during the preparation.

The HemiCAP® implant consists of a titanium alloy fixation component and a contoured, cap-like cobalt chrome alloy articular component. (Fig. 1). Both 15 and 20 mm diameter implant components come in a variety of incremental offset sizes which correspond to the superior/inferior and medial/lateral radius of curvatures at the implantation site. This study used the larger 20 mm implant with different offset sizes, matching the individual joint curvature of each specimen. For implantation, the knee was flexed to 90° to expose the central weight-bearing area. A drill guide was used to place a pin perpendicular to the joint surface representing the center of the defect. The center of the “testing defect” was determined by measuring the condylar width and bisecting the distance. The cannulated instrumentation set ensured that the vertical axis was maintained throughout the procedure. After drilling a pilot hole, the fixation component was inserted. A contact probe determined the radius of curvature in two planes. With a matching reamer, the site was prepared for implantation and a sizing trial with corresponding offsets was inserted to confirm the fit to the surrounding articular surface. Care was taken to ensure the prosthesis was positioned along its entire perimeter slightly recessed to the surrounding cartilage surface. The selected articular
component was oriented in the correct planes and connected to the anchoring screw with a tapered lock.

All specimens were tested in two different conditions: untreated knee (A); implantation of a 20 mm resurfacing prosthesis in the weight-bearing area of the medial femoral condyle (B). Each knee was tested through 40 dynamic knee-flexion cycles (5°–45°) with body weight GRF. The targeted level of GRF during the trial was set according to the living body weight of the cadaver donor (e.g. 70 kg–700 N). The loading rate for exploring the dynamic contact pressures was 0.1 Hz/s.

Peak contact and area contact pressures were computed by the software (I-Scan software v4,23, Tekscan, Boston, USA) with a frequency of ten values of contact pressure per second. The peak contact pressure reflected the highest-pressure area in the object (default size was one sensel), calculated as the force inside one sensel divided by the contact area. The area contact pressure reflected the pressure on all loaded sensels, which was calculated by dividing the force by the contact area. For data analysis, (1) the maximum peak and area contact pressure values for each cycle were averaged and compared between the two testing conditions. Furthermore, (2) the maximum value of all testing cycles of every respective specimen was compared. Mean and standard deviation values were evaluated using SPSS 11.0 (SPSS Inc., Chicago, IL, USA). Statistical analysis was done with a paired sampled t test to compare means (significance, \( P \leq 0.05 \)).

**Results**

Continuous data were obtained at every trial. Start and end values demonstrated even recording of average pressure values across each testing cycle. Sensor sensitivity appeared to stay consistent during the test cycles. Statistical analysis showed no statistically significant differences between the untreated and resurfaced testing conditions.

The average maximum peak contact pressure value of all 40 flexion cycles (5.17 ± 0.06 MPa) demonstrated an increase of 5.1% after resurfacing when compared to the untreated condition in the same knee (4.92 ± 0.03 MPa) (Fig. 3). The mean maximum peak contact pressure of all values obtained in every respective specimen (5.88 ± 2.96 MPa) showed an increase of 6.3% after implantation of the device compared to the untreated knees (5.53 ± 2.41 MPa).

The average maximum area contact pressure values of all flexion cycles (2.20 ± 0.03 MPa) stayed essentially the same compared to the untreated knees (2.18 ± 0.02 MPa) (Fig. 4). The mean maximum area contact pressure of all values obtained (2.53 ± 1.02 MPa) revealed to be 2.4% higher with the prosthetic than for the untreated knees (2.47 ± 0.70 MPa).

**Discussion**

This in vitro study investigated the effect of continuous dynamic cyclic knee bending with a surface matching metallic articular resurfacing device on the tibiofemoral contact pressure. The device is approved for international marketing via CE Mark and other regulatory bodies. The clinical use is currently under investigation. However, clinical data for the device are not yet available. The rationale of the study was the concern of increased contact pressures and edge loading of the prosthetic device during continuous joint loading. Although the results indicate...
slightly increased peak contact and area contact pressures, continuous loading with body weight GRF did not result in significantly increased peak pressures over the complete dynamic knee-flexion cycles with the implanted device.

Increased peak and average contact stresses along surfaces adjacent to the rim of a focal defect were shown using pressure sensitive films in in vitro tests \[7, 14\]. Additionally, finite element models of joints with focal defects predict increased strains in the tissue adjacent to a defect \[26\]. A recent experimental model examined the dynamic cartilage contact near defects and the complex sliding over the defect rim by video microscopy. The results indicate that defect presence has dramatic effects on dynamic cartilage deformation and that defect presence and edge characteristics influence tribological characteristics articular cartilage surfaces \[13\]. Thus, the treatment of full thickness chondral and osteochondral defects appears crucial to prevent progressive degeneration of cartilage and the development of osteoarthritis. As existing treatment options for middle-aged patients (40–60 years old) have several drawbacks \[20, 21, 23, 25\], these patients are mostly managed with conservative, non-surgical treatment or unicompartmental or total knee arthroplasty, which represent procedures of final resort for some of the affected patients. The HemiCAP\textsuperscript{R} resurfacing prosthesis may offer an alternative treatment strategy for the middle-aged patient with a focal full thickness articular cartilage defect. However, the stiffness of a metallic implant compared to the surrounding cartilage may cause damage to the opposing cartilage and meniscus. Custers et al. \[10, 11\] reported considerable cartilage damage to the articulating medial tibia when placing an oxidized zirconium or cobalt-chromium femoral tack implant (3.5 mm diameter) in the medial femoral condyle of rabbits. Flush placement of their prosthetic design, however, demonstrated the least degeneration compared to a deep or protruding position \[11\].

The functional and biological response of the HemiCAP\textsuperscript{R} implant was previously assessed in a goat model. Chondral damage in the operated joint was found in several goats in opposing locations on the proximal tibia, including some focal meniscal injury. Similar results, however less frequently, were encountered in the un-operated controls \[20\]. Although quantitative data were unavailable, subjectively the extent of the tissue damage was proportional to any elevation of the prosthesis above the adjacent cartilage surface. Thus, proud implantation of the device has to be strictly avoided. This was confirmed by our previous biomechanical evaluation of the implant when peak contact pressures with the implant being proud to the surrounding cartilage increased by an average maximum of 217% at 5\textdegree{} and 205% at 15\textdegree{} stance compared to untreated knees \[2\].

Recently, Custers et al. repeated their metallic device concept in a goat model and showed that oxidized zirconium implants (5 mm diameter) used as a treatment for established localized cartilage defects of the medial femoral condyle were associated with less cartilage degeneration than comparative microfracture. Histologic cartilage scores of the medial tibial plateau showed significantly more degeneration after direct articulation with the microfracture-treated defect compared to articulation with an oxidized zirconium metal tack implant \[12\].

Cartilage deformation occurs during joint loading. MRI-based techniques were used to quantify the cartilage deformation during mechanical loading in intact human cadaver knee specimen. Loading of the specimen with 120% body weight resulted in a mean thickness deformation of 2% of the femoral cartilage after 10 min loading. Maximum thickness deformation was shown to be 9%,
respectively [17]. In an in vivo magnetic resonance imaging and 3D digital image analysis in healthy volunteer’s, 30 knee bends resulted in an average cartilage deformation of 3.9 ± 9.4% of the medial femoral condyle with two legs and 3.2 ± 8.7% after 12 knee bends with one leg, respectively. These changes revealed not to be significant compared to the cartilage thickness prior to activity [13]. According to the manufacturer guidelines, the HemiCAP® resurfacing device is positioned slightly recessed to the adjacent cartilage surface providing a buffer zone for cartilage deformation at the implant-cartilage interface. It could be hypothesized that by these means cartilage deformation can occur without edge loading of the implant and increased contact pressures are prevented.

There are certain limitations of the present study. This is a human cadaver study and only approximation of the living system can be achieved. Knee bending was performed in vitro by a knee simulator through 40 cycles in 400 s using an electronic pressure sensitive sensor with known limitations as described previously [2, 3]. As in vivo cartilage deformation is a complex event that is determined by the load applied to the joint, the load distribution within the joint during the specific activity and cartilage mechanical properties, one cannot equate the deformatonal behaviour of cartilage directly with its material properties [13]. Thus, it is unknown if and how longer or higher tibiofemoral loading, preexisting osteoarthric changes, meniscal function, mechanical alignment, body mass index, age, gender, and other confounding factors may have resulted in different findings. However, the pre-selection of the applied load by the GRF gave the opportunity to load the specimens with the known body weight of the donor, and thus better approximate the forces that occur in the living system [30]. Furthermore, the knee bending dynamic measurement may have provided a more accurate reproduction of physiologic weight-bearing activity.

In conclusion, the data suggest that resurfacing with the contoured articular prosthetic device does not pose immediate deleterious effects to the opposing surfaces based on peak and area contact pressure in an in vitro application. It appears that an appropriately positioned surface matching implant suggests biomechanical safety and may not result in deleterious effects on surrounding biological structures in an in vivo application. However, long-term in vivo effects remain to be evaluated.

References


