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First Experience With ConforMIS Knee Interpositional Device

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Introduction

The concept of replacing cartilage with metallic wedges for the treatment of knee osteoarthritis is old. Fixed devices such as the McKeever provide good long-term results (1). The ConforMIS knee interpositional Device (iPD) is a novel personalized metallic interpositional device for the treatment of early and moderate medial or lateral osteoarthritis (ConforMIS Inc., Foster City, CA). Using novel proprietary software for image analysis, Magnetic Resonance (MR) scans of each patient are used to machine a personalized implant. The ConforMIS knee iPD is an FDA 510(k) cleared device. In contrast to unicompartmental and total knee arthroplasty, the insertion requires no bone or cartilage resection. The implant's upper surface has the shape of the tibia, including the meniscus. The undersurface matches the tibial surface and results in a stable fixation of the device with only a minimum of implant translation. We report the first experiences with respect to operative technique and early results of subjects treated.

Methods

Goal of a controlled, non-randomized, prospective, multi-center study started in June 2004, is the evaluation of safety and efficacy of the ConforMIS knee iPD. In total, the trial will include 100 subjects in Europe and the US. Patients are chosen by the physician based on their clinical exam, radiographically early or moderate osteoarthritic unicompartmental disease and findings on MRI. An independent radiologist reviews all radiographs and MRI. Novel 3D sizing tools allow to measure the dimension of cartilage loss, thickness and curvature of remaining cartilage and the topography of subchondral bone. With these algorithms, MRI data can be utilized to determine the implant surface and necessary thickness. For the current trial, standard cartilage sensitive MRI sequences (2D FSE, 3D SPGR) are used.

Subjects' informed consent is obtained and documented according to the principles of informed consent in the current version of the Declaration of Helsinki, U.S. Title 21 CFR 50.20 (FDA Code of Federal Regulations) and current HIPAA standards. In all study centers local Ethics Committees (IRB/EC) complied with the requirements of good clinical practices and the regulations regarding use of human subjects for research.

After arthroscopic removal of the posterior horn and body of the meniscus a mini-arthrotomy medial or lateral to the patella tendon is performed. The compartment is exposed, the remaining meniscus and osteophytes along the femoral condyle are removed and the implant inserted using valgus or varus stress. The insertion is facilitated using a special grasper. The implant is inspected in situ and under fluoroscopy in regard to its anterior and posterior translation as well to its internal or external rotation (Fig.1 and 2).

Results

From June 2004 to July 2005 8 patients received 6 medial and 2 lateral ConforMIS knee iPD implants. All subjects had isolated medial or lateral osteoarthritis (Outerbridge Type IV). The mean size of the arthrotomy was 5.2 cm (median 5.0cm, SD 3.3cm). Femoral osteophytes were removed in two patients and tibial osteophytes in one. No bone resection was performed. Range of motion observed intra-operatively was exactly the same as before (flexion: mean 125.0°, median 125.0°, SD 21.2°; extension: mean -5.0°, median -5.0°, SD 10.0°). There was no implant impingement; anterior and posterior shift of the implants were less than 2mm. There was no internal or external rotation observed with extension or flexion. Mean OR time from incision to closure was 49.4 minutes (median 50.0 min, SD 17.8 min). Mean time for implant insertion (from arthrotomy to placement) was 18.1 minutes (median 15.0min, SD 9.0min). Mean total blood loss was 134.4ml (median 60.3ml, SD 435.9ml). In all subjects a sufficient correction of preoperative varus or valgus knee deformity was observed (Fig. 3). The mean preoperative deviation of the physiological 7°-knee axis was 4.3° (median 4.0, SD 4.6°). The mean postoperative deviation was only 0.9° (median 1.5, SD 2.3). Preliminary clinical results from the multicenter trial are provided below. Six months after surgery patients return to normal activitiy levels (Fig. 4). 80% of patients can walk for more than 1 hour without crutches or other assistive walking devices (Fig. 5). All patients report at least two levels of improvement in joint line pain (Fig. 6). Range of motion is normal with full flexion re-established (Fig. 7).

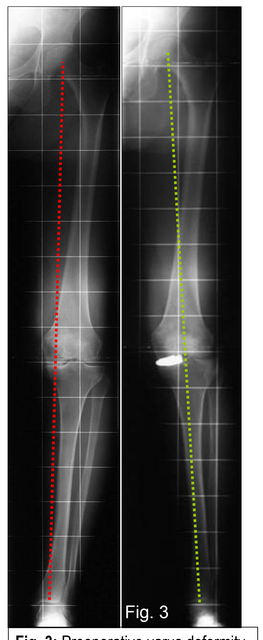
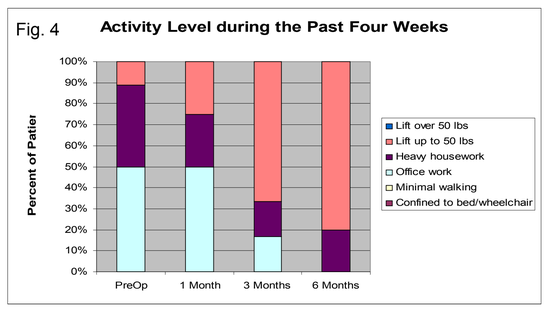
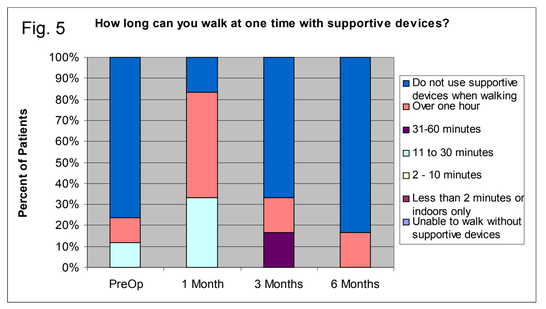
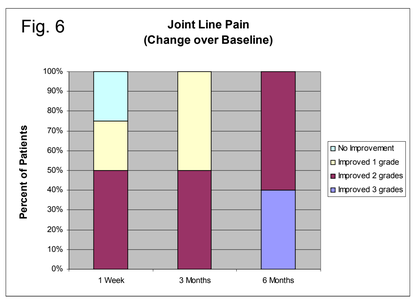
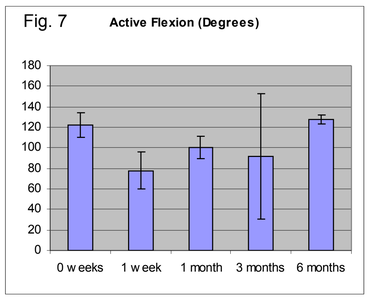


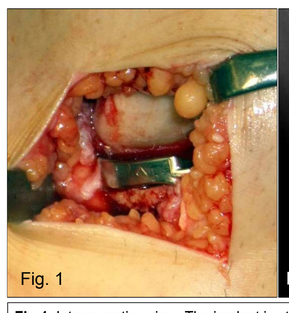
Fig. 3: Preoperative varus deformity (left) is corrected to neutral axis with the implant inserted (right).











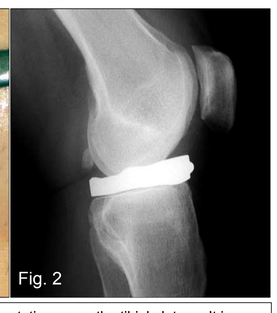


Fig.1: Intraoperative view. The implant is stationary on the tibial plateau. It is inserted via a mini-incision (typically 4-5cm).
Fig. 2: Lateral radiograph. The implant has a conformal fit with the tibia and the femur.

Discussion

Early experiences in regard to surgical technique, correction of deformity and post-operative motion and rehabilitation are promising. The implant is designed to be functionally fixated to the tibia with occasional minimal translation of not more than 2mm observed intraoperatively going from extension to flexion without internal or external rotation. Observation of the mobile interpositional device Unispacer® (Zimmer, Warsaw, IN) shows a different kinematic pattern during extension and flexion (2). With extension there is external rotation and with flexion internal rotation. The surgical technique of the Unispacer® is different, since the tibial plateau has to be flattened. The ConforMIS iPD functions as a fixed interpositional device, since the undersurface matches the tibia's topography. The surgical technique provided no surprises and blood loss was minimal. Since the implant thickness is determined from the patient's MRI, it did provide sufficient correction of pre-operative deformity from 4.3 to 0.9 degrees. Sisto et al (1) did not report a correction of post-operative alignment. The ConforMIS device restores alignment and functions essentially as an osteotomy would. Preliminary longitudinal follow-up data are very encouraging. This personalized device may provide a surgical alternative to current surgical alternatives, such as unicompartmental or total knee replacement, without any bone or cartilage resection and may have a role in the treatment of isolated moderate medial and lateral knee osteoarthritis. The ease of surgery, time to complete the operation, level of tissue preservation, and the functional results are promising and may make this implant ideally suited for early therapeutic intervention, while preserving all future treatment options.

Reference:

1) Scott RD, Joyce MJ, Ewald FC, Thomas WH: McKeever Metallic Hemiarthroplasty of the Knee in Unicompartimental Degenerative Arthritis, JBJS, 1985
2) Sisto DJ, Mitchell IL: Unispacer Arthroplasty of the Knee, JBJS 2005

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