FIRST EXPERIENCE WITH CONFORMIS KNEE INTERPOSITIONAL DEVICE

**INTRODUCTION:**

The ConforMIS Knee Interpositional Device (iPD) is a custom made metallic interpositional device for the treatment of early medial or lateral osteoarthritis (ConforMIS, Inc., Foster City, CA). Using novel proprietary software for image analysis, Magnetic Resonance Imaging (MRI) scans of each patient are used to machine a custom implant. The ConforMIS iPD is an FDA 510(k) cleared device. In contrast to unicompartmental and total knee arthroplasty, the insertion requires no bone resection. The implant’s undersurface matches the tibial surface and results in a stable fixation of the device. We report the first experience 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 respect to operative technique and early results of subjects treated. ConforMIS iPD. In total, the trial will include 120 subjects in Europe and the US. Patients are chosen by the physician based on their clinical exam, early osteoarthritic unicompartmental disease in the radiograph and findings in the MRI. An independent radiologist reviews all radiographs and the 3D tool to measure the size of cartilage loss, thickness and curvature of remaining cartilage and the topography of subchondral bone. With these algorithms, MRI imaging 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 practice and the regulations regarding use of human subjects for research. After arthroscopic removal of the dorsal meniscus, a miniarthroscopy 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 is inserted using valgus or varus stress. The implant is inspected with respect to anterior/posterior translation as well to internal/external rotation (Fig.1).

**RESULTS:**

From June 2004 to July 2005 8 patients received 6 medial and 2 lateral ConforMIS iPD implants. All subjects had isolated medial or lateral osteoarthritis (Outerbridge Typ IV). The mean size of the arthrotomy was 5.2cm (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 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, and 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. 2). The mean preoperative deviation of the physiological 7°-knee axis was 4.3° (median 4.0, SD 4.6°). The mean postoperative deviation was 0.9° (median 1.5, SD 2.3).

**DISCUSSION:**

Early experience in regard to surgical technique, correction of deformity, post-operative motion and rehabilitation is promising. There was 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 (1). With extension, there is external rotation, and with flexion internal rotation. The surgical technique of the Uni-spacer® 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. Furthermore, the implant is designed to cover the base of the medial or lateral spine, which may contribute to better fixation and less motion. 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 postoperative alignment. The ConforMIS device restores alignment and functions essentially as an osteotomy would.

This custom device may provide a surgical alternative to current surgical solutions, such as unicompartmental or total knee replacement, without any bone resection and may have a role in the treatment of isolated mild medial and lateral knee osteoarthritis.

Reference:

**First Author:**
Koecck, FX*; Linhardt, O; Anders S; Perllick, L; Gritka, J

**Affiliations:**
*Department of Orthopedic Surgery, University of Regensburg, Germany

**Contact:**
franz.koeck@klinik.uni-regensburg.de

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**Figure 1:** Inspection of implant stability in full knee extension and flexion.

**Figure 2:** Correction of varus deformity after insertion of a medial ConforMIS iPD.