

CURRENT STATE OF FOCAL PROSTHETIC RESURFACING OF THE FEMORAL CONDYLES: REVIEW OF BASIC SCIENCE AND CLINICAL RESULTS WITH FOLLOW-UP OF UP TO 6 YEARS

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ABSTRACT

Full thickness cartilage defects of the femoral condyles are frequent, can be highly symptomatic, and pose treatment challenges when encountered in middle-aged patients. Biological procedures are plentiful but are more effective in younger than older patients. Standard arthroplasty should be delayed in patients with isolated defects to foster joint preservation. The purpose of this report is to provide an overview on basic science and clinical evidence of focal prosthetic inlay resurfacing.

Preclinical results from a caprine model, finite element analysis, static and dynamic robotic trans-articular pressure testing, and mid-term clinical assessment are reviewed.

Basic science and clinical outcomes with follow-up of up to six years show significant benefits of focal resurfacing in middle aged patients. Patient selection and correct placement recessed to the surrounding healthy cartilage surfaces are crucial parameters for successful outcomes. The procedure adds a new layer to reconstructive treatment options in the long-term management of arthrosis and arthritis and allows for a sound clinical exit strategy into standard arthroplasty.

Key Words: Cartilage Injury, focal prosthetic resurfacing, condyle, arthrosis, arthritis

Level of Evidence: Review

Introduction

The treatment of isolated focal full thickness cartilage and osteochondral defects of the femoral condyles can be very challenging especially in the middle aged patient. These defects can be highly symptomatic and with their poor capacity to heal, if left untreated can progress to osteoarthritis (1-3). The treatment goal is focused on three main areas:

- Clinical improvements such as pain relief and functional restoration
- Achieving a biomechanically stable and congruent defect repair
- Preserving future options for the management of arthrosis and arthritis

The prevalence of defects in the femoral condyles is quite high with reports of over 60% in routine knee arthroscopies (4). Curl et al. (4) studied 31,516 arthroscopies in a cohort

of patients whose average age was 43 years, and found that approximately 20% of these lesions were Grade IV (chondromalacia) with a majority (53%) located on the medial and lateral femoral condyles.

The preservation of healthy articular surfaces, soft tissues and bone has been challenging when localized full thickness defects or revision needs of previous biological procedures have been encountered in the middle aged population (40 to 60 years old). To address this treatment gap, a focal contoured, prosthetic inlay resurfacing system was introduced several years ago with the goal of providing a localised cartilage defect reconstruction to delay standard arthroplasty.

The purpose of this report is to outline the targeted patient population, identify important parameters for successful outcomes and review the current knowledge surrounding the technology from a basic science and clinical perspective.

Biological precursor solutions have been found to be effective in younger patients, especially with smaller lesions: Bone-marrow stimulating procedures such as microfracture, abrasion arthroplasty, debridement, drilling and chondroplasty have shown positive results in younger patients, but when applied to patients over 30 years, results were inferior (5-7) (Figure 1).

Other biological treatments such as autologous chondrocyte implantation (ACI), mosaicplasty, allogeneous and autogenous osteochondral grafting were better in the younger than in older patients (8-11).

Individual patient assessment is crucial in forming a suitable treatment plan that accounts for a number of factors such as surgical history, length of symptoms, status of articular surfaces, the underlying disease process, mechanical alignment, meniscal and ligamentous status, body mass index, rehabilitation requirements and patient expectations.

Successor treatment solutions following focal prosthetic resurfacing such as unicondylar knee replacement provide a sound clinical exit strategy when larger surface reconstruction is warranted. However, in middle aged patients with isolated condylar defects, significant loss of healthy soft tissues and bone stock should be avoided (Figure 2a,b). Defect size specific, localized prosthetic

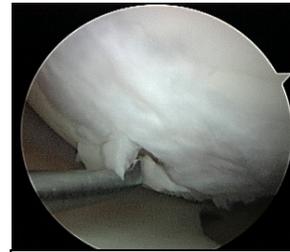


Figure 1: Arthroscopy medial femoral condyle two years post microfracture: Positive fill rate, but soft, fragmented fibrocartilage in a 58 year old, symptomatic patient.

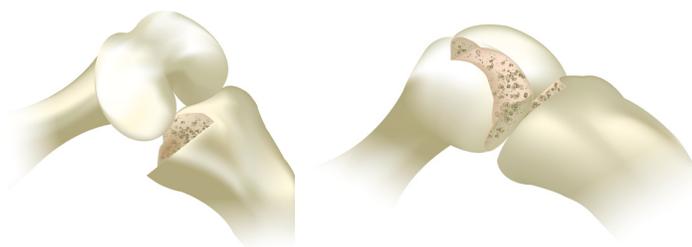


Figure 2a: Example of tibial soft tissue and bone loss in unicondylar knee replacement

Figure 2b: Example of femoral soft tissue and bone loss in unicondylar knee replacement

resurfacing provides a new solution expanding the range of reconstructive treatment options (Figure 3a,b,c) (HemiCAP[®] Focal Prosthetic Resurfacing Implant and Instruments Set, Arthrosurface, Inc., Franklin, MA).

This interim treatment solution for patients between 40 and 60 years old provides a biomechanically stable, congruent defect fill designed to protect the remaining normal cartilage thereby preventing further degeneration. It consists of 2 components, an articular component and a fixation component which are joined by a morse taper interlock. The Cobalt Chrome 15 or 20 mm articular components are each available in a variety of incremental offset convexities corresponding to the surface curvature of the patient's condyle to allow the implant to fit to the patient. The fixation component consists of a bead blasted titanium cancellous screw with full length cannulation. A continuous trabecular and subchondral bone interface is afforded with both screw and resurfacing unit (12) (Figure 4).



Figure 4: Example of 20mm HemiCAP[®] Focal Prosthetic, Inlay Resurfacing Components

Surgical Procedure

A small para-patellar incision is made over the defect location through which the device is implanted on the medial or lateral femoral condyle. With a drill guide and guide pin in place, the surgeon gains perpendicular access to the joint surface and drives a cannulated step drill into the bone until the proximal shoulder of the drill is flush to the articulating surface. The fixation component is placed at the correct height under visual controls and the patient specific joint surface curvature is measured intraoperatively (Figure 5). The implant socket is prepared using precision surface milling. A sizing trial allows for proper assessment of the cartilage – implant interface. The final articular component is aligned on the implant holder and inserted into the taper of the fixation component. Progressive tapping on the impactor engages articular and fixation components. Final placement of the surface prosthetic is targeted slightly recessed (0.5 - 1.0mm) to the surrounding articular cartilage to account for nearby cartilage thickness variations during weight bearing thereby avoiding any overloading or deleterious effects to the opposing side.



Figures 3a,b,c: Example of femoral HemiCAP[®] resurfacing in a 50 year old patient with isolated defect: Focal resurfacing allowed preservation of healthy femoral and tibial bone stock and soft tissues



Figure 5: Intraoperative surface mapping using the HemiCAP[®] instrumentation set

Basic Science Review

Preclinical Caprine Results

Kirker-Head et al. published results from a caprine model that reported on deep fixation and osteointegration, lateral fixation surrounding the articular component, cartilage-implant interface remodelling, and effects on opposing articular surfaces. No signs of loosening were reported surrounding the implant showing solid osteointegration (12). The cartilage-implant was free of cyst formation and demonstrated a cartilage flow over the edge of the implant that provided a contiguous weight bearing surface (Figure 6). No gross tibial plateau or meniscal lesions were apparent.

Radiographic results confirmed implant stability and second look arthroscopy showed a mechanically stable implant with a smooth articular surface showing no wear. There was no evidence of a residual adverse inflammatory reaction to the implant in any animal and no indication of subchondral cyst formation in the medullary tissue surrounding the device.



Figure 6: Caprine Model: Osteointegration of fixation and articular components. Cartilage flow extending over the implant margins

Finite Element Analysis

Von Hasselbach and Witzel presented their findings on Finite Element Analysis of the focal HemiCAP[®] Prosthesis (13). The goal was to assess the potential for pressure erosions on the tibial plateau, cartilage atrophy, and osteopenia occurring proximal to the articular resurfacing component due to a reduction in contact pressure.

Results have shown no apparent stress shielding supporting the minimal risk of implant loosening (Figures 7a-d). A key factor underlying positive findings is the limited tibio-femoral contact during daily dynamic knee function when implanted in the weight-bearing area of the femoral condyle. The amount of fractional condyle surface area taken up by the 20mm HemiCAP[®] is about 14% while the 15 mm HemiCAP[®] is only 10%. The remaining weight bearing condylar surface is maintained by normal, physiological cartilage surfaces.

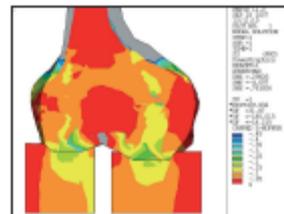


Figure 7a: Normal Knee: Physiological Stress Distribution

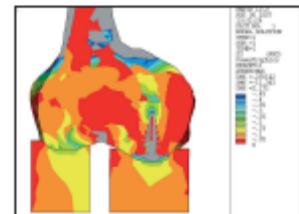


Figure 7b: HemiCAP[®] Implant: Physiological Stress Distribution

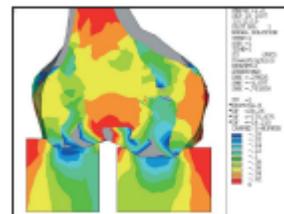


Figure 7c: Normal Knee: Higher Stress Distribution

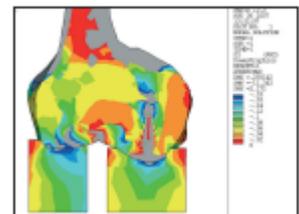
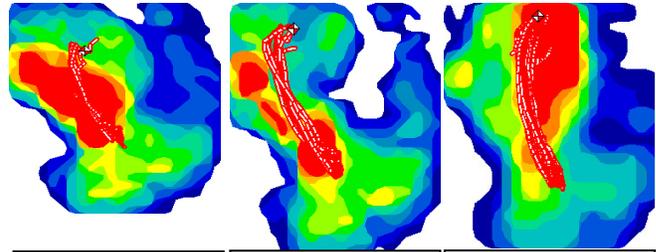


Figure 7d: HemiCAP[®] Implant: Higher Stress Distribution

Tibiofemoral Contact Pressure

In a series of tibiofemoral contact pressure studies using static and dynamic conditions in a closed loop in vivo robotic model, Becher et al. (14) found no significant differences in

peak contact pressure comparing the normal knee and 20mm focal prosthetic resurfacing. The authors stressed the importance of avoiding a proud placement of the implant showing substantial increase in peak contact pressure for elevated (1mm) prosthetic placement (Figures 8a-c).



<p>Figure 8a: Example of Normal, untreated knee: Peak Contact Pressure and Force Trajectory</p>	<p>Figure 8b: Example of contoured HemiCAP[®] resurfacing: Peak Contact Pressure and Force Trajectory</p>	<p>Figure 8c: Example of elevated HemiCAP[®] resurfacing: Peak Contact Pressure and Force Trajectory</p>
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The above results were reconfirmed in follow-up investigations showing a precise match of untreated and resurfaced forces during dynamic testing with 10 and 40 knee bending cycles (15,16). A complete posterior radial tear of the meniscus showed the expected significant increase in peak contact pressures when total loss of meniscal function was introduced. The authors concluded that possible effects of reduced meniscal tissue and the biomechanical integrity of the meniscus must be considered in the in-vivo application.

Review of Clinical Results

Several clinical studies of the HemiCAP[®] Focal Femoral Condyle Resurfacing Prosthesis have been undertaken to date showing encouraging results with follow-up out to 6 years.

Von Hasselbach and Witzel (13) reported on 121 patients with a mean age 52.5 years, who were implanted with the HemiCAP[®] Resurfacing Prosthesis and followed for a mean of 14 months. The follow-up Hospital for Special Surgery (HSS) Score was high (95.3) with an increase of 12% from baseline. Second-look arthroscopies performed for non device related indications showed no deleterious cartilage effects on opposing articular surfaces. Radiographs showed no peri-prosthetic radiolucency or implant subsidence.

36 patients in the prospective US phase II multicenter feasibility trial have completed their two year follow-up. 40 patients were treated with the device. 26 were male, 14 female. The average age was 47 years. 38 patients were treated for isolated full thickness defects of the medial femoral condyle and 2 on lateral side. Two subjects were lost to follow-up, 1 passed away before the two year endpoint, and one subject was converted to unicompartmental knee replacement. The average preoperative WOMAC domains showed significant baseline pain and functional deficiencies which had improved remarkably by three months after the procedure. The average results showed further improvement across all domains from one to two year postoperatively. The mean Total WOMAC score was best at the two year follow-up time point (Figure 9).

Bollars et al. (17) studied 18 patients with an average age of 51 years who had been implanted with the study device and found excellent results at a follow-up of 35.3 months. Eighty-three percent of these middle-aged patients had a normal or nearly normal IKDC score. When compared to normative age matched scores, the study patients showed a close match across all KOOS domains (Figure 10).

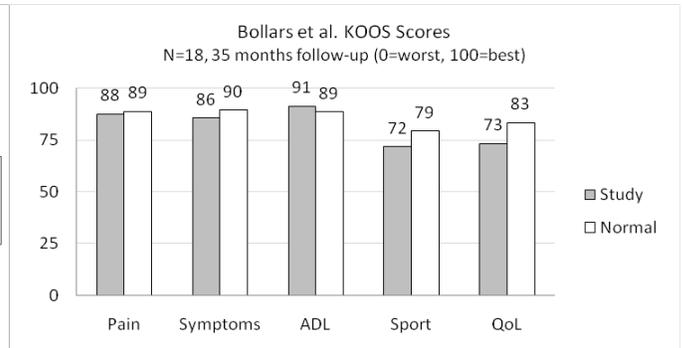
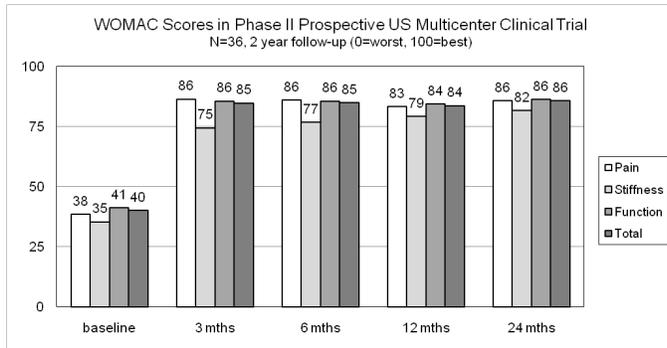


Figure 9: Converted mean WOMAC Scores across all time points. Scale from 0 (worst) -100 (best).
RELATED WOMAC RAW SCORES 0 (best) – 2400 (worst):

Domains	baseline	3 mths	6 mths	12 mths	24 mths
Pain	308	68	70	83	72
Stiffness	129	51	47	42	37
Function	999	246	245	266	233
Total	1436	365	361	391	341

Figure 10: Mean KOOS Scores compared to normative age matched data at 35 months follow-up (0=worst, 100=best)
NORMATIVE KOOS SCORES (FEMALES AGE 35-54):
 Paradowski PT, Bergman S, Sundén-Luminius A et al (2006) Knee complaints vary with age and gender in the adult population: population-based reference based data for the Knee Injury and Osteoarthritis Outcome Score (KOOS). BMC Musculoskelet Disord; 7:38-45.

Becher et al. studied 21 patients with a mean age of 54 years at the time of the initial focal resurfacing and a minimum follow-up of 5 years (range: 5-6 years). The authors demonstrated radiographic joint space preservation and statistically significant improvements across all KOOS Score subdomains, Tegner and SF-36 Scores (18).

To date, examples from second look arthroscopies have confirmed preclinical results. The prosthetic appears well incorporated, the superficial cartilage layer from adjacent healthy margins cover the implant cartilage interface, and opposing tibial surfaces have not shown any apparent response to the contoured prosthetic (Figure 11).

A second look arthroscopy was performed on one patient at eight months post-implantation due to painful HTO hardware. There was no sign of tibial damage and cartilage flow was observed over the edges of the articular component. The 18 month radiographs showed no sign of radiolucency, disassembly, subsidence or cyst formation.

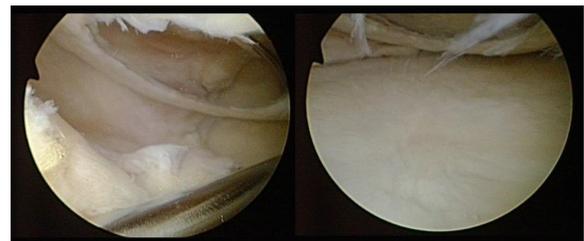


Figure 11 a,b: Example of second look arthroscopy and hardware removal in 58 year old male. 1 year prior: Medial compartment arthritis and isolated grade 4 condylar defect in the weight bearing zone treated with partial meniscectomy, open wedge high tibial osteotomy and 20mm HemiCAP® resurfacing.

Discussion

Articular cartilage defects are common in patients with symptomatic knees requiring arthroscopy (19) and have been found to have quality of life scores equal to an older

patient with severe osteoarthritis awaiting a knee replacement (20). The number of defects appears to be increasing as the middle aged population grows older and expects to stay physically active longer. Joint preservation becomes increasingly critical as end-stage conventional arthroplasty have survivorship limitations and early revision scenarios should be avoided. The natural history of full thickness chondral and osteochondral defects has shown a trend towards defect propagation. Guettler et al. (21) demonstrated rim stress concentrations for osteochondral defects of 10mm or greater and established a 1cm threshold size requiring defect fill to avoid lesion expansion. In a finite element study, Manda et al. (22) showed that tibiofemoral joint contact pressure increased with expanding defect diameters. FE calculations on a double curved metallic implant demonstrated reduced rim stress concentrations when compared to the untreated defect model. Biological treatments are more suited to the younger population (<30 yrs. of age) and result in inferior outcomes in older patients (>30 yrs. of age) (20,23,24,25). Steadman et al. (24) in his long term study found patients less than 35 had much greater improvement than those aged 35 to 45. Mithoefer (25) also found a trend towards better activities of daily living scores in his patients aged less than 30 when compared to older patients after a microfracture procedure. Knutsen et al. (26) performed a five year follow-up study comparing microfracture to autologous chondrocyte implantation (ACI) and found that his patients less than 30 years old had a significantly better outcome than his older patients regardless of their treatment group. The results of the microfracture technique have also been found to deteriorate over time (25,27,2).

Autologous chondrocyte implantation (ACI) was first introduced for clinical practise in Sweden in 1994 by Brittberg et al. (29). The procedure is intended to fill the defect with hyaline cartilage cultured from the patient's own articular cartilage. However, it has proven to be a technically demanding procedure with long rehabilitation requirements and mixed clinical results. Zaslov et al. (30) performed an international multi-center study of ACI for patients at a mean age of 34.5 years who had failed previous treatment of the focal defect. Twenty-four percent of the 154 patients were deemed treatment failures with a subsequent surgical procedure (SSP) rate of 49% (71 patients) during the four year course of the study. Forty percent of the patients underwent a SSP that was classified as directly related to the ACI procedure. Serious adverse events were reported in 54% of the patients. In 2005 Browne et al. (31) published the results of their ACI study of 100 patients with a mean age of 37 years. Twenty-two percent of the 87 patients who completed the 5 year follow-up felt that they were worse than at baseline. Thirty-seven of the patients (43%) had 51 SSPs and 13 patients (15%) considered treatment failures. Other biological procedures have produced similar results (5).

The recent clinical and basic science results of the HemiCAP[®] Resurfacing Prosthesis have shown encouraging results. This procedure is not however a replacement for biological treatment but an extension of focal treatments for patients who have failed previous surgeries for their defect and are too young for a knee replacement. Under the paradigm of long-term joint preservation, focal inlay resurfacing can be therefore regarded as the first metal implant a patient receives to delay arthroplasty and restore joint congruency in knee arthrosis. The clinical durability has to be re-confirmed in larger cohorts to further identify critical performance criteria. Patient selection and implant placement slightly recessed to the surrounding articular surface remain important factors for successful outcomes.

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The HemiCAP® Focal Femoral Condyle Resurfacing Implant is under FDA investigation. Scientific results and current understanding of the technology are intended for educational purposes only. The device is approved in international markets via CE Mark.

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