

A Comparison of the Outcomes for Cartilage Defects of the Knee Treated With Either Biologic Resurfacing Versus Focal Metallic Implants

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Purpose: To compare the results of focal metallic resurfacing with biologic procedures in patients more than 35 years of age with isolated, full thickness defects of the femoral condyle. **Methods:** A total of 61 patients met the selection criteria resulting in 30 patients treated with biological procedures, including debridement, microfracture, osteochondral autograft transplantation, osteochondral allograft, and autologous chondrocyte implantation (BIO group), and 32 patients treated with focal metallic resurfacing (CAP group). The BIO and CAP groups were matched according to treatment location, defect grade and size, and age profile. Outcomes included Western Ontario and McMaster Osteoarthritis Index (WOMAC), Short Form-12, and satisfaction. The primary combination endpoint was determined as a 20% improvement (minimum clinically important difference-20) on WOMAC pain and function at 2 years and no additional index lesion-related surgical intervention. Safety and effectiveness were also reported. **Results:** Thirty patients in the BIO group (mean age of 44.6, range 35-64) had an average follow-up of 2.6 years and 32 patients in the CAP group (mean age 47.9, range 37-68) were followed for 2.0 years. Fifty-three percent in the BIO group and 75% in the CAP group achieved success per the endpoint definition. The mean total WOMAC score improved significantly for both groups (BIO: 57-78; $P < .001$) (CAP: 41-86; $P < .001$). The physical component score (Short Form-12 PCS) improved significantly in the CAP group only (30-36.4; $P < .001$). Good to excellent patient satisfaction was achieved by 80% in BIO and 91% in CAP. There were 4 secondary procedures on the index lesion in the BIO group and 2 in the CAP group. **Conclusions:** Careful patient selection can achieve high satisfaction rates with both biological and focal metal resurfacing procedures for the treatment of isolated focal chondral lesions of the femoral condyle in the knee. Focal metallic resurfacing results in similar clinical outcomes and provides excellent success rates at short-term follow-up. **Level of Evidence:** Level III comparative study.

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Arthritis of the knee joint is a major debilitating musculoskeletal condition in our modern society. Both unicondylar and total knee replacements are the mainstay of patient care for advanced stages of arthritis. Although there are many factors causing arthritic degeneration of the knee, focal articular full thickness and osteochondral defects of the femoral condyle frequently result in severe and persistent pain and functional impairment.¹ Despite the limited defect size, the symptoms suffered by these patients can match those who are scheduled for knee arthroplasty.¹ Focal chondral lesions are of high prevalence in the young adult population.^{2,3} If left untreated, these lesions will most likely progress to osteoarthritis.⁴⁻¹³

Biological treatments for chondral lesions such as debridement, abrasion, microfracture, osteochondral autograft or allograft, and various other cell-based strategies have shown good results in young patients. However with increasing age, results have been less

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Twenty-four-month follow-up • Age 35-60 yr • Grade IV (International Cartilage Repair Society [ICRS]) articular surface defect located on the medial or lateral femoral condyle • Good joint stability in the affected joint, with grade 1 Lachman or less, with no pivot shift for anterior instability and no posterior translation of more than grade 1 • Passive motion deficit measured as a lack of extension less than 10°	• More than one grade IV (ICRS) articular surface defect on the medial or lateral femoral condyle • Varus or valgus joint malalignment greater than 7° from the neutral mechanical axis in the affected limb • Evidence of metabolic disorders that may impair the formation or healing of bone • Evidence of infections at remote sites, which may spread to the implant site • Evidence of rheumatoid arthritis, gross joint destruction, infectious/crystal arthropathies, or bone resorption visible on radiographs • Evidence of chronic instability or deficient soft tissues, vascular, or muscular insufficiency • A history of prior meniscal allograft or a failed osteochondral graft with the presence of cysts or partial joint replacement • Irresolvable joint pain or loss of function with an undeterminable cause • Medial or lateral femoral condyle defect is nonfocal or very large (greater than 20 mm) • Medial or lateral femoral condyle articular surface defect is not located relatively central to the femoral condyle so that the resurfacing implant would extend beyond the lateral or medial aspect of the condyle • Widespread degenerative or inflammatory conditions in the joint that would make pain mitigation as a result of the implant difficult to measure or insignificant • Significant damage (defined as worse than grade II changes) to the articular surface opposing the implant on the tibia • Significant damage (defined as worse than grade II changes) to articular surfaces in other compartments within the affected joint • Severely compromised soft-tissue support structures in the joint. Irregularly shaped or grossly degenerated femoral condyle, where restoration of a smooth continuous articular surface is not possible such as skeletal dysplasia, mal united fracture, osteochondrosis, or nonfocal lesions

encouraging with recurring symptoms and sometimes poor or little pain relief or functional improvement.¹⁴⁻¹⁶

Older patients tend to have larger chondral lesions and early signs of osteoarthritis.⁹ Contained, focal defects with healthy articular perimeters do not lend themselves to traditional arthroplasty procedures because the risk of revision surgery remains highest in patients younger than 50.^{14,17-21} In this population, focal metallic cartilage resurfacing could be a suitable treatment option before considering unicompartmental (UKR) or total knee replacement.

Until the development of focal metallic cartilage resurfacing, the transition from biological procedures to primary arthroplasty has not provided an intermediary step that maintains focal character while offering an unaffected exit into conventional joint replacement. This resurfacing procedure, under investigational device exemption (IDE) investigation in the United States, offers the advantage of contoured surface reconstruction and primary implant stability seen with arthroplasty while preserving healthy tissues through its focal nature.

The objective of this study was to compare the results of focal metallic resurfacing with biologic procedures in patients who are 35 years and older with isolated, full thickness defects of the femoral condyle. Our hypothesis was that focal resurfacing would result in similar clinical outcomes when compared with biologic procedures in a matched group of patients.

Methods

Design

This is a population-matched, comparative cohort study. The study endpoint and patient selection criteria for the CAP group were predetermined by the IDE approved protocol. The BIO group followed the same selection and endpoint criteria.

Eligibility Criteria

Both groups (BIO and CAP) included patients with complete preoperative and final 2-year follow-up data sets who met the inclusion and exclusion criteria for this study (Table 1). The CAP group was based on consecutive 2-year endpoint data in a Phase II IDE investigation. Any patient converted to traditional joint replacement before the 2-year endpoint was not followed after his or her revision procedure and was not included in the analysis. They were however included in the evaluation of failures and revision surgery.

All study activities were approved by governing institutional review boards and all participants signed an informed consent form. Patient level data were anonymized for the purpose of this investigation.

Selection Bias

To offset the drawback of a nonconcurrent multicenter investigation, the study placed emphasis on selection bias through various mechanisms to promote

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