Partial Resurfacing of the Knee with the BioPoly Implant

Interim Report at 2 Years

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Background: Current treatments for focal chondral and osteochondral lesions of the femoral condyle have been associated with variable outcomes. We conducted a clinical trial of the BioPoly RS Partial Resurfacing Knee Implant to address this unmet need.

Methods: We performed a single-arm, prospective study in which 33 patients with focal cartilage lesions affecting the femoral condyle were managed with the BioPoly RS Partial Resurfacing Knee Implant. Knee injury and Osteoarthritis Outcome Score (KOOS) scores, a visual analog scale (VAS) for pain, the Short Form-36 (SF-36) physical component score, and the Tegner activity score were used to assess outcomes preoperatively and at 6 months, 1 year, and 2 years postoperatively. The KOOS outcomes at 2 years were compared with historical outcomes following microfracture treatment.

Results: We found significant and clinically meaningful improvements in the KOOS scores, VAS pain score, and SF-36 physical component score ($p < 0.025$) when the values at all 3 postoperative time points were compared with the preoperative scores, and we also found significant improvements when the Tegner activity score at 2 years was compared with the preoperative score ($p < 0.025$). More than half of the cohort of patients had had a previous failure of cartilage-repair procedures. No significant differences were detected between younger patients ($≤$40 years) and older patients ($>$40 years). When compared with historical microfracture data, the BioPoly RS Implant demonstrated significantly superior KOOS scores for quality of life and sports.

Conclusions: The present study indicated that the BioPoly RS Partial Resurfacing Knee Implant is safe, that it resulted in significantly improved knee function by 6 months, and that this improvement was sustained for 2 years regardless of patient age. The BioPoly RS Knee Implant allows return to a higher level of sporting activity than microfracture. Additional long-term follow-up is needed to determine the long-term effects of the device.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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disabling and can result in a large economic burden due to both direct costs (e.g., hospital stay and insurance expenditure) and indirect costs (e.g., lost productivity and early retirement). While current late-stage treatments for cartilage defects in the knee (i.e., total or partial knee arthroplasty) have provided consistent, positive outcomes for elderly patients, the use in patients <55 years of age has become controversial because of concerns regarding implant longevity. As a result, biological treatments such as microfracture, the osteochondral autograft transfer system (OATS), autologous chondrocyte implantation (ACI), and matrix-induced ACI (MACI) are used in active younger and middle-aged patients. Most of these treatments have not demonstrated sustainable, consistent results, and some require long postoperative rehabilitation. In addition, the magnitude of the positive impact of biological treatments appears to significantly decrease with increasing patient age and when used for revision after the failure of previous biological treatments.

The BioPoly RS Partial Resurfacing Knee Implant was developed as an early intervention and treatment for patients with cartilage lesions who want to delay or eliminate the need for total or partial arthroplasty and quickly return to full activity. BioPoly is a biosynthetic implant that is manufactured from a combination of ultra-high molecular weight polyethylene and a hydrophilic lubricating molecule (hyaluronic acid) that is designed to be less dependent on patient biology and to require less rehabilitation time, with less bone resection in comparison with partial or total arthroplasty.

The objectives of the present study were (1) to assess clinical outcomes and complications after treatment with the BioPoly Knee Implant and (2) to compare clinical outcomes...
after such treatment with those after treatment with microfracture as reported in the historical literature.

Materials and Methods

We designed a multi-center, single-arm, historically controlled clinical investigation for the purposes of (1) comparing clinical outcomes between the BioPoly RS Knee Implant and microfracture (based on historical literature) and (2) comparing the postoperative clinical outcomes with preoperative findings. The primary end points were Knee injury and Osteoarthritis Outcome Score (KOOS)overall score and subscores, a visual analog scale (VAS) score for pain, the Short Form-36 (SF-36) physical component score, and the Tegner activity score at 2 years. While the focus of this interim report is current patient outcomes and the mean 18-month KOOS quality-of-life score of a historical microfracture patient, the study was designed to return patients to full activity quickly was used (see Appendix). The protocol allowed immediate weight-bearing and unrestricted range of motion as tolerated. This protocol differed from the suggested rehabilitation protocols for microfracture or other biological treatments, which often recommend return to full activity 6 to 8 months postoperatively.

Each clinical outcome score at 6 months, 1 year, and 2 years was compared with its preoperative value, and 2-sample, 1-tailed t tests (\(\alpha = 0.025\)) were conducted with use of speciﬁc comparisons with the results for historical microfracture controls, a literature review was conducted with use of the KOOS, VAS pain score, SF-36, and Tegner activity score. In addition, radiographs were taken. At the time of surgery, International Knee Documentation Committee (IKDC) surgical documentation forms were completed. Follow-up visits were conducted at 6 months, 1 year, and 2 years, at which times patient outcomes and radiographs were obtained.

The approved surgical technique for the BioPoly RS Partial Resurfacing Knee Implant was used in order to ensure that each implant was properly prepared and placed (Fig. 1). The implantation site was prepared with use of a simple, bone-sparing technique that establishes the correct implant orientation and depth relative to surrounding anatomy. Once the implantation site was deemed appropriate, the BioPoly implant was press-ﬁt into the site. The BioPoly RS Partial Resurfacing Knee Implant is a microcomposite of ultra-high molecular weight polyethylene and hyaluronic acid that is overmolded onto a grit-blasted titanium-alloy stem. Three sizes (15-mm diameter, 20-mm diameter, and 15 \(\times\) 24-mm racetrack-shaped) were used in the present study (Fig. 1), and the device was intended to articulate with tibial cartilage and the meniscus.

A 4-phase rehabilitation protocol that was designed to return patients to full activity quickly was used (see Appendix). The protocol allowed immediate weight-bearing and unrestricted range of motion as tolerated. This protocol differed from the suggested rehabilitation protocols for microfracture or other biological treatments, which often recommend return to full activity 6 to 8 months postoperatively.

Prior to the preoperative visit, an arthroscopic examination and magnetic resonance imaging (MRI) were conducted for each patient to evaluate and measure the defect. At the preoperative visit, the medical history was recorded and the patient was evaluated with use of the KOOS, VAS pain score, SF-36, and Tegner activity score. In addition, radiographs were taken. At the time of surgery, International Knee Documentation Committee (IKDC) surgical documentation forms were completed. Follow-up visits were conducted at 6 months, 1 year, and 2 years, at which times patient outcomes and radiographs were obtained.

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TABLE III Patient-Reported Outcome Scores at 6 Months, 1 Year, and 2 Years*

|                      | Preop. (N = 33) | 6 Mo (N = 24) | 1 Yr (N = 22) | 2 Yr (N = 12) |
|----------------------|-----------------|---------------|---------------|---------------|
| KOOS overall         | 44.9 ± 18.0†    | 67.9 ± 15.9   | 67.3 ± 18.9   | 77.6 ± 16.6   |
| Pain                 | 51.9 ± 20.4†    | 76.9 ± 14.9   | 75.6 ± 18.5   | 81.2 ± 16.2   |
| Quality of life      | 22.2 ± 18.4†    | 50.8 ± 26.7   | 48.9 ± 26.7   | 68.2 ± 22.5   |
| Sports               | 30.0 ± 27.4†    | 56.9 ± 22.1   | 56.4 ± 29.3   | 69.2 ± 25.8   |
| Activities of daily living | 64.2 ± 24.3†   | 84.9 ± 14.3   | 84.4 ± 16.1   | 89.0 ± 15.7   |
| Symptoms             | 56.2 ± 20.6†    | 70.2 ± 18.0   | 71.3 ± 19.2   | 80.4 ± 12.9   |
| VAS pain             | 4.1 ± 2.5†      | 2.4 ± 2.4     | 2.0 ± 2.0     | 1.4 ± 2.2     |
| SF-36 physical component | 42.3 ± 32.0†   | 69.7 ± 28.2   | 71.0 ± 27.7   | 81.9 ± 30.8   |
| Tegner activity      | 2.5 ± 1.7†      | 3.3 ± 1.4     | 3.1 ± 1.9     | 4.0 ± 1.9     |

*All values are given as the mean and the standard deviation. †P < 0.025 compared with scores at 6 months, 1 year, and 2 years. ‡P < 0.025 compared with score at 2 years.
(p < 0.025) in the VAS pain score and the SF-36 physical component score in comparison with the preoperative scores (Table III). At 2 years after surgery, there was significant improvement (p < 0.025) in the Tegner activity score. At the time of this progress report, 24, 22, and 12 patients had reached the 6-month, 1-year, and 2-year time points, respectively.

In order to evaluate the potential effects of age, the outcomes for younger patients (≤40 years old) were compared with those for older patients (>40 years old). Interestingly, no significant differences were detected between these 2 groups in terms of the overall KOOS (Fig. 3), VAS pain score, or SF-36 physical component score (p > 0.05); however, the sample size was limited at the later time points.

The BioPoly Knee Implant demonstrated noninferiority (p < 0.025) in terms of the KOOS quality-of-life score when compared with microfracture data. The BioPoly RS Partial Resurfacing Knee Implant demonstrated improved clinical outcomes in comparison
with historical outcomes following microfracture treatment as reported in multiple studies. When the 2-year mean KOOS subscores were compared with microfracture data from the literature, the BioPoly implant demonstrated superior clinical outcomes in terms of quality of life and sports and demonstrated similar clinical outcomes in terms of activities of daily living, pain, and symptoms (Fig. 4). Quality of life and sports are recognized as the most discerning KOOS domains for the assessment of treatment impact. This observation was verified by statistical testing, which demonstrated that the BioPoly implant yielded significantly superior (p < 0.025) outcomes in terms of quality of life when compared with all of the microfracture studies and demonstrated significantly superior outcomes (p < 0.025) in terms of sports and activities of daily living when compared with some of the microfracture studies.

Further examination of the KOOS quality-of-life data showed that the preoperative scores for the patients managed with the BioPoly implant were similar to those for the patients in the microfracture studies whereas the 2-year scores associated with the BioPoly implant were significantly superior (p < 0.025) to those in all of the microfracture studies (Fig. 5). The average age of the patients managed with the BioPoly implant in the present study was 7 to 9 years greater than that of the patients in the microfracture studies.

**Radiographic Observations**
Radiographically, it was observed that implants were stable after 6 months, 1 year, and 2 years. Integration with surrounding bone was observed, with no evidence of radiolucency or implant migration (Fig. 6).

**Discussion**
We observed that the BioPoly RS Partial Resurfacing Knee Implant is safe, that it resulted in significantly improved patient outcomes by 6 months, and that this improvement was sustained for 2 years, regardless of patient age (range, 22 to 65 years). Significant improvement was seen at 6 months for the overall KOOS (and all individual subscores), the VAS pain score, and the SF-36 physical component score. This improvement was maintained through 2 years, and the Tegner activity score demonstrated significant improvement at 2 years. Over half of the patients had had a failure of previous cartilage-repair procedures, and no significant differences in outcome scores were observed between younger and older patients. Radiographic evaluation demonstrated adequate device fixation and integration with surrounding bone. There were no serious, device-related adverse events. There was 1 revision, which occurred after the 2-year follow-up. The BioPoly Knee Implant demonstrated significantly
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superior KOOS quality-of-life scores at 2 years when compared with the historical outcomes of microfracture treatment as reported in the literature. The patients who were managed with the BioPoly implant were an average of 7 to 9 years older than those who were managed with microfracture.

Total knee arthroplasty has been extensively studied and has been shown to be consistently effective in older patients, with 20-year survival rates of as high as 97.8%. Patients ≤ 55 years old, however, present a challenge because they often desire to return to strenuous physical activity postoperatively, which is not recommended as part of the rehabilitation process and could increase implant wear and decrease implant longevity. Studies have shown decreased short and long-term implant-survival rates for younger patients, and 1 study demonstrated a 10-year revision rate of 16% in association with wear and/or osteolysis in younger patients. In a series of total knee arthroplasty patients < 50 years of age, a 2-year revision rate of 9% was reported.

Biological treatments, meanwhile, have been examined for use in active younger and middle-aged patients, but these treatments have not demonstrated sustainable, consistent results and require long postoperative rehabilitation. Microfracture is currently the most common biological treatment for the repair of early-stage focal defects, but tissue quality and outcomes consistently have been shown to deteriorate over time (typically beginning at 18 to 36 months) along with increases in the failure rate. ACI, MACI, and OATS also have been examined; however, studies have shown more positive outcomes for younger patients compared with middle-aged patients. The outcomes of those biological procedures are similar to those of microfracture. Those treatments also have been shown to be prone to failure in patients who have already had previous microfracture surgery, but that finding has not been reported in all studies.

The hydrophilic, low-wear properties of the BioPoly implant material have been shown in long-term, large-animal studies. This hydrophilic capability is illustrated by comparing the appearance of a water droplet on ultra-high molecular weight polyethylene with that on the BioPoly surface (Fig. 7).

It is notable that the BioPoly RS Knee Implant did not demonstrate outcome differences between younger and older patients. Mithoefer et al. examined 48 patients who were managed with microfracture and reported that a number of outcomes showed significant improvements after the microfracture treatment. It was noted, however, that there was a trend toward better outcomes in patients who were ≤ 50 years of age. It is also interesting to note that while the BioPoly implant demonstrated similar KOOS outcomes in terms of pain, activities of daily living, and symptoms when compared with microfracture studies, it demonstrated superior outcomes in terms of KOOS quality-of-life and sports scores. A possible explanation for this effect is that patients who are managed with microfracture are forced to accept a less-active lifestyle in order to mitigate knee pain and symptoms, whereas those who are managed with the BioPoly implant are able to regain their previous active lifestyle, as evidenced by increasing Tegner scores (Table III). Another possible factor could be the rehabilitation protocol for the BioPoly implant, which allows patients to immediately bear weight and return to activity more quickly than does a standard microfracture rehabilitation protocol.

Of the recent microfracture studies that were analyzed in the present study, the 2008 study by Saris et al. had the most similar patient population to our cohort, except that the average age in that study was 8 years lower than that in the present study. In that study, 61 patients with an average age of 33.9 years were managed with microfracture (average lesion size, 2.4 cm^2). The authors found no significant differences between the outcomes of cultured chondrocyte implantation and those of microfracture. The average KOOS quality-of-life score in the present study was significantly superior to that for the microfracture arm in the study by Saris et al. (68.2 compared with 52.54; p = 0.022).

The limitations of the present study include the lack of long-term clinical outcomes, the use of patient-reported outcome measures, and a comparatively small sample size. The lack of long-term outcomes can primarily be attributed to the recent release of the device.

While there is a need for longer-term clinical studies of the BioPoly RS Partial Resurfacing Knee Implant, the present short-term study demonstrated significant improvement in patient-reported outcomes and an exceptional safety profile for the device out to 2 years.

**Appendix**

A table showing the 4-phase rehabilitation protocol is available with the online version of this article at jbjs.org.

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