JB&JS OPEN ACCESS

The BioPoly Partial Resurfacing Knee Implant Provides Beneficial Clinical Outcomes

A Concise Follow-up, at 5 Years, of a Previous Report*

Dinesh Nathwani, MBChB, MSc, FRCS(Tr&Orth),
Michael McNicholas, BSc, MBChB, FRCS(Ed&Glasg), MD, FRCSEd(Tr&Orth), FFSEM, RCSI,
Alister Hart, MA, MD, FRCS(Orth), Jonathan Miles, MBChB, FRCS(Orth), and Vladimir Bobić, MD, FRCSEd

Abstract

We previously conducted a single-arm, prospective study in which 31 patients (mean age [and standard deviation], 42.5 ± 11.3 years) with cartilage lesions were treated with use of the BioPoly Partial Resurfacing Knee Implant. Treatment outcomes were compared with those reported for the standard of care, microfracture. We found that the mean KOOS (Knee injury and Osteoarthritis Outcome Score) Quality of Life score at 5 years in the BioPoly cohort was noninferior to ($p = 0.004$), and indeed greater than ($p = 0.021$), that in the microfracture cohort. The BioPoly cohort demonstrated improvement in the mean scores for all KOOS domains at every postoperative time point ($p < 0.025$). The mean score for the visual analog scale (VAS) for pain significantly improved ($p < 0.025$) at all time points up to 4 years and trended toward significant improvement at 5 years ($p = 0.027$). This study indicated that the BioPoly implant was safe, provided significant improvement starting at 6 months and continuing to 5 years, and provided greater improvement than microfracture for some outcome measures.

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

Background

We previously reported the 2-year results for a novel treatment of focal cartilage defects, the BioPoly Partial Resurfacing Knee Implant (BioPoly)[1]. The BioPoly implant was designed for use in patients with focal cartilage defects who are considered too young, healthy, and active for joint replacement but who may not be in the ideal category for biological treatment (e.g., because they are >40 years old, have large lesions [>2 cm^2], or have a history of a previously failed cartilage repair treatment)[2-10]. This implant is made from a hydrophilic biosynthetic material manufactured from hyaluronic acid (a hydrophilic, lubricating molecule found in cartilage) and ultra-high molecular weight polyethylene, which allows for direct articulation with cartilage. The use of such a material in the implant was intended to provide outcomes that are less dependent on patient factors, to return patients to activity faster than biological treatment[11], and to require less bone resection than that required for partial or total arthroplasty (Fig. 1).

Our study was a multicenter, single-arm, literature-controlled, clinical investigation with 2 purposes: (1) to compare clinical outcomes between patients who received the BioPoly implant and those who underwent microfracture (as reported in the literature), and (2) to compare the postoperative and preoperative clinical outcomes of the BioPoly cohort. Our main hypothesis was that the mean Knee injury and Osteoarthritis Outcome Score (KOOS) Quality of Life (QoL) score in the BioPoly implant cohort would be noninferior ($\alpha = 0.025$) to that in a historical microfracture cohort at 5 years postoperatively. Our second hypothesis was that patients treated with the BioPoly implant would show significant improvement ($\alpha = 0.025$) in the mean scores for the KOOS Overall and KOOS subscales[12], the visual analog scale (VAS) for pain[13], the Short Form-36 (SF-36) physical component[14], and the Tegner activity scale[15] at 5 years postoperatively, compared with the baseline values for these measures.

Methods

Five centers in the United Kingdom were selected as study sites and Good Clinical Practice Guidelines were followed. Of the identified sources of microfracture data[8,16-18], 1 study later

Original Publication: Nathwani D, McNicholas M, Hart A, Miles J, Bobić V. Partial Resurfacing of the Knee with the BioPoly Implant: Interim Report at 2 Years. JB JS Open Access. 2017 Apr 6;2(2):e0011.

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A564).

JBJS Open Access • 2023:e23.00008. **openaccess.jbjs.org** 2

Fig. 1

Different sizes of the BioPoly Partial Resurfacing Knee Implant (clockwise: 15-mm circle, 20-mm circle, 15 × 24-mm oval). Reproduced with permission from BioPoly, LLC.

reported outcomes at 5 years postoperatively[19] and was utilized as the main comparator for the analysis of the 5-year BioPoly outcomes. The study inclusion and exclusion criteria, examination methods, and implantation methods have been previously described[1].

The BioPoly postoperative rehabilitation protocol allowed full weight-bearing and unrestricted range of motion as tolerated, whereas the suggested rehabilitation protocol for microfracture recommended full return to activity after 6 to 8 months[11]. All patients provided informed consent, and the study protocol was approved by the Cambridge Central Research Ethics Committee (REC11/EE/0256). We performed follow-up at 6 months and at 1, 2, 3, 4, and 5 years, during which patient outcomes were collected and radiographs were made. Any missing data were queried and resolved.

Patient Population

As shown in Figure 2, a total of 40 patients were enrolled in the study. Four patients were withdrawn from the study during the screening stage or voluntarily prior to surgery. Three more patients were withdrawn at the time of surgery prior to implantation, resulting in a total number of 33 patients receiving a BioPoly implant. Of these patients, 2 were withdrawn according to the exclusion criteria (1 because of a kissing lesion on the tibia and the other because of a defect larger than the implant). The third patient had a small lesion that the surgeon opted to treat with microfracture instead of the BioPoly implant. Two patients were later excluded from the study because of protocol violations. Overall, 31 patients were included in the 5-year data analysis. Over the course of the study, 8 patients were lost to follow-up; therefore, the complete 5-year outcomes included data collected from 23 patients. Of those lost to follow-up, 2 were later located and reported implants that were still surviving after the 5-year time point, allowing survivorship data to be collected for 25 patients.

Statistical Analysis

With the level of significance set at $p < 0.025$ and the power set at 0.90, we determined that 25 patients were required for study enrollment (allowing 15% of patients to be lost to follow-up). This size was chosen to demonstrate the noninferiority of the mean KOOS QoL score at 24 months in the BioPoly group compared with the mean score at 18 months in a historical microfracture control group with an anticipated similar patient population[16].

For the first objective of this study, a 2-sample, 1-tailed t test ($\alpha = 0.025$) was utilized to compare the change in the mean KOOS QoL score from baseline to the 5-year follow-up between the BioPoly and microfracture cohorts. For the second objective, the mean score at each time point and the preoperative mean value were compared for each clinical outcome. We performed an additional subgroup analysis of all clinical outcomes to

JBJS Open Access • 2023:e23.00008. openaccess.jbjs.org 3

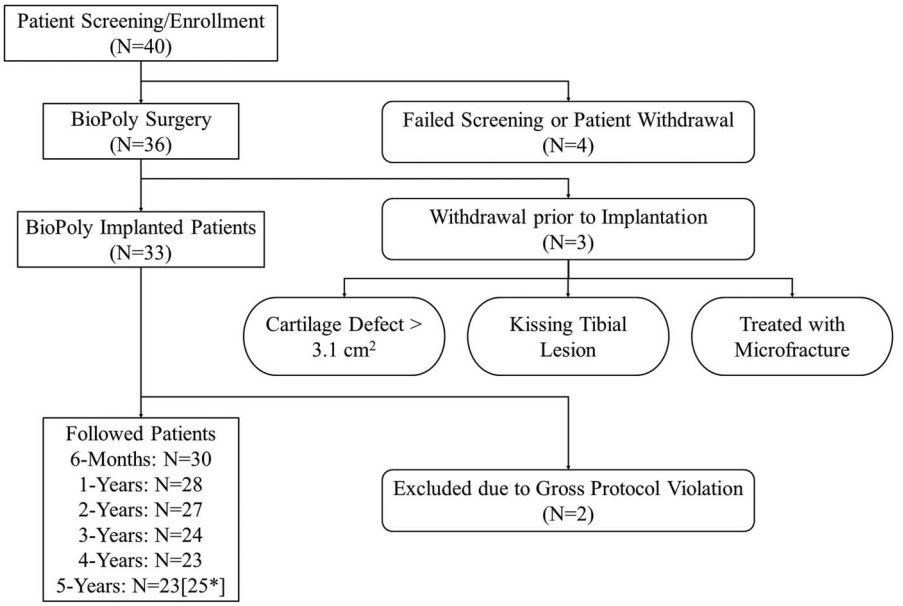

Fig. 2

Patient enrollment and follow-up. *Surviving implants were reported by 2 patients who had previously been lost to follow-up, but full outcomes were not available.

identify differences in the improvement from baseline (α = 0.025) for groups for whom biological repair was identified as a worst-case solution: patients who were older (>40 years old), who presented with large lesions (>2 cm^2), or who had previously undergone a cartilage repair treatment that failed.

Source of Funding

The study was funded by BioPoly LLC. No compensation was received for participation in the study other than reimbursement for study-related travel from long distances.

Results

Patient Baseline Characteristics

The mean age (and standard deviation [SD]) of patients in the BioPoly cohort was 43 ± 11 years; 11 patients were ≤40 years old and 20 patients were >40 years old. Approximately 31% of all defects were treated with 15-mm implants; 31%, with 20-mm implants; and 38%, with 15×24-mm implants. The mean (and SD) defect size was 2.1 ± 0.8 cm^2. More than half (58%) of the patients had previously undergone a cartilage repair surgery that had failed, but none underwent corrective procedures at the same time as the BioPoly procedure. Complete patient demographic characteristics are summarized in Table I.

Clinical Outcomes

Patients returned to full activity within 8 to 11 weeks after receiving the BioPoly implant, as detailed previously[1]. The mean scores for knee function (KOOS and SF-36), pain (KOOS and SF-36), return to activity (KOOS), and quality of life (KOOS) were significantly improved ($p < 0.025$) from baseline at every time point through 5 years postoperatively. A large Cohen effect size (Cohen d ≥ 0.8) was also observed in the mean scores for the KOOS Overall and for all KOOS subscales, for the Tegner activity scale, and for the SF-36 Physical Functioning outcome, with all other significantly improved measures having a medium effect size (Cohen d ≥ 0.5). The mean score for the Tegner activity scale was significantly improved

TABLE I Study Population Characteristics

Total no. of patients	31
Age* *(yr)*	42.5 ± 11.3
Age ≤40 years *(no. of patients)*	11 (35.5%)
Previous knee surgery *(no. of patients)*	26 (83.9%)
Cartilage repair†† *(no. of patients)*	18 (58.1%)
Other†§ *(no. of patients)*	8 (25.8%)
Contralateral knee status normal/nearly normal† *(no. of patients)*	24 (85.2%)
Body mass index* *(kg/m²)*	26.5 ± 3.8
Defect size*# *(cm²)*	2.1 ± 0.8
Involved knee† *(right/left)*	43.8%/56.3%
Involved compartment† *(medial/lateral)*	77.4%/22.6%
Type of injury† *(no. of patients)*	
Nontraumatic, gradual	12 (40.0%)
Nontraumatic, sudden onset	2 (6.7%)
Traumatic, noncontact	9 (30.0%)
Traumatic, contact	7 (23.3%)
Activity at injury† (*sporting/non-sporting*)	67.7%/32.3%

*Values are given as the mean and standard deviation. †Including microfracture, ACI, matrix-assisted ACI, and OATS. ‡Percentages are based on the number of patients for whom data were available, not the total number of patients. §Including meniscal, ligamentous, patellofemoral, or cartilage shaving surgery. #Defect size after debridement and before implant preparation.

JBJS Open Access • 2023:e23.00008.

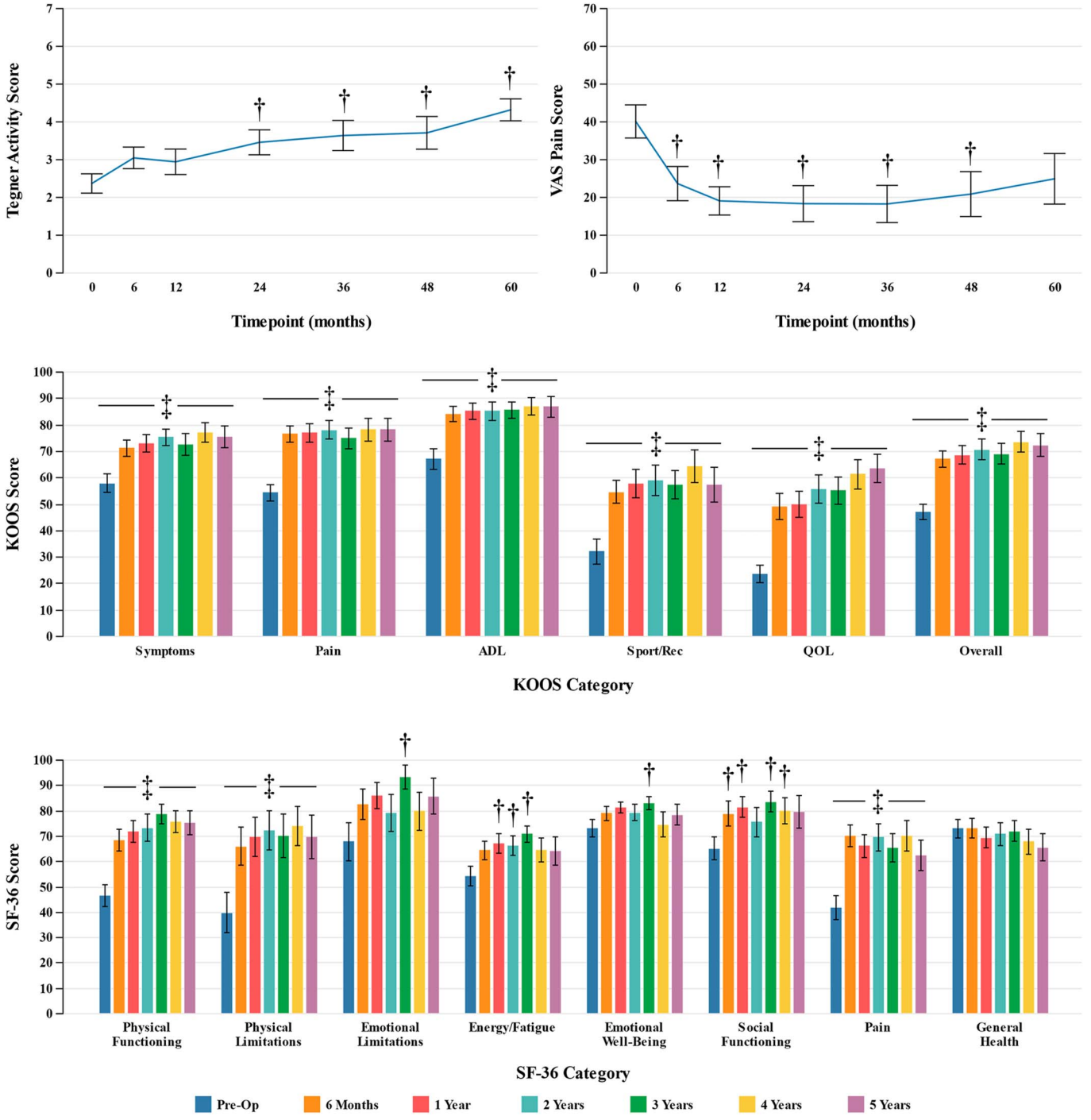

Fig. 3

BioPoly cohort clinical outcome scores over time. Data are presented as the mean, with error bars indicating the standard error (SE). ADL = Activities of Daily Living, Sport/Rec = Sports/Recreation, and QoL = Quality of Life. †The outcome was significantly higher than baseline ($p < 0.025$) at this time point. ‡The outcome was significantly higher than baseline at every time point ($p < 0.025$).

from baseline at the 2-year time point ($p = 0.005$; Cohen $d = 0.71$) and remained so at the 5-year time point ($p < 0.0001$; Cohen $d = 1.40$). The mean VAS pain score was improved, with a medium (Cohen $d \geq 0.5$) to large (Cohen $d \geq 0.8$) effect size, at every time point; the improvement was significant ($p < 0.025$) at every time point except at 5 years ($p = 0.027$). The mean scores for all clinical outcomes are reported in Figure 3 and Table II.

When compared with the 5-year microfracture data, the BioPoly implant demonstrated noninferiority in the mean KOOS QoL score ($p = 0.004$), which was the primary outcome

JBJS Open Access • 2023:e23.00008.

TABLE II Comparison of Preoperative and 5-Year Patient-Reported Outcome Scores

Outcome	Preop. (N = 31)*	5 Years (N = 23)*	Difference	95% CI of Difference	Cohen D	P Value
KOOS Symptoms	57.7 ± 3.5	75.3 ± 4.3	17.6	6.6-28.6	0.88	0.0014
KOOS Pain	54.1 ± 3.3	78.1 ± 4.3	24.0	13.3-34.7	1.24	<0.0001
KOOS Activities of Daily Living	66.9 ± 4.0	86.6 ± 3.9	19.7	8.3-31.1	0.95	0.0007
KOOS Sports/Recreation	31.9 ± 4.8	57.4 ± 6.6	25.5	9.5-41.4	0.88	0.0014
KOOS QoL	23.4 ± 3.2	63.3 ± 5.5	39.9	27.9-52.0	1.83	<0.0001
KOOS Overall	46.8 ± 3.0	72.2 ± 4.5	25.4	15.0-35.7	1.36	<0.0001
VAS pain	40.0 ± 4.3	24.8 ± 6.6	15.2	0.0-30.3	0.55	0.0269
Tegner activity	2.4 ± 0.3	4.3 ± 0.3	1.9	1.2-2.7	1.40	<0.0001
SF-36 Physical Functioning	46.5 ± 4.4	75.2 ± 4.8	28.7	15.6-42.0	1.21	<0.0001
SF-36 Physical Limitations	39.5 ± 8.0	69.6 ± 8.4	30.1	6.5-53.6	0.70	0.0076
SF-36 Pain	41.5 ± 4.6	62.3 ± 6.2	20.8	5.6-35.9	0.76	0.0047

*Values are given as the mean and standard error.

(Fig. 4), as well as in the mean KOOS Activities of Daily Living score ($p = 0.007$). For all KOOS subscales except Sports/Recreation and Activities of Daily Living, the baseline values in the BioPoly cohort were significantly lower ($p < 0.025$) than those in the microfracture cohort. Because the preoperative values were significantly different between the cohorts, the mean per-patient change in score from baseline was evaluated (Fig. 5). At 5 years postoperatively, this change in score was significantly

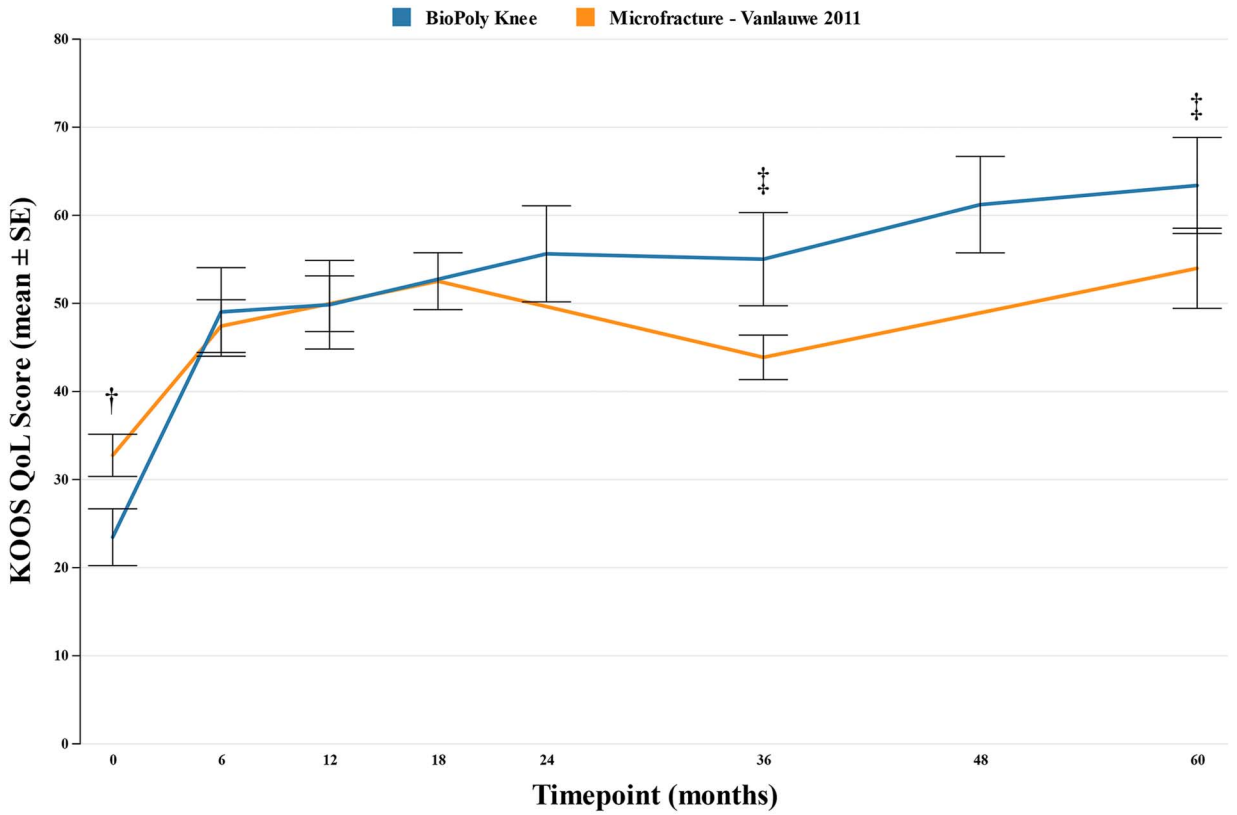

Fig. 4

KOOS QoL scores for the BioPoly cohort and the microfracture cohort over time. The error bars indicate the standard error (SE). †The baseline KOOS QoL score for the BioPoly cohort was significantly lower than that for the microfracture cohort ($p < 0.025$). ‡The mean per-patient change in the KOOS QoL score from baseline for the BioPoly cohort was significantly higher than that for the microfracture cohort ($p < 0.025$).

JBJS Open Access • 2023:e23.00008. **openaccess.jbjs.org** 6

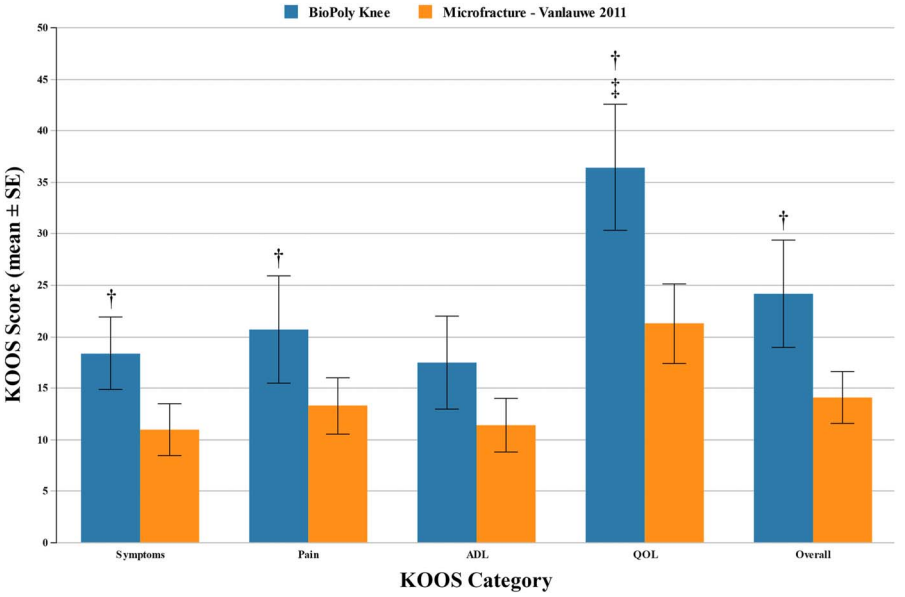

Fig. 5

Mean per-patient change in KOOS subscale scores from baseline to the 5-year follow-up. The error bars indicate the standard error. The baseline KOOS Sports/Recreation score was not provided in the microfracture study. ADL = Activities of Daily Living. †The baseline value for the BioPoly cohort was significantly lower than that for the microfracture cohort ($p < 0.025$). ‡The change in the KOOS score from baseline for the BioPoly cohort was significantly higher than that for the microfracture cohort ($p < 0.025$).

greater in the BioPoly cohort than in the microfracture cohort (mean difference, 15.18 points; $p = 0.021$).

The cumulative survival rate was 100% at 2 years and 89% at 5 years. These rates are more favorable than those reported for microfracture (96% at 18 months; 82% at 5 years). If considering patients who were lost to follow-up, with no survivorship data, as having experienced implant failure—the worst-case scenario and a more conservative approach than that utilized in the microfracture study—the survival rate at 5 years would have been 81% (Fig. 6).

As shown in the exploratory analysis (Table III), patients >40 years old, patients with lesion sizes of >2 cm^2, and patients with a previously failed cartilage repair surgery demonstrated significant improvement ($p < 0.025$) from baseline in most outcomes, whereas the inverse groups largely did not ($p \geq 0.025$).

Radiographic Observations

As observed on radiographs, the implants were stable at 6 months and remained stable as of the 5-year follow-up. Integration with the surrounding bone was observed, with no

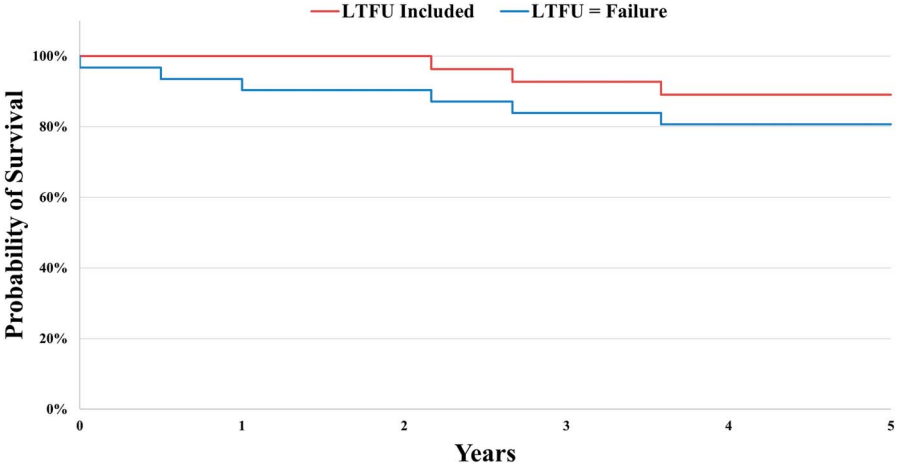

Fig. 6

Kaplan-Meier survival estimate for the BioPoly implant from the start of the study to follow-up at 5 years. The lines show both the standard Kaplan-Meier survivorship estimate and the worst-case scenario estimate that assumes that all patients lost to follow-up (LTFU) experienced implant failures if no survivorship data were available for them.

JBJS Open Access • 2023:e23.00008. **openaccess.jbjs.org** 7

TABLE III Exploratory Analysis of 5-Year Outcomes by Patient Subgroup*

Outcome	Age ≤40 Yr (N = 8)			Age >40 Yr (N = 15)		
	Mean Change†	P Value	Cohen D	Mean Change†	P Value	Cohen D
KOOS Symptoms	10.7 ± 26.9	0.2067	0.42	22.4 ± 23.0	**0.0011**	**1.23**
KOOS Pain	10.4 ± 29.4	0.1874	0.46	26.1 ± 22.1	**0.0001**	**1.51**
KOOS Activities of Daily Living	6.4 ± 19.8	0.2332	0.37	23.3 ± 21.4	**0.0014**	**1.20**
KOOS Sports/Recreation	19.4 ± 48.7	0.1153	0.63	32.3 ± 37.0	**0.0022**	**1.13**
KOOS QoL	29.7 ± 30.6	**0.0160**	**1.19**	40.0 ± 30.1‡	**<0.0001**	**2.07**
KOOS Overall	15.3 ± 27.2	0.0817	0.74	28.8 ± 24.4	**0.0001**	**1.62**
VAS pain	−22.2 ± 30.9	0.0907	0.70	−15.9 ± 32.5	0.0457	0.64
Tegner activity	1.4 ± 1.1	0.0415	**0.93**	2.3 ± 2.0	**0.0001**	**1.57**
SF-36 Physical Functioning	21.3 ± 25.0	0.0442	**0.92**	30.3 ± 30.7	**0.0004**	**1.37**
SF-36 Physical Limitations	21.9 ± 54.2	0.1750	0.48	36.7 ± 49.0	**0.0138**	**0.85**
SF-36 Pain	17.2 ± 38.8	0.1476	0.54	21.2 ± 29.0	**0.0125**	**0.88**
	Lesion ≤2 cm^2 (N = 14)§			Lesion >2 cm^2 (N = 9)§		
Outcome	Mean Change†	P Value	Cohen D	Mean Change†	P Value	Cohen D
KOOS Symptoms	6.6 ± 21.8	0.2312	0.28	21.8 ± 16.2#	**<0.0001**	**3.03**
KOOS Pain	9.9 ± 24.5	0.1215	0.45	37.3 ± 16.7‡	**<0.0001**	**3.54**
KOOS Activities of Daily Living	7.9 ± 18.7	0.1646	0.38	32.4 ± 18.8	**0.0003**	**2.54**
KOOS Sports/Recreation	17.5 ± 43.4	0.0776	0.55	43.9 ± 32.3	**0.0005**	**1.88**
KOOS QoL	27.2 ± 29.5	**0.0046**	**1.06**	50.7 ± 26.2‡	**<0.0001**	**3.30**
KOOS Overall	13.8 ± 24.3	0.0480	0.65	40.2 ± 19.2	**<0.0001**	**3.48**
VAS pain	−11.8 ± 35.7	0.1654	0.37	−21.1 ± 35.1	0.0319	**0.94**
Tegner activity	1.6 ± 1.7	**0.0036**	**1.10**	2.4 ± 1.9	**0.0005**	**1.89**
SF-36 Physical Functioning	17.1 ± 24.9	0.0349	0.71	42.7 ± 28.2	**<0.0001**	**2.48**
SF-36 Physical Limitations	16.1 ± 45.6	0.1808	0.35	55.6 ± 49.7	**0.0036**	**1.45**
SF-36 Pain	15.4 ± 34.2	0.0904	0.52	26.7 ± 28.4	**0.0153**	**1.12**
	No Previous Cartilage Repair (N = 10)			Previous Cartilage Repair (N = 13)		
Outcome	Mean Change†	P Value	Cohen D	Mean Change†	P Value	Cohen D
KOOS Symptoms	14.3 ± 19.4	0.0559	0.75	21.4 ± 28.2	**0.0124**	**0.94**
KOOS Pain	14.2 ± 25.6	0.0707	0.69	25.6 ± 25.1	**0.0011**	**1.35**
KOOS Activities of Daily Living	13.8 ± 22.7	0.0876	0.63	20.2 ± 21.9	**0.0020**	**1.25**
KOOS Sports/Recreation	17.5 ± 38.0	0.0924	0.62	35.8 ± 42.5	**0.0026**	**1.21**
KOOS QoL	25.0 ± 27.5	**0.0065**	**1.23**	45.2 ± 29.9#	**<0.0001**	**1.89**
KOOS Overall	17.0 ± 24.3	0.0373	**0.85**	29.7 ± 26.2	**0.0002**	**1.62**
VAS pain	−2.6 ± 34.7	0.4233	0.09	−30.0 ± 23.5	**0.0027**	**1.20**
Tegner activity	2.0 ± 1.8	**0.0036**	**1.36**	1.9 ± 1.8	**0.0014**	**1.30**
SF-36 Physical Functioning	25.5 ± 36.0	**0.0165**	**1.03**	28.5 ± 22.9	**0.0009**	**1.38**
SF-36 Physical Limitations	27.5 ± 54.6	0.0946	0.61	34.6 ± 48.5	0.0271	0.79
SF-36 Pain	14.0 ± 31.6	0.1214	0.54	24.2 ± 32.7	**0.0193**	**0.86**

*Bold indicates significance ($p < 0.025$) or a large effect size (Cohen $d \geq 0.8$). †Values are given as the mean and standard deviation. ‡Ending at a significantly higher ($p < 0.025$) end point value than in the compared group. §Defect size after debridement and before implant preparation. #Starting from a significantly worse ($p < 0.025$) baseline value than in the compared group.

JBJS Open Access • 2023:e23.00008.

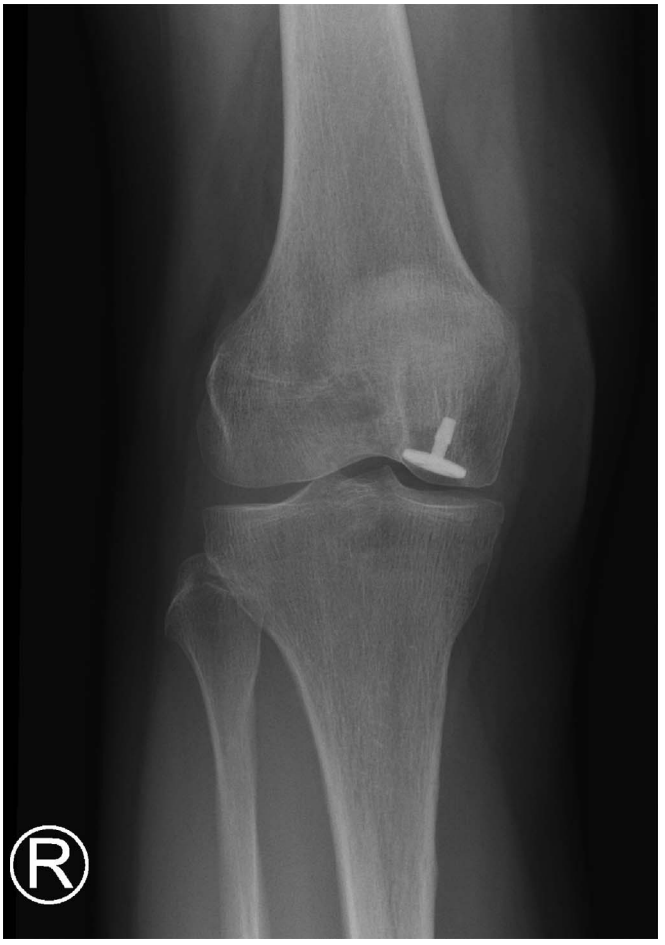

Fig. 7

Radiograph showing a 15-mm BioPoly implant in the medial femoral condyle at 1 year postoperatively.

evidence of radiolucency or implant migration in patients for whom use of this implant was indicated (Fig. 7).

Implant Safety

Among patients in the BioPoly cohort, those with defects that were within the indicated weight-bearing region of the condyle had no procedure-related adverse events (AEs). Those with defects outside of the indicated region had 3 AEs that were recorded as possibly procedure related. Of these, 1 resulted from a mismatch in the radius of curvature between the implant and the anatomy of the femoral condyle due to the posterior location of the defect, 1 resulted from ongoing knee pain in a different compartment from the implant, and 1 resulted from knee pain due to the defect being larger than the implant. The majority of the reported AEs (71%; 34 of 48) were of mild or moderate severity. The most common AE was knee pain (arthralgia). Additional AEs included posttraumatic pain, crepitation, stiffness, swelling, falling, wound infection, and loose cartilage body. No revisions occurred before the 2-year time point. By the 5-year time point, 3 revisions had occurred for the following reasons: 2 patients had had contraindications for the index procedure (inadequate subchondral bone and a defect larger than the implant), and 1 patient had received an implant that was placed posteriorly where the implant and anatomy curvatures no longer matched. These implant safety results provide a clear and positive safety profile.

Conclusions

As discussed in our 2-year report[1], research has shown that total knee arthroplasty is consistently effective for older patients[20] but does not provide optimal results for younger patients[21-24]. Biological treatments such as microfracture are better for younger patients but have less consistent outcomes[2-4]. Newer, more advanced treatments such as autologous chondrocyte implantation (ACI), matrix-assisted ACI, and osteochondral autograft transfer system (OATS) provide improved outcomes compared with microfracture but provide worse results for older patients who are still too young for total knee arthroplasty[6-9], worse results for patients with a previously failed cartilage repair treatment[11], or results that are equivalent to those of microfracture[7,25].

In the present study, 65% of patients who received the BioPoly implant (20 of 31) experienced an AE, whereas in the study by Vanlauwe et al., a total of 84% of patients who underwent microfracture experienced an AE[19]. In terms of the prevalence of procedure-related AEs, we reported a rate of 9.7% (3 of 31 patients), whereas Vanlauwe et al. reported a rate of 62%. Only 25% of AEs (12 of 48) in the BioPoly cohort versus 69% of the AEs in the microfracture cohort were reported after the 3-year time point, indicating that patients who received the BioPoly implant had fewer medium-term issues than those who underwent microfracture. Lastly, a serious AE rate of 40% was found in the microfracture cohort; in comparison, we found a much lower rate of 19% (6 of 31 patients) in the BioPoly cohort, with none of the AEs being implant related.

The 5-year randomized study by Vanlauwe et al. (with 2- and 3-year results reported by Saris et al.[16,26]) was selected as the main comparator for our study because it is recent, high quality, and investigated a similar patient population. One exception is that the microfracture cohort was significantly younger than the BioPoly cohort (difference in mean age, 8.6 years [95% confidence interval (CI), 4.4 to 12.8 years]; $p = 0.0003$) (Table IV). Another difference between the cohorts was that the BioPoly cohort had a significantly lower preoperative mean score for KOOS Overall (difference, 9; $p = 0.0074$; 95% CI, 2.2 to 15.8) and for KOOS QoL (difference, 9.3; $p = 0.0120$; 95% CI, 1.22 to 17.4). The finding of noninferiority in the mean KOOS QoL score between each cohort implies that the BioPoly implant is not as dependent on patient factors for the provision of good outcomes. Another factor likely contributing to this improved treatment of focal cartilage defects was the faster rehabilitation schedule for patients who received the BioPoly implant, which allowed for much earlier weight-bearing and return to activity than the microfracture protocol.

In our exploratory analysis, several subgroups that would have been at increased risk for biological treatment failure

JBJS Open Access • 2023:e23.00008. **openaccess.jbjs.org** 9

TABLE IV Demographic Comparison with the Referenced Microfracture Study*

Study	No. of Patients	Age *(yr)*	Preoperative Score		Defect Size† *(cm^2)*
			KOOS Overall†	KOOS QoL	
Present study	31	42.5 ± 11.3§	50.5 ± 16.8§	23.39 ± 18.0§	2.1 ± 0.8
Vanlauwe et al.[19] (2011)	61	33.9 ± 8.6	59.5 ± 15.0	32.7 ± 18.7	2.4 ± 1.2

*Values are given as the mean and standard deviation except as noted. †Reported without the KOOS Sports/Recreation domain. ‡Defect size post-debridement. §Significantly different ($p < 0.025$) demographic statistic.

showed significant improvement from baseline for most outcomes. One highlight was the KOOS QoL, which improved for every patient group, although the worst-case groups started at lower baseline values and/or reached higher end point values. Similarly, although the mean VAS pain score was not significantly improved at 5 years for the whole cohort ($p = 0.027$), it was significantly improved ($p = 0.003$) for the subgroup of patients with a previously failed cartilage repair surgery. These findings could indicate that the BioPoly implant fulfills its intended role as an option for patients who are too young for joint replacement but for whom biological repair is not ideal, since the BioPoly implant functions on the basis of biomechanical properties and healing of bone instead of relying on biological healing of cartilage tissue.

The limitations of this study include the use of patient-reported outcomes and the small sample size due to the loss of patients to follow-up. Additionally, the study was not controlled or randomized. However, the lack of longer-term outcomes mentioned in our previous paper[1] has now been alleviated by these 5-year data. Microfracture is the gold-standard procedure for the repair of cartilage defects that are 2 to 3 cm^2 in area[27], the size in the present study, but future research could include comparison of the BioPoly implant with other common cartilage repair technologies, such as osteochondral allograft, OATS, debridement, and ACI.

In summary, in this case series, the BioPoly Partial Resurfacing Knee Implant has been shown to provide significant improvement of notable magnitude for indicated patients and has proven to be safe in the medium term. In comparison with microfracture (as reported in the literature), the BioPoly implant provided noninferior results in the KOOS QoL score and offered the benefits of a faster return to activity and the circumvention of common patient contraindications for biological repair. ■

Dinesh Nathwani, MBChB, MSc, FRCS(Tr&Orth)[1,2]
Michael McNicholas, BSc, MBChB, FRCS(Ed&Glasg), MD, FRCSEd(Tr&Orth), FFSEM, RCSI[3]
Alister Hart, MA, MD, FRCS(Orth)[4,5,6]
Jonathan Miles, MBChB, FRCS(Orth)[4]
Vladimir Bobić, MD, FRCSEd[7]

[1]Imperial College Healthcare NHS Trust, London, United Kingdom

[2]The London Clinic, London, United Kingdom

[3]Liverpool University Hospitals NHS Trust, Liverpool, United Kingdom

[4]Royal National Orthopaedic Hospital, Stanmore, United Kingdom

[5]University College London, London, United Kingdom

[6]Cleveland Clinic London, London, United Kingdom

[7]Chester Knee Clinic, Nuffield Health, The Grosvenor Hospital, Chester, United Kingdom

Email for corresponding author: vbobic@kneeclinic.info

References

1. Nathwani D, McNicholas M, Hart A, Miles J, Bobić V. Partial Resurfacing of the Knee with the BioPoly Implant: Interim Report at 2 Years. JB JS Open Access. 2017 Apr 6;2(2):e0011.

2. Kreuz PC, Steinwachs MR, Erggelet C, Krause SJ, Konrad G, Uhl M, Südkamp N. Results after microfracture of full-thickness chondral defects in different compartments in the knee. Osteoarthritis Cartilage. 2006 Nov;14(11):1119-25.

3. Gobbi A, Nunag P, Malinowski K. Treatment of full thickness chondral lesions of the knee with microfracture in a group of athletes. Knee Surg Sports Traumatol Arthrosc. 2005 Apr;13(3):213-21.

4. Mithoefer K, Williams RJ 3rd, Warren RF, Wickiewicz TL, Marx RG. High-impact athletics after knee articular cartilage repair: a prospective evaluation of the microfracture technique. Am J Sports Med. 2006 Sep;34(9):1413-8.

5. Kreuz PC, Erggelet C, Steinwachs MR, Krause SJ, Lahm A, Niemeyer P, Ghanem N, Uhl M, Südkamp N. Is microfracture of chondral defects in the knee associated with different results in patients aged 40 years or younger? Arthroscopy. 2006 Nov;22(11):1180-6.

6. Knutsen G, Engebretsen L, Ludvigsen TC, Drogset JO, Grøntvedt T, Solheim E, Strand T, Roberts S, Isaksen V, Johansen O. Autologous chondrocyte implantation compared with microfracture in the knee. A randomized trial. J Bone Joint Surg Am. 2004 Mar;86(3):455-64.

7. Knutsen G, Drogset JO, Engebretsen L, Grøntvedt T, Isaksen V, Ludvigsen TC, Roberts S, Solheim E, Strand T, Johansen O. A randomized trial comparing autologous chondrocyte implantation with microfracture. Findings at five years. J Bone Joint Surg Am. 2007 Oct;89(10):2105-12.

8. Saris D, Price A, Widuchowski W, Bertrand-Marchand M, Caron J, Drogset JO, Emans P, Podskubka A, Tsuchida A, Kili S, Levine D, Brittberg M; SUMMIT study group. Matrix-applied characterized autologous cultured chondrocytes versus microfracture: two-year follow-up of a prospective randomized trial. Am J Sports Med. 2014 Jun;42(6):1384-94.

9. Mithoefer K, Williams RJ 3rd, Warren RF, Potter HG, Spock CR, Jones EC, Wickiewicz TL, Marx RG. The microfracture technique for the treatment of articular cartilage lesions in the knee. A prospective cohort study. J Bone Joint Surg Am. 2005 Sep;87(9):1911-20.

10. Minas T, Gomoll AH, Rosenberger R, Royce RO, Bryant T. Increased failure rate of autologous chondrocyte implantation after previous treatment with marrow stimulation techniques. Am J Sports Med. 2009 May;37(5):902-8.

11. Steadman JR, Rodkey WG, Rodrigo JJ. Microfracture: surgical technique and rehabilitation to treat chondral defects. Clin Orthop Relat Res. 2001 Oct; (391)(Suppl):S362-9.

12. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)—development of a self-administered outcome measure. J Orthop Sports Phys Ther. 1998 Aug;28(2):88-96.

13. Wallerstein SL. Scaling clinical pain and pain relief. In: Bromm B, editor. Pain measurement in man: neurophysiological correlates of pain. New York: Elsevier; 1984.

14. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992 Jun;30(6):473-83.

15. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. Clin Orthop Relat Res. 1985 Sep;198(198):43-9.

16. Saris DB, Vanlauwe J, Victor J, Haspl M, Bohnsack M, Fortems Y, Vandekerckhove B, Almqvist KF, Claes T, Handelberg F, Lagae K, van der Bauwhede J, Vandenneucker H, Yang KG, Jelic M, Verdonk R, Veulemans N, Bellemans J, Luyten FP. Characterized chondrocyte implantation results in better structural repair when treating symptomatic cartilage defects of the knee in a randomized controlled trial versus microfracture. Am J Sports Med. 2008 Feb;36(2):235-46.

17. Røtterud JH, Sivertsen EA, Forssblad M, Engebretsen L, Årøen A. Effect on Patient-Reported Outcomes of Debridement or Microfracture of Concomitant Full-Thickness Cartilage Lesions in Anterior Cruciate Ligament-Reconstructed Knees: A Nationwide Cohort Study From Norway and Sweden of 357 Patients With 2-Year Follow-up. Am J Sports Med. 2016 Feb;44(2):337-44.

18. Cole BJ, Farr J, Winalski CS, Hosea T, Richmond J, Mandelbaum B, De Deyne PG. Outcomes after a single-stage procedure for cell-based cartilage repair: a prospective clinical safety trial with 2-year follow-up. Am J Sports Med. 2011 Jun;39(6): 1170-9.

19. Vanlauwe J, Saris DB, Victor J, Almqvist KF, Bellemans J, Luyten FP; TIG/ACT/01/2000&EXT Study Group. Five-year outcome of characterized chondrocyte implantation versus microfracture for symptomatic cartilage defects of the knee: early treatment matters. Am J Sports Med. 2011 Dec;39(12):2566-74.

20. Ritter MA. The Anatomical Graduated Component total knee replacement: a long-term evaluation with 20-year survival analysis. J Bone Joint Surg Br. 2009 Jun;91(6):745-9.

21. Julin J, Jämsen E, Puolakka T, Konttinen YT, Moilanen T. Younger age increases the risk of early prosthesis failure following primary total knee replacement for osteoarthritis. A follow-up study of 32,019 total knee replacements in the Finnish Arthroplasty Register. Acta Orthop. 2010 Aug;81(4):413-9.

22. Rand JA, Trousdale RT, Ilstrup DM, Harmsen WS. Factors affecting the durability of primary total knee prostheses. J Bone Joint Surg Am. 2003 Feb;85(2):259-65.

23. Odland AN, Callaghan JJ, Liu SS, Wells CW. Wear and lysis is the problem in modular TKA in the young OA patient at 10 years. Clin Orthop Relat Res. 2011 Jan; 469(1):41-7.

24. Meehan JP, Danielsen B, Kim SH, Jamali AA, White RH. Younger age is associated with a higher risk of early periprosthetic joint infection and aseptic mechanical failure after total knee arthroplasty. J Bone Joint Surg Am. 2014 Apr 2; 96(7):529-35.

25. Van Assche D, Van Caspel D, Vanlauwe J, Bellemans J, Saris DB, Luyten FP, Staes F. Physical activity levels after characterized chondrocyte implantation versus microfracture in the knee and the relationship to objective functional outcome with 2-year follow-up. Am J Sports Med. 2009 Nov; 37(1)(Suppl 1):42S-9S.

26. Saris DB, Vanlauwe J, Victor J, Almqvist KF, Verdonk R, Bellemans J, Luyten FP; TIG/ACT/01/2000&EXT Study Group. Treatment of symptomatic cartilage defects of the knee: characterized chondrocyte implantation results in better clinical outcome at 36 months in a randomized trial compared to microfracture. Am J Sports Med. 2009 Nov;37(1)(Suppl 1):10S-9S.

27. Makris EA, Gomoll AH, Malizos KN, Hu JC, Athanasiou KA. Repair and tissue engineering techniques for articular cartilage. Nat Rev Rheumatol. 2015 Jan;11(1): 21-34.