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ORIGINAL ARTICLE

Clinical evaluation of a resurfacing device implant for femoral osteochondral defects greater than 1 cm^2 with a minimal follow-up of 4 years: a prospective cohort study

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Abstract

Purpose Osteochondral defects have a limited capacity to heal and can evolve to an early osteoarthritis. A surgical possibility is the replacement of the affected cartilaginous area with a resurfacing device BioPoly™ RS Partial Resurfacing Knee Implant. The aim of this study was to report the clinical and survival outcomes of the BioPoly™ after a minimum follow-up of 4 years.

Methods This study included all patients who had a BioPoly™ for femoral osteochondral defects greater than 1 cm^2 and at least ICRS grade 2. The main outcome was to observe the KOOS and the Tegner activity score were used to assess outcomes preoperatively and at the last follow-up. The secondary outcomes were the VAS for pain, the complications rate post-surgery and survival rate of BioPoly™ at the last FU.

Results Eighteen patients with 44.4% (8/18) of women were included with a mean age of 46.6 years (11.4), a mean body mass index (BMI) of 21.5 (kg/m^2) (2.3). The mean follow-up was 6.3 years (1.3). We found a significant difference comparing pre-operative KOOS score and at last follow-up [respectively, 66.56(14.37) vs 84.17(7.656), $p < 0.01$]. At last follow-up, the Tegner score was different [respectively, 3.05(1.3) vs 3.6(1.3), $p < 0.01$]. At 5 years, the survival rate was of 94.7%.

Conclusions BioPoly™ is a real alternative for femoral osteochondral defects greater than 1 cm^2 and at least ICRS grade 2. It will be interesting to compare this implant to mosaicplasty technic and/or microfracture at 5 years postoperatively regarding clinical outcomes and survival rate.

Level of evidence Therapeutic level III. Prospective cohort study.

Keywords Prosthetic button · Osteochondral defect · Knee injury · Sport medicine

Introduction

Lesions of the articular cartilage of the knee are common [1]. Arthroscopic examination of a painful knee reveals a localised or diffuse lesion in two thirds of patients [2, 3]. Chondral and osteochondral defects have a limited capacity to regenerate after injury and spontaneously transform into fibrous or fibrocartilaginous tissue of no functional value. The poor healing capacity of cartilage beyond a certain size is explained by its avascular nature and the very limited regenerative capacity of chondrocytes [4, 5]. This type of joint damage can lead to early osteoarthritis [6, 7]. Knee osteoarthritis is the final stage of cartilage damage and can result in a significant loss of autonomy for the patient [8]. It is also associated with significant costs to society, either direct (hospitalisation and treatment) or indirect (loss of productivity and early retirement) [9].

These cartilage lesions need to be treated to prevent them from progressing to osteoarthritis. There are three main types of treatment for cartilage loss. The first technique is to repair the cartilage defect by subchondral stimulation, which often results in fibrocartilage (microfractures [10], Pridie and abrasion). The second technique is to regenerate the cartilage by incorporating mature cartilage into an

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osteochondral unit (mosaicplasty and massive allograft) and the third technique is autologous chondrocyte implantation with or without matrix.

Another surgical option is to replace the affected area of cartilage with a resurfacing device. The BioPoly™ RS Partial Resurfacing Knee Implant is a prosthetic button whose main component is an assembly of highly cross-linked polyethylene and a molecule known for its lubricating properties: hyaluronic acid. This combination creates a hydrophilic polymer that attracts synovial fluid to its surface, effectively becoming a "self-lubricating" polymer. This resurfacing device could have a special place in the therapeutic options for the treatment of lesions > 1 cm^2 in size and grade 2, 3 or 4 of the International Cartilage Repair Society (ICRS) classification. This device could be used as a first-line treatment or in the event of failure of a biological technique (described above) and would provide an alternative to knee arthroplasty in patients with a focal defect [11, 12]. The treatment of cartilage loss with a prosthetic button is poorly reported in the literature and has only been the subject of one in vivo animal study [13] and one human clinical trial [14].

The aim of this study was to describe the clinical and survival outcomes of BioPoly™ after a minimal follow-up of 4 years.

Methods

The clinical protocol and informed consent were approved by the research ethics committee of *Maussins Clinic* under reference N°: Maus-2020-11-01.

Patients

This monocentric, retrospective cohort study was conducted at the Maussins-Nollet institution (France). All patients who underwent surgery for femoral chondral or osteochondral defects in our orthopaedic department between 1 September 2014 and 1 February 2019 were included. Inclusion criteria were: > 25 years of age; cartilage damage > 1 cm^2; at least grade 2 according to the ICRS classification [15]; without inflammatory disease, anterior cruciate ligament lesion or tibial kissing lesion. Patients with valgus or varus deformity > 10° were excluded. All included patients gave informed consent.

Procedure

The diagnosis was confirmed by physical examination with knee radiographs (anterior–posterior, lateral, and goniometry) and, in cases of doubt, magnetic resonance imaging or knee arthrocomputed tomography. All surgeries were performed by the same experienced surgeon (senior knee surgeon) on an outpatient basis. Each patient underwent an initial arthroscopic examination to assess the defect and confirm the indication for a BioPoly™ device. This device is a combination of ultra-high molecular weight polyethylene and hyaluronic acid moulded onto a grit-blasted titanium alloy stem. This combination creates a hydrophilic polymer. Synovial fluid is attracted to the surface of this polymer. Three sizes are available: 15 mm, 20 mm and 15 × 24 mm diameter. It was developed by BioPoly (Indiana, USA).

A medial parapatellar approach of approximately 10 cm was performed with preservation of the Hoffa fat pad. The implantation site was prepared to determine the correct implant orientation and depth relative to the surrounding anatomy. Depending on the surgical findings, the implant site could be prepared with a bone allograft: the

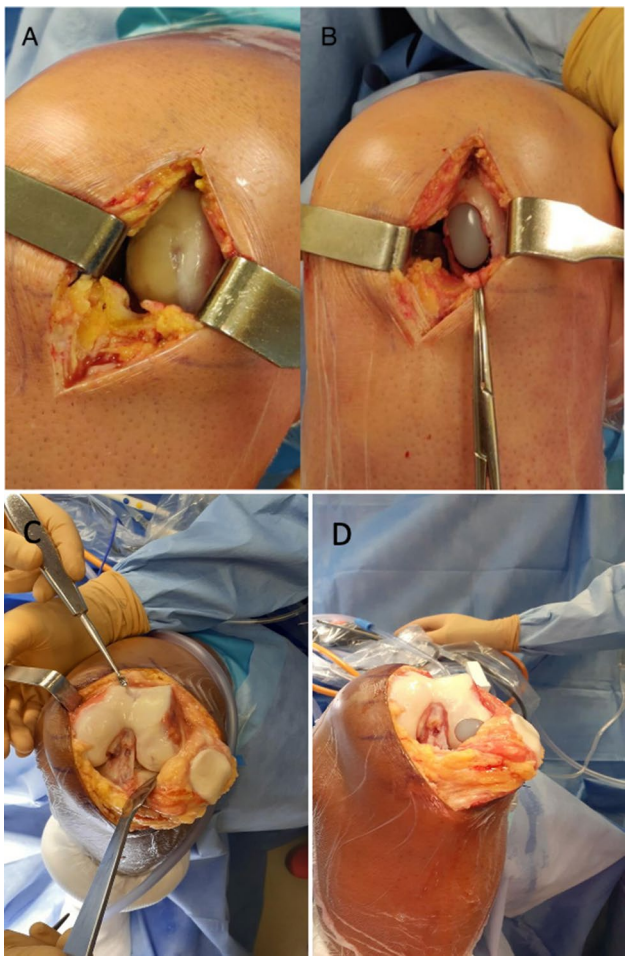

Fig. 1 Intraoperative image of the surgical technique used to insert the BioPoly™ device. **a** Intraoperative photograph showing the osteochondral defect. **b** Intraoperative photograph taken after implantation of a Biopoly™ device in the femoral condyle. **c** Intraoperative photograph showing the osteochondral defect in another patient. **d** Intraoperative photograph taken after the implantation of a Biopoly™ device in the femoral condyle of the second case.

Table 1 Demographic data

Parameters	Values	*N*	Statistics
Age (years)		18	46.56 (11.41)
BMI (kg/m^2)		18	21.45 (2.348)
Gender	F	8	44.44%
	M	10	55.56%
Side	Right	11	61.11%
	Left	7	38.89%
Sport level	Competition	1	5.56%
	Casual leisure level	10	55.56%
	Sedentary	7	38.89%
Localisation	Lateral condyle	8	44.44%
	Medial condyle	10	55.56%
Diagnosis	Osteonecrosis	7	38.89%
	Osteochondritis	3	16.67%
	Trauma	8	44.44%
Tegner score pre-operative		18	3.056 (1.305)
KOOS score pre-operative		18	66.56 (14.37)
Other symptoms score pre-operative		18	75.44 (14.2)
Pain score pre-operative		18	65.17 (22.67)
Function in daily living pre-operative		18	73.94 (16.86)
Function in sport and recreation pre-operative		18	47.22 (20.67)
Knee-related quality of life pre-operative		18	48.89 (22.01)
Numerical analogue pain scale pre-operative		18	4.22 (1.353)

osseocartilaginous lesion was removed and if the depth of the lesion was greater than 10 mm, an allograft was performed. Once the implant site was deemed suitable, the implant was gently inserted (Fig. 1, Video 1).

Post-operative care was identical for all patients. Patients were not immobilised after surgery and were encouraged to walk with two crutches for 3 weeks, with immediate full weight bearing authorised. Post-operative assessments took place during the first 3 weeks post-surgery, at 6 months and at 1 year.

Data collection

Demographic data (age, body mass index (BMI), sex), clinical scores (VAS pain score, KOOS [16] and Tegner score [17]) and sport level were recorded pre-surgery. Operative time, post-surgical complications and the characteristics of the lesion (localisation, size, and aetiology) were also recorded. VAS pain score, KOOS [16] and Tegner score were recorded at each post-operative visit and at the last follow-up. All patients were contacted by telephone in April 2023 and asked about any re-interventions on the operated knee.

Outcome measures

The primary endpoint was the clinical outcome at the last follow-up, evaluated using the KOOS and Tegner activity score. Secondary outcomes included VAS pain, clinical score at 2 years and the rate of complications 6 months post-surgery and at the last follow-up. The survival rate of the BioPoly™ device was also evaluated at the last follow-up. The start point was the day of surgery and the end point was 1 April 2023. Revision surgery for any cause was considered as an event. Patients who did not undergo revision surgery or were lost to follow-up on 1 April 2023 were censored.

Statistical analysis

Continuous quantitative variables are described as means and standard deviation (± SD). Continuous variables were compared using the Wilcoxon test. Dichotomous variables are described as number of events and percentage. Overall revision risk was estimated using the Kaplan–Meier method. Kaplan–Meier estimates of revision were plotted. The threshold of significance retained was 5% for a power of 80% and a risk of the first species at 5%. R software (version 3.5.0 spotted at the URL http://www.R-project.org) was used to perform the statistical analyses.

Table 2 Surgical procedure details

Parameters	Values	N	Statistics
Size of implant	15 mm	15	83.33%
	15×25 mm	3	16.67%
Allograft	No	16	88.89%
	Yes	2	11.11%
Operative time (min)		18	53.11 (18.45)
Complications	No	17	94.44%
	Yes	1	5.56%

Results

Study population

Between 1 September 2014 and 1 February 2019, a total of 18 patients received a BioPoly™ device. The mean (± SD) age of the patients was 46.6 ± 11.4 years, mean (± SD) BMI was 21.5 ± 2.3 kg/m^2 and the majority of patients of patients were male (55.6%, 10/18). Mean (± SD) follow-up was 6.3 ± 1.3 years. The demographic characteristics of the study population are shown in Table 1 and Appendix 1.

Surgical data

Among the 18 patients who received a BioPoly™ device, seven (38.89%) had osteonecrosis, three (16.67%) had sequellae of osteochondritis and eight (44.44%) had a post-traumatic lesion. The left side was injured in seven (38.89%) cases. The osteochondral defect was located on the medial condyle in ten patients (55.56%). The size of the implant was 15 mm in 83.3% of patients and 15−24 mm in 16.7% (Table 2). In two cases (11.1%), a bone allograft was also implanted.

Clinical outcomes

Mean (± SD) range of motion at 3 weeks post-surgery was 122.3 ± 14.5°. Preoperatively, the mean KOOS score was 66.56 ± 14.37. At the final follow-up, the mean KOOS score was 84.17 ± 7.656 (Table 3). This difference was statistically significant ($p < 0.01$) with an increase of approximatively 17 points (Fig. 2). All the different subscales of the KOOS also increased at the final follow-up. The difference was also significant for the "Other symptoms" subscale ($p < 0.01$), "Pain" subscale ($p < 0.01$) and "Function in daily living" subscale ($p < 0.01$) (Table 3). Mean (± SD) pre-operative VAS pain score was 4.22 ± 1.35. At the final follow-up, this decreased to 1.22 ± 1.1 ($p < 0.01$). These results are summarised in Table 3.

Table 3 Post-operative clinical outcomes

Parameters	Statistics
Tegner score	
2 years	3.389 (1.29)
Final follow-up	3.611 (1.335)
Koos score	
2 years	83.17 (9.984)
Final follow-up	84.17 (7.656)
Other symptoms score	
2 years	89.11 (11.35)
Final follow-up	91.26 (9.533)
Pain score	
2 years	87.28 (10.13)
Final follow-up	89.94 (8.734)
Function in daily living	
2 years	91.72 (8.13)
Final follow-up	92.89 (6.305)
Function in sport and recreation	
2 years	56.11 (23.98)
Final follow-up	70.83 (17)
Knee-related quality of life	
2 years	61.94 (16.49)
Final follow-up	71.33 (10.93)
Numerical analogue pain scale	
2 years	1.556 (1.097)
Final follow-up	1.222 (1.114)

Mean (± SD) pre-operative Tegner score was 3.05 ± 1.3. Seven patients were sedentary (38.89%), ten practiced sport at a casual level (55.56%) and one played sport at a competition level (5.56%). At the final follow-up, the mean (± SD) Tegner score was 3.6 ± 1.3. Only one patient had not regained their previous level of sport. These results are summarised in Table 4.

Implant survival rate, operative time and complications

Mean (± SD) follow-up was 6.3 ± 1.3 years. Overall survival rate at 5 years was 94.4% [95% CI 84.0−100.0] (Fig. 3). Only one case (5.6%) of aseptic loosening was observed at 1-year post-surgery. The main indication for Biopoly™ was osteonecrosis. All other patients had integration with surrounding bone on X-rays with no sign of aseptic loosening.

Mean (± SD) operative time was 53.11 ± 18.45 min. No complications were observed in the first year after surgery. At the final follow-up, the only complication was the

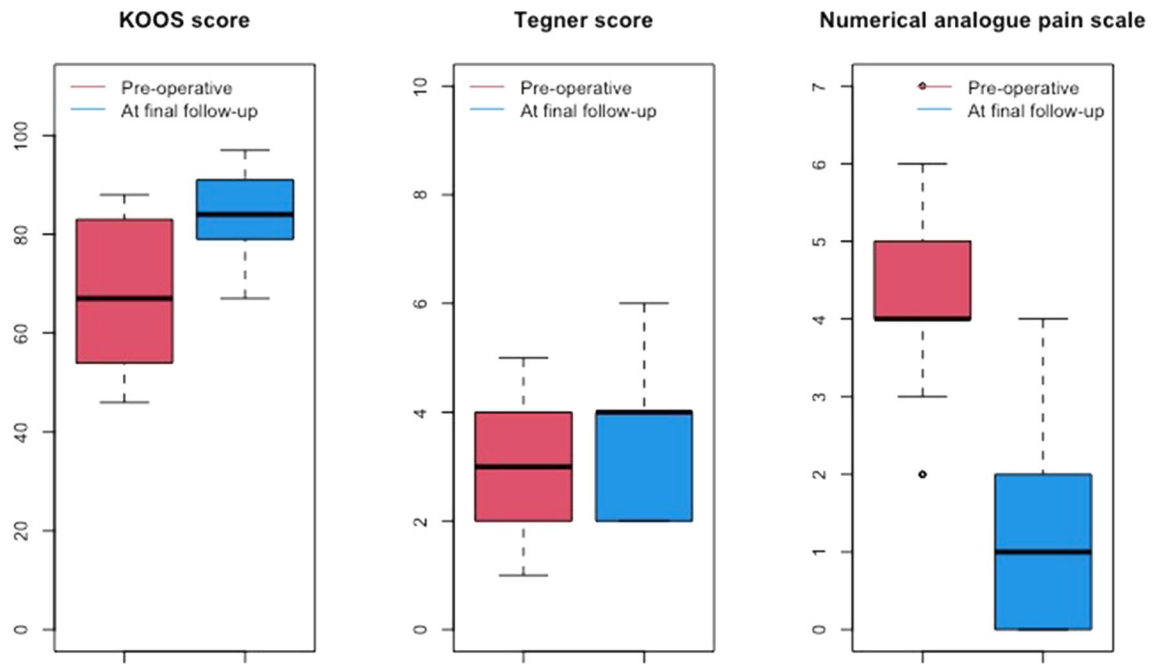

Fig. 2 Boxplot of the KOOS score, Tegner score and VAS pain score before surgery and at the final follow-up

Table 4 Difference between pre-operative score and at last follow-up (FU) for clinical outcomes

Parameters	Statistics
Tegner score difference	
2 years-preoperatively	0.3333 (1.815)
Last FU-preoperatively	0.5556 (1.756)
KOOS score difference	
2 years-preoperatively	16.61 (16.74)
Last FU-preoperatively	17.61 (16.15)
Other symptoms score	
2 years-preoperatively	13.67 (15.96)
Last FU-preoperatively	16.11 (18.88)
Pain score difference	
2 years-preoperatively	22.11 (24.42)
Last FU-preoperatively	24.78 (23.44)
Function in daily living	
2 years-preoperatively	17.78 (15.25)
Last FU-preoperatively	18.94 (15.87)
Function in sport and recreation difference	
2 years-preoperatively	8.889 (28.52)
Last FU-preoperatively	23.61 (23.31)
Knee-related quality of life difference	
2 years-preoperatively	13.06 (31.74)
Last FU-preoperatively	22.44 (26.29)

previously mentioned case of aseptic loosening. Figure 4 shows the implant appearance on second-look arthroscopy.

Discussion

The main finding of the present study was that the BiopolyTM device could be a real therapeutic alternative for femoral osteochondral defects > 1 cm^2. Good clinical results were observed after a mean follow-up of 4 years. An improvement in the global KOOS score and in most of its subscales was observed. A significant difference was observed between pre-operative and final follow-up scores, except for the knee-related subscale "quality of life" and the subscale "function in sports and recreation". These scores remained stable over time. In addition, patients were not immobilised and were encouraged to walk immediately after surgery. The results for the Tegner score and the KOOS subscale "Function in Sport and Recreation" at the last follow-up were not significantly different from the pre-operative values. These results can be explained by our study population. Only one patient participated in competitive sports. However, this patient was able to regain the same level as before surgery.

To our knowledge, only one study in the literature has reported the results of BiopolyTM device implantation. Nathwani et al. [14], with a series of 33 patients followed prospectively for 2 years, report results similar to ours with a significant improvement in both clinical scores (KOOS and Tegner) and in pain. Their results were stable over time,

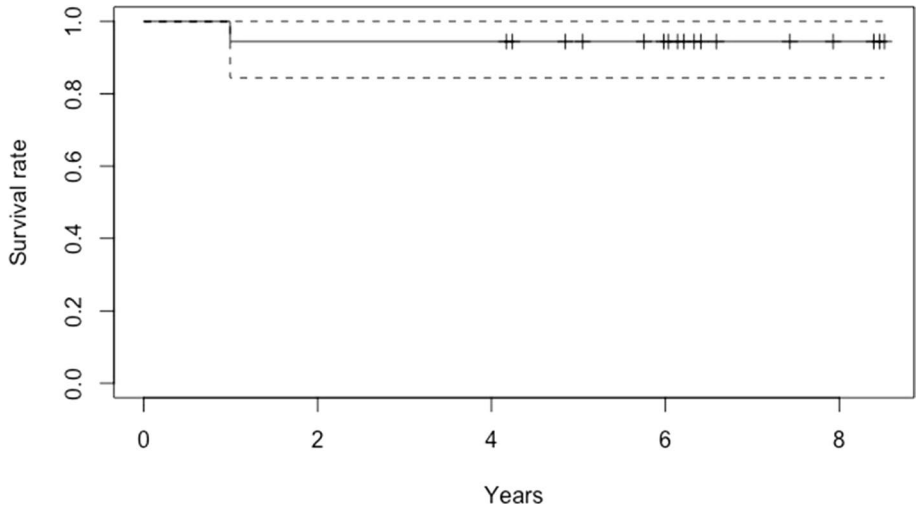

Fig. 3 Kaplan–Meier survival plot for the event "failure" after Biopoly™ implantation in the total study population ($N = 18$)

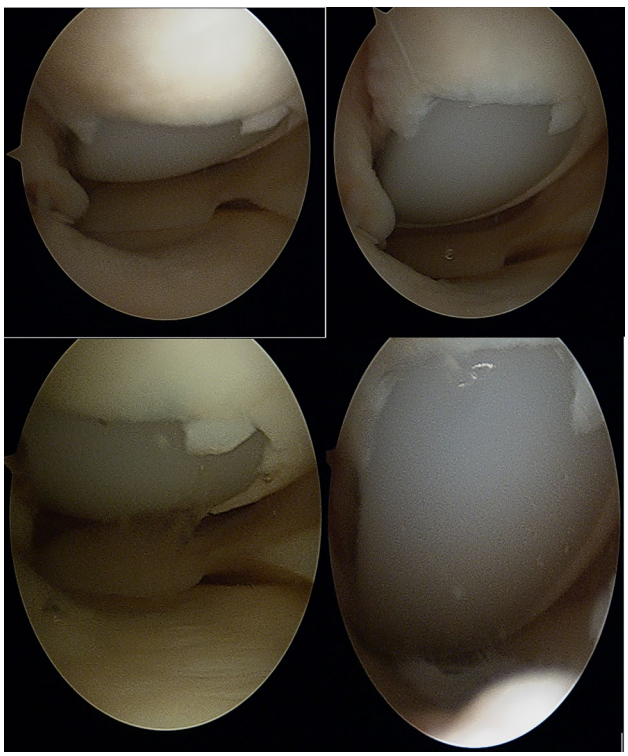

Fig. 4 Images of a second-look arthroscopy of an implant 2 years post-surgery

as there was no significant decrease in functional scores at 2 years after surgery. In our series, we observed only one complication at 1 year after surgery. This complication was an aseptic loosening of the implant. This patient was treated with a unicompartmental knee prosthesis. According to the authors, the non-integration of the implant could be explained by the poor selection of this patient for a BiopolyTM device. Indeed, this patient was found to have very poor bone quality at the time of surgery. Nathwani et al. also reported non-integration of an implant at 2 years in a patient with a history of surgery on the same knee (microfracture and ACL reconstruction). The authors hypothesised that the bone metabolism was locally altered by the two previous operations, leading to aseptic loosening [14]. In our study, we did not report any intraoperative or immediate post-operative complications. The 5-year survival rate was close to 95%.

One of the most commonly used surgical techniques to treat osteochondral lesions > 1 cm^2 is mosaicplasty. This autograft technique uses subchondral bone from non-weight-bearing areas [18]. This surgical technique provides good long-term clinical results. In fact, improvements in Hospital for Special Surgery (HSS) score, International Cartilage Repair Society (ICRS) score, Lysholm score and KOOS score have been observed in previous studies [19, 20]. Solheim et al. confirmed these results in the long term [21]. However, in some series the Tegner score did not seem to increase postoperatively and was similar to the pre-operative score [19]. The clinical results seem to be similar to those of Biopoly™. However, mosaicplasty requires an autograft from the same knee. This graft from the donor site is not trivial and carries significant risks. A review of the literature reported co-morbidities associated with the donor site [22]. The donor site for osteochondral damage included the edges of the femoral trochlea, the intercondylar notch, the patellofemoral joint and the superior tibiofibular joint. This study reported a mean donor site morbidity of 5.9% and 19.6% for knee and ankle mosaic procedures, respectively. The most common donor site morbidity complaints were patellofemoral pain, instability during daily activities or sports, and knee stiffness.

In terms of long-term survival, the results of mosaicplasty appear to be good with 92% survival at 4 years [23]. Survival seems to be similar for BioPolyTM and mosaicplasty based on the results of our series. For the other techniques, namely

autologous chondrocyte implantation, osteochondral allograft transplantation and matrix-induced autologous chondrocyte implantation, no differences between the procedures are reported in the literature [24, 25]. In a recent network analysis, Zamborski et al. [26] found that microfracture had significantly more poor outcomes than autologous chondrocyte implantation, osteochondral autograft transplantation and matrix-induced autologous chondrocyte implantation. There is no information on these different techniques after 2 years of follow-up [24, 26]. Another treatment option is metal implants such as Hemicap. Good long-term results and survival rates have been reported in the literature [27, 28]. These implants, like Bioply, are an alternative without donor site morbidity.

The main limitation of this study is the relatively small size of our population. This can be explained by the very careful selection of patients in the absence of data from the literature. Another limitation of the study is the lack of comparison with a control group. It would be interesting to compare the results of this technique with another technique such as mosaicplasty in the longer term.

In conclusion, BioPoly™ is a real alternative for femoral osteochondral defects > 1 cm^2 and at least ICRS grade 2 lesions. It allows recipients to return to the same level of sport. It will be interesting to compare the clinical results and survival of this implant with mosaicplasty and/or microfracture at 5 years after surgery.

Appendix 1

N°	Side	IMC	Gender	Age	Sport level	Biopoly size (mm)	Defect localization	Bony allograft	Meniscal lesion	Prior surgery	Diagnosis
1	Right	18.0	F	65	Sedentary	15	Lateral condyle	No	No	No	Osteonecrosis
2	Right	19.0	F	52	Occasional	15	Lateral condyle	No	No	No	Post-traumatic lesion
3	Right	18.7	F	36	Occasional	15	Medial condyle	No	No	No	Post-traumatic lesion
4	Left	22.1	M	36	Occasional	15 × 25	Medial condyle	Yes	No	No	Sequel of osteochondritis
5	Left	20.5	F	34	Occasional	15 × 25	Medial condyle	No	No	No	Sequel of osteochondritis
6	Left	19.8	M	40	Sedentary	15	Medial condyle	No	No	No	Osteonecrosis
7	Right	23.0	M	61	Sedentary	15	Medial condyle	Yes	No	No	Osteonecrosis
8	Right	24.8	M	55	Occasional	15	Medial condyle	No	No	No	Post-traumatic lesion
9	Left	21.0	M	46	Occasional	15	Medial condyle	No	No	No	Post-traumatic lesion
10	Left	24.7	M	30	Occasional	15 × 25	Medial condyle	No	No	No	Sequel of osteochondritis
11	Right	24.7	F	56	Sedentary	15	Lateral condyle	No	No	No	Post-traumatic lesion
12	Right	19.6	M	34	Occasional	15	Lateral condyle	No	No	No	Post-traumatic lesion
13	Right	22.8	F	56	Competition	15	Lateral condyle	No	No	No	Post-traumatic lesion
14	Right	19.8	F	47	Sedentary	15	Lateral condyle	No	No	No	Osteonecrosis
15	Left	22.9	M	29	Occasional	15	Lateral condyle	No	No	No	Osteonecrosis
16	Right	25.0	M	56	Occasional	15	Medial condyle	No	No	No	Osteonecrosis

N°	Side	IMC	Gender	Age	Sport level	Biopoly size (mm)	Defect localization	Bony allograft	Meniscal lesion	Prior surgery	Diagnosis
17	Left	19.0	F	58	Sedentary	15	Lateral condyle	No	No	No	Osteonecrosis
18	Right	20.7	M	47	Sedentary	15	Medial condyle	No	No	No	Post-traumatic lesion

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00590-023-03613-y.

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Declarations

Conflict of interest No conflicts of interest.

Ethical approval This study was approved by the research ethics committee of *Maussins Clinics* under the reference N° *Maus-2020-11-01*.

Informed consent All patients gave their consent to participate to the study. All authors gave their consent to publish the study.

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