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ORIGINAL PAPER

Arthroscopic treatment of osteochondral knee defects with resorbable biphasic synthetic scaffold: clinical and radiological results and long-term survival analysis

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Abstract

Purpose The aim of our study is to evaluate the long-term results in patients treated with a fully arthroscopic TruFit system for osteochondral lesions of the femoral condyle, analyzing the clinical and radiological outcomes, survival rate, complications, and correlations.

Methods The study included all patients treated with the TruFit system with a full-thickness focal lesion of the knee cartilage (grade IV according to the ICRS classification), entirely arthroscopically with a minimum follow-up of five years. All patients were evaluated clinically prior to surgery (T_0) and at two consecutive follow-ups (T_1 36.4 ± 17.03 months and T_2 101.63 ± 19.02 months), using the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Hospital for Special Surgery Score (HSS). At the final follow-up, the magnetic resonance imaging (MRI) was evaluated by two orthopaedists using the magnetic resonance observation of cartilage repair tissue (MOCART) score.

Results The sample was formed of 21 patients, of which 14 were males (67%) and 7 females (33%), with a mean age of 51.29 ± 10.70. Of the 21 patients, two underwent prosthetic knee replacement at 24 and 65 months, respectively. At T_0, the HSS and the KOOS score were, respectively, 60.71 ± 11.62 and 57.71 ± 6.11. For both clinical values, a significant improvement was noted between T_0 and T_1 ($p < 0.05$) and between T_0 and T_2 ($p < 0.05$). At the final follow-up, the MOCART value was found to be 45.78 ± 5.27.

Conclusions The study results highlighted the safety and potential of the arthroscopic TruFit system procedure, which offered a good clinical outcome with stable results at long-term follow-up although we found no correlations between the MRI and clinical results.

Keywords Scaffold · Osteochondral defects · Arthroscopy · Cartilage · MOCART · The Kaplan-Meier survival analysis

Introduction

Cartilage, like most other tissues, is composed of two components: the extracellular matrix (ECM), made up of various macromolecules and water, and the cells contained within the ECM, which produce and maintain the former [1, 2]. Cartilage repair requires the restoration of both components to produce a tissue that is biomechanically and biochemically able to withstand the demands of repetitive joint loading without early degeneration and failure [3]. Many current and future approaches have the objective of modifying the classic cell-based techniques through the addition of bioscaffolds, with the goal of simplifying the surgical technique, decreasing post-operative restrictions on the patient, expediting recovery and return to full activity, and improving outcomes [4]. The TruFit CB (cartilage/bone) (Smith and Nephew, San Antonio,

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TX) is a resorbable implant consisting of semiporous 75.25 poly D,L-lactide-co-glycolide (PLG) copolymer, calcium sulfate polyglycolide acid (PGA) fibers, and surfactant [5]. The copolymer is amorphous non-crystalline and resorbable. The double-layer design consists of a cartilaginous portion and a bone; the cartilage line is softer and more malleable in such a way that it can be shaped to the curvature of the joints. The system acts as a porous scaffold that allows both a structural support and a micro-environment that favors the neoformation of healing tissue [6]. The calcium phosphate is reabsorbed in the first months, while the rest of the polymer dissolves over 12–36 months allowing replacement with the repair tissue. The TruFit system is indicated for the repair of full-thickness chondral lesions or osteochondral lesions [7]. The ideal lesion size affects lesions < 2 cm^2, where the plug is completely surrounded by the surrounding cartilage. Instead, the use of the plug is contraindicated in the presence of large lesions in which the distance between the cylinders would be less than 2 mm [6, 7]. The aim of our study is to evaluate the long-term results in patients treated with a fully arthroscopic TruFit system for osteochondral lesions of the femoral condyle, analyzing their survival rate, complications, integration, and correlations.

Material and Methods

The study included all patients treated with the TruFit system with a full-thickness focal lesion of the knee cartilage, entirely arthroscopically.

Inclusion criteria were as follows: one or two symptomatic lesions of the femoral condyle (medial or lateral) of grade IV according to the ICRS classification confirmed at the time of diagnostic arthroscopy; patients with a follow-up of more than 60 months; skeletal maturity; ability to give informed consent; body mass index (BMI) between 18 and 35 kg/m^2 [8] (Fig. 1).

The exclusion criteria were instead the following: previous surgical interventions to the affected knee; not reached skeletal maturity; patients with > 2 lesions, bipolar lesions (or kissing lesions); patients with systemic diseases such as rheumatoid arthritis; patients with lower limb malalignment; BMI < 18 kg/m^2 or BMI > 35 kg/m^2; haemophilic or diabetic patients; patients with autoimmune diseases; pregnant women; and patients with ongoing chemotherapy.

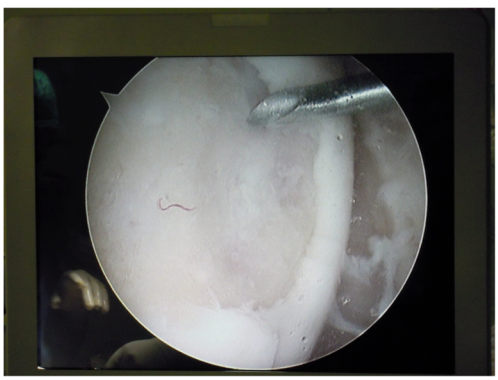

Fig. 1 Arthroscopic view from the anterolateral portal; the osteochondral lesion is evaluated and the degree of lesion for inclusion in the study is confirmed (grade IV according to the ICRS classification)

Concurrent reconstruction of the anterior cruciate ligament (ACL) during cartilage reconstruction with the TruFit system was not considered an exclusion criterion.

All patients were evaluated clinically prior to surgery and at two consecutive follow-ups using the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the Hospital for Special Surgery Score (HSS) [9, 10].

At the final follow-up, the magnetic resonance imaging (MRI) was evaluated by two orthopaedists, not involved directly in the surgical procedure, using the magnetic resonance observation of cartilage repair tissue (MOCART) score [11]. The MOCART score was designed to evaluate the treatment of chondral and osteochondral lesions in as subjective a way as possible. This scale evaluates the appearance of the repaired tissue, the covering of the lesion, the integration of the margins, the intensity of the signal, and the state of the subchondral lamina. The score ranges from a minimum of 0 (worst possible result) to a maximum of 100 (best possible result) [11].

In addition to clinical evaluations, survival analysis was performed using the Kaplan-Meier curves for patients who underwent replacement surgery (total or unicompartmental) on the same knee during the follow-up period [12].

We also evaluated the presence of correlations within our patient sample and analyzed the possible differences between groups as follows:

- men vs women
- young patients vs less young patients (using the cut-off value of 50 years, a value that approaches the average of our patients)
- normal weight patients vs overweight patients (using the cut-off as 25 as reported by WHO [13])
- who underwent an associated intervention of ACL reconstruction vs patients who underwent only osteochondral reconstruction surgery with TruFit system
- patients who have only one scaffold inserted vs patients undergoing double scaffold treatment

All clinical assessments were performed by a clinician who was not involved in surgical procedures.

Surgical technique

After examining the size and depth of the lesion in an arthroscopy, an adequate preparation of the injured site is performed creating a suitable cylindrical shape where the TruFit grafts

are subsequently positioned to press fit (Fig. 2). In the presence of an associated ACL lesion, the TruFit implant is performed at first and then the ligament reconstruction. Being a synthetic product, it has the advantage, compared to autologous chondral osteo-grafting techniques, the absence of the donor site, and the shorter duration of the intervention, while the disadvantages compared to autologous grafts concern its biological and mechanical properties.

Rehabilitation protocol

The basic principle is that the area subjected to grafting must be protected from the load for at least four weeks. Bending-extension movements without limits are permitted; in particular, active and passive movements are encouraged. The load is gradually recovered from the fourth post-operative week, while for sport, the recovery time is four tosix months.

Statistical analysis

Statistical analysis was followed using the SPSS 19 program (SPSS, Chicago, IL). For each continuous variable, the mean and standard deviation was calculated. The results were compared using the Student *t* test for parametric values. A p value < 0.05 was considered significant. The correlations were analyzed using the Pearson linear correlation coefficient. For survival analysis, the longitudinal curves of the Kaplan-Meier were used.

Results

The sample was formed by 21 patients, of which 14 were males (67%) and seven females (33%), with a mean age of 51.29 ± 10.70 (range 21–65) and a mean BMI of 27.20 ± 3.27 (range 21.6–34.67).

Patients were evaluated at three different time points: T_0 (before surgery), T_1 (36.4 ± 17.03 months after surgery), and T_2 (101.63 ± 19.02 months after surgery). Of the 21 patients included in the study, six underwent concomitant ACL reconstruction with semitendinosus and gracilis, while in seven cases, two scaffolds were used.

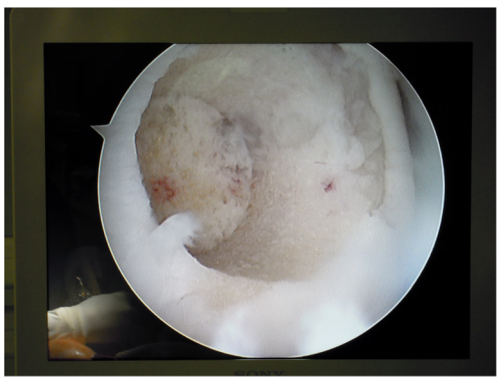

Fig. 2 Arthroscopic view from the anterolateral portal; preparation of the injured site, a suitable cylindrical shape is created, where the TruFit grafts are subsequently positioned to press fit

A total of 28 scaffolds were used, respectively: 3 of 7 mm, 8 of 9 mm, and 17 of 11 mm.

Of the 21 patients, two underwent replacement surgery at 24 and 65 months, respectively; for this reason, 20 patients were evaluated at T_1, while 19 were evaluated at T_2.

At T_0, the HSS and the KOOS score were, respectively, 60.71 ± 11.62 and 57.71 ± 6.11.

For both clinical values (KOOS and HSS), a significant improvement was noted between T_0 and T_1 and between T_0 and T_2. On the other hand, the improvement between T_1 and T_2 was not significant (Table 1).

At the final follow-up, the MOCART value was found to be 45.78 ± 5.27 (Figs. 3 and 4).

Correlations

The correlations found in the study show a significant positive association both in T_1 ($R = 0.97$; p value < 0.001) and T_2 ($R = 0.94$; p value < 0.001) between HSS and KOOS.

Analysis of groups

From the results obtained, it is possible to notice how in the comparison between males and females, the HSS in the female group was significantly lower than in the men both at T_1 (p value $= 0.02$) and at T_2 (p value $= 0.0089$). We also noted that patients who underwent ACL reconstruction surgery were significantly younger than patients who underwent isolated osteochondral reconstruction (p value $= 0.033$). No other significant differences were found in our groups. All results are shown in Table 2.

Survival analysis for prosthetic surgery

Two patients underwent total knee replacement surgery during follow-up, respectively, at 24 and 65 months after TruFit surgery. In this interval, the number of patients at risk is 21. In the first interval, there is a censored. In the second interval, the patients at risk become 20 and there is another censored. In the following interval, patients at risk become 19 until the end of our study. As can be seen in the first interval, the probability of survival is equal to 0.952; in the second interval, the cumulative survival is 0.904 and then remains constant over the rest of the time (Fig. 5).

Complications

With the exception of patients underwent replacement surgery, no complications were reported.

Table 1 Clinical and radiological results at T_0, T_1, and T_2

	T_0	T_1	T_2
HSS	60.71 ± 11.62	82.25 ± 16.02 vs T_0 $p < 0.0001$*	83.68 ± 13.03 vs T_0 $p < 0.0001$* vs T_1 $p = 0.739$
KOOS	57.71 ± 6.11	81.05 ± 4.76 vs T_0 $p < 0.0001$*	81.94 ± 4.58 vs T_0 $p < 0.0001$* vs T_1 $p = 0.064$
MOCART	/	/	45.78 ± 5.27

*Statistical significant difference

HSS Hospital for Special Surgery Score, *KOOS* Knee Injury and Osteoarthritis Outcome Score, *MOCART* magnetic resonance observation of cartilage repair tissue

Discussion

The aim of our work was to evaluate the long-term results (mean follow-up 101.63 ± 19.02 months) for the treatment of osteochondral lesions of high grade of the knee with TruFit system; our clinical results have shown that biphasic scaffold treatment can be considered effective, with a minimum failure rate (9.52%), even when performed in association with other surgical procedures, although it is not correlated with excellent radiological results (MOCART score 45.78 ± 5.27).

A similar study reported a five year follow-up after TruFit implantation evaluating clinical and radiological outcomes [14]. The authors reported a satisfactory integration of bone scaffolds and a satisfactory restoration of the articular cartilage in association with excellent clinical results (the Lysholm Knee Scoring 95.4/100 points). Neither of the patients underwent implant revision nor other surgery on the same knee [14].

Analyzing also the remaining existing literature, it is possible to highlight how the TruFit system, despite the use of different scales, leads to a significant clinical improvement, particularly in the short-medium term [15–17]. Our study, unlike the previous ones, is the only one to report a long-term follow-up, in association with a fully arthroscopic treatment, but as reported by the other studies, the biggest limitation is the lack of a control group.

Furthermore, although we performed subgroup analyzes (age, sex, weight, concomitant surgeries, and the number of scaffolds used), we did not find any predictive factors regarding the final result.

Joshi et al. treated ten patients with isolated cartilage lesions of the patella with the TruFit system. At the time of surgery, the patients had a mean age of 33.3 years and were evaluated prospectively in the 24-month successes at surgery. The number of plugs used for each patient ranged from one to four, and at one year of follow-up, eight out of ten patients were satisfied. At 18 months, the pain had disappeared in all patients, while at the final follow-up, the re-intervention rate was 70% [15].

Carmont et al. demonstrated how in some cases, the clinical improvement and the incorporation of the plug can take up to 24 months after TruFit intervention, even if this result is in contrast with the study of Joshi et al. [15, 16].

In 2014, Hindle et al. performed a retrospective comparison between 35 patients treated with the TruFit system and 31 with mosaicplasty, evaluating with the KOOS scale and the Cincinnati scale at a mean follow-up of 22 months for patients undergoing mosaicplasty and 30 months for patients undergoing TrufFit [17]. No significant difference was found with regard to the need for re-intervention, but the patients undergoing mosaicplasty had a higher return rate to the sport, a lower EQ-5D, and a greater KOOS regarding the activities of daily life.

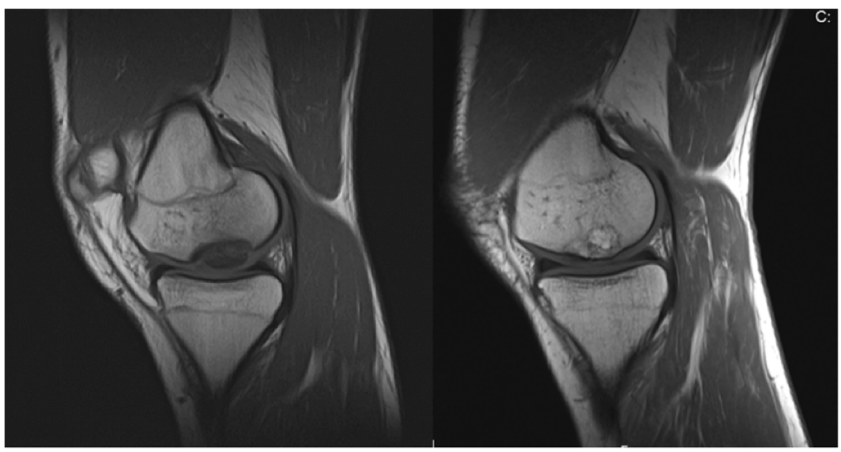

Fig. 3 Nuclear magnetic resonance, left knee, sagittal section. **a** Osteochondral lesion of the medial femoral condyle at T_0; **b** results of reconstruction of the osteochondral lesion at T_2 (examination performed 115 months after surgery) showing complete filling of the lesion

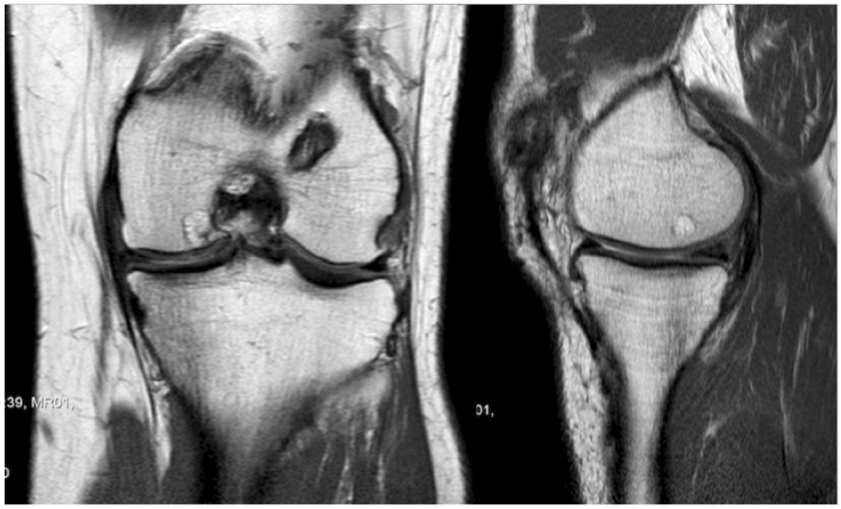

Fig. 4 Nuclear magnetic resonance, left knee. **a** Coronal section; **b** sagittal section. The examination highlights the integration of the scaffold and simultaneous reconstruction of the anterior cruciate ligament at a 96-month follow-up after surgery

Furthermore, in our study, we also evaluated the patients at the final follow-up using the MOCART scale, with a final result of 45.78 ± 5.27, but without any correlation with the clinical parameters.

As evidenced by the literature, the MOCART scale has a good reproducibility among the different observatories, with a correlation coefficient > 0.81 in eight of the nine variables, even if literature does not report a

Table 2 Comparison between different groups using the Student *t* test

1 Female vs male	Test	*p* value	2 Age < 50 vs age > 50	Test	*p* value	3 BMI < 25 vs BMI > 25	Test	*p* value
Age	54.86 < 49.50	0.182	Gender	0.89 > 0.50	0.052	Gender	0.83 > 0.60	0.293
BMI	29.33 > 26.13	0.058	BMI	26.6 < 27.62	0.474	Age	48.5 < 52.4	0.443
HSS T_0	59.29 < 61.43	0.698	HSS T_0	60.67 < 60.75	0.989	HSS T_0	59.67 < 61.13	0.793
KOOS T_0	57.43 < 57.86	0.897	KOOS T_0	57.11 < 58.17	0.700	KOOS T_0	57.83 > 57.60	0.946
HSS T_1	71.00 < 87.07	0.020*	HSS T_1	87.89 > 77.64	0.167	HSS T_1	78.00 < 84.07	0.545
KOOS T_1	80.17 < 81.43	0.601	KOOS T_1	81.89 > 80.36	0.487	KOOS T_1	81.17 > 81.00	0.938
HSS T_2	73.83 < 88.23	0.0089*	HSS T_2	88.75 > 80.00	0.142	HSS T_2	79.67 < 85.54	0.501
KOOS T_2	82.00 > 81.92	0.972	KOOS T_2	82.75 > 81.36	0.513	KOOS T_2	82.33 > 81.77	0.781
MOCART	47.8 > 45.0	0.424	MOCART	44.50 < 46.73	0.4084	MOCART	45.50 > 45.92	0.891
4	Test	*p* value	5	Test	*p* value			
ACL vs non-ACL			Double vs single scaffold					
Gender	0.83 > 0.60	0.293	Gender	0.71 > 0.64	0.756			
Age	45.5 < 53.6	0.033*	Age	46.86 < 53.50	0.285			
BMI	26.41 < 27.51	0.403	BMI	26.38 < 27.61	0.379			
HSS T_0	63.33 > 59.67	0.593	HSS T_0	60.71 = 60.71	1			
KOOS T_0	56.17 < 58.33	0.294	KOOS T_0	56.57 < 58.29	0.573			
HSS T_1	83.00 > 81.93	0.912	HSS T_1	83.67 > 81.64	0.814			
KOOS T_1	79.50 < 81.71	0.271	KOOS T_1	79.83 < 81.57	0.598			
HSS T_2	86.60 > 82.64	0.626	HSS T_2	87.40 > 82.36	0.434			
KOOS T_2	80.60 < 82.43	0.312	KOOS T_2	80.80 < 82.36	0.705			
MOCART	50.00 > 44.29	0.0687	MOCART	45.80 > 45.77	0.996			

The gender variable has the following encoding "M = 1", "F = 0"

*Statistically significant difference

HSS Hospital for Special Surgery Score, *KOOS* Knee Injury and Osteoarthritis Outcome Score, *MOCART* magnetic resonance observation of cartilage repair tissue, *BMI* body mass index, *ACL* anterior cruciate ligament

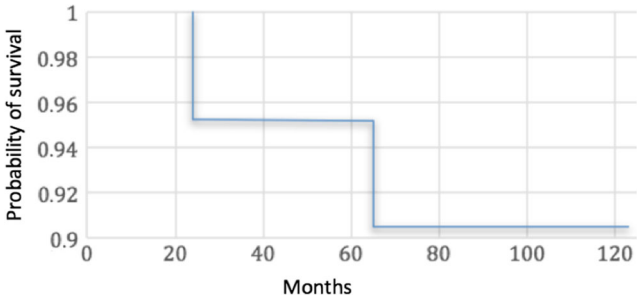

Fig. 5 The Kaplan-Meier estimate of survival within our sample throughout the follow-up period

relationship between MOCART score and clinical parameters [18].

The literature demonstrates how, on average, at six months, it is possible to observe in resonance a complete incorporation of the plug with a healing of the surrounding cartilage; over time, however, there is a deterioration in the medium term and a subsequent new improvement in the long term [19].

No study has demonstrated evidence for the formation of new subchondral bone, while there is no unanimous judgment regarding the biomechanical properties of the newly formed cartilage [19].

Histological studies confirm the findings radiologically, even if the limit of histological evaluation is linked to the fact that it can be performed only in cases of failure [19].

Resonance in these cases is the simplest and most effective test to be performed on patients, but difficulties persist in interpreting the characteristics of the repair tissue [20].

Joshi et al. claimed that the rapid radiological improvements are due to the formation of hyaline cartilage during the first 12 months, after which a deterioration of this neotissue occurs, due to the lack of subchondral bone [15]. This is confirmed by animal studies, in fact, histologic results from a goat model have shown osseointegration of the deep part of the implant, with resorption of the implant material and "hyaline-like" cartilage formation in the surface layer by 12 months [21]. Literature confirms that the cartilaginous layer is firmly bonded histologically to the underlying osseous tissue at the basal layer of the implant. This adherence of the neocartilaginous tissue to the underlying bone has been one of the problems with many other cartilage repair techniques, causing failure of the tissue when subjected to shear forces across the knee [6, 21].

Because bone formation is poor, after treatment with the TruFit system, the main doubt is whether this system can be used in osteochondral lesions. Future biphasic synthetic scaffolds should focus on creating and replacing the native subchondral bone that has the biomechanical and structural potential to support the formation of new cartilage [22, 23].

Unlike the other studies, we have used a fully arthroscopic technique with the advantage of having less tissue dissection and a faster recovery, both as regards hospitalization and as regards the return to work activities. Moreover, the first arthroscopic step allows a more precise evaluation of the type of lesion, reducing the risk of overestimating it as often happens in magnetic resonance.

Future studies will have to evaluate the use of regenerative medicine, in association with synthetic scaffolds; in fact, a 2013 study published by Betsch highlighted that the clinical application of bone marrow aspirate concentrate (BMAC) or platelet-rich plasma (PRP) in osteochondral defect healing is attractive because of their autologous origin and cost-effectiveness. Adding either PRP or BMAC to a biphasic scaffold led to a significantly better healing of osteochondral defects compared with the control group [24].

The main limitations of our study concern the lack of a control group and the assessment of the return to sport in patients, which we decided not to evaluate because of the high age at the final follow-up of the patients. Despite the lack of a control group, we tried to understand what the predictive factors were by making comparisons between different groups. For this reason, we decided not to consider the concomitant reconstruction of the ACL as an exclusion criterion, analyzing separately the patients who underwent this procedure to avoid possible bias. Another limitation of the study is the relatively high age of the patients, but in this case, there is no concordance in the literature, as in the similar studies, the average age of the patients ranged from 28.72 to 57.89 years [14, 19].

Conclusions

Our study reports the longest follow-up in patients undergoing treatment of osteochondral lesions of the femoral condyle using the TruFit system. The study results highlighted the safety and potential of this procedure, which offered a good clinical outcome with stable results at long-term follow-up although we found no correlations between the MRI and clinical results.

Future studies will have to develop biphasic scaffolds able to promote the regeneration of the subchondral bone, which is fundamental for obtaining a coating that is more similar to hyaline cartilage.

Author contributions All authors equally contributed to this paper, in terms of the conception and design of the study, literature review and analysis, drafting and critical revision and editing, and final approval of the final version.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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