The Knee xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

The Knee

Magnetic resonance evaluation of TruFit® plugs for the treatment of osteochondral lesions of the knee shows the poor characteristics of the repair tissue

Pablo Eduardo Gelber [a,b,*], Jorge Batista [c], Angélica Millan-Billi [b], Luciano Patthauer [c], Silvia Vera [c], Mireia Gomez-Masdeu [b], Juan Carlos Monllau [a,d]

[a] ICATME-Hospital Universitari Quirón-Dexeus, Universitat Autònoma de Barcelona, Sabino de Arana 5–19, 08028 Barcelona, Spain
[b] Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Sant Quintí 89, 08041 Barcelona, Spain
[c] Centro Artroscópico Jorge Batista S.A., Pueyrredón 2446 5° B, C1119ACU Ciudad Autónoma de Buenos Aires, Argentina
[d] Parc de Salut Mar, Universitat Autònoma de Barcelona, Passeig Marítim 25, 08003 Barcelona, Spain

ARTICLE INFO

Article history:
Received 31 December 2013
Received in revised form 22 April 2014
Accepted 27 April 2014
Available online xxxx

Keywords:
MOCART
Magnetic resonance imaging
Osteochondral lesion
Traumatic knee
TruFit plug

ABSTRACT

Background: Treatment of osteochondral lesions of the knee with synthetic scaffolds seems to offer a good surgical option preventing donor site morbidity. The TruFit® plug has frequently been shown to not properly incorporate into.
Objective: To evaluate the relationship between MRI findings and functional scores of patients with osteochondral lesions of the knee treated with TruFit®.
Methods: Patients were evaluated with MOCART score for magnetic resonance imaging assessment of the repair tissue. KOOS, SF-36 and VAS were used for clinical evaluation. Correlation between size of the treated chondral defect and functional scores was also analyzed.
Results: Fifty-seven patients with median follow-up of 44.8 months (range 24–73) were included. KOOS, SF-36 and VAS improved from a mean 58.5, 53.9 and 8.5 points to a mean 87.4, 86.6 and 1.2 at last follow-up ($p < 0.001$). Larger lesions showed less improvement in KOOS ($p = 0.04$) and SF-36 ($p = 0.029$). Median Tegner values were restored to preinjury situation (5, range 2–10). Mean MOCART score was 43.2 ± 16.1. Although the cartilage layer had good integration, it showed high heterogeneity and no filling of the subchondral bone layer.
Conclusions: TruFit® failed to restore the normal MRI aspect of the subchondral bone and lamina in most cases. The appearance of the chondral layer in MRI was partially re-established. This unfavourable MRI appearance did not adversely influence the patient's outcome in the short time and they restored their previous level of activity. There was an inverse linear relationship between the size of the lesion and the functional scores.
Level of evidence: Therapeutic case series; level 4.

1. Introduction

Focal chondral or osteochondral lesions are a frequent finding in knee arthroscopies, and most of them are related to a previous trauma [1]. The cartilage is an avascular, non-innervated tissue with a low mitotic turnover rate that makes its repair a particularly challenging therapeutic target. The morbidity associated with even small chondral defects is considerable. In fact, focal cartilage defects in the knee provide comparable KOOS pain scores to severe osteoarthritis [2] and hence numerous strategies have been pursued in order to regenerate the articular surface. When the subchondral bone plate is injured [3], the resultant full thickness osteochondral defect has been traditionally treated with osteochondral auto [4–7] (mosaicplasty) or allografts [8,9]. However, whilst the use of autograph is limited by the donor site size and its morbidity, the use of allografts carries the risk of disease transmission and it can also be difficult to obtain in some places. An alternative approach is to deliver a biomaterial scaffold that simplifies the surgical procedure and eliminates these limitations [10]. The use of bioabsorbable scaffolds for repair of chondral and osteochondral defects has recently been explored in laboratory and preclinical investigation [11,12] and has shown good clinical results in small defects at short-term evaluations [13,14]. One of them, the TruFit plug (Smith & Nephew, Andover, MA), has a biphasic structure to stimulate the two areas of coating defects: the articular cartilage and the subchondral bone. It is composed of polylactide-co-glycolide, calcium sulphate, and polyglycolide

* Corresponding author at: Department of Orthopaedic Surgery, Hospital de la Santa Creu i Sant Pau. Universitat Autònoma de Barcelona. Sant Quintí, 89-08041 Barcelona, Spain. Tel.: + 34 93 553 70 31; fax: + 34 93 553 70 33.
E-mail address: personal@drgelber.com (P.E. Gelber).

http://dx.doi.org/10.1016/j.knee.2014.04.013
0968-0160/

fibres and it is intended to serve as a scaffold for native marrow elements and matrix ingrowth. The manufacturer indicated its use for filling only bony voids or gaps and not for filling osteochondral defects. However, some studies have reported on the results with this device for repair of osteochondral defects.

Despite the reported short-term satisfactory clinical outcomes [13,14] in series with a low number of cases, controversy about its long-term utility persists due to some limitations in its proper incorporation in the host bone. Assessment of the articular cartilage with MRI has a high correlation to histologic changes [15,16]. Some studies have reported that the TruFit plug forms new tissue inside the plug with cartilage-like MRI characteristics [17,18]. Some others have reported cyst formation, giant cell reaction and early clinical failures [19,20]. On the other hand, some studies have reported that it can take more than 2 years for the TruFit implant to be incorporated and to provide good clinical results [21,22]. The controversial description of the imaging aspect in MRI might be attributed to the subjective parameters that have been commonly used in the previously referenced studies. It has also been described with different treatment modalities of osteochondral lesions that the clinical and radiographic outcomes are better when treating small rather than large chondral defects [4,5,7].

The modified Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) [20,23] has been described as an objective tool to assess the repaired osteochondral tissue in high-resolution MRI. Although the MOCART score has been used to assess the results of different treatment modalities for osteochondral lesions [6,20,21], it has not yet been used for the evaluation of TruFit implantations.

Thus, the main purpose of the study was to objectively evaluate the largest series of patients with osteochondral lesions of the knee treated with TruFit plugs at a minimum of two years after surgery in an MRI using the MOCART score. The relationship between the MRI findings and the functional scores was also an aim of this investigation. It was first hypothesized that the implant would fail in integration at the donor site. The second hypothesis was that the imaging aspect of the TruFit plug would have a correlation with the clinical outcomes. Finally, it was hypothesized that the size of the treated chondral lesions would have a clear impact on the functional and imaging outcomes.

2. Materials and methods

Patients who had been treated at two institutions with a TruFit implantation for focal full thickness articular cartilage defects with or without subchondral involvement of the knee were included in this study. Patients with a follow-up shorter than 24 months were excluded. The main inclusion criterion was a single symptomatic chondral lesion related to a trauma to the femoral condyles or to the femoral trochlea. All patients had a type III or IV lesion in the International Cartilage Research Society (ICRS) score system [24]. Concomitant surgeries were not considered as a basis for exclusion. On the other hand, patients with unaddressed axial malalignment, untreated instability, multiple (≥ 2) chondral defects including bipolar lesions on both sides of the joint or inflammatory arthritis were not considered for this study.

The clinical research ethics committee of the two involved institutions approved the study. All the patients signed informed consent to participate in the study as well as for the evaluation and publication of their results.

2.1. Clinical and functional evaluations

Clinical assessment was performed preoperatively and at the last follow-up. It included the Knee injury and Osteoarthritis Outcome Score (KOOS) [25], the Short-Form-36 (SF-36) Health Survey questionnaire [26] and the Tegner activity score. A ten-point Visual Analogue Scale (VAS) for pain was also used. Patient satisfaction was evaluated with a subjective score and graded as very satisfied (4 point), satisfied (3 points), neutral (2 points), somewhat dissatisfied (1 point) and not satisfied at all (0 points). The scores were filled in at the consultation upon the instruction of a single sports medicine surgeon, one at each of the two institutions, who were independent of the study.

2.2. Surgical procedure

In all cases the surgical procedure began with a knee arthroscopy to evaluate all the knee compartments for further lesions. The implantation of the TruFit plug(s) followed. This implantation was performed arthroscopically in those lesions localised to the femoral condyles. In those chondral defects of the femoral trochlea the TruFit were implanted using a mini-arthrotomy. The focal lesion was sized and prepared for TruFit implantation by drilling cylindrical holes in the subchondral bone of the diameter of the TruFit plug. The holes were drilled as orthogonal to the articular surface as possible (Fig. 1a and b). The decision to use multiple smaller plugs, a single large plug or a combination of plugs with different sizes was based on the size and characteristics of the lesion. In cases in which more than one plug was planned for implantation, the holes were drilled leaving a bone bridge of 1–2 mm. Debris from drilling was discarded and the bony wall of the drilled defect was checked for stability. After this, the TruFit delivery device (Trukor; Smith & Nephew, Andover, MA) was used to determine the depth of the defect and the implant length was trimmed accordingly at the bony site of the plug. The TruFit plug was finally implanted as tamped and flush with the articular surface as possible (Fig. 1c and d). When a concomitant injury needed to be addressed, it was always performed after the TruFit implantation but during the same surgery.

2.3. Postoperative protocol

The patients started with continuous passive motion the first day after surgery. Non-weight bearing knee motion was allowed as tolerated with the exception of those cases with a concomitant surgery that limited some degree of knee flexion (e.g. meniscal transplantation). After the first three weeks, the patients were trained to change from non- to full-weight bearing movement. From six weeks to four months, a gradual increase in knee activity and quadriceps muscle control was stimulated. After this, the patient was allowed to return to his previous sports activity as tolerated.

2.4. MRI evaluation

Magnetic resonance images with standard axial, coronal and parasagittal images were obtained for every patient at 24 months after surgery or at the last follow-up in those cases in which no MRI was performed at that point. All studies were performed with a 1.5-T superconducting magnet (Achieva; Philips; Netherland). A positioning device for the ankle was used to ensure uniformity. The standard knee protocol for each subject consists of the following sequence: Axial fast-spin-echo T2-weighted with fat saturation (TR: 2300 ms; TE: 30 ms; FA: 90°; ST: 3 mm; FOV: 20 cm), coronal fast spin-echo intermediate-weighted (TR: 2500 ms; TE: 30 ms; FA: 90°; ST: 3 mm; FOV: 18 cm), sagittal spin-echo intermediate-weighted with fat saturation (TR: 3500 ms; TE: 30 ms; FA: 90°; ST: 3 mm; FOV: 18 cm) and sagittal fast spin-echo T2-weighted (TR: 2500 ms; TE: 85 ms; FA: 90°; ST: 3 mm; FOV: 18 cm). The pixel size was set at 0.4 × 0.6 mm and the examination time was 3 min per sequence.

For assessment of the MRI, three of the authors, all of them orthopaedic surgeons, were instructed with the modified version of the MOCART score [20,23]. The MOCART score [27] was designed to objectively assess different parameters of treated osteochondral injuries. The MOCART score evaluates imaging aspects of the repair osteochondral tissue such as degree of filling of the defect, integration to the border zone, characteristics of the signal intensity and the state of the subchondral lamina. The recently reported modified version of this scale enhances the importance of some structural aspect of the repaired

Please cite this article as: Gelber PE, et al, Magnetic resonance evaluation of TruFit® plugs for the treatment of osteochondral lesions of the knee shows the poor characteristics of the repair tissue, Knee (2014), http://dx.doi.org/10.1016/j.knee.2014.04.013

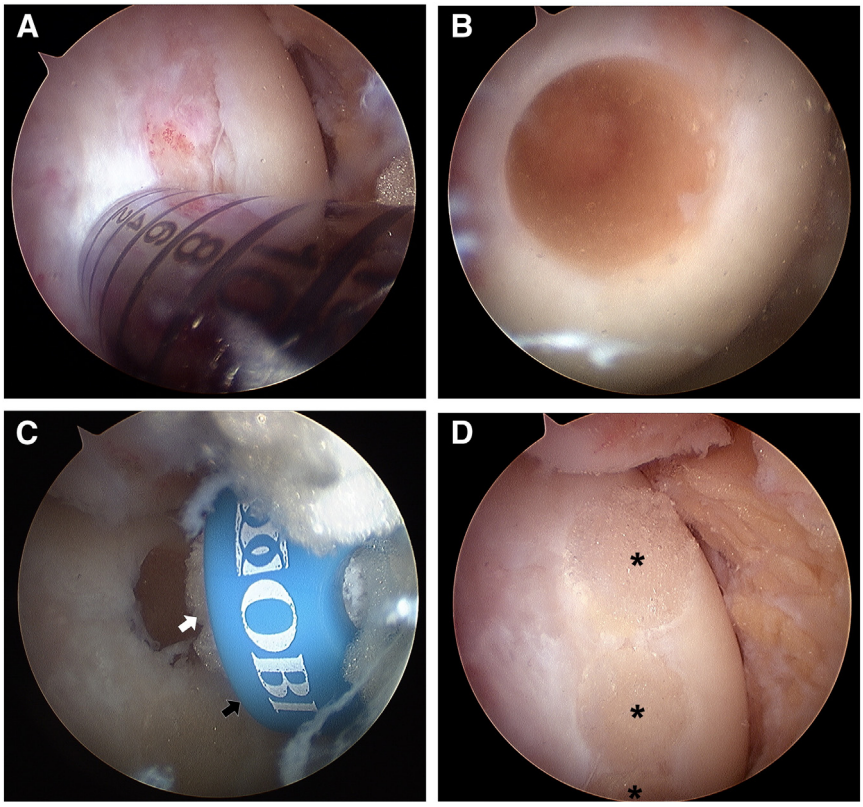

Fig. 1. Arthroscopic view of the TruFit implantation technique in a medial femoral condyle. (A) The host osteochondral defect is approached as orthogonally as possible to obtain a clean and perpendicular hole (B). (C) The TruFit plug (white arrow) is facing the defect inside the Trukor delivery device (black arrow). (D) Final aspect after implantation of three plugs (*).

tissue over the signal intensity characteristics [19]. The three authors performed the evaluation of the images that showed the implanted TruFit plug more clearly, usually in sagittal views, with the help of a printed guide with illustrations. Each of these three authors performed two assessments for every patient at a 30-day interval and the 6 resulting scores were then averaged. The frequencies of the specific findings of the nine different aspects evaluated with the MOCART score were also recorded.

2.5. Statistics

Statistical analyses were performed using SPSS 19 (SPSS, Chicago, IL).

Categorical variables are expressed as percentages and frequencies. Means and standard deviations as well as medians, minimums, and maximums were calculated for each continuous variable. The results were statistically analyzed and compared using a Student *t*-test for parametric data and contrasted using a Wilcoxon rank test. A p value of 0.05 was considered to be significant. The correlation between the size of the treated chondral defect and the studied variables were analyzed with the Pearson correlation coefficient. The results were contrasted with the Spearman's rank correlation coefficient for non-parametric variables.

Evaluation of the intraobserver and interobserver agreements with the use of the MOCART scale was performed using the Intraclass Correlation Coefficient (ICC). In those relevant cases, 95% confidence intervals (CIs) were calculated. Values ranged between 0 (poor) to 1 (very good) in terms of agreement.

3. Results

From February 2007 to March 2011, 57 patients who met the inclusion criteria received the synthetic reabsorbable TruFit graft in the knee at the two involved institutions. There were 51 men and six women, with a median age of 36 years (range, 25–53) and a mean body mass index of 25.49 ± 3 kg/m^2. In 30 patients (52.6%), the lesion was located in the right knee and in the left in the remaining 27 cases. The median follow-up was 44.8 months (range, 24–73). Most of the traumatic injuries were sustained during sport activities, most commonly soccer (n = 23), skiing (n = 11) and basketball (n = 2). In 14 cases, a vehicle accident was the cause of the lesion.

3.1. Surgical data

The chondral defect was of the medial femoral condyle in 22 cases (38.6%) and of the lateral femoral condyle in 15 cases (26.3%). In the remaining 20 patients (35.1%), the TruFit plugs were implanted in the femoral trochlea.

Although a single TruFit device was implanted in 42 of the patients (73.7%), two to four plugs were used in the remaining cases. Globally, the series averaged 1.4 plugs implanted. The sizes of the used TruFit plugs ranged from five to 11 mm.

Concomitant surgery was performed in 34 cases (59.6%). Twenty-two of the patients (38.6%) had an anterior cruciate ligament reconstruction performed in the same surgery. Other concomitant techniques were: three posterior cruciate ligament reconstructions, two partial meniscectomies, two medial meniscal transplantations, two varus osteotomies, one valgus osteotomy, one revision anterior cruciate ligament reconstruction, one meniscal repair, and one varus osteotomy plus lateral meniscal transplantation. The remaining 23 patients were treated with only TruFit implantations.

Complications occurred in only two patients. One patient with concomitant ACL reconstruction developed a deep vein thrombosis in the postoperative period. The other patient developed an acute septic arthritis, which was refractory to isolated arthroscopic lavage and required subsequent arthroscopic implant removal plus specific antibiotic therapy over a period of six weeks. An osteochondral allograft plug was finally implanted with no further complications.

3.2. Functional results

An overall improvement was obtained in terms of the KOOS and in the SF-36 questionnaire. The KOOS and the SF-36 improved from a preoperative value of 58.5 ± 7.2 and 53.9 ± 16.2 to 87.4 ± 7.3 and 86.6 ± 8.1 at the last follow-up ($p < 0.001$), respectively. There was also a decrease in pain as the VAS dropped from a mean preoperative value of 8.5 ± 2 to a mean postoperative value of 1.2 ± 1.5 ($p < 0.001$).

All but two patients were restored to the pre-injury Tegner activity level. The median was 5 (range 2–10) preoperatively as well as postoperatively ($p = 0.61$). No differences were observed when the preoperative and the last follow-up KOOS, SF-36 and VAS scores were compared between patients with isolated TruFit implantations versus those patients with concomitant surgeries ($p = 0.7$, $p = 0.49$, $p = 0.5$, respectively). Fifty-four out of 57

Please cite this article as: Gelber PE, et al, Magnetic resonance evaluation of TruFit® plugs for the treatment of osteochondral lesions of the knee shows the poor characteristics of the repair tissue, Knee (2014), http://dx.doi.org/10.1016/j.knee.2014.04.013

Table 1
Functional results.

	All-cases preoperative	Isolated-TruFit preoperative	TruFit + concomitant surgeries preoperative	All-cases final FU	Isolated-TruFit final FU	TruFit + concomitant surgeries final FU
KOOS	58.8 ± 7.2	55.2 ± 6.7	60.3 ± 8 p = 0.28	87.4 ± 7.3 p < 0.001	86.1 ± 5	88.8 ± 8.1 p = 0.7
SF-36	54 ± 16.2	50 ± 13.9	56 ± 18.1 p = 0.37	86.6 ± 8.1 p < 0.001	89.1 ± 10.3	85.5 ± 5.8 p = 0.49
VAS	8.5 ± 2	8.8 ± 1.4	8.4 ± 2.1 p = 0.54	1.2 ± 1.5 p < 0.001	1.8 ± 1.6	1 ± 0.5 p = 0.5
Tegner	5 (2–10)	5 (2–8)	5 (2–10) p = 0.34	5 (2–1) p = 0.61	4 (2–7)	5 (2–10) p = 0.19

patients were very satisfied (56.1%) or satisfied (38.6%) with the procedure, with a mean satisfaction score of 3.5 ± 0.3. The data of functional results is summarized in Table 1.

There was a lineal relationship between the size of the treated chondral lesion with the SF-36 questionnaire as well as with the KOOS. It was seen that the larger the lesion, the lower is the improvement in the KOOS (p = 0.04) and in the SF-36 questionnaire (p = 0.029). On the other hand, no correlation was observed between the size of the treated lesion and the VAS (p = 0.47) and Tegner (p = 0.68) scores.

3.3. MRI findings

In 42 patients, the MRI was performed 24 months after the surgery. In the remaining 15 cases, the MRI was done at the last follow-up (median 51 months; range 30–73 months). The MOCART score obtained a mean 43.2 ± 16.1. No relationship was observed between the size of the lesion and the MOCART score obtained (p = 0.23). Although complete filling of the cartilage was observed in only 8.7% of the cases, two thirds of the patients had a filling of the cartilage layer of at least 50% in relation to the adjacent cartilage. A complete integration of the graft was observed in most cases, but the surface and the intrasubstance MRI signal of the repair tissue were seldom fully restored. The subchondral lamina was not restored in 84.3% of the cases and subchondral bone changes (edema, granulation tissue, cyst, and sclerosis) were observed in every patient (Figs. 2 and 3). A summary of the frequencies of the 9 evaluated items of the MOCART scale can be seen in Table 2.

The calculated intraobserver variability of the MOCART score was very good, with an ICC of 0.83 (95% CI 0.71–0.91). The interobserver agreement was good, with an ICC of 0.72 (95% CI 0.44–0.86).

4. Discussion

The use of the TruFit® implant in this large series of posttraumatic osteochondral injuries of the knee failed to restore the MRI aspect of the subchondral layers of the lesion. In fact, the lowest scored aspects of the MOCART scale were related to the subchondral bone and subchondral lamina. Although the chondral layer in the MRI evaluation was somewhat better re-established, the first hypothesis was basically confirmed. This somewhat dichotomic MRI aspect did not adversely influence the patient's outcome in the short time and they were restored to their previous level of activity, which was in contrast with our second hypothesis. Conversely, the third hypothesis was partially confirmed, as the defect size did show a negative influence in the functional outcomes but did not in the MOCART score.

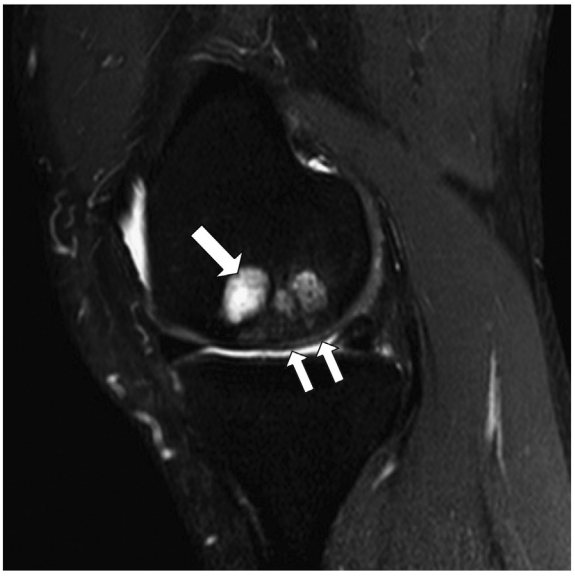

Fig. 2. Magnetic resonance imaging (1 T) of an osteochondral lesion of the medial femoral condyle treated with a TruFit plug 2 years before. Sagittal spin-echo intermediate-weighted with fat saturation (TR: 3500 ms; TE: 30 ms; FA: 90°; ST: 3 mm; FOV: 18 cm). Despite good scaffold integration and partial filling of the chondral layer (double arrow), subchondral bone changes were clearly seen (arrow) in this MRI sequence.

The TruFit implant is a 3D polymer scaffold that consists of poly (d,l-lactide co-glycolide) and is designed in a two layer structure. They were originally intended to fill the donor site in mosaicplasty and as such were authorized in United States by the FDA [14] (http://global.smith-nephew.com/us/product23822.htm).

In Europe it was approved in 2005 as a support matrix for connective tissue for the treatment of acute articular cartilage or osteochondral defects [14]. However, its commercialization was definitively stopped in the entire world at the beginning of 2013. The TruFit plug was originally designed to fully reabsorb over time, potentially allowing for complete filling of the defect with repair tissue [28]. Histology from a goat model showed osteointegration of the osseous layer of the TruFit implant with reabsorption of the surface layer being replaced by a hyaline-like cartilage with excellent bonding with the native cartilage [29].

Following these encouraging experimental reports, its clinical use was initiated showing satisfactory short-term results [8,14,21]. However, several studies have raised concerns about the imaging aspect of the TruFit implants. In the study performed by Baber et al. [19], the synthetic implants showed no evidence of bone ingrowth or ossification in CT scans evaluated at 13 months. Thus the authors concluded that this synthetic scaffold could not be recommended for primary repair of articular osteochondral defects. However, the best imaging technique for assessment of the articular cartilage is the MRI, which has shown a high correlation with the chondral histopathologic changes [15,16]. Interestingly, other studies that evaluated the MRI aspect of the TruFit plugs were in concordance with those findings [30,31]. In those investigations, the MRI scans were taken within the first year after implantation, even though it has been suggested that a delayed integration of the TruFit plugs can occur and it might take 2 years until its final outcome is obtained [21]. In addition, those studies evaluated the TruFit's MRI aspect mostly in T2-weighted sequences. However, the use of T2-weighted MRI is questionable for assessing the bony integration of the plugs during the first year as they usually show a high signal secondary to oedema within the implant as a consequence of the normal resorption of the polylactic acid/PLG scaffold [13]. Conversely, MRI scans have shown good integration of the TruFit plugs in other studies [14–18]. However, no objective and validated method was used to assess the TruFit implantation in any of these referenced studies [22]. The MOCART score used in this investigation is an objective and validated method to assess the repaired osteochondral tissue in high-resolution MRI [22] although rarely used for evaluation of TruFit implantations. The results were more in concordance with those showing inadequate incorporation in the host osteochondral tissue. Whilst the deep layer of the TruFit failed

Please cite this article as: Gelber PE, et al, Magnetic resonance evaluation of TruFit® plugs for the treatment of osteochondral lesions of the knee shows the poor characteristics of the repair tissue, Knee (2014), http://dx.doi.org/10.1016/j.knee.2014.04.013

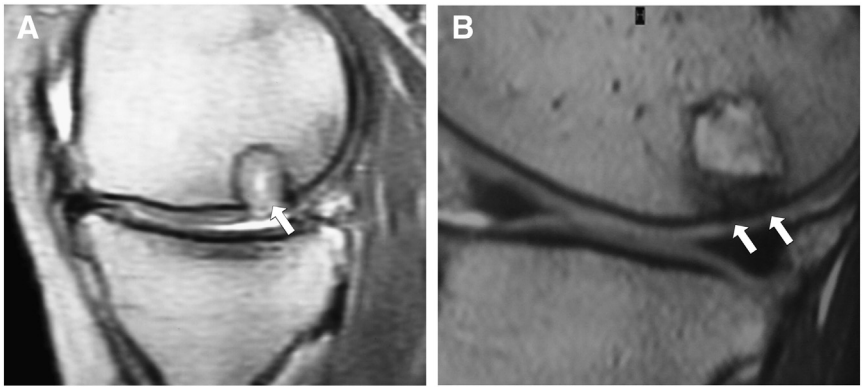

Fig. 3. The subchondral lamina was rarely restored with the TruFit plugs. (A) In 48 cases, the subchondral lamina (arrow) was not restored, as can be clearly seen in this MRI view. (B) In only 9 cases, the subchondral lamina (double arrow) was observed in continuity with the host tissue.

to stimulate bone formation, the cartilage layer was more favourably re-established. However, this cartilage layer showed some degree of fibrillation, only partial filling of the defect and incomplete integration to the border zone of the host cartilage. The low mean MOCART score obtained was considerably lower than those reported after other treatment modalities [6,20,32]. This suggests that globally, the TruFit plugs are not a good option to obtain a refilling of an osteochondral defect with high-quality newly formed tissue. Surprisingly, the low results of the MRI assessment showed no relationship with the favourably clinical short-term outcomes. This is in concordance with a recent meta-analysis that concluded that morphological MRI is not reliable in predicting clinical outcomes after cartilage repair [33].

Table 2
Frequencies of the 9 variables of the MOCART score.

Variable	Number of patients
Degree of repair and filling of the defect	
Complete (on a level with adjacent cartilage)	5 (8.7%)
Hypertrophy (over the level of the adjacent cartilage)	18 (31.6%)
Incomplete (under the level of the adjacent cartilage; underfilling)	
>50% of the adjacent cartilage	17 (29.8%)
<50% of the adjacent cartilage	14 (24.5%)
Subchondral bone exposed (complete delamination/dislocation and/or loose body)	3 (5.4%)
Integration to border zone	
Complete (complete integration with adjacent cartilage)	30 (52.6%)
Incomplete (incomplete integration with adjacent cartilage)	
Demarcating border visible "split like"	10 (17.7%)
Defect visible	
<50% of the length of the repaired tissue	12 (21.0%)
>50% of the length of the repaired tissue	5 (8.7%)
Surface of the repair tissue	
Surface intact (lamina splendens intact)	3 (5.2%)
Surface damaged (fibrillations, fissures and ulcerations)	
<50% of repair tissue depth	24 (42.2%)
>50% of repair tissue depth or total degeneration	30 (52.6%)
Structure of the repair tissue	
Homogeneous	4 (7.0%)
Inhomogeneous or cleft formation	53 (93.0%)
Signal intensity of the repair tissue	
Dual T2 FSE	
Isointense	22 (38.6%)
Moderately hyperintense	31 (54.4%)
Markedly hyperintense	4 (7.0%)
D-GE-FS	
Isointense	2 (3.5%)
Moderately hyperintense	45 (78.9)
Markedly hyperintense	10 (17.6%)
Subchondral lamina	
Intact	9 (15.7%)
Not intact	48 (84.3%)
Subchondral bone	
Intact	0
Edema, granulation tissue, cysts, sclerosis	57 (100%)
Adhesions	
No	45 (79.0%)
Yes	12 (21.0%)
Effusion, synovitis	
No	45 (79.0%)
Yes	12 (21.0%)

There is general consensus that the clinical outcome of the mosaicplasty technique is related to the size of the defect [5,7]. Good results have been reported in small lesions, but large defects are associated with fibrous tissue formation, fissuring between the graft and the host tissues and poor clinical results, not to mention the limitation to obtain sufficient autograft plugs [4,5,7]. Conversely, no relationship was observed between the size of the filled defect and the MOCART score in this investigation. However, it was observed that when the lesion was larger, there was less improvement in the KOOS and in the SF-36 questionnaire. Thus, the third hypothesis was only partially confirmed.

This study is the largest series ever reported on the use of TruFit plugs. The good short-term results observed were in concordance with the clinical results observed in other osteochondral treatment modalities [5,7,8,27,34]. However, the long-term effect of the deficient radiological findings remains uncertain and it needs assessment of the radiological and clinical outcomes at a considerable longer follow up.

The study was mainly limited in the lack of any randomization or control group. A comparison with a conservatively treated group of patients, or better with another treatment modality might have allowed for arriving at much stronger conclusions. However, the main purpose of the study was to evaluate the MRI aspect of the TruFit implant with the MOCART score for the first time and to relate it to the posttraumatic osteochondral defect size and to the clinical outcomes. Another important limitation was that the study group included patients undergoing isolated TruFit implantation as well as patients with concomitant surgeries like ACL reconstructions. This is an obvious limitation that makes a more accurate assessment of the device's implantation difficult because combined procedures introduce a degree of performance bias into the results. The short-term follow-up was another relevant weakness, as the functional and radiologic effect of the observed partial reabsorption of the TruFit plugs could not be elucidated. Also, the modified MOCART score is not easy to use [18] and the fact that three orthopaedic surgeons performed the MRI evaluation might add some bias attempting to correlate MRI with the clinical outcomes. However, the calculated intra and interobserver variabilities were considered good and very good respectively. Finally, the fact that not all the MRI were performed at the same time after surgery might alter their evaluation as it is known that the TruFit plugs need time to obtain their final aspect.

Please cite this article as: Gelber PE, et al, Magnetic resonance evaluation of TruFit® plugs for the treatment of osteochondral lesions of the knee shows the poor characteristics of the repair tissue, Knee (2014), http://dx.doi.org/10.1016/j.knee.2014.04.013

However, no MRI was taken before 24 months, which is considered as the time needed to heal completely [18,21].

Although these weaknesses did not allow for the verification of whether there is any advantage to TruFit implantation in the knee over other treatment modality, the results of this study showed that the device failed to properly re-establish the normal osteochondral architecture. Considering the unknown significance of poor integration into the host bone and despite the low complication rate, the technique cannot be recommended as a first-choice option for treatment of post-traumatic osteochondral defects of the knee.

In conclusion, the use of the TruFit® implant to treat osteochondral lesions of the knee failed to restore the normal MRI aspect of the subchondral bone and the subchondral lamina in most cases. The aspect of the chondral layer in MRI was partially re-established. This unfavourable MRI aspect did not adversely influence the patient's outcome in the short time and they restored their previous level of activity. There was an inverse linear relationship between the size of the lesion and the functional scores. The long-term effect of this MRI aspect remains uncertain.

Acknowledgements

We are grateful to Ignaci Gich for assisting in the statistical analysis. We also thank Eric Goode for his help in correcting the manuscript. This study paper was partially funded by a CICYT grant (MAT2010-21611-C03-02). We have not received any other funding or sponsorship for this study, including funds or materials (e.g., surgical supplies, specimens).

References

[1] Hjelle K, Solheim E, Strand T, Muri R, Brittberg M. Articular cartilage defects in 1000 knee arthroscopies. Arthroscopy 2002;18:730–4.
[2] Heir S, Nerhus TK, Rotterud JH, Loken S, Ekeland A, Engebretsen L, et al. Focal cartilage defects in the knee impair quality of life as much as severe osteoarthritis. Am J Sports Med 2010;38:231–7.
[3] Gomoll AH, Madry H, Knutsen G, van Dijk N, Seil R, et al. The subchondral bone in articular cartilage repair: current problems in the surgical management. Knee Surg Sports Traumatol Arthrosc 2010;18:434–47.
[4] Hangody L, Feczkó P, Bartha L, Bodó G, Kish G. Mosaicplasty for the treatment of articular defects of the knee and ankle. Clin Orthop Relat Res 2001;391:328–37 [Suppl.].
[5] Solheim E, Hegna J, Oyen J, Harlem T, Strand T. Results at 10 to 14 years after osteochondral autografting (mosaicplasty) in articular cartilage defects in the knee. Knee 2013;20:287–90.
[6] Tetta C, Busacca M, Moio A, Rinaldi R, Delcogliano M, Kon E, et al. Knee osteochondral autologous transplantation: long-term MR findings and clinical correlations. Eur J Radiol 2010;76:111–23.
[7] Wang CJ. Treatment of focal articular cartilage lesions of the knee with autogenous osteochondral grafts: a 2- to 4-year follow-up study. Arch Orthop Trauma Surg 2002;122:169–72.
[8] Chahal J, Gross AE, Gross C, Mall N, Dwyer T, Chahal A, et al. Outcomes of osteochondral allograft transplantation in the knee. Arthroscopy 2013;29:575–88.
[9] Giorgini A, Donati L, Cevolanib Frisonib T, Zambianchi F, Catani F. Osteochondral allograft is a suitable alternative for wide cartilage defect in the knee. Injury 2013;44(S1):16–20.
[10] Vaquero J, Forriol F. Knee chondral injuries: clinical treatment strategies and experimental models. Injury 2012;43:694–705.
[11] Bedi A, Williams III RJ. Cartilage resurfacing using synthetic composite plugs. Tech Knee Surg 2009;8:29–36.
[12] Getgood AMJ, Kew SJ, Brooks R, Aberman H, Simon T. Evaluation of early-stage osteochondral defect repair using a biphasic scaffold based on a collagen-glycosaminoglycan biopolymer in a caprine model. Knee 2012;19:422–30.
[13] Melton JTK, Wilson AJ, Chapman-Sheat P, Cossey AJ. Trufit CB(r) bone plug: chondral repair, scaffold design, surgical technique and early experiences. Expert Rev Med Devices 2010;7:333–41.
[14] Williams RJ, Gamradt SC. Articular cartilage repair using a resorbable matrix scaffold. Instr Course Lect 2008;57:563–71.
[15] Gahunia HK, Babyn P, Lemaire C, Kessler MJ, Pritzker KP. Osteoarthritis staging: comparison between magnetic resonance imaging, gross pathology and histopathology in the rhesus macaque. Osteoarthritis Cartilage 1995;3:169–80.
[16] Link TM, Sell CA, Masi JN, Phan C, Newitt D, Lu Y, et al. 3.0 vs. 1.5 T MRI in the detection of focal cartilage pathology—ROC analysis in an experimental model. Osteoarthritis Cartilage 2006;14:63–70.
[17] Bekkers JE, Bartels LW, Vincken KL, Dhert WJ, Creemers LB, Saris DB. Articular cartilage evaluation after TruFit plug implantation analysed by delayed gadolinium-enhanced MRI of cartilage (dGEMRIC). Am J Sports Med 2013;41:1290–5.
[18] Joshi N, Reverte-Vinaixa M, Díaz-Ferreiro EW, Dominguez-Oronoz R. Synthetic resorbable scaffolds for the treatment of isolated patellofemoral cartilage defects in young patients: magnetic resonance imaging and clinical evaluation. Am J Sports Med 2012;40:1289–95.
[19] Barber FA, Dockery WD. A computed tomography scan assessment of synthetic multiphase polymer scaffolds used for osteochondral defect repair. Arthroscopy 2011;27:60–4.
[20] Dhollander AA, Huysse WC, Verdonk PC, Verstraete KL, Verdonk R, Verbruggen G, et al. MRI evaluation of a new scaffold-based allogenic chondrocyte implantation for cartilage repair. Eur J Radiol 2010;75:72–81.
[21] Carmont MR, Carey-Smith R, Saithna A, Dhillon M, Thompson P, Spalding T. Delayed incorporation of a TruFit plug: perseverance is recommended. Arthroscopy 2009;25:810–4.
[22] Hindle P, Hendry JL, Keating JF, Biant LC. Autologous osteochondral mosaicplasty or Trufit™ plugs for cartilage repair. Knee Surg Sports Traumatol Arthrosc April 16 2013. http://dx.doi.org/10.1007/s00167-013-2493-0 [Epub ahead of print].
[23] Marlovits S, Striessnig G, Resinger CT, Aldrian SM, Vecsei V, Imhof H, et al. Definition of pertinent parameters for the evaluation of articular cartilage repair tissue with high resolution magnetic resonance imaging. Eur J Radiol 2004;52:310–9.
[24] Brittberg M, Winalski CS. Evaluation of cartilage injuries and repair. J Bone Joint Surg Am 2003;85(Suppl. 2):58–69.
[25] Windt TS, Raijmakers NJ, Dhert WJ, Saris DB. Validation of the knee injury and osteoarthritis outcome score (KOOS) for the treatment of focal cartilage lesions. Osteoarthritis Cartilage 2009;17:1434–9.
[26] Ware Jr JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–83.
[27] Marcacci M, Filardo G, Kon E. Treatment of cartilage lesions: what works and why? Injury 2013;44(S1):S11–5.
[28] Hettrich CM, Crawford D, Rodeo SA. Cartilage repair: third-generation cell-based technologies—basic science, surgical techniques, clinical outcomes. Sports Med Arthrosc 2008;16:230–5.
[29] Niederauer GG, Slivka MA, Leatherbury NC, Korvick DL, Harroff HH, Ehler WC, et al. Evaluation of multiphase implants for repair of focal osteochondral defects in goats. Biomaterials 2000;21:2561–74.
[30] Dhollander AA, Liekens K, Almqvist KF, Verdonk R, Lambrecht S, Elewaut D, et al. A pilot study of the use of an osteochondral scaffold plug for cartilage repair in the knee and how to deal with early clinical failures. Arthroscopy 2012;28:225–33.
[31] Sgaglione NA, Florence AS. Bone graft substitute plug failure with giant cell reaction in the treatment of osteochondral lesions of the distal femur: a report of 2 cases with operative revision. Arthroscopy 2009;25:815–9.
[32] Filardo G, Kon E, Di Martino A, Busacca M, Altadonna G, Marcacci M. Treatment of knee osteochondritis dissecans with a cell-free biomimetic osteochondral scaffold. Clinical and imaging evaluation at 2-year follow-up. Am J Sports Med 2013;41:1786–93.
[33] de Windt TS, Welsch GH, Brittberg M, Vonk LA, Marlovits S, Trattnig S, et al. Is magnetic resonance imaging reliable in predicting clinical outcome after articular cartilage repair of the knee? A systematic review and meta-analysis. Am J Sports Med 2013;41:1695–702.
[34] Dozin B, Malpeli M, Cancedda R, Bruzzi P, Calcagno S, Molfetta L, et al. Comparative evaluation of autologous chondrocyte implantation and mosaicplasty: a multicentered randomized clinical trial. Clin J Sport Med 2005;15:220–6.

Please cite this article as: Gelber PE, et al, Magnetic resonance evaluation of TruFit® plugs for the treatment of osteochondral lesions of the knee shows the poor characteristics of the repair tissue, Knee (2014), http://dx.doi.org/10.1016/j.knee.2014.04.013