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Clinical and radiological outcome for Trufit Plug in the treatment of chondral and osteochondral lesions at a minimum of 2 years

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ABSTRACT

The aim of this study was to evaluate the functional and radiological outcome of TruFit plugs. We retrospectively reviewed 10 patients who underwent treatment for a symptomatic chondral/osteochondral lesion using one or more Trufit Plugs. Full incorporation of the bony portion of the plug occurred in only 3 and partial incorporation in 7 lesions. The remaining portion of these 7 lesions looked cystic on MRI. The significance of this cystic change is not clear. Though all 10 patients showed some improvement on the IKDC scoring system but the amount of the improvement was small.

1. Introduction

The treatment of chondral knee injuries remains a challenge for the orthopaedic surgeon, mainly owing to the characteristics of the cartilage tissue, which promote low potential for regeneration. Chondral lesions can be caused by metabolic stimulation, or by genetic, vascular and traumatic events, and are classified according to the size and thickness of the affected cartilage.

Despite the development and research in osteoarthritis and cartilage regeneration, currently there is no consensus as to the best treatment option for chondral damage in young patients.[1] The surgical techniques used for the treatment of partial thickness defects are Debridement and Ablation. These techniques aim to improve symptoms, since they do not restore normal structure and function of the cartilage. For full-thickness defects (osteochondral lesion), available treatments are Abrasion, Drilling, Microfracture, Osteochondral Autologous and Allogeneic Transplantation, and biological techniques such as the use of Autologous Chondrocyte Transplantation and stem cells.

Mosaicplasty is an accepted technique for the treatment of localized full-thickness articular cartilage defects in the weight-bearing areas of the knee. However the size of area that can be treated is limited by graft availability and donor site morbidity.[2] A synthetic osteochondral plug, if successful, has the potential to overcome some of these issues.

The Trufit plug, a bi-layer scaffold implant, (Smith&Nephew) (Picture 1) has been developed to treat chondral and osteochondral defects. This synthetic plug is designed to be inserted into the articular surface providing a scaffold to encourage chondrocyte regeneration to repair such defects.[3] The aim of this study is to assess the 2 year MRI appearance of a series of Trufit plugs, used in the knee joint in order to evaluate their incorporation. It has previously been recognized that the plug can take up to 24 months to incorporate.[3]

2. Method

2.1. Patient selection

Between December 2007 and August 2009, 10 patients who underwent treatment of 12 symptomatic chondral or osteochondral lesions using Trufit Plugs at our institution were evaluated. These patients had not previously undergone any other surgical procedure for their osteochondral or chondral lesion. Patients with history of inflammatory arthritis, infective arthritis and any major trauma to the knee were excluded. Patients below 18 years and above 50 years of age were also excluded. Of the 10 patients, 7 were male and 3 were female with mean age of 35.2 years (range 22–49).

2.2. Details of the lesions and TruFit plugs used

There were 12 lesions treated with one or 2 plugs used for each lesion. A total of 14 Trufit plugs were used. The plug sizes used were; 3 × 5 mm, 2 × 7 mm, 5 × 9 mm and 4 × 11 mm10 lesions were in the medial femoral condyle with the remaining 2 lesions in the lateral femoral condyle. 1 or 2 plugs were used per lesion. 9 of the 12 lesions were chondral defects. The other 3 lesions were osteochondral. 1

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Picture 1. Arthroscopic view showing Trufit plug insertion into the femoral chondral defect.

patient also underwent ACL reconstruction and 2 patients had a concomitant meniscal repair.

2.3. Outcome measures

At a minimum of 2 years, MRI scan was performed with a 1.5 T MRI scanner with PD fat sat sagittal, coronal, axial and PD sagittal sequence. An independent Consultant Musculoskeletal Radiologist reviewed the scan for evidence of incorporation according to the descriptive modified magnetic resonance observation of cartilage repair tissue (MOCART) Scoring system.[4] This system was devised to systematically record only those observations that can most accurately and reproducibly be determined and to avoid ambiguous terms. It has been shown to be reliable and to have excellent intra-observer reproducibility.[4] All patients were prospectively scored with IKDC before and 2 years after the operation.

2.4. Statistical analysis

The nonparametric Wilcoxon signed rank test was used to determine differences between the data of pre-operative and follow-up IKDC scores.

3. Results

Table 1 summarizes the result of the MOCART scoring. 8 of 12 lesions showed congruent articular cartilage cover with a surface with a similar thickness and signal to the surrounding articular cartilage and reconstitution of the subchondral bone plate (Pictures 2 and 3). 2 lesions had a thicker congruent articular surface with a similar signal to the surrounding articular cartilage without restoration of the subchondral bone plate. 2 lesions showed no graft incorporation at all and were filled with granulation tissue (Picture 6). Full incorporation of the bony portion of the plug had occurred in only 3 lesions with partial incorporation in 7 lesions. The remaining portion of these 7 lesions looked cystic on MRI (Pictures 4 and 5).

All 10 patients showed improvement on the IKDC scoring system. The overall mean IKDC score improved from 41.8 preoperatively to 57.4 at two years. Although this improvement was statistically significant (Wilcoxon signed rank test $p = 0.028$), the amount of clinical improvement was small.

Table 1
MOCART scoring on MRI scan at 2years.

Variable	No. of patients (12 lesions in 10 patients)
A − Degree of defect repair and defect filling	
1- Complete (on level with adjacent cartilage)	10
2- Hypertrophy (over the level of adjacent cartilage)	00
3- Incomplete (under the level of adjacent cartilage)	00
3a − > 50% of adjacent cartilage	00
3b − < 50% of adjacent cartilage	00
4- Subchondral bone exposed	02
B- Integration to border zone	
1- Complete (complete integration with adjacent cartilage)	10
2- Incomplete	00
3- Demarcating border visible (split like)	00
4a- < 50% of the length of the repair tissue	00
4b- > 50% of the length of repair tissue	02
C- Surface of the repair tissue	
1- Surface intact	10
2- Surface damaged (fibrillations, fissures and ulcerations)	00
2a- < 50% of repair tissue depth	00
2b- > 50% of repair tissue depth or total degeneration	02
D − Structure of the repair tissue	
1- Homogeneous	10
2- Inhomogeneous or cleft formation	02
E- Signal intensity of the repair tissue	
1- Isointense	10
2- Moderately hyperintense	00
3- Markedly hyperintense	02
F- Subchondral lamina	
1- Intact	08
2- Not intact	04
G- Subchondral bone	
1- Intact	01
2- Oedema, granulation tissue, cysts, sclerosis	
2a- Cyst	07
2b- Granulation tissue	02
2c- Oedema and sclerosis	02
H- Adhesions	
1- No	12
2- Yes	00
I- Effusion	
1- No effusion	07
2- Effusion	05

4. Discussion

The Trufit plug is a biphasic construct attempting to reproduce the osteochondral unit. Each layer of this synthetic graft is made from a poly-lactide-co-glycolide copolymer. The 2 layers are designed to allow the ingrowth of bone and articular cartilage respectively. The 2 layers have differing porosities with the bone portion containing calcium sulphate and the cartilage layer containing a surfactant. The plug is designed to act as a wick bringing blood from the subchondral bone to the articular surface of the plug to stimulate healing of the defect.

As the plug is synthetic, there is no donor site morbidity, no risk of transmitted infection and no need to culture cells or for 2 surgeries. However, it is recognized that the plugs often take a long time to fill in (up to 2 years)[3] and in 2/12 cases in this series there was no evidence of any healing even after 2 years. In order to insert the plug, a core of bone has to be removed, so if the plug does not heal, a larger bone and