SUBSPECIALTY PROCEDURES

CELL-FREE BIOMIMETIC OSTEOCHONDRAL SCAFFOLD

Implantation Technique

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Abstract

Background: This 1-stage cell-free scaffold-based technique is indicated for the treatment of full-thickness chondral and osteochondral lesions in the knee, regardless of the lesion size. The aim of the procedure is restoration of the osteochondral unit while avoiding the issues of donor site morbidity and those related to cell management.

Description: The surgical technique is simple and can be performed as a 1-stage procedure. The lesion site is visualized through a standard knee medial or lateral parapatellar arthrotomy. The defect is prepared by excision of the injured cartilage and subchondral bone to ensure adequate bone-marrow blood flow and to create a squared, regularly shaped lodging for the device. The scaffold is then shaped and sized according to the dimensions of the prepared lesion site and implanted by press-fitting or with addition of fibrin glue. Finally, the complete range of motion is tested to assess the stability of the implant before and after releasing the tourniquet.

Alternatives: Nonsurgical alternatives have been reported to include non-pharmacological modalities, such as dietary supplements, and pharmacological therapies as well as physical therapies and novel biological procedures involving injections of various substances¹. There are several surgical alternatives, including among others microfracture, mosaicplasty, osteochondral allograft, and total knee arthroplasty, depending primarily on the disease stage and etiology as well as the specific patient conditions^{2,3}.

Rationale: This cell-free device is engineered in 3 layers to mimic the structure and composition of the osteochondral unit in order to guide resident cells toward an ordered regeneration of both bone and cartilage layers, providing a better quality of regenerated articular surface. The treatment approach offers a useful alternative to current procedures in the field of osteochondral lesions, in particular for young and middle-aged patients affected by symptomatic defects in which subchondral bone is likely involved. The advantages of this scaffold include the ability to perform a 1-stage surgical procedure, off-the-shelf availability, a straightforward surgical technique, and lower costs compared

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with cell-based regenerative options. Furthermore, in contrast to some more traditional treatments, it can be used for large lesions.

Introduction

This cell-free scaffold-based technique for the treatment of deep chondral and osteochondral lesions in the knee is a simple fast procedure, completed in 1 operative stage (as opposed to alternative techniques such as autologous chondrocyte transplantation that require 2 stages), which provided satisfactory clinical outcomes with no donor site morbidity or lesion-size limitation.

Indications & Contraindications

Indications

- Symptomatic full-thickness chondral and osteochondral defects (ICRS [International Cartilage Repair Society] grades III and IV) of the knee joint.
- Traumatic lesions, degenerative lesions, and osteochondritis dissecans.
- Defects ranging from 2 to 10 cm².
- Patient age between 15 and 60 years. (Even if there is no precise age cutoff for this scaffold, it is known that, as is the case for bone-marrow stimulating techniques, a high regenerative potential is needed.)
- A body mass index (BMI) of ≤ 30 kg/m² is preferable.

Contraindications

- Severe osteoarthritis.
- Untreated comorbidities such as malalignment or ligament instability.
- Rheumatic and autoimmune diseases.
- Infection.
- Obesity.

Step-by-Step Description of Procedure (Video 1)

Video 1 Case simulation with patient positioning, skin incision, identification and preparation of the defect, sizing and fixation of the scaffold, stability testing, and tourniquet removal. (Video provided by Fin-Ceramica Faenza and modified by the authors.)

Step 1: Positioning of Patient and Incision

With the patient supine, without elevation of the hip, incise the skin, lateral or medial to the patella, for approximately 6 to 8 cm.

- Perform the surgery with the patient under spinal or limb anesthesia.
- Position the patient supine on a straight table, without elevating the hip.
- Apply a tourniquet to the proximal part of the thigh.
- Identify the medial or lateral patellar edge on the basis of the lesion site.
- Incise the skin, lateral or medial to the patella, for approximately 6 to 8 cm, as needed (starting above the patella and ending approximately 1 cm proximal to the joint line). The incision should be parallel to the quadriceps tendon and patellar tendon.
- Expose the joint capsule by subcutaneous dissection.
- Perform an arthrotomy of the same length as the skin incision.

Step 2: Identification and Debridement of the Osteochondral Lesion, and Preparation of the Defect

After identifying the lesion, create a 6 to 7-mm-deep area with a flat bottom and stable perpendicular sides to house the scaffold.

- Identify the lesion with guidance by magnetic resonance imaging (MRI) and confirm it by intraoperative visual evaluation (Fig. 1).
- Prepare the lesion by removing the injured cartilage and the sclerotic subchondral bone using a scalpel and an osteotome. Do not use a high-speed burr.
- Create an area of approximately 6 to 7 mm in depth to house the scaffold (MaioRegen; Finceramica) (Fig. 2). The bottom should be flat and regular, and the defect sides should be stable and nearly perpendicular (Figs. 3 and 4).
- Measure the lodging size accurately.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1 The osteochondral lesion is identified and exposed.

Fig. 2 A 6 to 7-mm-deep lodging with stable shoulders is created at the lesion site, using a surgical osteotome, for placement of the implant.

Fig. 3 A well-defined and regular lodging area with perpendicular sides and an even, flat bed should be obtained.

Fig. 4 The area is carefully cleaned of debris and sclerotic bone before applying the scaffold.

Step 3: Scaffold Sizing

Cut the smooth cartilage-like layer of the scaffold with a scalpel and the subchondral bone-like layer with surgical scissors.

- Template the defect by using an aluminum foil or, if preferred, a surgical ruler (Fig. 5).
- Cut the smooth cartilage-like layer of the scaffold, preferably with a scalpel, according to the dimension and shape of the prepared lesion site.
- Surgical scissors are preferable to cut the subchondral bone layer.

Fig. 5

Fig. 5 The scaffold is prepared, using an aluminum foil or surgical ruler, to obtain a size and shape of the graft that exactly match the prepared lesion area. The use of a scalpel is advisable to cut the superficial cartilage-like layer, while scissors are more appropriate to cut the bone-like layer.

Step 4: Fixation

Press-fit the scaffold into the lodging area and apply fibrin glue before and after insertion to obtain additional stability.

- Identify the bottom layer of the scaffold by its “bumps” (rough surface) for correct orientation (Fig. 6).
- Insert the scaffold with a gentle press-fit technique, making sure that the bottom layer is in contact with the bone floor (Fig. 7).
- Apply fibrin glue on the perimeter interface between the scaffold and host bone and on the superficial layer to obtain additional stability⁴.

Fig. 6

Fig. 7

Fig. 6 The scaffold consists of 3 layers. The top (cartilage-like) layer is smooth while the bottom (bone-like) layer is rough. When applying the scaffold, the surgeon must pay attention to placing the smooth collagen (cartilage-like) layer at the top side, facing the joint. HA = hydroxyapatite. (Reproduced with permission from Fin-Ceramica Faenza.)

Fig. 7 The scaffold is press-fit into the defined area. Use of fibrin glue on the upper/perimeter area of the scaffold is advised to improve stability.

Step 5: Stability Test and Tourniquet Removal

Perform cyclic bending of the knee to assess the implant stability.

- Before and after tourniquet removal, perform cyclic bending of the knee to assess the implant stability (Fig. 8).
- Suture the knee capsule as well as the subcutaneous tissue and the skin.

Fig. 8

Fig. 8 The tourniquet is removed in order to allow the scaffold to absorb blood and be colonized by bone-marrow-derived progenitor cells.

Step 6: Postoperative Care

Start range-of-motion, isometric, and isotonic exercises on day 1; gradual progressive weight-bearing at 3 to 4 weeks; and full weight-bearing at 6 to 8 weeks.

- Active and passive ranges of motion of the knee are allowed starting from day 1 after the operation.
- Early isometric and isotonic exercises can be performed starting from day 1; weight-bearing is not allowed.
- After approximately 3 to 4 weeks, gradual progressive weight-bearing is permitted.
- The patient can progress to full weight-bearing by 6 to 8 weeks.

Results

This osteochondral scaffold showed promising results in preclinical tests in animal models, which were subsequently confirmed by the clinical findings in patients treated with this technique.

A first pilot study showed promising clinical improvement at 24 months postoperatively, which was faster in patients with higher preinjury activity levels^{5,6}. Another study, with 2 years of follow-up, showed positive clinical results for the treatment of osteochondritis dissecans⁷. Short-term improvement was confirmed in a wider study, of 79 patients treated for defects of the femoral condyles or trochlea. In that series, treatment of degenerative lesions had significantly worse results than treatment of traumatic ones or osteochondritis dissecans⁸. However, positive findings were reported even in small series of patients treated for early⁹ or unicompartmental¹⁰ osteoarthritis in whom the scaffold was implanted concurrently with combined procedures to address multiple comorbidities. A specific study confirmed the benefits of the osteochondral approach for challenging conditions—i.e., “complex” knee lesions—by showing higher clinical scores compared with those following a chondral approach¹¹. Other authors reported good clinical results for large defects¹² or explored different indications for this scaffold, such as spontaneous osteonecrosis of the knee¹³. These satisfactory clinical findings confirmed the versatility of this procedure for various conditions affecting the whole osteochondral unit. The results of using the technique for patellar defects were good but less favorable, with some abnormal MRI findings¹⁴.

We are aware of only 2 studies of the outcomes of this technique at midterm follow-up, and both confirmed stable and satisfactory clinical scores up to 5 years postoperatively^{15,16}. However, imaging of the graft has shown less positive evidence. In fact, despite good integration of the implant even at early postoperative evaluation⁶, most authors

observed abnormalities in the graft structure and limited bone regeneration^{6,14-17}; these findings improved but were still seen at midterm follow-up^{15,16}. These issues do not seem to affect the clinical outcome^{15,16}.

Pitfalls & Challenges

- This 1-stage scaffold-based technique is a reliable procedure for the treatment of chondral and osteochondral lesions in the knee and provides good results over time if there are no other abnormal conditions. In cases of varus or valgus deformation of the knee or ligament instability, osteotomies or ligament reconstructions have to be considered.
- An arthrotomy is performed to implant this material so care must be taken to avoid an iatrogenic joint lesion.
- Stable defect shoulders, important for implant stability, can be challenging to obtain in locations such as the edge of the condyle. Implant fit must be checked after tourniquet removal since the scaffold size slightly increases when blood flow is restored.
- Biomechanical studies demonstrated that adding commercial fibrin glue to the implant improves fixation⁴. Use of glue is particularly useful to optimize the early stability of the scaffold, allowing safer early joint mobilization.
- MRI studies showed limited tissue regeneration. However, no correlation was demonstrated between abnormal imaging signal and overall results, and the clinical outcome remains pivotal for patient management^{15,16}.
- Strategies are currently being investigated to improve the tissue quality and extend the indications to more complex conditions or salvage procedures.

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