ChondroFiller^{gel}

Surgical Technique


ChondroFiller Gel
ChondroFiller Gel
AMEDRIX

Introduction

There are a variety of methods for the treatment of articular cartilage defects to choose from. These procedures have very different advantages and disadvantages.
The autologous chondrocyte implantation (ACI) is the Gold Standard at the moment for articular cartilage treatment. It was first adopted in 1987 by Brittberg et al. In this first generation of ACI, the cartilage defect was covered with a periosteal flap. However, this technique had several disadvantages such as the periosteal hypertrophy, the loss of cells, the complexity of the surgical technique and the associated high revision rate. Therefore in the second generation carrier substances were designed which should solve the above mentioned problems. In this approach, the cells were placed in a 3-dimensional matrix, and then transplanted. The most widespread matrices where collagen-based. This kind of ACI was called matrix induced autologous chondrocyte implantation (MACI).

Despite the promising clinical results of the ACI/MACI, the serious disadvantage of this method is that it must be done in two steps: first a cartilage biopsy has to be done to recover the cells and in another surgery, the cultured cells with the support matrix have to be inserted into the defect. These methods are timeconsuming and involve high costs.
Therefore, there have been increasing efforts to develop a cartilage repair treatment with a cell-free and one-stage process in recent years.

A new approach is the use of a collagen gel which is already well established as a cell-based method (Andereya et al. 2006, Schneider et al. 2011). Further animal studies proved that the cell migrates into the collagen gel and differentiates into cartilage-like cells over time (Gavenis et al. 2010).
This results in a perfectly integrated and well-differentiated cartilage tissue that comes very close to an embryonic cartilage tissue (Schneider et al. 2011). First clinical applications of this cell-free matrix showed in the treatment of smaller local cartilage defects very good clinical and MRI results (Efe et al. 2012).
To insert these cell-free implants a mini arthrotomy of the joint is necessary.

What is ChondroFiller^{gel} ?

ChondroFiller^{gel} is an autoregenerative collagen implant for treating traumatic or degenerative defects of the articular cartilage. The matrix is dimensionally stable and has a gel like consistency. The ready to use implant is made from pure, native collagen type I which is isolated from rat tail tendons of specific pathogen-free animals. The collagen content is 8 mg/mL. ChondroFiller^{gel} is available in two diameters (2 & 4 cm) and three heights (4, 6 & 8 mm).

Indications/Contraindications

Indications

As with every new process, it is important to follow the indications and to consider contraindications. The following basic requirements should be met to ensure the successful application of the ChondroFiller^{gel} technique:

- Preserved cartilage shoulder
- Intact surrounding cartilage
- Intact corresponding articular surface (damage to the corresponding articular surface up to an Outerbridge classification of grade II is permitted)
- Intact meniscus (a partial resection of up to max 1/3 of the total volume is permitted)
- Intact ligaments, physiological leg axis
- Free joint mobility
- Patients age > 18
- Outerbridge classification: grade III and IV
- Defect size: < 3.5 cm in diameter (non-prepared defect)

Contraindications

In the presence of the following exclusion criteria, the ChondroFiller^{gel} technique should not be applied:

- Hypersensitivity and/or allergy to collagen or rat protein
- Multi-compartmental arthrosis
- Hematopoetic disorders
- Malignant disorders
- Neurological diseases
- Increased risk of bleeding
- Pregnant or breast feeding women
- Incapacitated and compulsory treatment patients
- Joint stiffness
- Arthrofibrosis
- Joint infections
- Metabolic diseases
- Leg malalignment of > 5°

Surgical Technique ChondroFiller^{gel}

Surgical access

The surgical access depends on the location of the cartilage defect, medial or lateral to the patella. The length of the section of skin depends on the position of the defect and the defect size. Only when all indication criteria are met should this method be applied.
Accompanying joint pathologies such as meniscal damage, ligament insufficiency, false position of the axis etc. should be treated first in the same session.

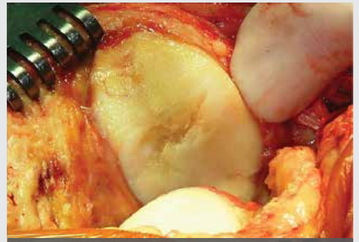
Preparation of the implant

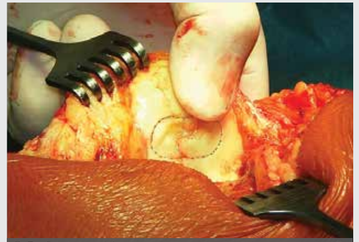
After confirmation of the indication for carrying out the ChondroFiller^{gel} method the implant should be thawed. The thawing process takes about 30 minutes depending on the implant size and the surrounding temperature. The implant should be transferred using a blunt instrument (e.g. the back of tweezers or a spattle). The optimal processing temperature is 20-35 °C. Higher temperatures lead to irreversible collagen damage.

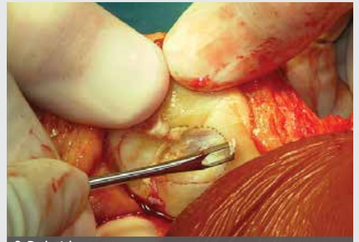
Debridement of the defect

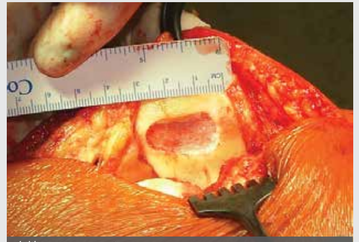
The debridement of the cartilage defect can be done after a mini arthrotomy either with a sharp spoon or with appropriately sized curettes. The adaption of the defect is carried out with the freehand-technique (Fig. 1 left) or by using a preformed punch (Fig. 1 right). To guarantee a press-fit anchorage the defect should have a diameter 1-2 mm smaller compared with the implant size. In case of the punch-technique diameters with a variance of 1-2 mm should be used. It is important that all diseased components are removed and a stable cartilage shoulder remains on all sides. During the preparation of the defect it is important to ensure that the subchondral plate is not broken. It has paid off to undermine the cartilage edges with a small sharp spoon so that a good anchoring of the gel in the defect can be achieved. For good documentation the debrided defect should be measured accurately (Fig. 1 left pic 4).
In the presence of an osteochondral defect zone the bone defect can be filled and impacted with autologous bone graft in the same surgery until a complete and stable reconstruction of bone tissue is achieved.

Freehand-technique


1 Cartilage defect


2 Defect marking


3 Debridement


4 Measurement

Punch-technique


1 Cartilage defect


2 Defect punching


3 Debridement


4 Debrided defect

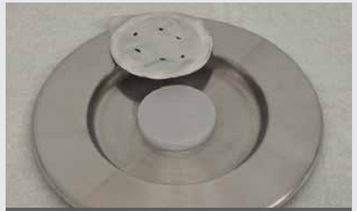
Fig. 1 Defect preparation

Surgical Technique ChondroFiller^{gel}

Implant preparation

First the outer blister pack and then the sterile blister pack with the ChondroFiller^{gel} implant is opend. The implant should be transferred using a blunt instrument (e.g. the back of tweezzers or a spattle). The adaptation of the implant is carried out by using preformed punches (Fig. 2 right) or the freehand-technique with irregularly shaped defects (Fig. 2 left). Here the shape of the defect is traced with a foil (e.g. the foil of the sterile inner blister) and cut accordingly (Fig. 2 left pic 1-6). The Implant is cut with a shear (preferred) or a 12-scalpel on a stable, cut resistant surface. The implant is placed on the foil and the tailored overlapping edges cut without compressing the implant. The size and height of the implant should always be 1-2 mm larger than the defect size itself to ensure the press-fit anchorage of the matrix into the defect.

Freehand-technique

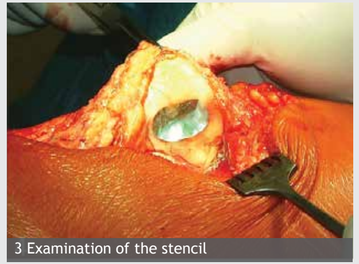


1 Marking the defect silhouette on the blister foil

2 Cut out the stencil

4 Stencil on ChondroFiller^{gel}

5 ChondroFiller^{gel} cut out



3 Examination of the stencil

6 Applicable ChondroFiller^{gel}

Punch-technique

1 ChondroFiller^{gel}

2 Punching of ChondroFiller^{gel}

3 Punched ChondroFiller^{gel}

4 Applicable ChondroFiller^{gel}

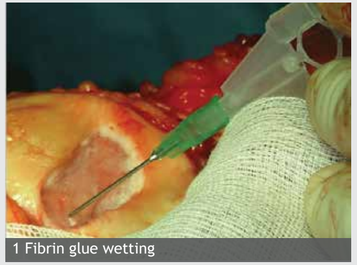
Fig. 2 Implant preparation ChondroFiller^{gel}

Surgical Technique ChondroFiller^{gel}

Application of ChondroFiller^{gel}

Before applying ChondroFiller^{gel} the cartilage defect area should be dry. The basic defect and the edge regions of the prepared cartilage defect were sparingly moistened with fibrin glue (Fig. 3 left pic 1; right pic 1). Preferably the fibrin glue Tissucol/Baxter should be used because it has been used most efficiently. Then the immediate transfer of the prepared implant into the defect carefully occurs with blunt forceps or a spatula. After the fibrin glue has set (approx. 2-3 min) the implant can be modelled press-fit (Fig. 3 left, pic 3; right pic 3) and adjusted to the height level of the surrounding healthy cartilage. If an implant dehiscence occurs the fissures can be filled with fibrin glue. Afterwards the joint is gently moved and the correct position of the implant is checked. Flushing of the joint and using a Redon drainage should be avoided.
After dressing the wound the treated joint should be immobilized with a brace for 48 hours in a neutral position.

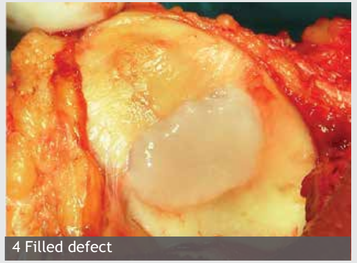
Freehand-technique



1 Fibrin glue wetting

2 Press-fit anchorage

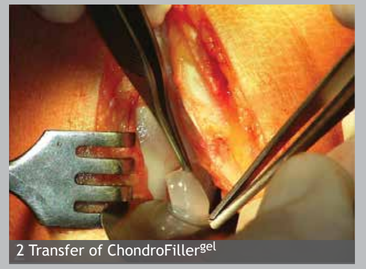
3 Modelling



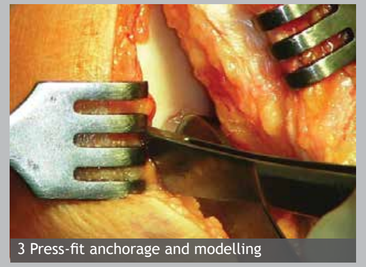
4 Filled defect

Punch-technique

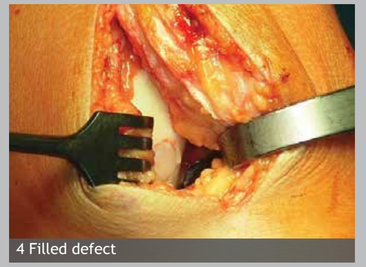
1 Fibrin glue wetting



2 Transfer of ChondroFiller^{gel}



3 Press-fit anchorage and modelling



4 Filled defect

Fig. 3 Application of ChondroFiller^{gel}

After-Treatment

The post-operative treatment

The treatment is mainly determined by the anatomic location of the defect in the joint. There are two basic ways: 1. defects are located in the main load area of the joint and are thus subjected to axial load and 2. defects that are located on the patella or at the corresponding articular surface, e.g. at the femoral trochlea, and loaded only during flexion of the joint. In both cases the rehabilitation program is based on the respective recommendations of the professional societies for trauma surgery DGU and orthopedics DGOOC (Pietschmann, 2012):

Main loading zone of the femoral condyles/talus:

- Mobilization at day 2 post-operative
- 20 kg partial weight bearing on the operated limb for 6 weeks
- Exercise bar (CPM) at least twice a day for 1 hour
- From the 7th week on load up to 30 kg, 2 weeks to full weight bearing
- After reaching full load capability cycling and swimming are allowed, careful muscle formation through isometric training
- Jumping, running and contact sports are allowed after 1 year

Patella and retropatella bearings:

- Mobilization on day 2 post-operative
- The knee flexion is limited by an IROM-rail for 3 weeks on 0-0-30°
- 20 kg partial weight bearing on the operated limb for 1 week
- From the 2nd week full load allowed
- After the 3rd week increase in flexion to 30° every 2 weeks, from 90° of flexion the IROM-rail will be removed
- After reaching 90° flexion cycling and swimming are allowed, careful muscle formation through isometric training
- Sports with a high risk of falls are allowed after 1 year

Literature

Andereya S, Maus U, Gavenis K, Muller-Rath R, Miltner O, Mumme T, Schneider U (2006) First clinical experiences with a novel 3D-collagen gel (CaReS) for the treatment of focal cartilage defects in the knee. Z Orthop Ihre Grenzgeb 144:272–280

Brittberg M, Lindahl A, Nilsson A, Ohlsson C, Isaksson O, Peterson L (1994) Treatment of deep cartilage defects in the knee with autologous chondrocyte transplantation. N Engl J Med 331:889–895

Efe T, Theisen C, Fuchs-Winkelmann S, Stein T, Getgood A, Rominger MB, Paletta JR, Schofer MD (2012) Cell-free collagen type I matrix for repair of cartilage defects-clinical and magnetic resonance imaging results. Knee Surg Sports Traumatol Arthrosc. Oct;20(10):1915-22. Epub 2011 Nov 18.

Gavenis K, Schmidt-Rohlfng B, Andereya S, Mumme T, Schneider U, Mueller-Rath R (2010) A cell-free collagen type I device for the treatment of focal cartilage defects. Artif Organs 34:79–83

Pietschmann M F, Horng A, Glaser C, Albrecht D, Bruns J, Scheffer S, Marlovits S, Angele P, Aurich M, Bosch U, Fritz J, Frosch KH, Kolombe T, Richter W, Petersen J P, Nöth U, Niemeyer P, Jagodzinsky M, Kasten P, Ruhnau K, Müller PE (2012) Post-treatment rehabilitation after autologous chondrocyte implantation : State of the art and recommendations of the clinical tissue regeneration study group of the German Society for Accident Surgery and the German Society for Orthopedics and Orthopedic Surgery.Unfallchirurg. 2012 Nov 25.

Schneider U, Schmidt-Rohlfng B, Gavenis K, Maus U, Mueller-Rath R, Andereya S (2011) A comparative study of 3 different cartilage repair techniques. Knee Surg Sports Traumatol Arthrosc. Dec;19(12):2145-52.

Schneider U, Rackwitz L, Andereya S, Siebenlist S, Fensky F, Reichert J, Löer I, Barthel T, Rudert M, Nöth U (2011) A prospective multicenter study on the outcome of type I collagen hydrogel-based autologous chondrocyte implantation (CaReS) for the repair of articular cartilage defects in the knee. Am J Sports Med. 2011 Dec;39(12):2558-65.

Schüttler KF, Schenker H, Theisen C, Schofer MD, Getgood A, Roessler PP, Struewer J, Rominger MB, Efe T. Use of cell-free collagen type I matrix implants for the treatment of small cartilage defects in the knee: clinical and magnetic resonance imaging evaluation. Knee Surg Sports Traumatol Arthrosc. 2013 Nov 7

This surgical instruction serves as an educational tool for the clinical support of medical professionals to use specific Amedrix products. Finally medical professionals decide about the technique and how to use the product. Medical professionals should act corresponding to their education and experience and refer to medical literature or the instruction for use.

ChondroFiller^{gel}

AMEDRIX

Producer:

Amedrix GmbH
Schelztorstr. 54-56
D-73728 Esslingen
info@amedrix.de, www.amedrix.de