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MEDICINE

THREE-DIMENSIONAL ACELLULAR SCAFFOLDS (MAIOREGEN) IN ISOLATED CHONDRAL DEFECT

Gilyen BOTOND[1], Solyom ARPAD[2], Bataga TIBERIU[3] and Fodor PAL[4]

[1]University of Medicine and Pharmacy, Technological Science "G. E. Palade" Târgu Mureş,
Department of Orthopaedics and Traumatology, gilyenbotond@gmail.com;
[2]Correspondent author, University of Medicine and Pharmacy, Technological Science "G. E. Palade" Târgu Mureş,
Department of Orthopaedics and Traumatology, Strada Ariesului nr. 15, Targu Mures, Jud. Mures, solyomarpad@yahoo.com;
[3]University of Medicine and Pharmacy, Technological Science "G. E. Palade" Targu Mures,
Department of Orthopaedics and Traumatology, tbataga@gmail.com;
[4]University of Medicine and Pharmacy, Technological Science "G. E. Palade" Targu Mures,
Department of Orthopaedics and Traumatology, fodorpaly22@gmail.com.

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Introduction. Chondral damage of the knee is often asymptomatic and is frequently diagnosed during knee arthroscopy. Cartilaginous tissue does not regenerate spontaneously when injured and the success of current clinical treatment methods is questionable.

The aim of this study is to evaluate the clinical outcomes in patients with significant cartilage lesions of the knee, which were surgically treated with three dimensional acellular scaffolds in restoring osteochondral defects.

Materials and methods. The present study included a consecutive series of ten patients with age between 45 and 60 years, BMI between 20 and 30, and full thickness ICRS grade 3 and 4 cartilage lesions with size ≥4 cm (diagnosed with pre-operative MRI), who underwent cartilage repair by using an open AMIC technique.

Results. We used different scoring techniques pre and postoperatively: IKDC subjective score, KOOS score, Tegner Lysholm score and we compared our results. We found a high rate of good clinical outcome in patients treated using MaioRegen for osteochondral lesions of the knee.

Keywords: chondral defect, arthroscopy, MaioRegen, orthobiology, Stem cells.

INTRODUCTION

Chondral damage is frequently diagnosed during knee arthroscopy, present in more than 50% of the arthroscopies performed for various indications, and an important part of cartilage injuries were linked with other intraarticular findings, such as anterior cruciate ligament tear and medial meniscus tear.[1]

Focal cartilage injuries in all joints are a main problem for orthopaedic surgeons. These lesions are a challenge in particular in young patients. These types of osteochondral lesions are common involving only the cartilage surface or associated with subchondral bone lesions.[2]

Cartilaginous tissue does not regenerate spontaneously when injured and the current clinical treatment methods suffer from high cost and relatively high failure rates. This calls for new treatment methods to be developed.[3]

Early detection of osteochondral lesion is crucial and should be detected before subchondral bone is involved. Treatment strategies includes a lot of option from conservative treatment to surgical procedures such as marrow stimulation, osteochondral autograft transplantation, or autologous chondrocyte implantation. By stimulating the bone marrow Stem cells invade the defect where they try to differentiate into cartilaginous cells to blanket the lesion. With potential for chondrogenesis from a rich and readily available cell source such as the bone marrow, mesenchymal cell therapy is a potential area for the treatment of knee cartilage defects and osteoarthritis.[4]

Cartilage treatment can be palliative, repair or restoration type. For lesion larger than 4 cm, ACI and OCA may improve patient outcomes.[5]

Collagen scaffolds are cell-free strategies that indirectly utilize the repair and the regeneration potential of stem cells[6].

The aim of this study is to evaluate the clinical outcomes in patients which were surgically treated with three dimensional acellular scaffolds in restoring osteochondral defects.

MATERIALS AND METHODS

The present study included a consecutive series of ten patients who underwent cartilage repair by using an open AMIC technique was considered.

Inclusion criteria were as follows: age between 45 and 60 years; BMI between 20 and 30; full thickness ICRS grade 3 and 4 cartilage lesions with size ≥4 cm; and clinical symptoms of pain, swelling, locking or giving way.

Co-existing knee pathologies such as tibiofemoral axial malalignment, patellofemoral maltracking and ligamentous insufficiency were treated during the same surgical procedure.

Exclusion criteria were as follows: deep osteochondral lesions requiring bone grafting; Kellgren and Lawrence grade ≥2, tricompartmental OA, osteonecrosis and inflammatory arthropathy; patients with other general medical conditions (diabetes mellitus, rheumatoid arthritis, etc.);

All patients gave informed consent prior to their inclusion in the study and all the procedures were performed by the senior author.

Functional evaluation was performed using International Knee Documentation Committee Score (IKDC), Knee injury and Osteoarthritis Outcome Score (KOOS), and Tegner Lysholm score, documented preoperatively, at 6 months and at 12 months postoperatively.

Radiographic and magnetic resonance imaging (MRI) results were also collected at the same time points.

Standard radiographic evaluation included standing antero-posterior (AP) long-leg views including hips and ankles, standing AP/lateral views of the knee, skyline patellofemoral views. MRI protocols were not standardized since the MRI scans were performed at different facilities.

SURGICAL TECHNIQUE

At the time of the surgery, the patient was positioned supine and the table was set to allow 90° of knee flexion. The tourniquet was placed tight and activated at the beginning of the arthrotomic procedure. A diagnostic arthroscopy was performed in order to confirm the chondral lesion and evaluate the overall status of the knee joint. An 8–12 cm medial parapatellar skin incision was then performed with the knee at 90° flexion. A standard medial parapatellar arthrotomy allowed the articular surfaces of the knee join to be exposed. The chondral lesion was measured and debrided. Intra-osseous drilling was made for decompression and to liberate the mesenchymal Stem cells from the bone in order to ill the acellular matrix. Lodging was created according to the device to be implanted (7–8 mm). A template corresponding to the size of the prepared lesion was created. Lastly, the MaioRegen matrix, properly shaped using the template, was placed on the defect and fixed with fibrin glue. The tourniquet was then released to allow proper bleeding of the subchondral bone further liberating the Stem cells. The stability of the implant was tested by several cycles of flexion–extension. Drainage without aspiration was placed intraarticularly, whereas the capsule and the other tissue were sutured following the standard way.

RESULTS

We enroled 10 patients in this study (10 males). The mean age at surgery was 42,9 years, the mean area of the lesion was 4,35 cm^2. According to the ICRS classification, a grade 3 lesion was reported in 4 patients, grade 4 lesions in 6 patients. No surgery-related adverse events were recorded during the entire duration of the follow-up period.

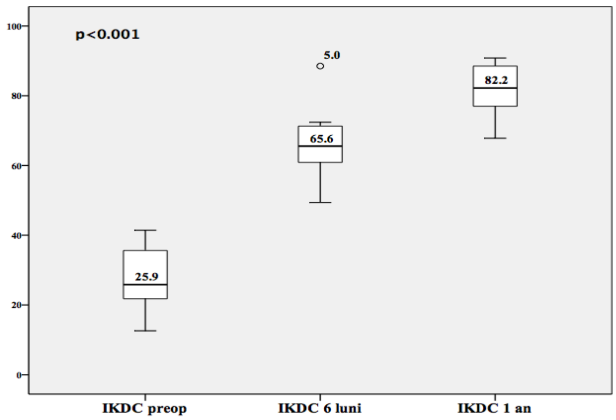
The average preoperative IKDC subjective score was: 25.9. At 6 months IKDC subjective score improved statistically significant with an average of 65.6. At 12 months IKDC subjective score improved with an average of 82.2.

The average preoperative KOOS score was: 36.8%. At 6 months KOOS score improved statistically significant for patients with an average of 78.8%. At 12 months KOOS score improved with an average of 88.3%.

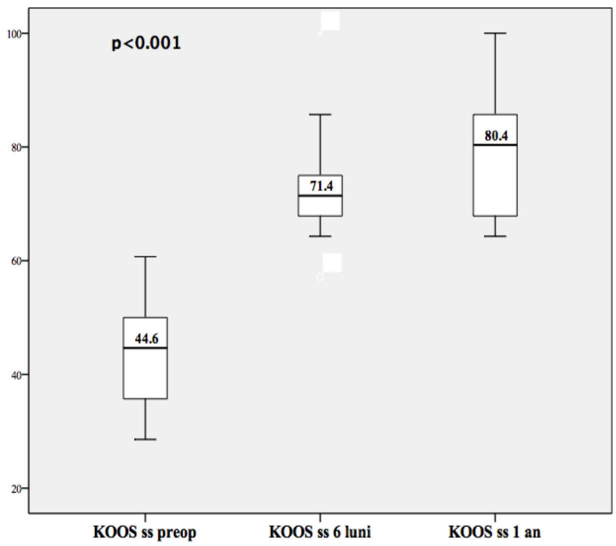
Regarding the five subscales of the KOOS score at 6 months, we found a statistically significant difference ($p<0.05$) in three out of five subscales: pain, activities of daily living, quality of life.

The average preoperative Tegner Lysholm score was: 26.5. At 6 months Tegner Lysholm score improved statistically significant for patients with an average of 78. At 12 months Tegner Lysholm score improved with an average of 88.

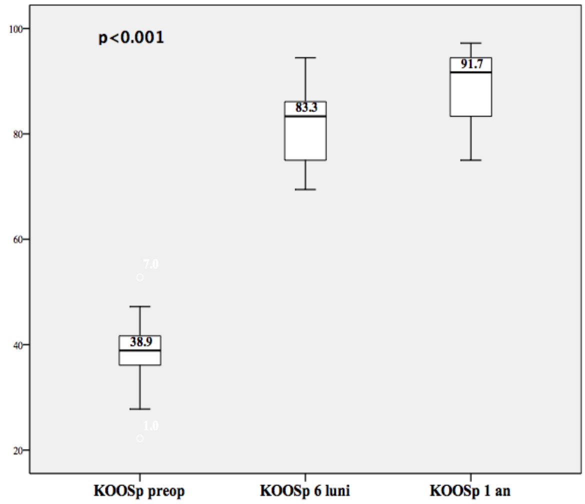
Figure 1. 2 cases before and after the implantation of MaioRegen.



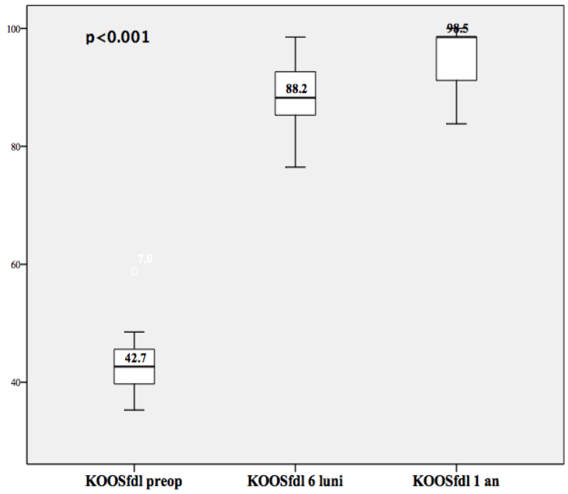
Scheme 1. IKDC score, preoperatively, 6 months postoperatively and 1 year postoperatively.



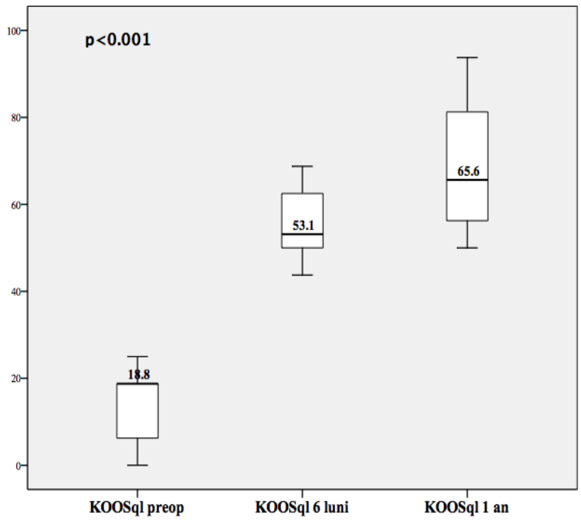
Scheme 2 KOOS score (symptoms and stiffness) preoperatively, 6 months postoperatively and 1 year postoperatively.



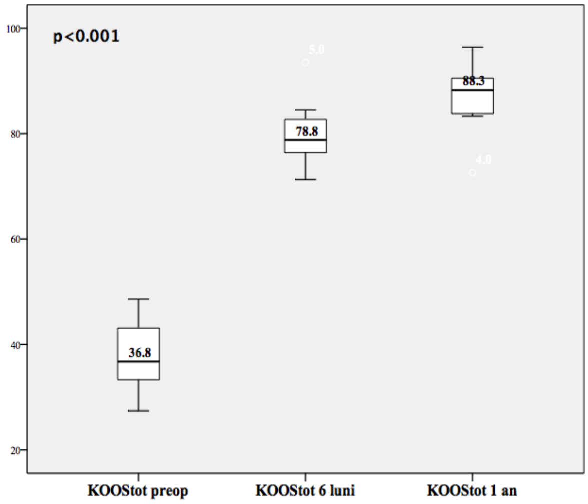
Scheme 3 KOOS score (pain) preoperatively, 6 months postoperatively and 1 year postoperatively.



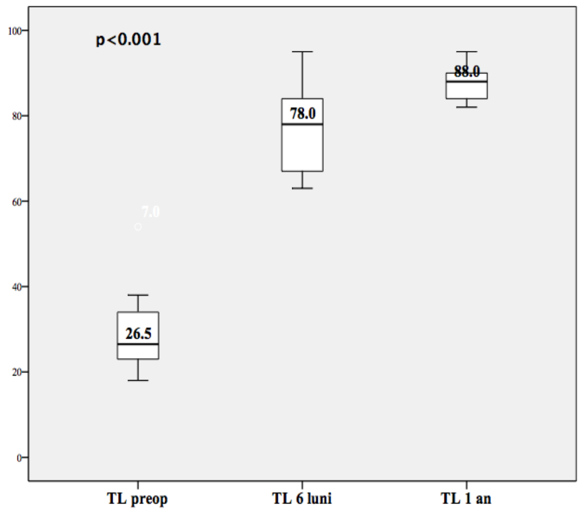
Scheme 4 KOOS score (function and daily living) preoperatively, 6 months postoperatively and 1 year postoperatively.



Scheme 5 KOOS score (quality of life) preoperatively, 6 months postoperatively and 1 year postoperatively.



Scheme 6 KOOS score (total) preoperatively, 6 months postoperatively and 1 year postoperatively.



Scheme 7. Tegner Lysholm score preoperatively, 6 months postoperatively and 1 year postoperatively.

DISCUSSION

There are various methods to treat isolated chondral injuries. As a part of orthobiology and regenerative medicine, chondral supplementation is the treatment of the future and has a lot of benefits in joint surgery. In deep osteochondral lesions some authors provided results with various type of tissue supplementation. There is a lot of evidence on effect of collagen scaffolds in moderate chondral injuries.

Over the last decade, a number of natural and artificial biomaterials have been used as scaffolds for cartilage reformation. Scaffolds may be monophasic, biphasic, triphasic or multiphasic in structure, consisting of one or more layers. They play important roles in maintaining mechanical integrity and withstanding mechanical stresses.[7]

Some authors shows that 3D collagen scaffolds yield good medium term clinical outcomes in large defects.[8] Our results are showing the same clinical outcomes in medium size chondral defects. Bjørn Borsøe Christensen at al. concluded that osteochondral defects in the ankle and knee joint with a biomimetic scaffold resulted in incomplete cartilage repair and poor subchondral bone repair at 1- and 2.5-year follow-up. We used collagen scaffolds only in chondral injuries more than 4 cm. (HA-Collagene type I three-layer scaffold (Maioregen™, Finceramica, Italy). One of our exclusion criteria was the chondral defect associated with deep subchondral bone injury. This can explain good clinical results in our study.[9] Considering our clinical results, we should also follow up the imaging results of this patients. Some studies shows that imaging results after 2–3 years shows a failure of biomimetic scaffold implant.[10] Andrea Sessa et al. have almost the same clinical results as in our study but the MRI showed an persisting subchondral alteration.[11] According to Marco Decogliano et al. the use of MaioRegen scaffolds is a good procedure for treatment for large osteochondral defects. Their data shows a significant improvement of Tegner activity score and also IKDC score improved from a mean 35,7 to 67,7. These results is almost same as we found after clinical evaluation of our included patients.[12]

In conclusion, we found a high rate of good clinical outcome in patients treated using MaioRegen for osteochondral lesion of the knee. However, this data needs to be confirmed by larger studies to better understand the applicability of this biomimetic scaffold for the treatment of large osteochondral defects.

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