Arthroscopic Repair of Acetabular Cartilage Lesions by Chitosan-Based Scaffold: Clinical Evaluation at Minimum 2 Years Follow-up

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Purpose: To evaluate the functional outcome of using chitosan-based material in our patients after 2 years of follow-up. **Methods:** Nonarthritic nondysplastic femoroacetabular impingement patients with an acetabular chondral lesion, 18 to 55 years of age, were included for arthroscopic repair between May 2013 and July 2015. Full-thickness chondral defects $\geq$2 cm^2 were filled with chitosan-based implant after microfractures. Follow-up consisted of alpha angle assessment and clinical outcome in the form of the Non Arthritic Hip Score (NAHS), International Hip Outcome Tool 33 (iHOT33), Hip Outcome Score of Activities of Daily Living (HOS-ADL), and Hip Outcome Score of Sports Specific Scale (HOS-SSS). **Results:** Twenty-three patients were included. The mean follow-up was 38.4 $\pm$ 7.0 months (range, 24-50 months). The mean defect size was 3.5 $\pm$ 1.0 cm^2, principally involving zone 2 and to a lesser extent in zones 1 and 3. Using femoroplasty, the alpha angle was corrected from a mean 70.5 $\pm$ 6.3° to 44.3 $\pm$ 4.9° (P = .00001). Significant improvement occurred comparing the preoperative to the first-year postoperative patient-reported outcomes: P = .00001 for the NAHS, P = .00004 for the iHOT33, P = .00005 for the HOS-ADL, and P = .0002 for the HOS-SSS. No statistically significant change has been observed in the patient-reported outcomes obtained at the endpoint when compared with the first-year values (P = .13 for the NAHS, P = .21 for the HOS-ADL, and P = .29 for the HOS-SSS), except for the iHOT33, which showed further significant improvement (P = .02). Up to 91% of the patients met or exceeded the minimal clinically important difference. One patient needed total hip arthroplasty. Perineal hypoesthesia occurred in 3 patients, who recovered within 2 to 6 weeks, and 1 patient needed a prolonged physiotherapy program for postoperative muscular stiffness. **Conclusions:** The arthroscopic combined treatment of microfractures and chitosan-based scaffold has maintained satisfactory clinical outcomes in 91% of the patients with s large ($\geq$2 cm^2) full-thickness acetabular chondral defect associated with femoroacetabular impingement at a mean follow-up of 38.4 months. The study could not definitely draw any conclusion regarding the safety of chitosan-based material for use in the hip joint. **Level of Evidence:** Level IV, case series.

Acetabular cartilage damage occurs in association with femoroacetabular impingement (FAI) owing to the abnormal shear stresses, mostly in the anterosuperior area, leading to chondral delamination and labral tears.[1,2] This continuous pathologic process in young active patients may lead to early osteoarthritis.[3]

Lesion size and severity are considered primary determining factors for the strategy of management and the expected prognosis.[4,5] One of the treatment procedures is the technique of microfractures, which depends on stimulation of the subchondral bone marrow through liberating the progenitor cells, and finally formation of a fibrocartilage patch that covers the defect, but this fibrocartilage tissue has poor biomechanical properties.[6,7] When the defect is large in size, the fibrocartilage repair patch tends to shrink over time and separate from the surrounding structures.[7,8]

Scaffold augmentation techniques have emerged to enhance the biomechanical and biochemical properties of cartilage repair tissue after microfractures. Different scaffold materials, such as polyglycolic acid/hyaluronan, chitosan-glycerol phosphate blood, and chondroitin

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sulfate/hydrogel composites, have been studied in experimental animal trials and have shown a significant improvement in the mechanical properties and a histologic structure similar to the native cartilage.[8-11] Clinical trials of chitosan-based scaffold for treating chondral defects in the femoral condyle of human knees showed adequate safety for clinical practice and presented favorable histologic and functional results.[12,13]

In our work, we used the technique of scaffold augmentation, using chitosan-based implant, for treatment of large full-thickness acetabular cartilage lesions associated with FAI. This study was conducted to evaluate the functional outcome of using chitosan-based material in our patients after 2 years of follow-up. Depending on the previous studies, we hypothesized that the technique will give satisfactory clinical results and improvement in the patient-reported outcome (PRO) scores.

Methods

Patient Selection

From May 2013 to July 2015, we included patients between 18 and 55 years old who had a clinical diagnosis and radiologic evidence of FAI associated with an acetabular chondral lesion. Exclusion criteria were inflammatory joint disease, radiologic signs of osteoarthritis (Tönnis grade $\geq$2), or hip dysplasia (lateral center edge angle of Wiberg $<25^{\circ}$, acetabular index angle of Tönnis $>10^{\circ}$). Final inclusion in the study was decided during the arthroscopic procedure when the patient had a full-thickness acetabular cartilage lesion $\geq$2 cm^2 after adequate debridement.

Arthroscopic treatment was indicated primarily for patients who presented with groin pain related to hip motion and a clinical examination suggestive of impingement (limited range of motion [ROM], mainly internal rotation, and tests for flexion, adduction, and internal rotation, flexion abduction external rotation, and dynamic internal rotation, as well as the dynamic external rotatory impingement test).[14,15] Diagnosis was confirmed by radiologic assessment. Initially, plain radiographs in the standard anteroposterior view and 45° Dunn lateral view were obtained. The lateral center edge angle of Wiberg and acetabular index angle were measured in the anteroposterior view to exclude dysplastic cases. The alpha angle was measured in the 45° Dunn view (which correlates with the 1:00-2:00 o'clock position) to determine the cam morphology.[16,17] All patients were investigated preoperatively by magnetic resonance angiography to evaluate the labrum and the articular cartilage.

All patients who had indications for the procedure and met the inclusion criteria received an adjuvant treatment of the acetabular chondral lesion by microfracture and chitosan-based scaffold, in addition to treatment of the underlying FAI. Primary treatment of FAI consisted of arthroscopic femoroplasty for cam deformity, acetabuloplasty for pincer impingement, and repair of associated labral tears.[18-20] All patients participating in the study provided a written informed consent after fulfilling the rules of the Ethical Committee of Clinical Research.

Surgical Technique

The technique of application of chitosan-based implant has been described by Tey et al.,[21] which provided a guide for the surgical procedure in the current study. The operations were performed by 2 senior surgeons (M.T., J.M.), who strictly followed the original technique and steps. Diagnostic hip arthroscopy began with exploration of the central compartment with the patient in the supine position, and appropriate traction was applied to the operating limb. The acetabular cartilage was classified according to the Outerbridge classification[22] (as a standard method) and Beck's system[1] (as a hip-specified system). Full-thickness acetabular cartilage lesions (Outerbridge IV or Beck's III, IV) were treated by full debridement and microfracture (Figs 1 and 2). A motorized shaver and a curette were used for removal of the damaged cartilage and exposure of subchondral bone, then microfractures were performed by 60° arthroscopic awl with a depth of 2 to 3 mm every 5 mm through the entire defect. After adequate debridement, the size of the defect was measured by a calibrated arthroscopic probe and the lesion was localized according to the geographic zone method.[23] Lesions $\geq$2 cm^2 were further treated by the

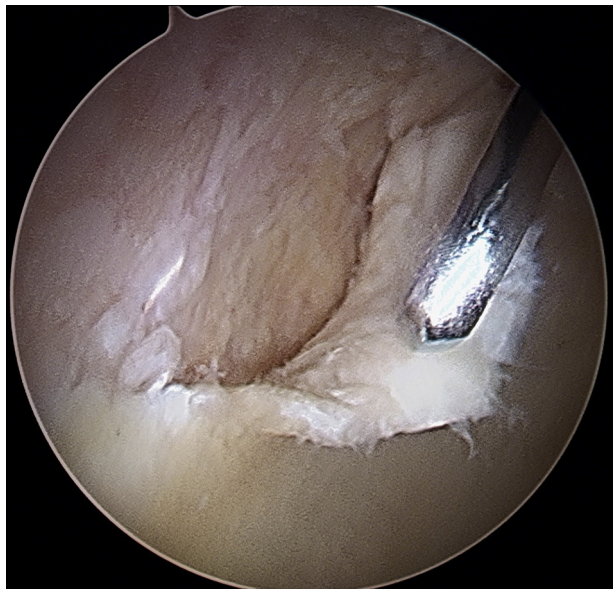

Fig 1. Arthroscopic image of a right hip (viewed from the anterolateral portal) demonstrating delaminated chondral flap in the acetabular cartilage involving zone 2. A full-thickness lesion can be seen exposing the subchondral bone.

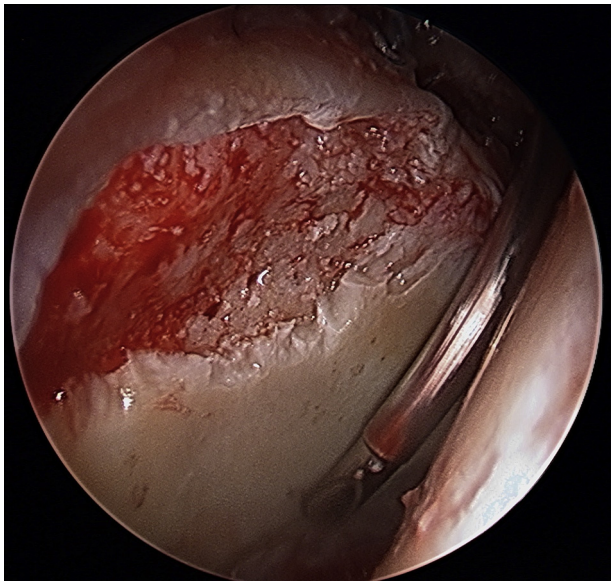

Fig 2. Arthroscopic image of a right hip (viewed from the anterolateral portal) after debridement and microfractures of the chondral defect. Stable chondral margins and bleeding base with bone punctures.

chitosan-based scaffold material at the end of the procedure. Pincer impingement was corrected by acetabuloplasty, and labral tears were repaired by suture anchors (3-5 based on the extent of the lesion), then traction of the limb was released to access the peripheral compartment. For better visualization, the capsule was opened in a T-fashion, which facilitates proper identification and resection of the cam deformity.

The chitosan-based implant (BST-CarGel; Smith & Nephew, London, UK) material was prepared, according to manufacturer instructions, by mixing the components with the patient's blood sample to form the final product that was applied to cover the defect.[21] Traction was reapplied to the limb, and fluid was drained outside the joint space; small gauze swabs were delivered inside to dry the defect surface. Once the surface was clean and good vision was obtained, the mixture was applied using a large 18-G needle that was previously bent to direct the drops toward the sloping surface (Fig 3), covering the whole defect with successive layers that consolidate within 15 minutes. Traction was released again. Great attention was given to close the capsule completely, 2 or 3 sutures were applied first at the distal part of the T-capsulotomy, and then 1 or 2 sutures were applied to close the interportal capsulotomy.

Postoperative Rehabilitation

We asked the patients to move the hip passively and then actively from the first day and use crutches for partial weight bearing for $\leq$6 weeks, with a focus on restoration of full ROM. Activity was allowed to be increased gradually as patients tolerated. Return to full sports activities, especially impaction and twisting movements, were avoided the first year after surgery.[12,21] It was not feasible to ensure applying a formal physiotherapy protocol for all patients; however, the previous points were followed precisely.

Postoperative Evaluation

Follow-up visits were scheduled at 6 weeks; 3, 6, and 12 months; and every year. The patients were evaluated for pain, ROM, and signs of impingement (tests for flexion, adduction, and internal rotation, flexion abduction external rotation, and dynamic internal rotation impingement, as well as the dynamic external rotatory impingement test).[14] Postoperative radiographs were obtained at 3 months for assessment of correction in the alpha angle and the acetabular resection. The Non Arthritic Hip Score (NAHS), International Hip Outcome Tool 33 (iHOT33), and Hip Outcome Score of both subscales (Activities of Daily Living [HOS-ADL] and Sports Specific Scale [HOS-SSS]) were collected during the visits before and after the procedure. We planned to assess the short-term and midterm functional outcomes of cartilage management, so the PROs were collected at 12 and 24 months and then yearly until the end of the study.

Statistical Analysis

The mean value and standard deviation (SD) were calculated for each parameter. Statistical analyses were performed using SPSS software version 22 (SPSS, Chicago, IL). The Shapiro-Wilk test was used to evaluate

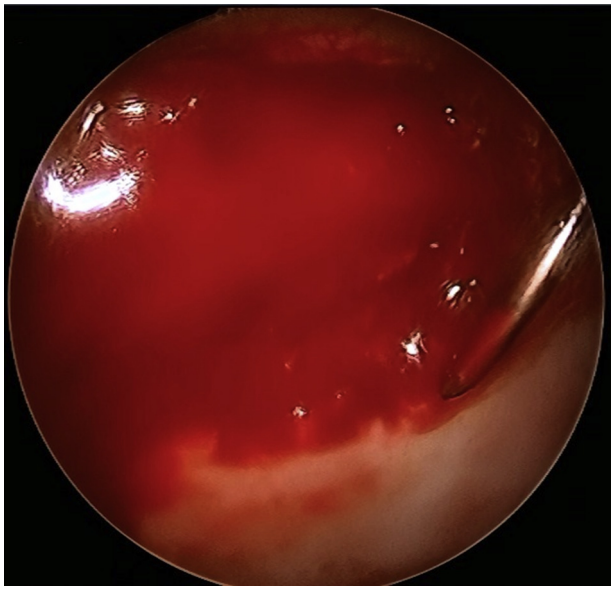

Fig 3. Arthroscopic image of a right hip (viewed from the anterolateral portal) during application of the chitosan–blood mixture by the 18-G needle. The scaffold mixture adheres to the base of the lesion and covers the entire defect.

the data with regard to normality of distribution. Data analysis was performed with the Wilcoxon signed-rank test for comparison of the preoperative and postoperative PROs; $P < .05$ was considered statistically significant.

Results

Twenty-three patients were included in this study—18 men and 5 women. Demographic data including age, body mass index, and Tegner sports level are summarized in Table 1. According to the preoperative evaluation, 15 cases (65%) had cam-type FAI, 8 cases (35%) had mixed type, and no case was diagnosed as pincer-only FAI. The mean preoperative alpha angle was 70.5 ± 6.3°, and the values of the preoperative PROs (mean ± SD) were 55.2 ± 13.4 for the NAHS, 43.1 ± 14 for the iHOT33, 59.7 ± 14.1 for the HOS-ADL, and 30.9 ± 13.9 for the HOS-SSS.

Included patients had a full-thickness acetabular chondral defect with a mean size of 3.5 ± 1 cm^2. Zone 2 was involved in all of the cases; 13 cases extended to zone 3, 2 cases extended to zone 1, and 8 cases were confined to zone 2. The labrum was torn in all patients in the same zones corresponding with the cartilage lesion. Three patients had an associated chondral lesion in the femoral head: 1 had an Outerbridge grade II lesion in zone 2 and was treated by debridement only, whereas the other 2 cases had grade IV lesions in zones 2 and 3 and were treated by microfracture and filling with the same preparation of chitosan-based scaffold.

The postoperative radiographs showed an alpha angle of 44.3 ± 4.9° (mean ± SD). The mean follow-up of the patients was 38.4 ± 7.0 months. Twenty-one patients reported improvement in functional scores within first 12 months and maintained their achieved scores through the follow-up period. Two patients showed no significant change from their baseline levels: 1 patient was 54 years old, with a radiologic image of mild osteoarthritis (Tönnis 1) and an associated chondral lesion (grade IV) in the femoral head, and ultimately required total hip arthroplasty because of the limiting pain; the other patient was 38 years old (Tönnis 1) and had an acetabular chondral defect of 6 cm^2. At month 12, postoperative functional scores (mean ± SD) were 81.9 ± 13.6 for the NAHS, 72.4 ± 16.6 for the iHOT33, 82.6 ± 16.7 for the HOS-ADL, and 64.8 ± 26.3 for the HOS-SSS, and the functional scores obtained at the endpoint of the study (mean ± SD) were 85.6 ± 14.5 for the NAHS, 78.5 ± 15.6 for the iHOT33, 86.7 ± 15.9 for the HOS-ADL, and 70.8 ± 26.2 for the HOS-SSS (Table 2).

Table 1. Demographic and Basic Patient Data

No. of Patients	23	
Male	18 (78%)	
Female	5 (22%)	
Age, yr	40.9 ± 7	(25-54)
BMI	23.8 ± 2.0	(20-27)
Tegner Level	6.0 ± 1.5	(3-10)
Follow-up, mo	38.4 ± 7.0	(24-50)
Cam-type FAI	15 (65%)	
Mixed-type FAI	8 (35%)	
Acetabular Lesions		
Size, cm^2	3.5 ± 1 cm^2	(2-6)
Zone 1	2 (8%)	
Zone 2	23 (100%)	
Zone 3	13 (54%)	
Femoral Head Lesions		
Size	0.7-1.2 cm^2	
Zone 2	2 (8%)	
Zone 3	1 (4%)	

NOTE. Values are n (%) or mean ± standard deviation (range).
BMI, body mass index; FAI, femoroacetabular impingement.

The immediate postoperative period showed normal recovery for all patients without important clinical incidents. For the patients who improved with the intervention, we observed satisfactory rehabilitation progress, namely disappearance of preoperative pain, attainment of full ROM, and negative tests of impingement at the last follow-up. One patient developed periarticular muscular pain and stiffness that improved after 6 months of continuous physiotherapy. Three patients had postoperative perineal hypoesthesia that recovered spontaneously within 2 to 6 weeks. One patient required total hip arthroplasty 2 years after the intervention.

The recently published values of a minimal clinically important difference were used for interpretation of the individual outcomes on each of the used PROs.[24] At the first-year follow-up, 91% of the patients met or exceeded the minimal clinically important difference for the NAHS, iHOT33, and HOS-ADL and 82% for the HOS-SSS. At the endpoint of the follow-up, the proportions were 87% for the NAHS, 91% for the iHOT33 and the HOS-SSS, and 82% for the HOS-ADL. By comparing the final scores with the corresponding first-year values, 13% achieved further improvement on the NAHS, 48% on the iHOT33, and 8% on the HOS-ADL and HOS-SSS (Table 3). Interestingly, 2 male patients had an associated chondral defect (grade IV) in the femoral head and a radiologic image of mild osteoarthritis (Tönnis 1). One of the patients, who was 54 years old, had 24-month postoperative versus preoperative scores as follows: NAHS, 41.3 versus 39; iHOT33, 34 versus 30; HOS-ADL, 45.8 versus 47.0; and HOS-SSS, 5.5 versus 7.0. Ultimately, this patient required total hip arthroplasty 2 years postoperatively because of limiting pain. The other patient, who was 49 years old, had 24-month postoperative versus preoperative scores as follows: NAHS, 87 versus 53; iHOT33, 93 versus 61; HOS-ADL, 100 versus 72; and HOS-SSS, 95 versus 24.

Discussion

Microfractures augmented by chitosan-based scaffold provided satisfactory short-term to midterm outcomes for treatment of large full-thickness acetabular chondral

Table 2. Alpha Angle and PRO Values

	Preoperative	12-Month Follow-up		Endpoint Follow-up	
Alpha Angle					
Mean ± SD	70.5 ± 6.3	44.3 ± 4.9	$P = .00001$		
Range	56-80	34-52			
NAHS					
Mean ± SD	55.2 ± 13.4	81.9 ± 13.6	$P = .00001$	85.6 ± 14.5	$P = .13$
Range	23.7-78.7	41.3-98.7		41.3-100	
iHOT33					
Mean ± SD	43.1 ± 14	72.6 ± 16.6	$P = .00004$	78.5 ± 15.6	$P = .02$
Range	10.8-65.4	34-96.7		34-97.6	
HOS-ADL					
Mean ± SD	59.8 ± 14.1	82.6 ± 16.7	$P = .00005$	86.7 ± 15.9	$P = .21$
Range	24.3-89.5	45.8-100		45.8-100	
HOS-SSS					
Mean ± SD	30.9 ± 13.9	64.8 ± 26.3	$P = .0002$	70.8 ± 26.2	$P = .29$
Range	2.8-55.5	5.5-100		5.5-100	

NOTE. Preoperative values (alpha angle and PROs) are compared with the corresponding 12-month postoperative values. The PROs of the endpoint are compared with the 12-month values.

HOS-ADL, Hip Outcome Score of Activities of Daily Living; HOS-SSS, Hip Outcome Score of Sports Specific Scale; iHOT33, International Hip Outcome Tool 33; NAHS, Non Arthritic Hip Score; PRO, patient-reported outcome; SD, standard deviation.

defects. The results of the current study showed a significant improvement in the 4 PROs of patients during the first year ($P = .00001$ for NAHS, $P = .00004$ for iHOT33, $P = .00005$ for HOS-ADL, and $P = .0002$ for HOS-SSS). The improvement achieved during the first year was maintained through the endpoint of the study. No changes were observed by comparing the endpoint PROs with the corresponding first-year PROs ($P = .13$ for NAHS, $P = .21$ for HOS-ADL, and $P = .29$ for HOS-SSS), except for iHOT33, which showed further significant improvement ($P = .02$). Twenty-one patients (91%) reported improvement. Two patients did not change from their baseline: 1 patient had an associated chondral lesion in the femoral head, and the other patient had an extreme lesion size (6 cm^2) in the acetabulum. The mean age of the patients at time of surgery was 40.9 ± 7.0 years, and most patients were used to performing a moderate or high level of sports activity before reporting the hip complaint (mean Tegner scale of 6.0 ± 1.5); therefore, it was important for those patients to achieve satisfactory results not only regarding the daily activities but also returning to the previous level of sports. Continuous improvement in iHOT33 scores after 2 years would be related to the emotional, social, and recreational parts of the iHOT33 test, which are not present in NAHS or HOS subscales. Thus, the further increase in iHOT33 scores, in our speculation, may reflect both physical and psychological improvement and more satisfaction over time.

Clinical studies of chondral defects of the knee and hip recommend performing microfractures for small focal well-defined lesions <4 cm^2 to obtain good results,[5,25,26] although later studies limit the indication for a lesion area <2 cm^2,[27] particularly in athletic patients seeking to return to their previous activities.[28] Considering these recommendations and the nature of our patients, we decided to apply the chitosan-based material for full-thickness defects ≥2 cm^2 after adequate debridement and a precise microfracture technique. The mean size of the acetabular cartilage defect in our results was 3.5 ± 1.0 cm^2, involving 2 zones (zones 1 and 2 or 2 and 3) or confined to zone 2 only. Consequently, these relatively nonextensive lesions may have contributed to the satisfactory results of this study; supporting this belief, we observed that 1 patient with an extreme defect size (6 cm^2) did not show significant improvement in the PROs through the entire follow-up period. The surgical procedure also may have affected the results, because we could resect the impinging cam deformity properly in all cases with a mean postoperative alpha angle of 44.93 ± 4.90° ($P = .00001$) and repaired the labrum in all of them with suture anchors, using the standard technique for microfracture described by Steadman et al.[29]

The microfracture technique has been used extensively in the knee and provides excellent early results

Table 3. Subjects Who Met or Exceeded the Minimal Clinically Important Difference

	MCID[24]	First Year Postoperatively	Endpoint Postoperatively	
			Overall Change	Year 2 Change
NAHS	10	21 (91)	20 (87)	3 (13)
iHOT33	6.1	21 (91)	21 (91)	11 (48)
HOS-ADL	9	21 (91)	19 (82)	2 (8)
HOS-SSS	6	19 (82)	21 (91)	2 (8)

NOTE. Values are n (proportions) for the PROs used in the first year and at the endpoint of follow-up.

HOS-ADL, Hip Outcome Score of Activities of Daily Living; HOS-SSS, Hip Outcome Score of Sports Specific Scale; iHOT33, International Hip Outcome Tool 33; MCID, minimal clinically important difference: NAHS, Non Arthritic Hip Score; PROs, patient-reported outcomes.

and significant improvement in quality of life; however, long-term follow-up has shown a decline in outcomes and has failed to maintain patient satisfaction.[30,31] Similarly, microfracture as an adjunct to hip arthroscopy for FAI has, in general, positive outcomes in short- to midterm follow-up,[32] but long-term follow-up is not yet available. Comparing the results of microfractures only versus chitosan-augmented microfractures (the study at hand), studies of microfractures in the hip have reported lesions with a mean size smaller than the minimal size in our study, in addition to the variable outcomes. Philippon et al.[33] published a study of 9 patients who underwent revision hip arthroscopy after an average of 20 months of initially being treated with microfracture for acetabular chondral lesions with an average size of 163 mm^2: 8 patients had 95% to 100% coverage of the chondral lesion, and 1 patient had only 25% coverage. Similarly, Karthikeyan et al.[34] performed second-look arthroscopies after an average of 17 months of initial treatment with microfracture and found a mean fill of 96% in 19 of 20 patients who had had acetabular chondral defects with an average size of 154 mm^2. Histologic analysis of full-thickness biopsy revealed that the tissue was primarily fibrocartilage with some staining for type II collagen in the region closest to the bone. In contrast, Domb et al.[35] compared microfractures in a group of 79 patients with full-thickness acetabular chondral lesions with a control group of 158 patients with partial-thickness lesions who did not receive a specific cartilage treatment. The mean age was 44 years, and the mean size of the chondral defect was 189 $\pm$ 98 mm^2; the results revealed no statistically significant difference in postoperative modified Harris Hip Score, HOS-ADL, HOS-SSS, and NAHS scores between the microfracture and control groups, except for the visual analog scale scores at 2 years, which were significantly superior in the control group.

Experimental animal studies attempted to use chitosan-based material as a scaffold to potentiate the biomechanical properties of the repair tissue after microfractures and found a significant similarity between repair tissue and native hyaline cartilage with regard to the content of glycosaminoglycan and arrangement of collagen type II, as well as proper incorporation to the surroundings.[8,10]

Previous clinical studies on chitosan-based implant, although few, support our findings. The same preparation of chitosan-based material has been used previously for treatment of full-thickness cartilage defects in the knee.[12,13] Patients treated with this technique showed significant functional improvement for $\leq$5 years and maintained quantity and quality of the repaired cartilage (percentage of filling and T2 relaxation time) more than patients treated by microfractures only.[12,13] Second-look arthroscopy after 13 months has confirmed the superior results of the chitosan-treated cartilage; better filling, surface quality, and integration to the surroundings and biopsy analysis showed more similarity to native hyaline cartilage, as measured by polarized light microscopy scoring.[36]

With regard to the application of chitosan-based implant in hip pathologies, a preliminary study[37] included quantitative magnetic resonance imaging evaluation of 10 patients after 18 months using similar methods. The results showed >90% filling of the defects with imaging properties comparable to the normal articular cartilage and significant improvement in HOS scores. This short-term and small-volume study provided a promising preliminary result, but it is not sufficient to conclude the clinical effectiveness of this method of cartilage repair.

Limitations

Important limitations to our work are the lack of a control group to compare the results and the wide range of follow-up (24-50 months) at the endpoint of the study. In addition, the cases were operated by 2 senior surgeons (M.T., J.M.), and this factor may be a source of bias, even though both surgeons strictly followed the same technique and steps. An a priori power analysis was not performed, so there is a risk of statistical type 2 error with the small sample size of our study. Because of the small number of patients, we could not definitely conclude the safety of chitosan implant for use in the hip joint. The results can be attributed to several factors, such as nonextensive chondral defects (maximally involving 2 zones), the short preoperative period of symptoms (mean 32.0 $\pm$ 10.4 months), and initial improvement after cam resection and labral repair. Thus, it is difficult to conclude the specific contribution of chitosan-based material in the results.

Conclusions

The arthroscopic combined treatment of microfractures and chitosan-based scaffold has maintained satisfactory clinical outcomes in 91% of the patients with a large ($\geq$2 cm^2) full-thickness acetabular chondral defect associated with FAI at mean follow-up of 38.4 months. However, this study could not definitely draw any conclusion regarding the safety of chitosan-based material for use in the hip joint.

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