Autologous Costal Cartilage Grafting for a Large Osteochondral Lesion of the Femoral Head

A 1-Year Single-Arm Study with 2 Additional Years of Follow-up

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Background: There is currently no ideal treatment for osteochondral lesions of the femoral head (OLFH) in young patients.

Methods: We performed a 1-year single-arm study and 2 additional years of follow-up of patients with a large (defined as >3 cm^2) OLFH treated with insertion of autologous costal cartilage graft (ACCG) to restore femoral head congruity after lesion debridement. Twenty patients ≤40 years old who had substantial hip pain and/or dysfunction after nonoperative treatment were enrolled at a single center. The primary outcome was the change in Harris hip score (HHS) from baseline to 12 months postoperatively. Secondary outcomes included the EuroQol visual analogue scale (EQ VAS), hip joint space width, subchondral integrity on computed tomography scanning, repair tissue status evaluated with the Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) score, and evaluation of cartilage biochemistry by delayed gadolinium-enhanced magnetic resonance imaging of cartilage (dGEMRIC) and T2 mapping.

Results: All 20 enrolled patients (31.02 ± 7.19 years old, 8 female and 12 male) completed the initial study and the 2 years of additional follow-up. The HHS improved from 61.89 ± 6.47 at baseline to 89.23 ± 2.62 at 12 months and 94.79 ± 2.72 at 36 months. The EQ VAS increased by 17.00 ± 8.77 at 12 months and by 21.70 ± 7.99 at 36 months ($p < 0.001$ for both). Complete integration of the ACCG with the bone was observed by 12 months in all 20 patients. The median MOCART score was 85 (interquartile range [IQR], 75 to 95) at 12 months and 75 (IQR, 65 to 85) at the last follow-up (range, 24 to 38 months). The ACCG demonstrated magnetic resonance properties very similar to hyaline cartilage; the median ratio between the relaxation times of the ACCG and recipient cartilage was 0.95 (IQR, 0.90 to 0.99) at 12 months and 0.97 (IQR, 0.92 to 1.00) at the last follow-up.

Conclusions: ACCG is a feasible method for improving hip function and quality of life for at least 3 years in young patients who were unsatisfied with nonoperative treatment of an OLFH. Promising long-term outcomes may be possible because of the good integration between the recipient femoral head and the implanted ACCG.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Osteochondral lesions are characterized by impaired articular surface integrity and can lead to osteoarthritis in physically active persons[1,2]. Arthroscopic microfracture, with the aim of inducing the formation of fibrocartilage, can achieve satisfying function, especially for patients with small defects[3-6]. However, the functional outcome regained after

Disclosure: The **Disclosure of Potential Conflicts** of Interest forms are provided with the online version of the article (http://links.lww.com/JBJS/H281).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H283).

microfracture deteriorates over time because fibrocartilage has a weaker structure than hyaline cartilage[7,8]. Thus, many alternative and adjunct techniques to achieve a hyaline-like repair, including matrix-induced autologous chondrocyte implantation (MACI)[9], autologous matrix-induced chondrogenesis[10], bone marrow concentrate[11], platelet-rich plasma[12], and hyaluronic acid[13], have been developed and recommended.

Restoring impaired osteochondral structure is clinically challenging, especially for large defects (defined as >3 cm^2) in hips. Although various surgical techniques have been developed, most are only applicable to the knee and ankle, and not the hip[14,15]. A previous study suggested that up to 40% of hips with small chondral defects treated with microfracture subsequently require hip replacement[16,17]. Although many previous studies have reported that fresh osteochondral allografts permit treatment of large defects, the long-term outcomes were only fair, with a mean Harris hip score (HHS) of 77.4 at a mean follow-up of 68.8 months[18]. Additionally, the limited number of osteochondral allograft donors remains a challenge in clinical practice[18,19].

In this study, we aimed to explore the use of autologous costal cartilage graft (ACCG), which is hyaline cartilage, to treat large osteochondral lesions of the femoral head (OLFHs). Costal cartilage is the largest source of hyaline cartilage in the human body and is easily accessible[20]. Free costal cartilage grafts have been used in plastic surgery of non-weight-bearing portions of the body, including rhinoplasty[21] and auricular reconstruction[22,23]. We have previously shown that costal grafts are able to repair large osteochondral defects in rabbit knees, and the implanted costal cartilage grafts integrated into the bone bed and formed an osteochondral interface-like structure[24]. Based on that preclinical study, the current study aimed to assess the potential efficacy, safety, and feasibility of using ACCG for treating large OLFHs.

Materials and Methods

Study Design

We designed a 1-year single-arm study with 2 years of additional follow-up in alignment with the Idea, Development, Exploration, Assessment and Long-term follow-up (IDEAL) framework for surgical procedure innovation[25], and reported in accordance with the Preferred Reporting Of CasE Series in Surgery (PROCESS) guideline[26]. The study abides by the Declaration of Helsinki; was approved by the Human Ethics Committee of Shanghai Sixth People's Hospital Affiliated with the Shanghai Jiao Tong University School of Medicine, in the People's Republic of China (Approval No. 2018-027); and was registered in the Chinese Clinical Trial Registry (ChiCTR1800015544).

We recruited patients 14 to 40 years old with a large (defined as >3 cm^2) OLFH at a single center. The diagnosis and size measurement of the osteochondral lesion were determined by magnetic resonance imaging (MRI) in accordance with previous reports[27-29]. The inclusion criteria were a score on a visual analogue scale (VAS) for pain of ≥6 and/or HHS of ≤69 after failed nonoperative therapy including pain-relieving medication and physical therapy. Patients were excluded if they had a history of corticosteroid therapy (n = 17); additional hip-joint deformities except for femoroacetabular impingement (n = 8); contradictions to elective hip surgery, including poorly controlled diabetes (n = 1), pregnancy (n = 0), or lactation (n = 0); computed tomography (CT)-confirmed severe rib ossification (n = 3); or an age of >40 or <14 years (n = 8).

Lesion Depth Grading

The International Cartilage Repair Society (ICRS) classification system[30] was used to evaluate the lesion depth. Grade 0 represents normal intact cartilage; Grade 1, chondral softening and blistering, superficial lesions, fissures and cracks, and/or a soft indentation; Grade 2, fraying, lesions, and fissures extending <50% of the cartilage depth; Grade 3, partial loss of cartilage thickness and/or cartilage lesions extending >50% of the cartilage depth and down to the calcified layer; and Grade 4, full-thickness cartilage loss with subchondral bone exposure.

Study Interventions

ACCG was harvested according to previous recommendations[31] (Fig. 1; see also Video 1). The detailed surgical procedure is shown in Figure 2 and described in the Appendix. The rehabilitation protocol is listed in Table I.

Patient-Reported Outcomes

The primary outcome was the improvement in the HHS from baseline to 12 months postoperatively. The HSS assesses hip function and can range from 0 to 100 points, with a larger number indicating better function[32]. The secondary outcomes included the EuroQol visual analogue scale (EQ VAS) and University of California Los Angeles (UCLA) activity scale. The EQ VAS assesses self-rated health and can range from 0 to 100, with 0 and 100 representing "the worst" and "the best" health that the patient can imagine, respectively[33]. The UCLA scale assesses physical activity participation and can range from 1 to 10, with 1 defined as "no physical activity, dependent on others" and 10 defined as "regular participation in impact sports."[34] The baseline UCLA value was retrospectively collected at 12 months by patient recall.

Imaging Outcomes

Radiographs were made at baseline and postoperatively at 6 weeks, 6 months, 12 months, and annually thereafter; MRI and CT scanning were performed at baseline and postoperatively at 6 weeks, 6 months, and 12 months according to the study protocol. After the first year, we encouraged participants to receive either CT or MRI examinations, depending on their preference, with a frequency of no more than once per year. All patient information on the imaging assessments was deidentified by 1 independent researcher. Final outcomes were the mean or majority of 3 readouts from 3 independent evaluators. Postoperative changes in the joint space width were assessed in accordance with a previous report[35] (see Appendix Figure S1).

Bone cysts were assessed by identifying the layer showing the largest cut through the cyst and then creating a line along the long axis of the cyst to determine the maximum cyst

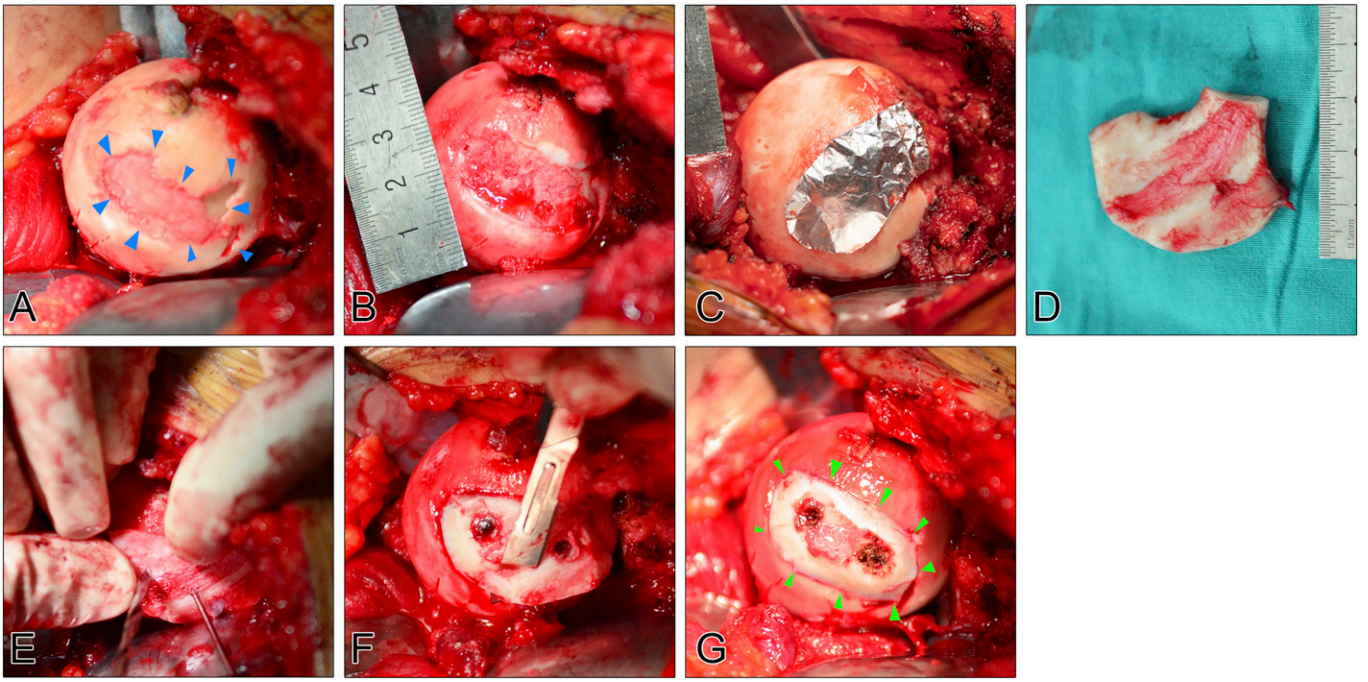

Fig. 1

Figs. 1-A through 1-G Surgical procedure for repairing femoral head osteochondral lesions using autologous costal cartilage graft (ACCG) in young patients. **Fig. 1-A** A femoral head with a cartilage lesion in the weight-bearing region (blue arrows) was exposed via a Smith-Petersen approach. **Fig. 1-B** The cartilage lesion was thoroughly debrided to a bleeding bone bed. **Figs. 1-C and 1-D** A segment of costal cartilage without perichondrium was collected from the right sixth rib. **Fig. 1-E** The graft was implanted into the debrided area and was fixed using 2 absorbable screws (FreedomScrew; Inion). **Fig. 1-F** The surface of the fixed graft was carved using a scalpel to match the contour of the articular surface. **Fig. 1-G** The articular surface has been restored by the implanted ACCG (green arrows).

diameter. ACCG integration with bone was defined as the disappearance of the low-density fissure between the ACCG and the bone bed (including recipient bone and bone autograft, if used) on CT scans (see Appendix Figure S2). The Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) score was used to evaluate the structure of repaired cartilage (range, 0 to 100; a higher score represents better structural qualities of the repair)[36,37]. Delayed gadolinium-enhanced MRI of cartilage (dGEMRIC), T2 mapping, and 3D double-echo steady-state sequences were used to assess whether the implanted ACCG maintained its phenotype of hyaline cartilage after surgery[38]. The dGEMRIC results were analyzed by calculating the ratio of the relaxation times of the ACCG and recipient articular cartilage. An ACCG/recipient ratio close to 1 indicates that the implanted ACCG has biochemical constituents similar to those of the recipient articular cartilage, namely hyaline cartilage.

Statistical Analysis

We expected the mean HHS improvement between baseline and 12 months to be 10 (1 grade), which is considered clinically important, according to the HHS grading systems. Assuming that the maximum standard deviation was 1.2 times the mean, a sample size of 14 patients could provide 82.2% power to detect that at an alpha level of 0.05. Since the minimum sample size is generally set to 20 patients in exploratory research, the final sample size was increased to 25 to take a potential 20% dropout rate into consideration.

A paired t test was used to compare the change in the HHS between baseline and 12 months, and a 95% confidence interval (CI) was calculated for the change. A mixed model for repeated measures was used to test the change in the HHS score over time, with pairwise comparisons of the difference between different time points over the 36-month follow-up period. Changes in the EQ VAS between baseline and 12 or 36 months were assessed using the McNemar test or Fisher exact test. Comparisons for other continuous variables (UCLA, MOCART, joint space width) were performed using a paired t test or Wilcoxon signed-rank test. Data analysis was performed according to the intention-to-treat (ITT) principle, under which the full analysis set was used to estimate the treatment effect. All reported p values are 2-sided, and <0.05 was considered significant. Corrections for multiple testing were not applied. All analyses were performed using SAS software (version 9.4; SAS Institute). Statistical graphs were plotted using Prism (GraphPad Software).

Source of Funding

This study was funded by the National Natural Science Foundation of China (no. 81820108020) and Shanghai Shen Kang Hospital Development Center (no. SHDC2020CR1025B).

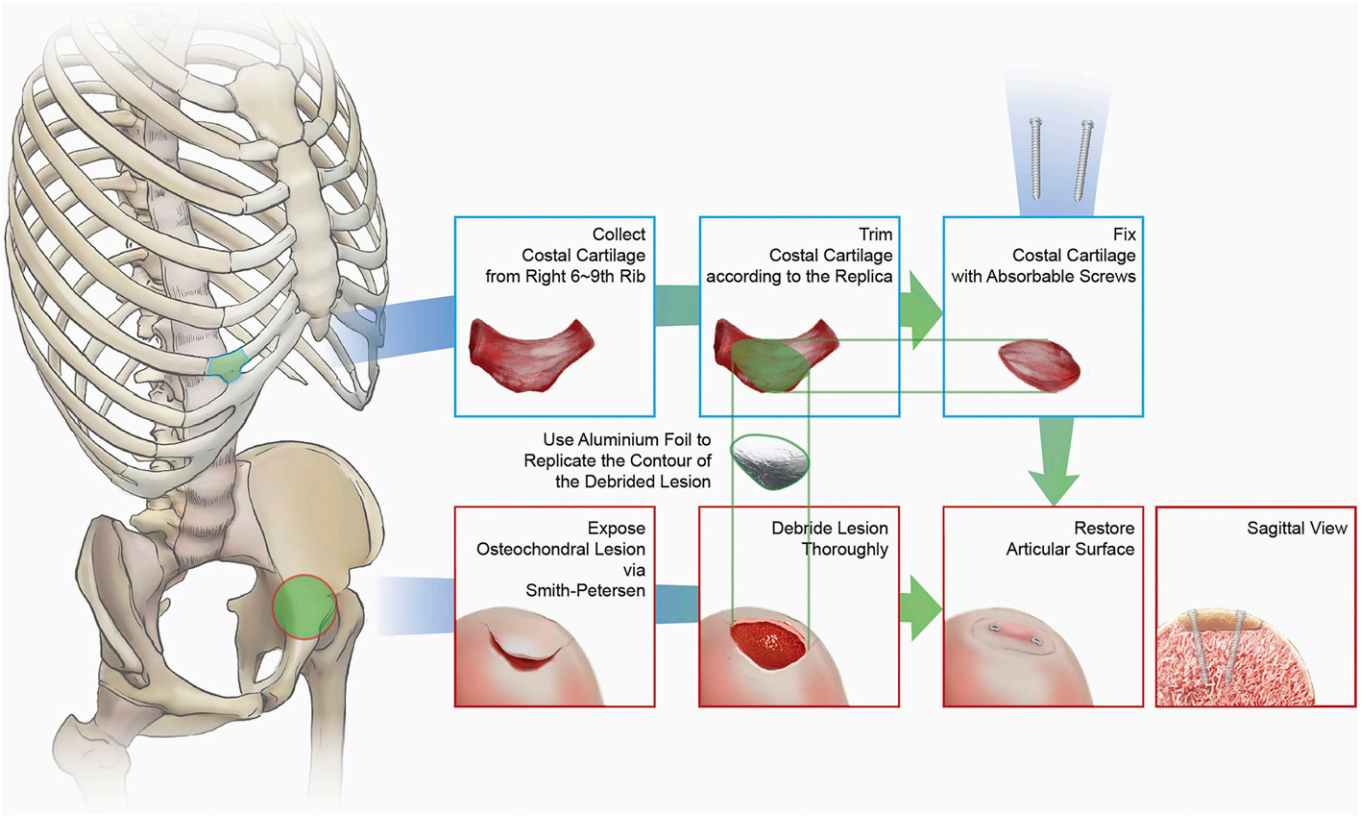

Fig. 2

A schematic illustration of the ACCG procedure.

TABLE I Postoperative Rehabilitation Training Protocol

First day after surgery

- Supine to semirecumbent position
- Full active and passive range of motion of the hip joints
- Patients can sit up and support their weight on the unaffected leg or using crutches, without weight-bearing activities on the affected leg

2 weeks after surgery

- Active full-range-of-motion functional exercises of the hip joint after stitch removal

1 month after surgery

- Depending on the activity status of the hip joint, gradually progress muscle-strengthening exercises of the affected limb with sandbags
- Depending on the healing of the surgical area (usually femoral head-iliac bone healing can be seen on CT), gradually progress weight-bearing exercises to recover hip joint function and muscle strength
- Touch-down weight-bearing (TDWB): the foot can touch the ground when resting, but is not allowed to touch the ground when walking
- Toe-touch weight-bearing (TTWB): the toe can lightly touch the ground while maintaining balance. The patient can imagine the affected limb stepping on an egg, which would break if too much weight is applied. Clinically, TTWB is ≈5% of body weight, only slightly more than TDWB
- Weight-of-leg weight-bearing (WOLWB): the affected limb can share 10%-20% of the body weight, which is equivalent to the weight of the affected leg
- Partial weight-bearing (PWB): the affected limb can share 20%-50% of the body weight. The patient can stand on both legs without crutches, but cannot walk without crutches

6 months after surgery

- Weight-bearing as tolerated (WBAT): most or all of the weight to the affected limb (50%-100% of body weight) can be loaded on the affected limb for as long as the patient can bear. At this time, most enrolled patients have already transitioned to walking with 1 crutch
- Progress to full weight-bearing (FWB): the affected limb can bear 100% of body weight, and normal walking is permitted

Results

Between April 1 and December 31, 2018, 57 patients with progressive hip pain were screened; 20 patients met the inclusion criteria and were enrolled in the study. All 20 patients subsequently completed the 36-month follow-up for patient-reported outcomes. Nineteen patients completed MRI and CT scanning at 12 months in accordance with the study plan. The latest MRI scanning of these 19 patients was performed at a mean (and standard deviation) of 31.7 ± 4.0 months (range, 24 to 38 months) after surgery. Patient baseline characteristics are shown in Table II and Appendix Supplementary Tables 1-1 through 2. The mean age of the enrolled patients was 31.02 ± 7.19 years. The median duration of symptoms was 12.50 months (interquartile range [IQR], 5.00 to 22.50), and the mean baseline HHS score after nonoperative treatment was 61.89 ± 6.47. The mean body mass index (BMI) was 24.04 ± 2.93 kg/m^2. All of the osteochondral lesions were classified as ICRS grade IV, with 11 cases involving subchondral bone cysts. The median OLFH size was 7.65 cm^2 (range, 3.31 to 15.10 cm^2).

TABLE II Baseline Characteristics and Clinical Outcomes (N = 20)

Age* *(yr)*	31.02 ± 7.19
Female sex *(no. [%])*	8 (40)
Body mass index* *(kg/m^2)*	24.04 ± 2.93
Duration of symptoms†‡ *(mo)*	12.50 (5.00, 22.50)
Symptomatic hip *(no. [%])*	
Right	9 (45)
Left	11 (55)
Area of cartilage lesion† *(cm^2)*	7.65 (5.47, 10.27)
ICRS grade IV *(no. [%])*	20 (100)
History of injury *(no. [%])*	9 (45)
Diabetes *(no. [%])*	0 (0)
Hypertension *(no. [%])*	0 (0)
Smoking *(no. [%])*	4 (20)
Drinking *(no. [%])*	0 (0)
Operative time* *(min)*	122.25 ± 35.78
Intraoperative blood loss† *(mL)*	300 (255.00, 375.00)
Baseline HHS*§	61.89 ± 6.47
12-month HHS*§	89.23 ± 2.62
36-month HHS*§	94.79 ± 2.72
12-month EQ VAS change from baseline*	17.00 ± 8.77
36-month EQ VAS change from baseline*	21.70 ± 7.99
12-month MOCART score†	85 (75, 95)
36-month MOCART score†	75 (65, 85)
Baseline UCLA activity scale*	3.45 ± 1.32
12-month UCLA activity scale*	5.65 ± 1.39
36-month UCLA activity scale*	7.95 ± 1.23

*The values are given as the mean and standard deviation. †The values are given as the median, with the interquartile range in parentheses. ‡Retrospective, as reported by the patient at 12 months. §From 0 (poorest hip function) to 100 (best hip function).

The improvement in the HHS at 12 months after surgery, relative to the baseline score, was 27.34 ± 6.71 ($p < 0.001$), which was a clinically important difference in hip function. There was no significant functional deterioration by 36 months (mean change, 32.91 ± 7.16 [$p < 0.001$] compared with baseline). The EQ VAS increased by 17.00 ± 8.77 at 12 months and by 21.70 ± 7.99 at 36 months (both $p < 0.001$ compared with baseline). In the imaging analysis, the joint space width temporarily increased from 2.66 ± 1.05 mm at baseline to 3.47 ± 1.22 mm immediately after the ACCG implantation ($p = 0.0408$), followed by a decline to 2.15 ± 0.70 mm at 12 months, which was maintained at 2.20 ± 0.76 mm at 36 months ($p = 0.8067$ between 12 and 36 months). The UCLA physical activity participation score increased from 3.45 ± 1.32 at baseline to 5.65 ± 1.39 at 12 months and 7.95 ± 1.23 at 36 months (Table II). Complete integration between the ACCG and the underlying recipient bone was achieved in the imaging performed at 12 months postoperatively in all 20 cases (100%; 95% CI, 83.16% to 100.00%) based on CT scans(Fig. 3-B). The MOCART score was calculated for 19 patients at 12 months postoperatively and at the last follow-up (range, 24 to 38 months) to evaluate the structural status of the ACCG (Table II). The median MOCART score at 12 months was 85 (IQR, 75 to 95). As expected, structural deterioration could be observed at the last MRI follow-up (at 31.7 ± 4.0 months; range, 24 to 38 months), with a drop in the median MOCART score to 75 (IQR, 65 to 85). The median relaxation time of the implanted ACCG in T2 mapping was close to that of the recipient cartilage (ACCG/recipient ratio, 0.95 [IQR, 0.90 to 0.99] at 12 months and 0.97 [IQR, 0.92 to 1.00] at the last follow-up) (Fig. 3-C), indicating that the biochemical constituents of the implanted cartilage graft were similar to those of the recipient hyaline cartilage.

No major local or systemic complication was recorded during the 36-month follow-up. The treatment-emergent adverse events were wound complications (2 patients), itching (1 patient), and ankle pain (1 patient), which were all short-term. The 2 wound complications were both superficial wound infections and were treated with oral antibiotic therapy.

Discussion

Successful reconstruction of a large OLFH remains clinically challenging. In several previous studies of patients with OLFH, cartilage repair surgery including microfracture[39,40] and autologous chondrocyte transplantation[41,42] yielded no benefit in comparison with the control group, especially for those with large defects. Thus, nonoperative treatment is currently the accepted option for OLFH[43]. Free costal cartilage grafts have been used in plastic surgery of non-weight-bearing portions of the body, including rhinoplasty[21-23]. In a preclinical study, researchers demonstrated that implanted costal cartilage could integrate well with subchondral bone and articular

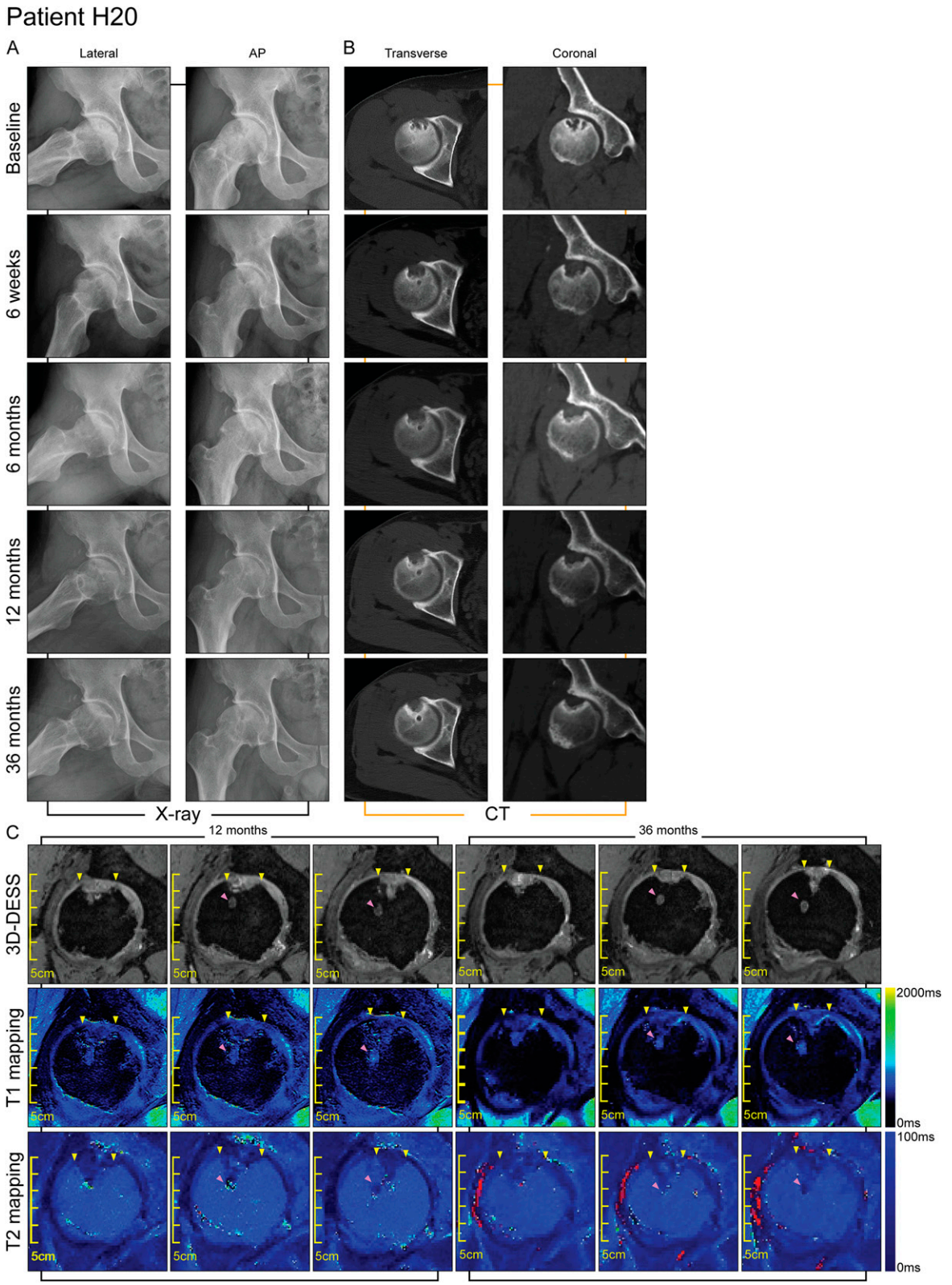

Fig. 3

Radiographic (**Fig. 3-A**), CT (**Fig. 3-B**), and MRI (**Fig. 3-C**) images at different time points from a patient with an osteochondral lesion on the right femoral head who had received an ACCG. Yellow arrows indicate the margin of the ACCG, and pink arrows indicate the absorbable screws. AP = anteroposterior, and DESS = double-echo steady-state.

cartilage in weight-bearing joints[24]. Thus, the current single-arm study implemented the IDEAL framework to investigate whether ACCG is a feasible option to repair OLFHs after the failure of nonoperative treatment. The 3-year results from this study were promising in terms of both function and structural integrity of the femoral head, with only mild donor-site morbidity.

Long-term success has been achieved by osteochondral autograft and allograft transplantation for the treatment of osteochondral lesions in the ankle and knee[44,45]. Osteochondral autografting has been reported to successfully repair small osteochondral lesions, but this technique is unlikely to be able to repair large lesions because of the limited amount of available osteochondral autograft[46]. Many studies have reported on the treatment of large defects in the hip with fresh osteochondral allograft, but the long-term outcomes of this procedure were clearly unsatisfactory. The mean HHS was 77.4 at a mean follow-up of 68.8 months in 1 study of osteochondral transplantation in the hip[18], and another study reported a similar mean HHS of 72.9 at a mean follow-up of 41.6 months[47]. In contrast, ACCG transplantation achieved an HHS of 94.79 ± 2.72 at 36 months in the current study.

It has been well established that MRI findings correlate with clinical outcomes in the short term after cartilage repair surgery[48,49]. In the current study, we observed a good structural repair, in terms of the MOCART score, at 12 months after use of ACCG to treat OLFHs. Structural and functional outcomes are expected to deteriorate over time after all types of cartilage repair surgery[7,8,50]. The conventional explanation for this phenomenon is that the cartilage produced by the surgery is initially fibrous or gradually degenerates into fibrocartilage[7,8]. Previously, researchers believed that the structural deterioration would not occur if a hyaline phenotype of the transplant could be maintained after surgery[7,8,50]. In our study, however, structural deterioration was still observed (as indicated by the decrease in the median MOCART score from 85 at 12 months to 75 at the last MRI follow-up), although perhaps at a different speed, even though all of the implanted grafts had maintained their hyaline phenotype at the last follow-up.

Elevated BMI at baseline is a well-established risk factor for poor outcomes in all cartilage repair procedures in the ankle, knee, and hip[51-54]. The resulting tissue has less mechanical strength compared with uninjured cartilage[7,8]. Thus, the repaired cartilage is expected be more susceptible to elevated BMI[50]. However, we did not observe an association between the baseline BMI and the functional and structural outcomes, possibly because of our limited sample size. Future studies with larger sample sizes could further investigate the association between the prognosis after ACCG implantation and BMI.

The current study has several limitations. First, it had a small sample size and was performed in a single-arm fashion because no other surgery has currently been proven to be efficacious at this phase for large OLFHs. Additionally, given that ACCG implantation is an invasive procedure, it would clearly have been unethical to perform a sham surgery as the control. Thus, we chose to perform an exploratory single-arm study with a small sample size that would be sufficient to obtain preliminary evidence of the efficacy, safety, and feasibility of ACCG implantation. Second, the current study only involved repair of large OLFHs using ACCG, whereas repair of small OLFHs using osteochondral autografts has been performed sporadically and promising outcomes have been reported[55]. It remains unclear whether ACCG implantation is a suitable option for small osteochondral lesions of the hip because of its invasive nature. Finally, the study plan called for imaging assessment, including CT or MRI, at 1 and 5 years, but at this time we are only able to report imaging outcomes at 24 to 38 months. A 3-year follow-up is not long enough to demonstrate the long-term efficacy of ACCG implantation with respect to functional outcomes. However, a future study with longer follow-up and more participants has become realistic on the basis of the current study.

In conclusion, our results demonstrate that ACCG can improve hip function and relieve pain for at least 3 years in young patients with an OLFH in whom nonoperative treatment has failed. Harvesting of costal cartilage is safe and minimally invasive. This study has provided initial verification of the safety and feasibility of repairing osteochondral lesions in a weight-bearing joint with ACCG, potentially improving the prognosis for young patients.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H282). ■

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