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Collagen Meniscal Scaffold Implantation Can Provide Meniscal Regeneration in Asian Patients with Partial Meniscal Defects: A Prospective Randomized Controlled Study with Three-Dimensional Volume Analysis of the Meniscus

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Background: To date, the efficiency of collagen meniscal scaffold implantation in Asian patients with partial meniscal defects has not been evaluated. In addition, no study has quantitatively analyzed meniscal regeneration using three-dimensional (3D) volume analysis after collagen scaffold implantation. We aimed to compare meniscal regeneration using 3D volume analysis between Asian patients undergoing collagen-based meniscal scaffold implantation after partial meniscectomy and those undergoing only partial meniscectomy.

Methods: Nineteen patients who underwent collagen-based meniscal scaffold implantation and 14 who underwent partial meniscectomy were analyzed with a prospective randomized control design for 12 months postoperatively. The demographic characteristics, Kellgren-Lawrence grade, and location of the injury lesion (medial or lateral meniscus) were not significantly different between the groups. Using 3D volume analysis with magnetic resonance imaging (MRI), the meniscus-removing ratio during the operative procedure and the meniscus defect-filling ratio were measured during the 12-month postoperative period. Clinically, the visual analog scale, International Knee Documentation Committee score, and Knee Injury and Osteoarthritis Outcome Score were evaluated. The Whole-Organ Magnetic Resonance Imaging Score (WORMS) and Genovese grade were also evaluated using MRI.

Results: In the 3D volume analysis, the average meniscus-removing ratio during surgery was not significantly different between the groups (–9.3% vs. –9.2%, $p = 0.984$). The average meniscus defect-filling ratio during the postoperative 12-month period was 7.5% in the scaffold group and –0.4% in the meniscectomy group ($p < 0.001$). None of the clinical results were significantly different between the scaffold and meniscectomy groups at 12 months postoperatively. The average change in the total WORMS score was not significantly different between the groups (0 vs. 1.9, $p = 0.399$). The Genovese grade of the implanted collagen scaffold did not significantly change during the follow-up period in terms of morphology and size ($p = 0.063$); however, the grade significantly improved in terms of signal intensity ($p = 0.001$).

Conclusions: Definite meniscal regeneration and stable scaffold incorporation were observed after collagen-based meniscal scaffold implantation in Asian patients during 12 months of follow-up. A long-term follow-up study with a larger cohort is required to determine the advantages of collagenous meniscal scaffold implantation in Asian patients.

Keywords: *Knee, Meniscus, Collagen scaffold, Meniscectomy, Regeneration*

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The meniscus plays a crucial role in the transmission and distribution of load across the knee, as well as shock absorption, joint stability, lubrication, and congruity.[1,2] Loss of the meniscus, even in partial instances, can cause an imbalance of homeostasis in the knee joint and lead to the development of degenerative osteoarthritis.[1] Collagen meniscal scaffold implantation has been suggested as a method to restore the partial meniscal defect, offering a template for cells and potentially facilitating meniscal regeneration.[3] Safety and satisfactory clinical results have been reported using collagen meniscal scaffolds in long-term retrospective studies.[4,5]

Asians engage in distinctive cultural activities that often require deep flexion of the knee, which can increase tibiofemoral contract pressure and damage the meniscus.[6] Additionally, they exhibit different anatomic morphologies compared with those of other races, including slight varus limb alignment and high tibial slope.[6,7] These characteristics may be responsible for the different results after collagen meniscal scaffold implantation compared to those in other populations. Although previous studies have analyzed collagen meniscal scaffold implantation performed in populations in Western countries,[4,5,8,9] no study has analyzed the results of collagen meniscal scaffold implantation in only Asian patients with partial meniscal defects.

A prospective randomized trial, conducted in the United States, confirmed meniscal regeneration in 141 patients who received a collagen meniscal scaffold at 1-year second-look arthroscopy.[10] Other previous studies have also shown scaffold incorporation by regenerative tissue in magnetic resonance imaging (MRI) findings after collagen meniscal scaffold implantation.[11,12] However, no studies have quantitatively analyzed meniscal regeneration using three-dimensional (3D) volume analysis after collagen scaffold implantation, although 1 previous study performed 3D volume analysis after polyurethane scaffold implantation.[13]

Our primary aim was to compare meniscal regeneration through 3D volume analysis between Asian patients undergoing collagen-based meniscal scaffold implantation after partial meniscectomy and those undergoing only partial meniscectomy. The secondary aim was to evaluate and compare overall clinical, radiographic, and MRI outcomes between the 2 groups. We hypothesized that collagen meniscal scaffold implantation would provide better or more favorable results in all evaluations even in Asian patients.

METHODS

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Institutional Review Boards of Kyung Hee University Hospital (No. KHUH 2021-03-044; 2022-01-12), Myongji Hospital (No. MJH 2021-03-016; 2022-02-11), Samsung Medical Center (No. SMC 2021-03-097; 2022-01-21). All participants provided written informed consent.

Study Design and Participants

This prospective, randomized, open-label, multicenter study was performed between June 2021 and November 2022 and the study was registered at the Clinical Research Information Service (KCT0009031). A screening was conducted among participants with partial meniscal injury of the knee (diagnosed through MRI before the study).

Those who provided written informed consent were assessed for eligibility based on the inclusion/exclusion criteria. The inclusion criteria were (1) Asian patients, (2) age of 15–60 years,[10] (3) meniscal injury requiring partial resection of the medial or lateral meniscus, (4) and remaining meniscal rim with a width of ≥ 1 mm with maintained tension. The exclusion criteria were (1) meniscal injury requiring total or subtotal meniscectomy resulting in loss of meniscal rim continuity, (2) severe cartilage lesion (Outerbridge grade IV), (3) degenerative osteoarthritis of Kellgren-Lawrence (K-L) grade IV, (4) varus or valgus limb malalignment with hip knee ankle angle ≥ 5°, (5) knee instability owing to ligament injury, (6) history of inflammatory or infectious arthritis, (7) osteonecrosis of the knee, (8) history of allergic reaction to collagen or sodium chondroitin sulfate of bovine origin, (9) systemic administration of corticosteroids, antitumor agents, and immunostimulators or immunosuppressants within 30 days before surgery, (10) epidemic infectious disease, (11) pregnancy, (12) and cases of patients with cancer, immu-

nological disorder, and neurological diseases.

Eligible patients were simply randomized by sequentially applying permutations of random numbers generated using SAS software (ver. 9.4; SAS Institute) and assigned to either the scaffold group (treated with collagen meniscal scaffold implantation after partial meniscectomy) or the meniscectomy group (treated only with partial meniscectomy).[14] Randomly assigned treatments were concealed within sealed opaque envelopes. After the opening of an envelope, the patients and physicians were aware of the assigned treatment.

Surgical Techniques and Rehabilitation

The surgical procedure was performed through only an arthroscopic approach under general anesthesia. In the scaffold group, leg holder position was used. The meniscal lesion was prepared with partial meniscectomy and debridement of the degenerative tissue. The prepared meniscal defect was measured along the peripheral edge using a ruler guide. Subsequently, the collagen meniscal scaffold (Biomeniscus; Cellumed; Biomeniscus is a porous meniscus-shaped collagen scaffold, approved as a clinical trial product by the Korea Ministry of Food and Drug Safety [product number: B04280.01(4) :18-823] after passing tests for biological stability and safety) (Fig. 1, Table 1) was trimmed to fill the defect. The scaffold was inserted into the defect using a holder via a medial or lateral portal (Fig. 2); the portal for the scaffold insertion was made slightly larger through more incision to facilitate easy insertion. The scaffold was secured to the meniscal remnant using an inside-out absorbable suture with a double-arm needle (TM Global) under dry arthroscopic conditions. Vertical stitches were placed every 5 mm (Fig. 2). Scaffold stability was assessed using a probe after suture completion. In the meniscectomy group, partial meniscectomy was only performed for the lesion with a supine position.

In the scaffold group, non-weight-bearing was recommended for 6 weeks postoperatively, after which partial weight-bearing was allowed and gradually increased up to full weight-bearing by 12 weeks postoperatively. Knee motion was limited to 3 weeks postoperatively with the brace in extension; the motion was allowed to flexion of 90° until 6 weeks postoperatively, and exercising with full range of motion (ROM) was allowed thereafter. Daily light sports activity, such as jogging or swimming, was encouraged after 3 months postoperatively. Performing competitive sports activities, such as soccer and basketball, was recommended after 6 months postoperatively. In the meniscectomy group, free weight-bearing and exercising with full ROM were allowed immediately postoperatively.

Primary and Secondary Outcomes

The primary outcomes were meniscus removing and defect-filling ratio to accurately evaluate meniscal regeneration. To measure the meniscus-removing and defect-filling ratio, the 3D volume of the meniscus (excluding the scaffold) was measured after 3D MRI modeling (3D

Table 1. Property of the Collagen Scaffold

Main component	Type 1 collagen (bovine origin)
Additional components	Sodium, hyaluronate, sodium chondroitin sulfate
Wet basis moisture content (%), mean ± SD	4.0 ± 1.0
Pore size (μm), range	50–500
Shrinkage temperature (°C), mean ± SD	66 ± 6
Loss on drying (%), range	20–30
Minimal suture tensile strength (N)	8.9

SD: standard deviation.

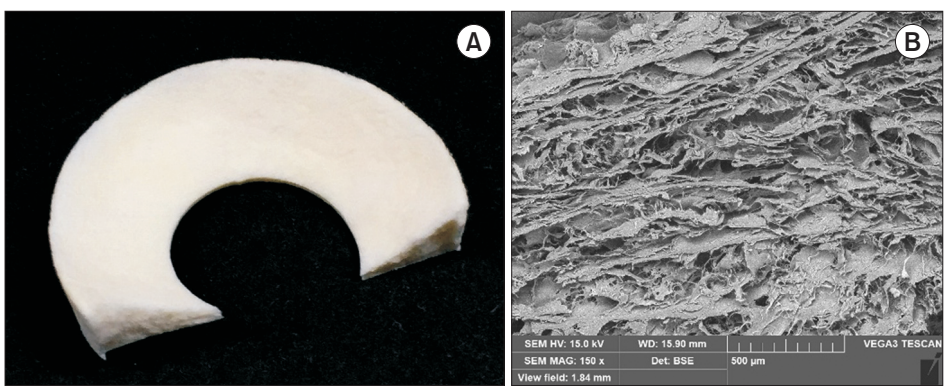

Fig. 1. Collagen meniscus scaffold. (A) Gross shape. (B) Scanning electron microscopic image.

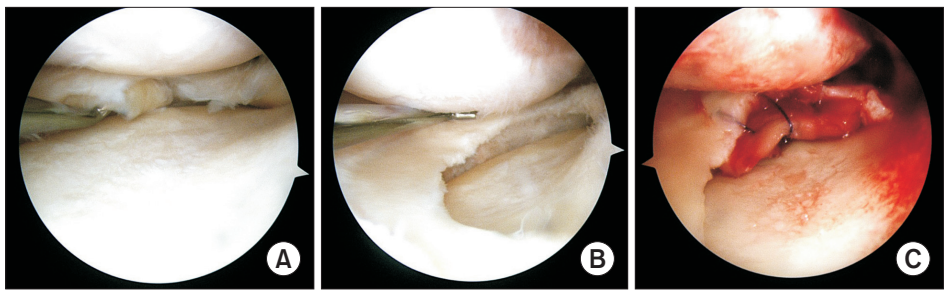

Fig. 2. Arthroscopic images of collagen meniscus scaffold implantation. (A) Oblique tear of the posterior horn of the medial meniscus. (B) Prepared meniscal lesion after partial meniscectomy and debridement of the degenerative tissue. (C) Implanted collagen meniscal scaffold.

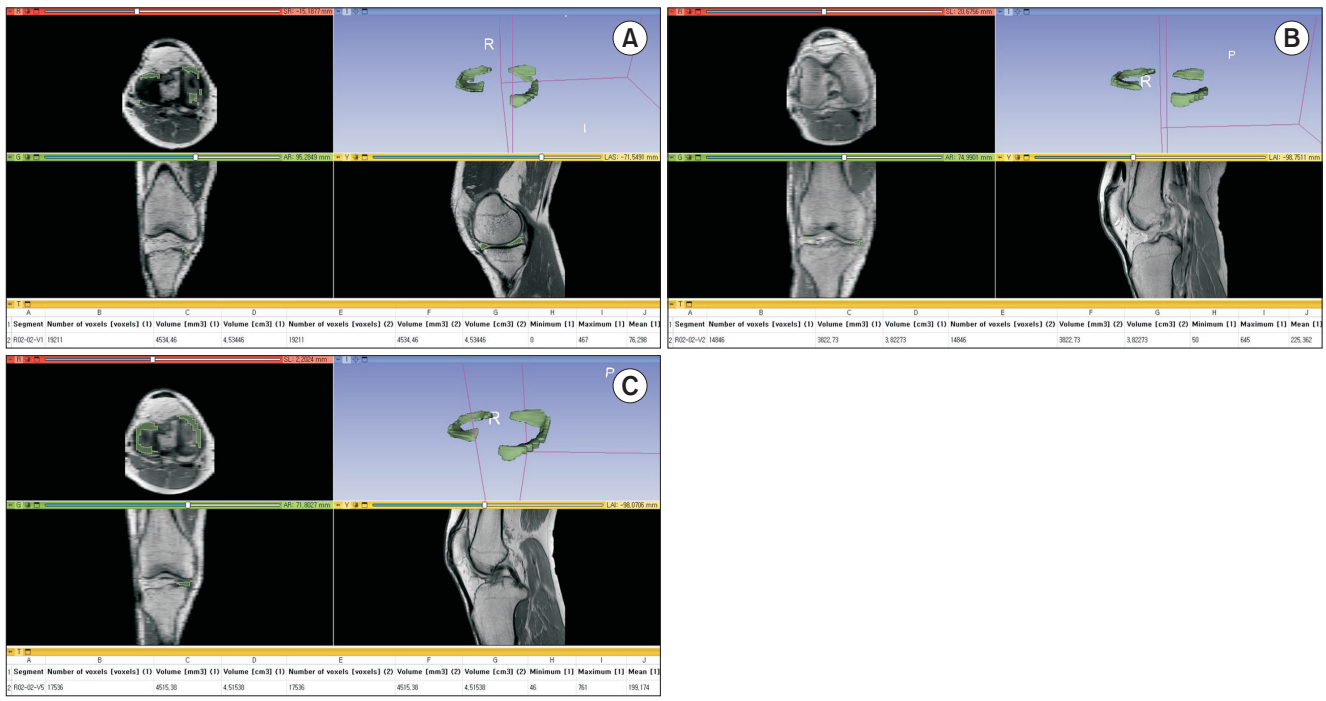

Fig. 3. Three-dimensional volume analysis of the medial meniscus after collagen meniscal scaffold implantation. (A) Preoperative meniscus volume (4,534.5 mm^3). (B) Meniscus volume at 1 day after preparation for the scaffold implantation (3,882.7 mm^3). (C) Meniscus volume after regeneration through the scaffold at 12 months postoperatively (4,515.4 mm^3).

Slicer, InVesalius, ITK-SNAP, and VuePACS3D)[15,16] (Figs. 3 and 4). The preoperative volume of the injured meniscus (volume A) was measured in both groups. The volume of the remnant meniscus after preparation (scaffold group) or partial meniscectomy (meniscectomy group) was measured 1 day postoperatively (volume B). The meniscus volume (including the regenerative meniscal tissue in the scaffold group) was measured 12 months postoperatively (volume C). The meniscus-removing ratio was defined as the percentage ratio obtained by subtracting the original meniscal volume before surgery (A) from the meniscus tissue volume immediately after surgery (B) and dividing it by the original meniscus volume (B – A / A × 100%). The meniscus defect-filling ratio was defined as the percentage ratio obtained by subtracting the meniscus tissue volume immediately postoperatively (B) from the meniscal volume at 12 months postoperatively (C) and dividing it by the original meniscal volume (C – B / A × 100%).

The secondary outcomes were clinical results, radiographic degenerative change, and joint space narrowing and other MRI findings including the Whole-Organ Magnetic Resonance Imaging Score (WORMS) and Genovese grade. Clinical results were evaluated preoperatively (at screening) and at 3, 6, and 12 months postoperatively using the visual analog scale (VAS; 100-mm scale) score, International Knee Documentation Committee (IKDC) score, and Knee Injury and Osteoarthritis Outcome Score (KOOS), which assesses 5 items (pain, symptoms, activities of daily living, sports and recreation, and quality of life).[17,18] Patients visited the outpatient department in

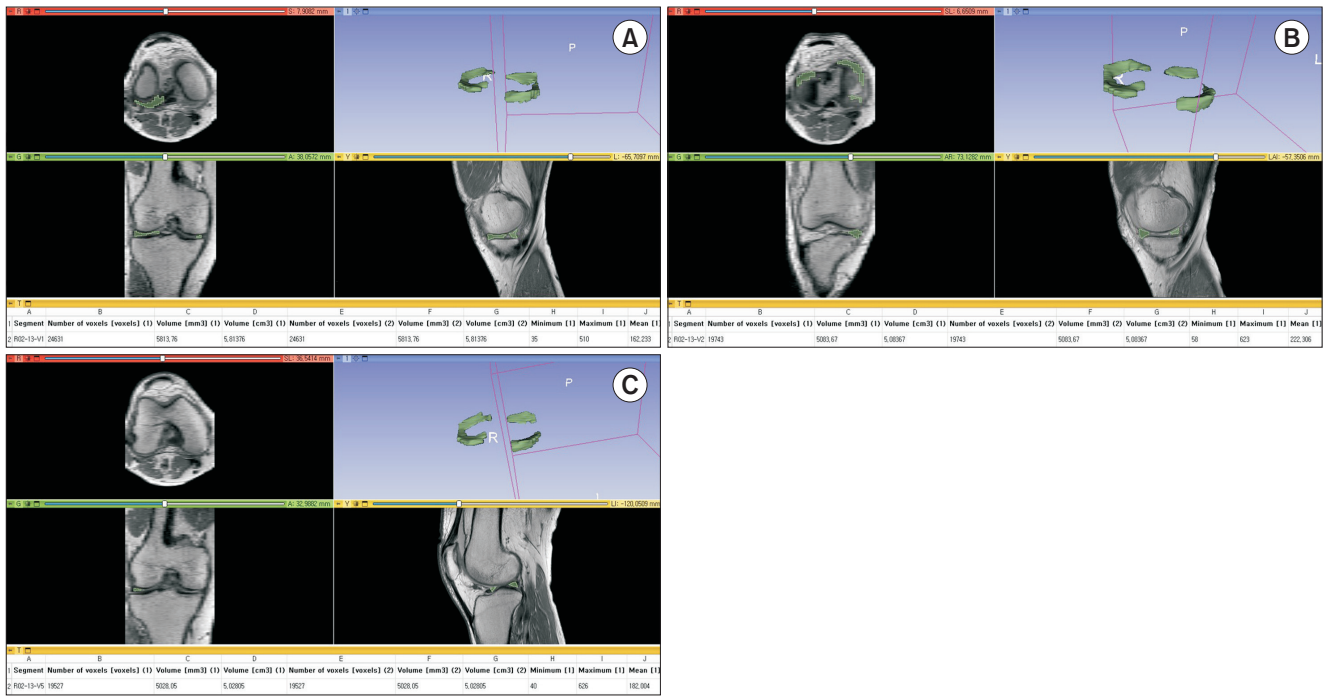

Fig. 4. Three-dimensional volume analysis of the medial meniscus after partial meniscectomy. (A) Preoperative meniscus volume (5,813.8mm^3). (B) Meniscus volume at 1 day after partial meniscectomy (5,083.7mm^3). (C) Meniscus volume at 12 months postoperatively (5,028.1 mm^3).

person and completed a self-administered questionnaire regarding the scoring systems.

Radiographically, the K-L grade was evaluated on standing anteroposterior radiographs preoperatively and at 12 months postoperatively. The degenerative change was determined in cases where an increase of the K-L score ≥ 1 was observed. In addition, joint space narrowing was evaluated in the compartment with the meniscus injury and was defined as the joint space width at 12 months postoperatively minus the preoperative joint space width. The joint space width was measured as the shortest distance between the femoral condyle and the medial tibial plateau in the compartment with the meniscus injury.[19]

Using MRI, the WORMS and Genovese grade were evaluated at 1 day and 12 months postoperatively. The WORMS was used to evaluate the multi-feature, whole-organ assessment of the knee in terms of articular cartilage integrity, subarticular bone marrow abnormality, subchondral bone cysts, subchondral bone attrition, marginal osteophytes, medial and lateral meniscal integrity, ligaments integrity, and synovitis/effusion.[20] The Genovese grade was used to evaluate morphology and size (grade 1, total resorption; grade 2, small with regular and/or irregular morphology; and grade 3, identical shape and size as the normal meniscus) and signal intensity (grade 1, markedly hyperintense; grade 2, slightly intense; and grade 3, isointense relative to the normal meniscus) of the implanted collagen meniscal scaffold in the scaffold group.[21]

A single independent radiologist (who was not involved in the surgeries) with clinical experience ≥ 15 years evaluated the MRI and radiographic findings twice with a 2-week interval. The intraobserver reliability of the meniscal volume and joint space narrowing were assessed using the intraclass correlation coefficient, which was > 0.8. Therefore, the average values of the 2 evaluations were used in the analysis. Intraobserver agreement for determining the K-L grade and the grade of each variable in the WORMS and Genovese system was assessed using Cohen's kappa coefficient. All kappa coefficients were > 0.8. Thus, the grades determined during the initial evaluation were used in this study.

Adverse Events

Any adverse events related to the operative procedure, including swelling, infection, and synovitis, were investigated.[22]

Statistical Analysis

The Kolmogorov-Smirnov test was used to confirm the normality of the data. The meniscus defect and removing filling ratios were compared between the scaffold and meniscectomy groups using the independent *t*-test. All

clinical results were compared using the independent *t*-test. The proportion of radiographic degenerative change was compared between the 2 groups using Fisher's exact test, and radiographic joint space narrowing was compared using the independent *t*-test. The total WOMRS score and cartilage variable in the WORMS score were compared between the groups using the independent *t*-test, and the other variables in the WORMS score were compared using the Mann-Whitney test. The Genovese grade immediately after surgery and 12 months postoperatively were compared using the Wilcoxon signed-rank test. Statistical analyses were performed using IBM SPSS statistics for Windows ver. 25 (IBM Corp.), with statistical significance set at $p < 0.05$.

A priori power analysis was performed based on preliminary data of an initial group of 10 cases to determine the minimum sample size affording sufficient power, with the meniscal defect-filling ratio being the most important primary outcome. The analysis was performed to achieve power for detecting significant differences between the groups. The mean ± standard deviation values of the defect-filling ratio were 11.2% ± 4.8% and 0.0% ± 1.3% in the preliminary scaffold and meniscectomy groups, respectively. The effect size was 3.19, and the alpha and power values were set at 0.05 and 80%, respectively. The results of the sample-size calculation showed the need for including at least 3 cases in each group. Consequently, our sample size was determined to have sufficient power.

RESULTS

Initially, 19 and 17 patients were assigned to the collagen scaffold and partial meniscectomy groups, respectively. However, 3 patients in the meniscectomy group dropped out: 2 refused to participate during the study and 1 did not have the appropriate indication. Finally, 19 and 14 patients were included in the scaffold and meniscectomy groups, respectively (Fig. 5). There were no significant differences between the 2 groups in the baseline demographic characteristics and K-L grade (Table 2). The injury lesion was located in the medial and lateral meniscus in 11 and 8 cases in the scaffold group and in 11 and 3 cases in the meniscectomy group, respectively ($p = 0.213$) (Table 2).

In 3D volume analysis using MRI, the volume of the removed meniscus during surgery was not significantly different between the 2 groups ($p = 0.982$). The average meniscus-removing ratio was −9.3% in the scaffold group and −9.2% in the meniscectomy group ($p = 0.984$). The average meniscal volume increased in the scaffold group during the follow-up period, but did not increase in the meniscectomy group (Table 3). The average meniscal defect-filling ratio was 7.5% in the scaffold group and −0.4% in the meniscectomy group ($p < 0.001$) (Table 3).

Clinically, the VAS, IKDC, and KOOS were not significantly different between the scaffold and meniscectomy groups during the postoperative 12 months, except for the IKDC and the Sports and recreation item in the KOOS at 3 months postoperatively (Fig. 6). Radiographically, 1 patient in the scaffold group (5.3%) and 2 patients in the meniscectomy group (14.3%) showed degenerative changes during the follow-up period ($p = 0.548$). The average joint space narrowing was 0 mm (standard deviation [SD], 0.6 mm) in the scaffold group and –0.1 mm (SD, 0.6 mm) in the meniscectomy group ($p = 0.911$).

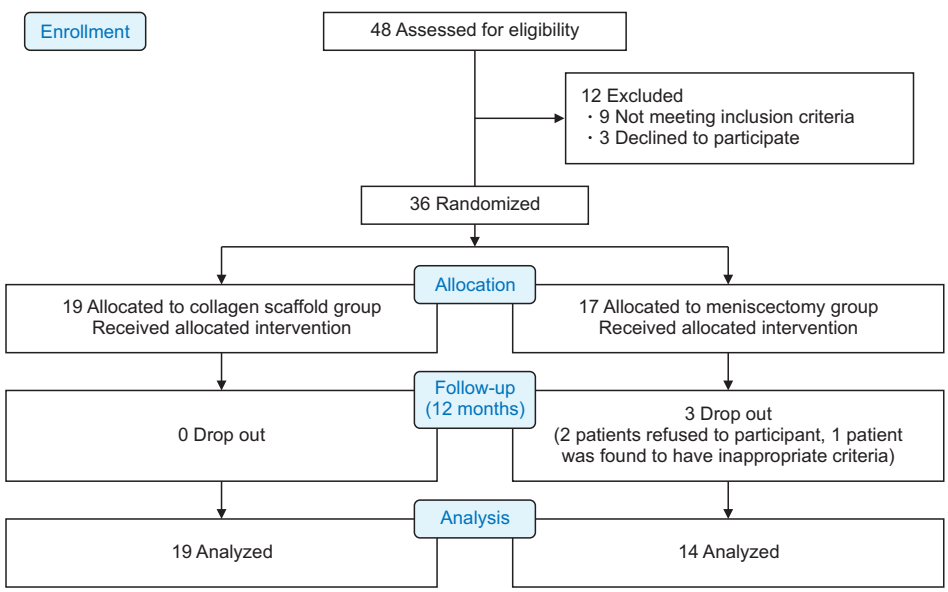

Fig. 5. Flowchart.

Table 2. Patient Demographic Characteristics

Variable	Scaffold	Meniscectomy	*p*-value
Number of knees	19	14	-
Age (yr), mean ± SD	39.5 ± 14.3	41.9 ± 12.4	0.621
Male : female	15 : 4	13 : 1	0.366
Body mass index (kg/m^2), median (IQR)	25.9 (24.6–28.2)	24.8 (23.9–27.4)	0.186
Kellgren-Lawrence grade (0 : 1 : 2 : 3 : 4)	5 : 8 : 6 : 0 : 0	5 : 9 : 0 : 0 : 0	0.660
Injury site (medial : lateral meniscus)	11 : 8	11 : 3	0.213

SD: standard deviation, IQR: interquartile range.

Table 3. Meniscus Volume, Meniscus-Removing Ratio, and Meniscus Defect-Filling Ratio

Variable		Scaffold	Meniscectomy	*p*-value
Meniscal volume (mm^3)	Preoperatively (A)	4,671.1 ± 1,371.0	4,755.0 ± 846.5	0.830
	Immediately postoperatively* (B)	4,137.9 ± 1,194.2	4,219.3 ± 784.9	0.826
	Postoperative 12 mo (C)	4,580.2 ± 1,315.6	4,213.9 ± 796.0	0.329
	Removing (B – A)	–533.2 ± 331.7	–535.8 ± 306.1	0.982
	Filling (C – B)	442.3 ± 276.0	–5.4 ± 59.7	< 0.001
Meniscus-removing ratio (%)	(B – A) / A × 100	–9.3 ± 6.1	–9.2 ± 7.1	0.984
Meniscus defect-filling ratio (%)	(C – B) / A × 100	7.5 ± 5.4	–0.4 ± 0.6	< 0.001

Values are presented as mean ± standard deviation.
*Immediately postoperatively: 1 day postoperatively.

The total WORMS score and several variables such as cartilage and osteophytes were higher in the scaffold group immediately postoperatively and at the last follow-up examination; however, the changes in the total score and all variables during the follow-up period were not significantly different between the groups (Table 4). The Genovese grade of the implanted collagen scaffold did not significantly change during the follow-up period in terms of morphology and size (p = 0.063); however, the grade significantly improved in terms of signal intensity (p = 0.001) (Table 5). There were no adverse events related to the operative procedure in all cases.

DISCUSSION

The most significant finding of the present study was the definite recovery of the meniscal volume after collagen meniscal scaffold implantation in Asian patients with partial meniscal defects. Collagen meniscal scaffold implantation provided satisfactory outcomes in cases of partial meniscal defect in populations in Western countries.[4,11,12] However, to date, no study has evaluated the efficiency of collagen meniscal scaffold implantation only in Asian individuals. Accordingly, this prospective randomized study attempted to objectively demonstrate the meniscal regeneration after collagen scaffold implantation in Asian patients through 3D volume analysis of the meniscus. In our 3D volume analysis, despite the similar volume of the removed meniscus and removing ratio, the average increased meniscal volume and meniscal defect-filling ratio were significantly greater in the collagen scaffold group than in the partial meniscectomy group. This study will be valuable to be the first to quantitatively demonstrate the regenerative advantage of collagen scaffolds through 3D volume analysis in Asians.

There were no significant differences in the clinical results, radiographic degenerative change, and joint space narrowing at the 12-month postoperative period between the groups. Rodkey et al.[10] also reported similar average VAS, Lysholm, and self-assessment satisfaction scores

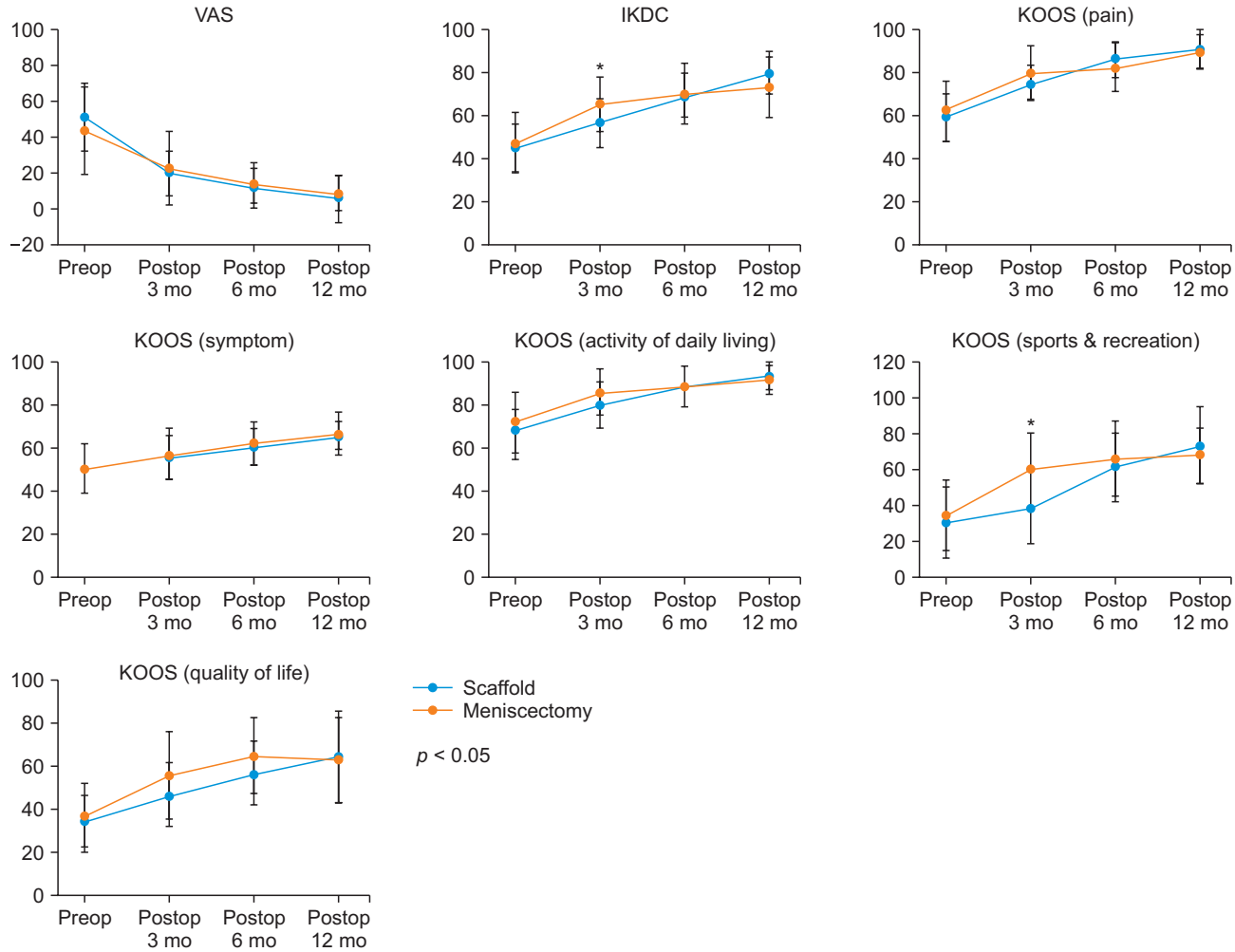

Fig. 6. Clinical results. Values are presented as mean with error bars representing one standard deviation. Preop: preoperative, Postop: postoperative, VAS: visual analog scale, IKDC: International Knee Documentation Committee, KOOS: Knee Injury and Osteoarthritis Outcome Score.

between the groups with and without a collagen meniscal scaffold at a short-term follow-up period of a mean of 58 months. However, another prospective study with a minimum follow-up period of 10 years clearly demonstrated superior clinical outcomes in the VAS, IKDC, Tegner index, and 36-item short form survey scores; additionally, there was less joint space narrowing observed in the radiographic findings in the collagen meniscal-scaffold group compared to the partial meniscectomy group.[12] If our follow-up period had been longer, the clinical and radiographic advantages of meniscal scaffolds would likely have become evident.

Regarding the other MRI outcomes, an advantage of the scaffold did not appear in the WORMS score, which represented the overall condition of the knee including cartilage. This may also be attributed to the fact that the duration of the follow-up period was not sufficient to prove the advantage of collagen scaffold implantation for other structures, including cartilage. The Genovese grade of the implanted scaffold improved in terms of signal intensity at 12 months postoperatively and the grade tended to improve in terms of size and morphology, although the difference was not statistically significant. Butt et al.[23] also reported that most patients with implanted collagen scaffold showed a Genovese grade III in size and morphology, and grade II/III in signal intensity at 2 years postoperatively. However, further evaluation is necessary to analyze the changes in Genovese grade using a longer follow-up period. Zaffagnini et al.[11] reported that the size of the implanted collagen meniscal scaffold decreased significantly, and < 10% of the implanted scaffold presented a size similar to that of the native meniscus (grade III) at 10 years of follow-up.

This study has several limitations. First, the sample size was fairly small. Even though our sample size had ad-

Table 4. Whole-Organ Magnetic Resonance Imaging Score

Variable		Scaffold	Meniscectomy	*p*-value
Total score	Immediately postoperatively*	36.5 ± 13.1	21.8 ± 14.7	0.005
	Postoperative 12 months	36.5 ± 13.3	23.6 ± 14.4	0.013
	Change	0 ± 6.9	1.9 ± 5.0	0.399
Cartilage	Immediately postoperatively	17.3 ± 6.4	10.4 ± 8.8	0.021
	Postoperative 12 months	18.2 ± 5.8	12.3 ± 8.5	0.023
	Change	0.9 ± 5.8	1.9 ± 2.9	0.568
Bone marrow abnormalities	Immediately postoperatively	0 (0–1)	0 (0–0)	0.679
	Postoperative 12 months	0 (0–0.5)	0 (0–0)	0.815
	Change	0 (0–0)	0 (0–0)	0.653
Subchondral bone attrition	Immediately postoperatively	1 (0–2)	0 (0–1.75)	0.418
	Postoperative 12 months	1 (0–2)	1 (0–1.75)	0.577
	Change	0 (0–0)	0 (0–0)	0.928
Subchondral bone cyst	Immediately postoperatively	0 (0–0)	0 (0–0)	0.627
	Postoperative 12 months	0 (0–0)	0 (0–0)	0.815
	Change	0 (0–0)	0 (0–0)	0.815
Osteophytes	Immediately postoperatively	10 (5–14)	3 (1–5)	0.010
	Postoperative 12 months	10 (6–15.5)	5 (1–7.25)	0.012
	Change	0 (0–0.5)	0 (0–1)	0.627
Meniscus	Immediately postoperatively	4 (4–4)	4 (3.25–4)	0.321
	Postoperative 12 months	4 (3.5–4)	4 (3–4)	0.529
	Change	0 (0–0)	0 (0–0)	0.483
Ligaments	Immediately postoperatively	0 (0–0)	0 (0–0)	0.815
	Postoperative 12 months	0 (0–0)	0 (0–0)	0.928
	Change	0 (0–0)	0 (0–0)	0.733
Synovitis	Immediately postoperatively	2 (2–2)	2 (1–2)	0.304
	Postoperative 12 months	1 (0–1)	1 (0–1)	0.788
	Change	–1 (–2 to 1)	–1 (–1 to –1)	0.461

Values are presented as mean ± standard deviation or median (interquartile range).
*Immediately postoperatively: 1 day postoperatively.

equate power, the small sample size may have limited the validity of our findings. Second, the follow-up period was only 1 year. That period was insufficient to clearly show the advantage of collagen meniscal scaffold implantation. Third, as this was a multicenter study, there might have been heterogeneity in surgical techniques. However, we could demonstrate the efficacy of the scaffold under more

Table 5. Genovese Grade of Implanted Collagen Meniscal Scaffold

Genovese grade	Immediately preoperatively	Postoperative 12 months	*p*-value
Morphology and size (1 : 2 : 3)	1 : 15 : 3	1 : 10 : 8	0.063
Signal intensity (1 : 2 : 3)	13 : 5 : 1	1 : 10 : 8	0.001

diverse and general conditions. Fourth, the present study did not analyze the specific pattern of meniscus tears before the operative procedures. More robust results could have been obtained, if a meniscal injury or defect had been analyzed using the elaborate classification system, such as the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine classification.[24] Fifth, several confounding factors, such as the location of the scaffold implantation that can affect the survival of the scaffold, were not controlled thoroughly.[25] Additionally, regarding the WORMS score, there was a significant difference in the cartilage and osteophyte variables preoperatively. Finally, the meniscal regeneration was evaluated only by performing an MRI examination. A gross examination using arthroscopy or histological analysis was not performed. However, it is unethical to perform unnecessary procedures to examine patients without complications.

Definite meniscal regeneration and stable scaffold incorporation were observed after collagen-based meniscal scaffold implantation in Asian patients during 12 months of follow-up. A long-term follow-up study with a larger cohort is required to determine the advantages of collagenous meniscal scaffold implantation in Asian patients.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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