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Atelocollagen Injections Improve Outcomes in the Nonsurgical Treatment of Grade III Medial Collateral Ligament Injuries

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Background: The purpose of this study was to evaluate the clinical outcomes of atelocollagen injections in isolated grade III medial collateral ligament (MCL) injuries of the knee joint.

Methods: A total of 50 participants were included in this retrospective study. Twenty-six patients underwent conservative treatment with a single atelocollagen injection, while the remaining patients underwent only typical conservative treatment. All participants underwent magnetic resonance imaging to identify and grade MCL injury. Valgus stress radiography was performed on both knees at 6 and 12 months after the injury. The visual analog scale (VAS) score was collected at the first visit and at 2 weeks, 6 weeks, 6 months, and 12 months after injury. The International Knee Documentation Committee (IKDC) formula activity level and Lysholm score were evaluated for patient-reported outcomes at the first visit and at 6 and 12 months after injury. The participant's return to the pre-injury activity level ratio was measured by comparing the IKDC formula activity level at 12 months after the injury with that before the injury.

Results: The VAS and Lysholm scores improved over time in both groups. The VAS and Lysholm scores were significantly better in the collagen injection group than in the control group. Regarding the activity level, the collagen injection group showed significantly better results at the 6-month follow-up, but there was no significant difference at the 12-month follow-up. The medial gap in the injured knee and the side-to-side difference (SSD) in both groups gradually decreased over time. The SSD in the collagen injection group was significantly smaller than that in the control group.

Conclusions: Atelocollagen injections resulted in better clinical and radiologic outcomes along with a higher rate of return to the pre-injury activity level, thereby exhibiting a positive effect in the nonsurgical treatment of grade III MCL injuries.

Keywords: *Atelocollagen injection, Knee, Medial collateral ligament, Conservative treatment*

Medial collateral ligament (MCL) injury is one of the most common ligamentous injuries in the knee.[1,2] The MCL is the primary static stabilizer of the medial side of the knee joint and provides support against the valgus and rotational forces.[1] MCL injuries usually occur from valgus stress with or without rotational forces[3] and most commonly involve the femoral attachment or the midsubstance portion of the ligament.[4]

The MCL has great healing potential after injury due to its extra-articular location and sufficient vascularization.[5] Therefore, most isolated MCL injuries are treated nonsurgically. Nonsurgical treatment of an MCL injury mostly consists of a brief period of immobilization followed by stabilized range of motion (ROM) exercises and quadriceps strengthening using a hinged knee brace.[6] This

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nonsurgical treatment has demonstrated satisfactory results; however, some studies have reported poor outcomes such as persistent pain and instability after a high-grade MCL injury.[7-9]

Recently, several studies have reported the usefulness of bio-scaffolds such as atelocollagen in the healing of tendons and ligaments.[10,11] Collagen, a group of structural proteins in the extracellular matrix, is known to help in the healing mechanisms of tendons and ligaments.[12] Some animal studies have reported the effect of collagen on the healing of MCL injuries by promoting cell migration and enhancing vascularization.[13-15] However, the clinical evidence regarding it in the current scientific literature is scarce.

Therefore, this study aimed to evaluate the clinical outcomes of atelocollagen injections in isolated grade III MCL injuries. It was hypothesized that atelocollagen injections in MCL injuries would provide better outcomes than in those without atelocollagen injections.

METHODS

The Institutional Review Board of Wonju Severance Christian Hospital approved this study (No. CR322147). This retrospective study was based on clinical and radiologic information collected during treatment, and written consent from patients was waived. This retrospective study included 85 patients who underwent nonsurgical treatment for acute grade III MCL injury of the knee between January 2017 and December 2021. The inclusion criteria for this study were as follows: (1) patients visiting within 2 weeks of the injury accompanied by a confirmed diagnosis of grade III MCL injury using magnetic resonance imaging (MRI); (2) patients over 18 years of age; and (3) patients followed up for more than 12 months after their first visit. Patients with a contralateral knee injury (n = 2), a Stener-like lesion (n = 1), any knee injection without atelocollagen injection within 12 months after injury (n = 2), MCL re-injury prior to the 1-year follow-up (n = 4), and a diagnosis other than MCL injury on the injured knee (n = 16) were excluded from this study. Additionally, 10 patients who did not complete the evaluation within 12 months were also excluded. Regarding the choice of the treatment protocol, all patients were informed about the nonsurgical treatment process and prognosis after MCL injury, together with the effect, cost, and treatment process of the atelocollagen injection. The administration of the atelocollagen injections was determined by the patient's choice. A total of 50 participants were included in the study. Twenty-six patients underwent conservative treatment with a single atelocollagen injection, while the remaining patients underwent only typical conservative treatment (Fig. 1).

Treatment Protocol

All patients performed gentle ROM exercises using a hinged knee brace after 2 weeks of immobilization. Weight-bearing was allowed if the pain was tolerable. Quadriceps strengthening exercises were started at 2 weeks and knee brace use was discontinued after 6 weeks. Subsequently, lower-extremity strength and proprioception training were gradually allowed. Excessive activity and risky sports were restricted for up to 3 months.

In the atelocollagen injection group, along with the same immobilization and rehabilitation treatment, atelocollagen was injected after confirming MCL injury using MRI. Ultrasound-guided atelocollagen injection was performed using a LOGIQ E10 (GE Healthcare, Milwaukee, WI, USA) with a 6–15 MHz linear-array transducer by an orthopedic surgeon who completed fellowship training in sports medicine (YHJ). The medial femoral condyle was palpated, and a large area of the surrounding skin was

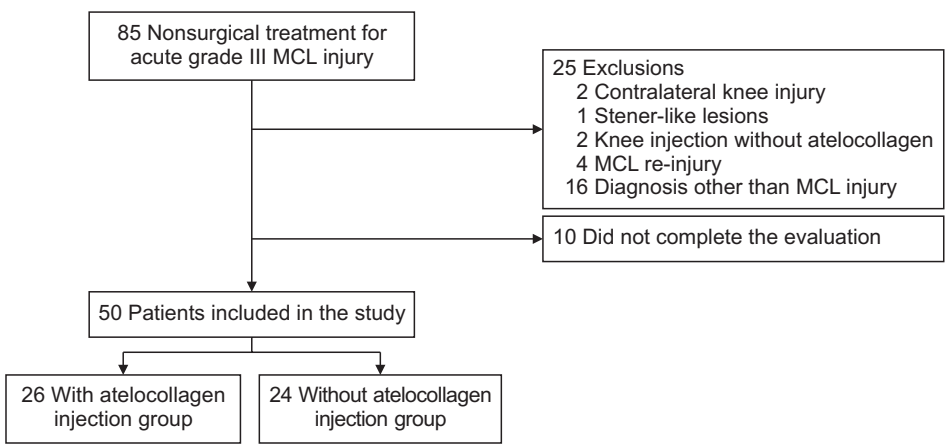

Fig. 1. Flow diagram of study participants. MCL: medial collateral ligament.

sterilized. The location of the MCL injury was confirmed using an aseptic draped transducer, and a needle was inserted using an in-plane approach. The tip of the needle was placed at the confirmed injury site, and 0.5 mL of gel-type atelocollagen (Collashield; HI Partner Corp. & AITIS Korea Corp., Seoul, Korea) was injected (Fig. 2).

Data Collection

All participants underwent MRI using a 3.0T scanner (Magnetom Vida, Siemens Healthcare, Erlangen, Germany) to identify and grade MCL injury. MCL injury was classified using Mink and Deutsch's grade.[16] An intact ligament with periligamentous edema is a grade I injury, a partial tear with surrounding edema is a grade II injury, and a grade III injury is a complete tear of the ligament.

Valgus stress radiography was performed on both knees using Telos device (Telos, Griesheim, Germany) at 6 and 12 months after injury. All radiographs were obtained with the knee 30° flexed along with the applied valgus force (15 kiloponds). A "medial gap" was defined as the shortest distance between the distal end of the medial femoral condyle and the corresponding medial tibia plateau.[17] On the valgus stress radiograph, the difference between the medial gaps of the injured knee and the contralateral normal knee was defined as the side-to-side difference (SSD).[18] The SSD was measured by two orthopedic surgeons who had completed their fellowship training in sports medicine (SHK and JSP). The authors were not involved in the measurement. To ensure the measurement reliability, the SSD was measured twice by the two examiners at each time, who were blinded to the purpose of the study. The average of the measured values was used for analysis.

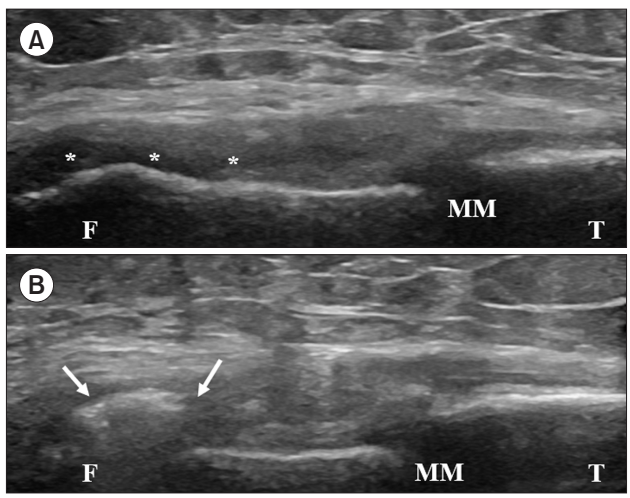

Fig. 2. (A) Ultrasound image of a medial collateral injury with the hypoechoic area (asterisks) at femoral insertion. (B) Ultrasound image after an atelocollagen injection. Injected atelocollagen filled the hypoechoic area (arrows). F: femur, MM: medial meniscus, T: tibia.

Clinical and radiographic assessments were performed by a single orthopedic surgeon who was blinded to the purpose of the study (SHK). At the first visit, data on age, sex, dominant foot, time of injury, and previous medical history were collected. The visual analog scale (VAS) score was collected at the first visit and at 2 weeks, 6 weeks, 6 months, and 12 months after injury. The International Knee Documentation Committee (IKDC) formula activity level and Lysholm score were evaluated for patient-reported outcomes at the first visit and at 6 and 12 months after injury. The participant's return to the pre-injury level ratio was measured by comparing the IKDC formula activity level at 12 months after injury with that before injury.

Statistical Analysis

The primary goal of this study was to achieve a 10-point difference in Lysholm scores between the two groups. The sample size was calculated based on a similar study on nonsurgical treatment of MCL injuries.[19] A sample size of 17 patients was required for each group to provide a power of 90% and to detect a difference at a significance level of $p < 0.05$.

Statistical analysis was performed using IBM SPSS software version 28.0 (IBM Corp., Armonk, NY, USA). All data were assessed for normality using the Shapiro-Wilk test. To compare the data of the two groups, the independent samples *t*-test (normal distribution) or Wilcoxon signed-rank test (non-normal distribution) was used for continuous variables, and Pearson's chi-square test and Fisher's exact test (when $n \leq 5$) were used for nominal variables. The significance level was set at $p < 0.05$.

RESULTS

All 50 patients were followed up during the year through a visit at the outpatient department at each scheduled appointment. There were no significant differences between the two groups with respect to age, sex, injured knee, MCL injury site, or time from injury to first visit (Table 1). In the collagen injection group, the mean time from injury to injection was 10.1 days after injury. After 1 year of follow-up evaluation, 2 patients in the without collagen injection group underwent MCL reconstruction due to pain and instability.

The VAS and Lysholm scores improved over time in both groups (Table 2). In regard to the VAS score, there was no significant difference through 6 weeks of follow-up; however, at 6 and 12 months, the collagen injection

Table 1. Patient Demographics

Variable	Collagen injection group (n = 26)	No collagen injection group (n = 24)	*p*-value
Age (yr)	27.2 ± 7.0	26.4 ± 6.7	0.705
Sex (male : female)	19 : 7	18 : 6	0.877
Injured knee (right : left)	11 : 15	12 : 12	0.786
MCL injury site (femoral : midsubstance : tibial)	15 : 8 : 3	14 : 7 : 3	0.989
Time from injury to first visit (day)	5.7 ± 4.0	5.8 ± 3.8	0.899
Time from injury to injection (day)	10.1 ± 3.8	-	-

Values are presented as mean ± standard deviation or number.
MCL: medial collateral ligament.

Table 2. Clinical Outcomes

Variable	Collagen injection group (n = 26)	No collagen injection group (n = 24)	*p*-value
Visual analog scale			
Initial visit	4.6 ± 1.3	4.7 ± 1.1	0.792
2 Weeks after first visit	2.8 ± 1.1	2.6 ± 0.7	0.314
6 Weeks after first visit	2.1 ± 0.8	2.0 ± 0.8	0.873
6 Months after first visit	0.7 ± 0.7	1.3 ± 0.9	0.012
12 Months after first visit	0.4 ± 0.6	0.8 ± 0.9	0.045
p-value*	< 0.001	< 0.001	
Lysholm score			
Initial visit	31.3 ± 10.7	31.7 ± 7.4	0.877
6 Months after first visit	92.9 ± 7.4	88.2 ± 9.0	0.048
12 Months after first visit	95.8 ± 5.9	91.4 ± 8.9	0.041
p-value*	< 0.001	< 0.001	
Activity level†			
Before injury	3.0 ± 0.9	2.9 ± 0.9	0.861
6 Months after first visit	2.5 ± 1.1	2.0 ± 0.9	0.043
12 Months after first visit	2.8 ± 0.9	2.4 ± 0.9	0.146
Return to pre-injury level	22 (84.6)	14 (58.3)	0.039

Values are presented as mean ± standard deviation or number (%).
**p*-value between preoperative and 12 months after Latarjet. †International Knee Documentation Committee formula activity level: 4, jumping, pivoting, hard cutting, football, and soccer; 3, heavy work, skiing, and tennis; 2, light manual work, jogging, and running; 1, sedentary work and activities of daily living.

group showed significantly better results. The Lysholm score was also significantly better in the collagen injection group than in the control group.

Regarding the activity level, the collagen injection group showed significantly better results at the 6-month follow-up, but there was no significant difference at the 12-month follow-up (Table 2). However, the return to the pre-injury activity level was significantly better in the col-

Table 3. Radiologic Outcomes

Variable	Collagen injection group (n = 26)	No collagen injection group (n = 24)	*p*-value
Medial gap* at 6 months after injury (mm)			
Injured knee	6.9 ± 1.9	7.7 ± 2.2	0.162
Contralateral normal knee	4.8 ± 1.3	4.8 ± 1.2	0.842
Side-to-side difference	2.1 ± 1.4	3.0 ± 1.7	0.044
Medial gap at 12 months after injury (mm)			
Injured knee	6.2 ± 1.9	7.1 ± 2.2	0.157
Contralateral normal knee	4.8 ± 1.3	4.7 ± 1.1	0.806
Side-to-side difference	1.4 ± 1.5	2.3 ± 1.7	0.048

Values are presented as mean ± standard deviation.
*The shortest distance between the distal end of the medial femoral condyle and the corresponding medial tibia plateau in valgus stress radiography (knee flexed to 30°, 15 kilopond valgus force).

lagen injection group (84.6%) than in the control group (58.3%).

The medial gap in the injured knee and the SSD in both groups gradually decreased over time. The SSD in the collagen injection group was significantly smaller than that in the control group (Table 3). The intraclass correlation coefficient (ICC) for SSD was 0.876, demonstrating good reliability (ICC < 0.75, moderate reliability; 0.75–0.90, good reliability; and ICC > 0.9, excellent reliability).[20]

DISCUSSION

The most important finding of the present study was that the atelocollagen injection provided better clinical and radiologic outcomes for the nonsurgical treatment of grade III MCL injuries.

The MCL has an extra-articular structure and has a high healing potential; therefore, most MCL injuries are treated nonsurgically. However, biomechanical studies have shown that a healed MCL does not return to normal and recovers to lower strength and stiffness.[21,22] This can be one of the causes of persistent pain and instability. Recent clinical studies have reported the beneficial effects of atelocollagen on ligament and tendon healing.[10,11] However, there is scarce evidence on the impact of atelocollagen on MCL injuries. Therefore, the results of this study can further strengthen the evidence for the effectiveness of atelocollagen in the nonsurgical treatment of grade III MCL injury.

The role of atelocollagen in ligament healing has not yet been clearly demonstrated. Healing of an MCL injury occurs through four overlapping stages: bleeding, inflammation, proliferation, and remodeling.[23] Bleeding fills the injury site and cytokines are secreted to attract macrophages.[24] After the inflammation stage, fibroblasts produce collagen and matrix proteins to form scar tissue.[25] Then, type III collagen is changed to type I collagen, and scar tissue is remodeled more densely and along the direction of ligament fibers during the remodeling stage.[26] A previous study using animals reported histological findings that atelocollagen has good potential for cell migration in the first stage of healing.[12] Also, type I collagen predominated over type III collagen and the regenerated tissue showed better maturation with return to normal structure during the remodeling stage in the collagen injection group.[12] Therefore, atelocollagen serves as a scaffold for cell migration and provides a positive effect in the remodeling stage.

Several studies have shown good results from nonsurgical treatment of grade III MCL injuries;[27,28] however, residual instability was more frequently reported compared to satisfactory patient-reported outcomes.[7,8] Previous studies have reported 1.7 mm SSDs after nonsurgical treatment of grade III MCL injuries.[19] In the current study, both groups had similar results compared to previous studies (collagen injection group: 1.4 mm, control group: 2.3 mm). Both groups also had fewer SSDs after 12 months compared to 6 months after injury. In grade III MCL injury, the gap between both ligament ends is filled with type III collagen.[25] Then, through the remodeling process, the tissue gradually becomes denser and returns to its previous normal tissue state.[26] The remodeling process lasts from months to years.[21] This may be related to the improvement of SSDs over time. Additionally, the

collagen injection group showed significantly better SSDs than the control group. This shows that atelocollagen has clinical benefits in restoring ligament stability.

In this study, both groups showed satisfactory VAS and Lysholm scores during the 1-year follow-up. The atelocollagen injection group showed better VAS and Lysholm scores than those without atelocollagen injection at the 6- and 12-month follow-up. However, the VAS score was higher in the collagen injection group at the 2- and 6-week follow-ups. After injection, some patients complained of increased pain, and this injection procedure may have stimulated the injured knee.

Activity levels showed no significant differences between the two groups at the 12-month follow-up. Previous studies have reported a lack of correlation between objective radiologic and clinical findings and subjective activity level.[29] The reasons may have to do with the patient avoiding risky activities during sports or reducing the instability and pain with muscle function and coordination. After nonsurgical treatment, activity levels gradually improved in both groups, and there was a higher rate of return to pre-injury levels in the atelocollagen injection group. Thus, atelocollagen injection may have led to a better return to the pre-injury level of activity.

This study illustrates that atelocollagen injection could improve the clinical outcome of the nonsurgical treatment of MCL injury. Additionally, it substantiates the clinical results of atelocollagen injections, which currently lack clinical evidence in the scientific literature. Until now, the nonsurgical treatment of MCL injury has demonstrated good clinical results, but persistent instability and pain have been reported in some patients. Since this study showed better stability and clinical outcome in the atelocollagen injection group, adding an atelocollagen injection to the nonsurgical treatment of MCL injury may be considered.

The current study has several limitations. First, this study is retrospective, and it included a relatively small number of participants. In addition, the administration of the atelocollagen injection was determined by the patient's choice, which may indicate bias. Therefore, a randomized controlled trial will be needed to further verify the functionality of this promising treatment protocol using atelocollagen. Second, the initial medial gap could not be measured because of pain. However, the remaining instability could be evaluated by comparing the medial gap to the contralateral normal knee, and the difference between the two groups was analyzed. Third, this study has a relatively short follow-up period. However, this study aimed to determine the difference in recovery after acute MCL injury, and 1 year is enough time for the MCL to heal. Fourth, healing of the MCL injury could not be objectively confirmed using follow-up MRI. However, stability was confirmed using a valgus stress radiograph to evaluate the function of the MCL, which was also used as a tool to confirm MCL healing in previous studies.[29]

Atelocollagen injection resulted in better clinical and radiological outcomes along with a higher rate of return to the pre-injury activity level, thereby exhibiting a positive effect in the nonsurgical treatment of grade III MCL injuries.

CONFLICT OF INTEREST

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

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