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The effects of applying adhesion prevention gel on the range of motion and pain after TKA

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ABSTRACT

A mixed solution of sodium hyaluronate and sodium carboxymethylcellulose (HA/CMC) has been shown to be effective for decreasing postoperative adhesions in various kinds of surgeries. We evaluated the clinical efficacy and safety of HA/CMC gel on the early postoperative range of motion and pain relief after total knee arthroplasty (TKA). Thirty one patients who underwent bilateral TKA as a single-stage procedure for primary osteoarthritis were included in the study. At the completion of surgery, among both knees, the HA/CMC gel was applied to one knee (the HA/CMC group) and HA/CMC gel was not applied to the other knee (the control group). The primary outcome measure was the early assessment of range of motion and the secondary outcome measures were the VAS pain scores and the number of complications in each group. Periarticular application of HA/CMC gel was safe without causing any wound problems or infection. However, local application of HA/CMC gel neither increased the range of motion nor reduced the pain during the early postoperative period of TKA.

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1. Introduction

Previous animal study has postulated beneficial effects of intraarticular injections of hyaluronate (HA) for the prevention or treatment of joint contracture [1]. And it was reported that intraarticular HA injection after anterior cruciate ligament reconstruction showed good result in postoperative rehabilitation [2]. Anti-inflammatory effect has been reported to inhibit the migration of polymorphonucleated cells and to decrease the inflammation status, which may be helpful in pain control and recovery of function after total knee arthroplasty (TKA) [3]. Sodium carboxymethylcellulose (CMC) is a relatively low molecular weight, water-soluble substance that is generated by the chemical modification of cellulose. Because the human body does not have enzymes to degrade it, it is not immediately absorbed and so it remains in the surface of tissue. Thus, it is used as a vector by the drug and food industries [4].

HA/CMC mixed products have been shown to be effective for decreasing postoperative adhesions in various kinds of surgeries [5–9]. Even though HA/CMC gel is not commonly used in orthopaedic surgeries, it has its own advantages: it can easily spread over and widely coat the surface of tissue [6–8,10]. We postulated that HA/CMC gel can be safely and effectively used after TKA to prevent adhesion because intraarticular and extraarticular surfaces of the knee joint are easily coated with the gel. However, to the best of our knowledge, there have been no studies on the use of the gel. Although DesJardins et al. [11] reported that HA supplemented bovine serum lubricant can cause CoCr femoral component pitting, roughening, and polyethylene damage, their study was to formulate a TKA lubricant which would mimic the rheological and biochemical properties of the *in vivo* synovial fluid.

In this study, we evaluated the hypothesis that applying HA/CMC gel to the periarticular tissues during TKA would be efficacious and safe in reducing pain and improving the range of motion.

2. Materials and methods

From January to April 2008, we carried out a prospective clinical trial to determine if HA/CMC gel provides a better result for decreasing pain and increasing the range of motion for TKA patients. The study was approved by our hospital institutional review board. Participation in the study was entirely voluntary and written informed consent was obtained from all the patients. The inclusion criterion was osteoarthritis patients on both knees who were scheduled for bilateral TKAs. TKA candidates who had previous knee surgery on either knee were excluded. Two patients were excluded because of the history of arthroscopic surgery. Finally 31 consecutive patients undergoing single-stage bilateral TKAs were included in the study. There were 27 women and four men with a mean age 69.0 ± 5.9 years (range: 56–79) at time of TKA.

Randomization to apply HA/CMC gel or not was accomplished with the use of a sealed envelope that contained a number (1 or 2), and this was opened in the operating room before performing wound

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closure for the 1st of the 2 sequential TKAs. After opening of the randomization envelope, the 1st knee received the treatment indicated by the envelope and the other knee received the opposite treatment. Each of the 31 patients received HA/CMC gel on one side and no material on the contralateral side.

Single-stage bilateral TKAs were performed during one session of general anesthesia. All the operations were done by one surgeon with using Vanguard posterior stabilized components (Biomet, Warsaw, Ind). Both knees were prepped and draped. A tourniquet was used for all knees. The first surgery was performed on the most symptomatic knee. The subvastus approach was done through a midline skin incision, as described by Hofmann et al. [12]. The tourniquet was deflated after insertion of the polyethylene. Meticulous bleeding control was done by using electrocautery. The HA/CMC gel (Guardix-sol., Hanmi Pharmaceutical Co., Seoul, Korea) was in a sterile condition, and we used the package of 5-mL solution contained in a syringe with a catheter tube (Fig. 1). HA/CMC gel was applied to the intraarticular tissues such as anterior synovium and capsule (Fig. 2). After insertion of a closed suction drain, the capsule and medial patellar retinaculum were closed. Then, the HA/CMC gel was also applied to the superficial fascia layer I and the joint capsule. After operation wound closure and applying a sterile dressing, a Jones bandage was applied with the knee in extension and this was retained for the day immediately after the operation. The first day after the operation, all the patients began full weight-bearing walking with using a walker 3 times daily for 30 min each and they began working on active range of movement. The closed suction drain was removed 48 h after operation. We didn't use a continuous passive motion machine or physical therapy, but supervised and encouraged active range of motion exercise for gaining the full range of motion. We used oral medication, celecoxib 200 mg q day, for pain control in all patients for 1 month.

The patients' pain was evaluated with the use of an ordinal visual analogue scale (VAS) of 0 to 10, with 0 indicating no pain and 10 indicating maximum pain. The active range of motion was measured with using a standard 60 cm-long goniometer by one of the study's authors, who was all kept "blinded" to the treatment. The patients were told to bend their knees as much as they could in a supine position. The degree of knee flexion was measured by centering the fulcrum of a goniometer over the lateral epicondyle of the femur. The proximal arm of the goniometer was aligned with the lateral midline of the femur, with using the greater trochanter for reference. The distal arm of the goniometer was aligned with the lateral midline of the fibula with using the lateral malleolus and fibular head for reference. The pain and range of motion were scored and measured on six different occasions by one of the study's authors, who was all kept "blinded" to the treatment: pre-operatively, 3 days postoperatively, 7 days postoperatively, 1 month postoperatively, 6 months postoperatively, and 1 year postoperatively. No patients were lost to follow-up for 1 year.

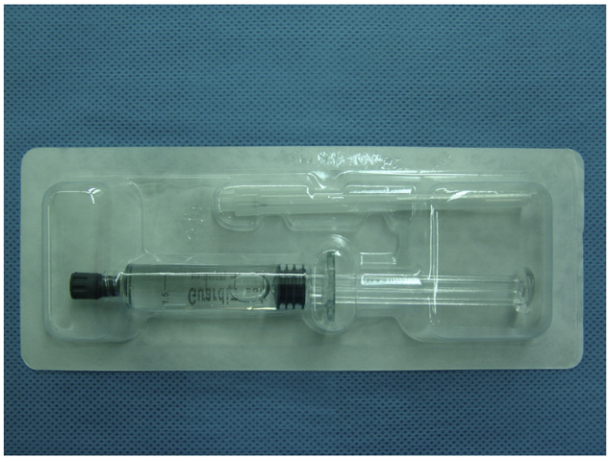

Fig. 1. HA/CMC gel is a colorless and transparent solution in a sterile condition, and the package of 5-mL solution contained in a syringe with a catheter tube.

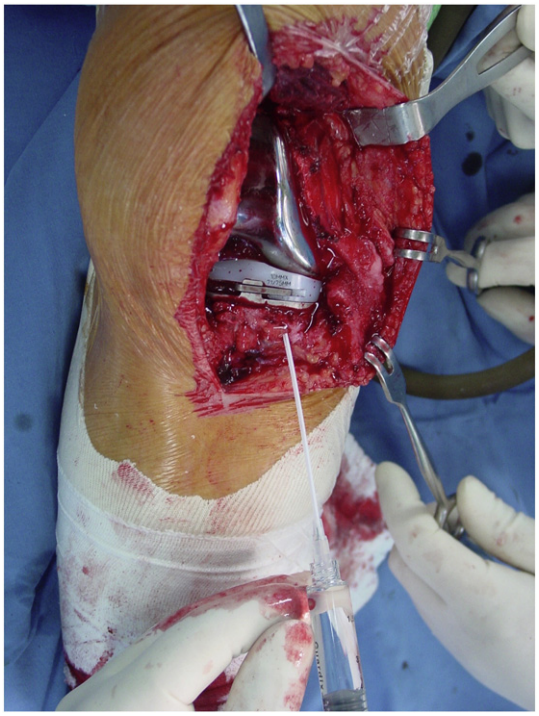

Fig. 2. After meticulous bleeding control, HA/CMC gel was applied to the periarticular tissues.

Statistical comparison of the clinical results was done using SPSS version 13.0 software (SPSS Inc., Chicago, Ill). Means and standard deviations were used to describe the data. The differences between groups were calculated using a parametric test for independent samples (Student's *t*-test). A P value of <0.05 was considered statistically significant.

Twenty three knees in each group were needed to give the study 80% statistical power to find the 10° differences between the groups with regard to the range of motion of the knees at the 5% significance level. Thirty one knees in each group were needed to give the study 80% statistical power to find the 1.0 point difference between groups for the amount of pain (VAS) at the 5% significance level.

3. Results

The patients' preoperative demographics are summarized in Table 1. There were no significant differences in the preoperative lower extremity alignment and range of motion of the knee between the control group and the test group and similarly, no

Table 1
Preoperative data.

	Control ($n=31$)	HA/CMC ($n=31$)	P value
Alignment (°)	Varus 2.9 ± 4.7 (range, valgus 5.8–varus 12.5)	Varus 4.1 ± 4.4 (range, valgus 6.1–varus 15.5)	0.295
Flexion contracture (°)	7.4 ± 7.0 (range, 0–25)	7.7 ± 7.1 (range, 0–30)	0.859
Maximum flexion (°)	128.3 ± 19.5 (range, 85–150)	127.5 ± 20.0 (range, 80–150)	0.873
Range of motion (°)	121.1 ± 22.0 (range, 65–150)	119.8 ± 23.2 (range, 5–150)	0.823
HSS score	61.9 ± 9.6 (range, 41–79)	59.3 ± 9.4 (range, 41–76)	0.292

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