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Far-Infrared Radiation to Improve Clinical Outcomes after Arthroscopic Rotator Cuff Repair: A Prospective Randomized Comparative Clinical Study

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Background: The efficacy of far-infrared radiation (FIR) after rotator cuff repair has not been demonstrated yet. The aim of this study was to evaluate the effects of postoperatively applied FIR with regard to early pain, range of motion (ROM), and tendon-to-bone healing after arthroscopic rotator cuff repair.

Methods: A total of 64 consecutive patients who underwent arthroscopic rotator cuff repair with small- to medium-sized tears were enrolled in this prospective comparative study and randomly divided into an FIR group (n = 31) and a control group (n = 33). In the FIR group, FIR using a radiator device (Aladdin-H) was applied for 30 minutes per session twice daily from the first postoperative day. This application lasted for 10 weeks during the postoperative period. Clinical outcomes were assessed using a visual analog scale for pain (pVAS) at 5 weeks and ROM at 3 and 6 months postoperatively. Functional scores were evaluated at 6 months postoperatively. Healing of the repaired rotator cuff was also evaluated using ultrasonography at 3 months and magnetic resonance imaging at 6 months postoperatively.

Results: In both groups, clinical and functional outcomes were improved up to 6 months compared with preoperative values. At 5 weeks and 3 months postoperatively, the average pVAS was significantly lower in the FIR group than in the control group (1.7 ± 1.0 vs. 2.8 ± 1.4; p = 0.002 at 5 weeks, 2.4 ± 1.3 vs. 3.2 ± 1.8; p = 0.041 at 3 months). However, there was no significant difference in ROM, functional score, or healing rate between two groups at each follow-up time point.

Conclusions: The application of FIR after arthroscopic rotator cuff repair could be a safe and effective procedure to decrease postoperative pain, especially in the early postoperative period. This effective application of FIR can be considered to facilitate painless rehabilitation in the postoperative period after arthroscopic rotator cuff repair.

Keywords: *Rotator cuff tear, Infrared, Postoperative pain*

The main treatment goals of rotator cuff repair are pain relief and functional improvement with the healing of repaired cuff. Oh et al.[1] have suggested that pain relief is the main expectation of patients who undergo rotator cuff repair. Prediction and prevention of uncomfortable pain are especially important during the early postoperative period as such pain can result in shoulder stiffness and continued decrease in function.[2,3] Arthroscopic repair has become a common surgical technique for rotator cuff tears. It might have additional benefits of decreasing postoperative pain

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and improving early functional recovery because of its minimal invasiveness.[4] Despite being characterized as a minimally invasive procedure, arthroscopic rotator cuff repair is associated with significant postoperative pain in the acute perioperative period.[5,6] Such significant pain after arthroscopic surgery often needs more procedures that might have various side effects such as sedation and hypotension, which may induce the need for hospital admission and subsequent extension of stay.[7,8] To minimize postoperative complications and ultimately decrease pain in the acute perioperative period, several preoperative procedures for pain control have been used after arthroscopic surgery such as intralesional analgesia, suprascapular nerve blocks with or without an axillary nerve block, and interscalene brachial plexus blocks.[5,9,10] As a reduction of postoperative pain can facilitate painless rehabilitation, patients with less pain may achieve more rapid functional recovery after surgery.

According to the literature, far-infrared radiation (FIR) may increase tissue oxygenation and improve wound healing by eliminating chronic inflammation, improving pain and swelling, and inducing relaxation of musculotendinous structures.[11,12] Some animal studies have demonstrated that FIR can increase nutrient supply to tissues, accelerate tissue regeneration, and elevate pain thresholds.[11,13] In orthopedic fields, Wong et al.[12] have concluded that FIR can promote local neovascularization, improve capillary flow after total knee arthroplasty, and possess wound healing and analgesic effects. In the current study, we assumed that FIR could improve postoperative pain, functional recovery, and healing rate after rotator cuff repair. We had previously conducted a clinical prospective pilot study with a short-term follow-up.[14] This pilot study included 38 patients (randomly divided into the FIR group and control group) who underwent arthroscopic rotator cuff repair related to a small- to medium-sized tear. It demonstrated that the average visual analog scale for pain (pVAS) was significantly lower in the FIR group at 5 weeks postoperatively. The average forward flexion was also better in the FIR group than in the control group at 3 months postoperatively without any adverse effects. Based on the results of this previous study, we decided to conduct a prospective clinical trial by expanding the number of enrolled patients and duration of the radiation as continued pain control is important up to 3 months after surgery when the range of motion (ROM) should be normalized.

Therefore, we aimed to investigate whether there would be a difference in pain relief and functional recovery including ROM and tendon-to-bone healing rate by increasing the number of enrolled patients and extending the FIR period from 5 weeks (period of brace wearing) to 10 weeks (period by which normal ROM should be achieved) in the current prospective randomized clinical trial. We hypothesized that compared with those in the previous pilot study, better ROM, functional scores, and healing rate could be achieved in the FIR group through early pain relief due to a longer period of FIR.[14]

METHODS

Study Design and Patient Selection

This prospective comparative study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (No. E-1902/523-004). The study was designed in accordance with the Declaration of Helsinki, and written informed consent including patient's exposure for research and publication of papers was obtained from all patients before enrollment. Consecutive patients who underwent arthroscopic rotator cuff repair between November 2019 and June 2020 were enrolled. We prospectively enrolled patients who met the following inclusion criteria: preoperative magnetic resonance imaging (MRI) diagnosis of a small- to medium-sized (< 3 cm) tear involving supraspinatus and infraspinatus tendons and evaluation of anatomical healing at 6 months using an MRI. As FIR after arthroscopic rotator cuff repair was significantly effective in terms of early pain relief compared to the control group in a previous pilot study,[14] the sample size was determined according to the previous pilot study to compare postoperative pVAS between the FIR group and the control group. The statistical power of the current study was calculated by G-Power software ver. 3.1.9.2 (Kiel, Germany). Using the average pVAS at 5 weeks postoperatively of 1.5 ± 0.8 (FIR group) and 2.7 ± 1.7 (control group) based on a previous study,[14] we determined that a sample size of 56 patients (28 patients per group) was necessary to achieve a power (1-beta) of 90% at a significant level (alpha) of 5%. Taking a dropout rate of 20% into account, the total sample size should be 34 patients per group. Thus, we decided to enroll 68 patients who underwent arthroscopic rotator cuff repair in the current study. Among 84 patients identified, we excluded 16 patients, including those with any previous surgery on the same shoulder (n = 2), large-sized tears (n = 3), or refusal to participate (n = 11). A total of 68 patients were enrolled. They were then randomly divided into two groups (FIR group and control group) using a randomization table. Since two patients were lost to follow-up and two patients had a discontinued FIR intervention, 64 patients were included in the final analysis (Fig. 1).

Surgical Treatment and Rehabilitation

All arthroscopic procedures were done by a single senior surgeon (JHO). Any pathological lesions in the glenohumeral joint were managed. Subacromial decompression with bursectomy and acromioplasty was then performed in the lateral decubitus position for all patients. Tear sizes were measured intraoperatively using a calibrated probe after limited debridement of the mucoid degeneration or a frayed tendon edge. The retraction size was measured as the distance between the lateral end of the torn rotator cuff and the lateral end of the footprint. The anteroposterior size was checked at the lateral edge of the footprint. Rotator cuff repair was then performed using a single- or double-row suture bridge technique with suture anchors according to tear size and tear configuration. Postoperative pain management was administered to all patients of both groups, using the same oral medication, such as tramadol, for only 2 weeks postoperatively. Immobilization with an abduction brace was applied for 5 weeks with shrugging motions of the shoulder and active motions of the elbow were permitted immediately after surgery. After being weaned from the brace, active-assisted ROM was followed according to a pre-established protocol. Muscle-strengthening exercises were initiated after full passive ROM was achieved. All sports activities were permitted 6 months postoperatively. All physical therapy protocols were followed with the supervision and cooperation of a rehabilitation physician.

Protocol of Applied FIR

We confirmed the efficacy and safety of postoperatively applied FIR in the previous clinical pilot study.[14] In the FIR group of the current study, FIR using a radiator device (Aladdin-H; Taerim Medical, Seongnam, Korea) was applied from the first postoperative day in the hospital. After discharge, the radiator device could be rented to patients' home. It lasted until the end point of the active-assisted ROM rehabilitation, which was approximately 10 weeks postoperatively. It was planned to be applied to the affected shoulder for 30 minutes per session twice daily. No FIR was applied to the control group. Other rehabilitation programs were done in the same manner as those of the FIR group. The radiator device was located at a distance of 30–35 cm from the patient's skin. Patients themselves marked on a checklist whether FIR was applied to them (Fig. 2).

Clinical Outcome Assessments

Each patient assigned using a randomization table was assessed by a clinical researcher (KSJ) who was single-blinded to the FIR in the current study at the following time points: preoperatively and 5 weeks, 3 months, and 6 months postoperatively. The pVAS was checked with a scale from 0 to 10. Active ROM in forward flexion and external rotation (with the arm by the side) was measured using a goniometer in the supine position or with the scapula's position maintained by a hand. Internal rotation at the back was measured according to the vertebral level that the patient could reach with the tip of the thumb while in the sitting position. We numbered the vertebrae serially as follows: 12 for the 12th thoracic vertebra, 13 for the 1st lumbar vertebra, and 17 for the 5th lumbar vertebra.[3,15] These were evaluated at 3 and 6 months postoperatively. The American Shoulder and Elbow Surgeons (ASES) score, Simple Shoulder Test (SST) score, and Constant score were also evaluated at 6 months. Anatomic heal-

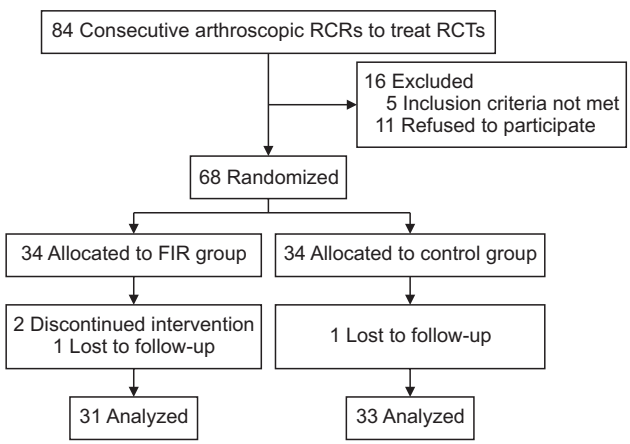

Fig. 1. Flow diagram of the study design. Application of far-infrared radiation (FIR) using a radiator device (Aladdin-H, Taerim Medical, Seongnam, Korea) lasted for 10 weeks during the postoperative period. RCR: rotator cuff repair, RCT: rotator cuff tear.

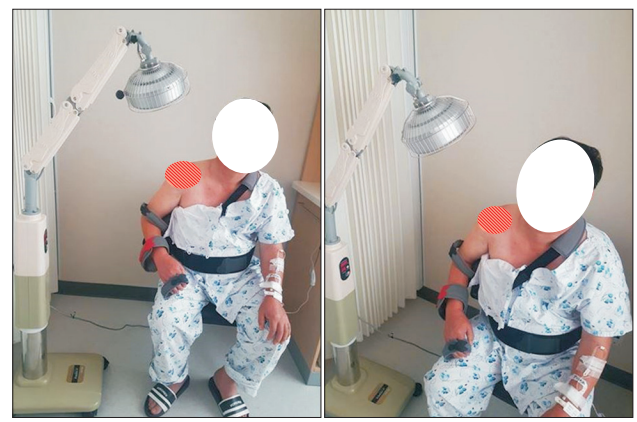

Fig. 2. Far-infrared radiation using a radiator device with a wavelength of 2–25 μm (Aladdin-H; Taerim Medical, Seongnam, Korea).

ing of the repaired rotator cuff was evaluated at 3 months postoperatively using ultrasonography and at 6 months postoperatively via MRI.[16] A musculoskeletal radiologist (YK) with more than 10 years of experience interpreted ultrasonography and MRI findings. On the basis of MRI findings, type IV or V of the Sugaya classification was regarded as a healing failure.[17]

Statistical Analysis

Patient characteristics such as age, sex, and tear size were analyzed and their mean values were obtained. Continuous data are presented as means ± standard deviations. Categorical data are presented as numbers. Continuous and categorical data were analyzed using an independent t-test and chi-square test, respectively. Differences in values between the two groups were set at p-value < 0.05 to be statistically significant. All statistical analyses were performed using IBM SPSS ver. 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Each patient was given a self-checklist to record the exact time and site of the irradiation throughout the treatment period. The mean age of patients was 59.7 ± 9.4 years (range, 38–76 years) with 6 months of follow-up. The mean anteroposterior dimension of the tear was 12.0 ± 3.6 mm (range, 7.0–27.0 mm) and the mean retraction was 13.1 ± 5.3 mm (range, 7.0–25.0 mm). Preoperatively, there were no significant differences in age, sex, rotator cuff tear size, pVAS, or ROM between the two groups (Table 1).

The average pVAS improved from 6.0 ± 1.7 points preoperatively to 1.3 ± 1.6 points at the final follow-up (p < 0.001). Functional scores (ASES score, SST, and Constant score) also demonstrated significant improvement postoperatively (ASES score: 59.2 ± 5.4 to 64.6 ± 3.9; SST: 5.1 ± 3.0 to 8.9 ± 3.7; and Constant score: 56.9 ± 6.4 to 63.9 ± 6.7; all p < 0.05). The pVAS at 5 weeks postoperatively, the primary outcome of this study, was 1.7 ± 1.0 in the FIR group, which was statistically significantly lower than that in the control group (2.8 ± 1.4, p = 0.002) (Table 2). At postoperative 3 months, corresponding to the endpoint of radiation, the FIR group also showed significantly lower pVAS (2.4 ± 1.3 vs. 3.2 ± 1.8, p = 0.041) than the

Table 1. Preoperative Characteristics and Intraoperative Findings

Characteristic	FIR group (n = 31)	Control group (n = 33)	p-value
Age (yr)	60.4 ± 8.9	59.1 ± 9.9	0.567
Sex (male : female)	15 : 16	11 : 22	0.227
Hand dominance (yes : no)	20 : 11	20 : 13	0.800
Forward flexion (°)	155.5 ± 14.3	158.5 ± 8.0	0.310
External rotation at the side (°)	58.9 ± 10.5	57.7 ± 9.4	0.647
Internal rotation at the back (level)*	9.4 ± 2.1	9.5 ± 2.0	0.845
Rotator cuff tear size (mm)			
Anteroposterior	12.1 ± 3.9	11.9 ± 3.4	0.760
Retraction	12.9 ± 5.4	13.2 ± 5.5	0.835
pVAS	6.1 ± 1.5	5.9 ± 1.8	0.769
ASES score	32.3 ± 9.1	31.5 ± 9.2	0.711
SST	5.3 ± 2.9	4.9 ± 3.1	0.589
Constant score	57.2 ± 6.7	56.6 ± 6.1	0.730

Values are presented as mean ± standard deviation.
pVAS: visual analog scale for pain, ASES: American Shoulder and Elbow Surgeons, SST: Simple Shoulder Test.
*Measured based on the vertebral level that the patient was able to reach with the thumb and numbered serially as follows: 1 to 12 for the 1st to 12th thoracic vertebrae, 13 to 17 for the 1st to 5th lumbar vertebrae, and 18 for any level below the sacral region.

Table 2. Clinical Outcomes at 5 Weeks and 3 Months after Arthroscopic Rotator Cuff Repair

Variable	FIR group (n = 31)	Control group (n = 33)	p-value
At 5 weeks postoperative			
pVAS	1.7 ± 1.0	2.8 ± 1.4	0.002†
At 3 months postoperative			
pVAS	2.4 ± 1.3	3.2 ± 1.8	0.041†
Forward flexion (°)	123.7 ± 20.0	122.3 ± 24.2	0.797
External rotation at the side (°)	38.9 ± 12.6	39.1 ± 10.2	0.939
Internal rotation at the back (level)*	12.8 ± 3.4	12.7 ± 2.9	0.920
Tendon-to-bone healing (n)			0.999
Healed tendon	31	33	
Healing failure	0	0	

Values are presented as mean ± standard deviation.
pVAS: visual analog scale for pain.
*Measured based on the vertebral level that the patient was able to reach with the thumb and numbered serially as follows: 1 to 12 for the 1st to 12th thoracic vertebrae, 13 to 17 for the 1st to 5th lumbar vertebrae, and 18 for any level below the sacral region. †Statistically significant difference between groups (p < 0.05).

Table 3. Clinical and Functional Outcomes at 6 Months after Arthroscopic Rotator Cuff Repair

Variable	FIR group (n = 31)	Control group (n = 33)	*p*-value
At 6 months postoperative			
pVAS	1.4 ± 1.6	1.2 ± 1.5	0.605
Forward flexion (°)	145.8 ± 17.1	147.9 ± 15.4	0.611
External rotation at the side (°)	61.6 ± 10.7	60.6 ± 13.2	0.740
Internal rotation at the back (level)*	9.7 ± 1.6	9.9 ± 1.9	0.600
Tendon-to-bone healing (n)			0.484
Healed tendon	30	33	
Healing failure	1	0	
ASES score	40.2 ± 5.0	39.2 ± 6.3	0.592
SST	8.9 ± 2.8	8.9 ± 4.5	0.978
Constant score	63.7 ± 7.1	64.1 ± 6.0	0.822

Values are presented as mean ± standard deviation.
FIR: far-infrared radiation, pVAS: visual analog scale for pain, ASES: American Shoulder and Elbow Surgeons, SST: Simple Shoulder Test.
*Measured based on the vertebral level that the patient was able to reach with the thumb and numbered serially as follows: 1 to 12 for the 1st to 12th thoracic vertebrae, 13 to 17 for the 1st to 5th lumbar vertebrae, and 18 for any level below the sacral region.

control group. At 6 months postoperatively, there were no significant differences in functional scores including pVAS between the two groups.

In terms of ROMs, there were no significant differences between the two groups at 3 months after surgery or at the final follow-up (Tables 2 and 3). At 3 months after surgery, the average forward flexion was 123.7° ± 20.0° in the FIR group. However, it was not significantly different from that in the control group (122.3° ± 24.2°, $p = 0.797$). Other ROMs were not significantly different between the two groups at 3 or 6 months postoperatively either. Regarding anatomical healing, which was assessed using MRI at 6 months postoperatively, 1 (3.2%) healing failure occurred only in the FIR group, showing no significant difference between the two groups (Tables 2 and 3). Potential adverse effects of FIR such as skin burn, rash, infection, wound problem, hypersensitivity reaction, and body temperature elevation did not occur in any patients.

DISCUSSION

This prospective randomized comparative study aimed to investigate the therapeutic effect of continuous FIR application up to 10 weeks after arthroscopic rotator cuff repair in patients with small- to medium-sized rotator cuff tears. In the current study, patients had a sufficient application of FIR during brace wearing period and postoperative stretching rehabilitation period (approximately 10 weeks), unlike in the previous pilot study.[14] Such sustained FIR application could provide a significant benefit of early pain relief up to 3 months after surgery without deteriorating postoperative ROM or rotator cuff healing.

Infrared radiation is subdivided into three categories according to its wavelength: near-infrared radiation (0.8–1.5 μm), middle-infrared radiation (1.5–5.6 μm), and FIR (5.6–1,000 μm).[13] FIR has several biological effects such as thermal effects, radiation, and resonance.[12] It carries energy that is accepted as heat by thermos-receptors on the skin. It can penetrate up to 4 cm beneath the skin.[18] FIR can induce beneficial effects, including improving endothelial function, promoting wound healing, and keeping unassisted patency of arteriovenous fistulae in both *in vitro* and *in vivo* studies.[13,19,20] These physiological characteristics and basic functions of FIR have been also described in detail in a previous study.[14] Recently, the interest in using FIR for improving clinical outcomes has been increasing in many medical fields related to these physiological functions. Li et al.[19] have reported significant reductions of limb circumference measurements and improvement of quality of life after FIR therapy in patients with lymphedema. Furthermore, laboratory examinations showed that FIR therapy could decrease deposition of protein, fat, and concentrations of tumor growth factor-β1 and interleukin-18 and improve the swelling condition. Hu and Li[20] reported that in patients with allergic rhinitis, symptoms of eye or nasal itching sense, rhinorrhea, and sneezing all significantly improved during the period of FIR therapy without any obvious adverse effects. Chang et al.[21] have also demonstrated that FIR therapy is a non-invasive intervention that can decrease dialysate glucose degradation products in peritoneal dialysis patients by improving the peritoneal transport rate and solute removal clearance while maintaining dialysis adequacy. These findings indicate that an application of FIR can improve clinical outcomes in non-orthopedic departments.

Pain is an important factor experienced by patients after elective orthopedic surgery. It usually occurs due to nerve injury and soft-tissue damage, which can adversely affect patients' biologic, physical, and psychological status. According to previous studies,[12,22] more than 80% of patients experienced postoperative pain and up to 50% of this same group felt moderate pain. FIR has been considered to be a selective option of a lot of methods to reduce

pain ultimately in the acute perioperative period. However, research studies on correlations between FIR and the improvement of clinical outcomes in the orthopedic department are lacking. There have been a limited number of studies on the clinical effects of FIR in the musculoskeletal department. Ervolino and Gazze[23] have reported that site-specific FIR therapy for 4 weeks could significantly improve pain scales and psychological distress in office workers with refractory low back pain. Lai et al.[24] have also explored the effects of a device containing a far-infrared on myofascial neck pain. Although differences in pVAS and pressure-pain threshold scores between the experimental group and the control group were not statistically significant, they concluded that the clinical improvement of muscle stiffness symptoms in the experimental group could encourage further investigation of the long-term effects of FIR treatment for pain management. The efficacy of FIR in orthopedic surgery has been also proven by including molecular evidence. Wong et al.[12] have demonstrated that FIR could decrease pain scores and discomfort of patients during the postoperative period of total knee replacement arthroplasty. They also proved that the application of FIR could decrease serum levels of interleukin-6 and endothelin-1, which are known to be subjective indicators of pain. Although a laboratory examination of immune factors could not be conducted in the current study, the benefit in terms of early pain relief until the endpoint of FIR could be confirmed after arthroscopic rotator cuff repair. As early pain relief could be obtained due to postoperatively applied FIR, authors expect facilitation of painless successful rehabilitation in the early postoperative period. However, another prospective study is needed to determine correlations between FIR application and rehabilitation tolerance.

To the best of our knowledge, this is the first prospective randomized comparative clinical study to demonstrate the effects of applied FIR until postoperative 10 weeks for at least 30 minutes per session twice daily on functional outcomes, including postoperative pain, ROM, and tendon-to-bone healing after arthroscopic rotator cuff repair. These sustained FIR applications could provide a significant benefit for reducing early pain up to 3 months after surgery. Compared with the control group, there were no significant deteriorations in postoperative ROM, functional scores, or healing. However, the current investigation has some limitations. First, this study has a relatively short-term (6 months) follow-up because the authors investigated the efficacy of postoperatively applied FIR related to the early pain relief, ROM, and healing rate after arthroscopic rotator cuff repair following the previous pilot study. Although it is known that a little adverse effect such as hypersensitivity reaction may occur in the early postoperative period, long-term follow-up research might be needed to evaluate the efficacy and safety of FIR. Second, although authors expected better clinical outcomes in the FIR group because of the longer period of FIR application than the previous pilot study, there was a significant difference in only early pain relief between the two groups, but not in ROM, functional score, or healing rate. The authors presumed that the efficacy of applied FIR could not be fully demonstrated because this study was conducted on patients who underwent arthroscopic rotator cuff repair with small- to medium-sized tears who had relatively less pain and lower healing failure rate after surgery.[25] Reported healing failure rates after rotator cuff repair are around 20%. They increase with increasing tear size, pain,[17,25] and older age.[25,26] Several systematic reviews have explained that patients with large-sized rotator cuff tears have a healing failure rate of more than 40%.[27,28] As non-orthopedic studies have demonstrated that FIR could promote access of blood flow and wound healing, there might be significant differences in postoperative pain, ROM, functional scores, and tendon-to-bone healing for patients with large-sized cuff tears depending on whether FIR is applied or not. The safety and efficacy of FIR could be confirmed through the results of the previous pilot study and the current study. However, further prospective studies are needed to determine whether postoperatively applied FIR is effective for patients with large-sized or massive rotator cuff tears reported to have more pain and higher healing failure rates. Third, with regard to the benefit of FIR, more objective evidence such as a decrease in limb circumference or interleukin-6 could not be proposed. If the swelling condition of a surgical site could be checked and if laboratory evidence such as inflammation factor decrease could be provided during an applied FIR period, FIR application will be more attractive. Fourth, the compliance with FIR application could not be checked, although we provided a self-checklist to get accurate time and site of irradiation during the treatment period. Finally, the difference of about 1 point in pVAS between the two groups at 5 weeks and 3 months postoperatively might have little clinical significance even with a statistical meaning. However, FIR can be applied conveniently with excellent compliance per session twice daily without any related complications. Thus, if preoperative pVAS was quite high related to a rotator cuff tear compared to the normal side, FIR can be used postoperatively to reduce early pain or facilitate painless rehabilitation.

In conclusion, the application of FIR after ar-

throscopic rotator cuff repair could be a safe and effective procedure to decrease postoperative pain, especially in the early postoperative period. This effective application of FIR can be considered to facilitate painless rehabilitation in the postoperative period after arthroscopic rotator cuff repair.

CONFLICT OF INTEREST

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

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