Immobilization in External Rotation After Shoulder Dislocation Reduces the Risk of Recurrence

A Randomized Controlled Trial

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Background: An initial anterior dislocation of the shoulder becomes recurrent in 66% to 94% of young patients after immobilization of the shoulder in internal rotation. Magnetic resonance imaging and studies of cadavera have shown that coaptation of the Bankart lesion is better with the arm in external rotation than it is with the arm in internal rotation. Our aim was to determine the benefit of immobilization in external rotation in a randomized controlled trial.

Methods: One hundred and ninety-eight patients with an initial anterior dislocation of the shoulder were randomly assigned to be treated with immobilization in either internal rotation (ninety-four shoulders) or external rotation (104 shoulders) for three weeks. The primary outcome measure was a recurrent dislocation or subluxation. The minimum follow-up period was two years.

Results: The follow-up rate was seventy-four (79%) of ninety-four in the internal rotation group and eighty-five (82%) of 104 in the external rotation group. The compliance rate was thirty-nine (53%) of seventy-four in the internal rotation group and sixty-one (72%) of eighty-five in the external rotation group ($p = 0.013$). The intention-to-treat analysis revealed that the recurrence rate in the external rotation group (twenty-two of eighty-five; 26%) was significantly lower than that in the internal rotation group (thirty-one of seventy-four; 42%) ($p = 0.033$) with a relative risk reduction of 38.2%. In the subgroup of patients who were thirty years of age or younger, the relative risk reduction was 46.1%.

Conclusions: Immobilization in external rotation after an initial shoulder dislocation reduces the risk of recurrence compared with that associated with the conventional method of immobilization in internal rotation. This treatment method appears to be particularly beneficial for patients who are thirty years of age or younger.

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

The shoulder is the most commonly dislocated major joint[1]. The recurrence rate after an initial dislocation ranges between 20% and 48%[2-8]. However, the recurrence rate among young patients is much higher, although the reported rates vary greatly. These rates have been reported to be 66% to 94% in patients under the age of twenty years[4-8], 92% in patients between fourteen and seventeen years of age[9], and 50% to 64% in patients younger than thirty years of age[5,10].

Why the recurrence rate is so high among young patients is unknown. Detachment of the inferior glenohumeral ligament-labrum complex from the glenoid, the Bankart lesion, is found in 94% to 97% of shoulders after an initial dislocation[11-13]. If the Bankart lesion heals, recurrence is less likely. There are several facts that suggest that the Bankart lesion has the ability to heal. First, the shoulder never redislocates after the initial dislocation in 52% to 80% of patients[2,3], which indicates that the Ban-

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TABLE I Patient Demographics

	Internal Rotation Group	External Rotation Group	P Values*
Number of patients	94	104	—
Average age (range) *(yr)*	37 (12-89)	35 (12-90)	0.55*
Male/female	63/31	73/31	0.63†
R/L	48/46	50/54	0.67†
Sports injuries	64 (68%)	71 (68%)	0.98†

*Determined with the Student t test. †Determined with the chi-square test.

kart lesion may have healed in these patients. Also, recurrent dislocations spontaneously cease in 20% of patients with recurrent dislocations[2]. In these cases, the Bankart lesion may have healed after the last dislocation. Despite the potential healing ability of the Bankart lesion, the recurrence rate does not depend on how long the shoulder is immobilized or how rigidly it is immobilized[7]. Furthermore, it may not depend even on whether the shoulder is immobilized or not[2,7]. A logical explanation for these findings would be that the Bankart lesion is not well reduced in the conventional position of immobilization— i.e., internal rotation.

Motivated by the lack of sufficient evidence that the Bankart lesion is well reduced by immmobilization in internal rotation, we initiated a study with use of magnetic resonance imaging, which demonstrated that the Bankart lesion is separated from the bone with the arm in internal rotation and is apposed to the bone with the arm in external rotation[14]. On the basis of this observation, we hypothesized that immobilization in external rotation would decrease the recurrence rate. In order to prove this hypothesis, we initiated a prospective clinical study to compare patients who had the shoulder immobilized in internal rotation with those who had the shoulder immobilized in external rotation. The preliminary outcome of this prospective study supported our hypothesis[15]. The purpose of the present study was to report the two-year results of this study.

Materials and Methods

Participants

In January 2000, we started a randomized prospective study comparing immobilization in internal rotation with immobilization in external rotation at our institutes (Akita University Hospital, Tazawako Municipal Hospital, Ogachi Chuo Hospital, and Honjo Daiichi Hospital). The preliminary results of treatment of forty patients at these four institutes were previously reported[15]. In October 2000, we began to recruit patients from eleven other institutes nationwide to increase the number of patients in the study. Between October 2000 and March 2004, 229 patients with an initial traumatic anterior dislocation of the shoulder were treated at one of these institutes. The inclusion criteria were (1) an initial anterior dislocation caused by a substantial traumatic event, (2) presentation within three days after the dislocation, and (3) no associated fractures of the shoulder detectable on routine radiographic examination. Of the 229 patients, fifteen did not meet the inclusion criteria and sixteen refused to participate in this study, leaving 198 patients for enrollment. There were 136 male patients and sixty-two female patients, with an average age of thirty-seven years (range, twelve to ninety years). After routine radiographic examination (anteroposterior, axillary, and scapular Y views), the shoulder dislocation was reduced manually. The methods of reduction were the elevation method (101 shoulders), the Hippocratic method (twenty-two shoulders), the external rotation method (seventeen shoulders), the Kocher method (sixteen shoulders), the Stimson method (fourteen shoulders), and others (twenty-eight shoulders).

The Akita University Ethics Research Committee provided ethics approval (number 10-5). All enrolled participants gave written informed consent.

Procedures

The patients were randomly assigned to one of two groups: immobilization in internal rotation (internal rotation group) or immobilization in external rotation (external rotation group). Randomization was performed with use of a random-number table created by the principal investigator (E.I.). Co-investigators allocated the patients at their institutes with use of this random-number table. There were ninety-four patients in the internal rotation group (average age, thirty-seven years; range, twelve to eighty-nine years) and 104 patients in the external rotation group (average age, thirty-five years; range, twelve to ninety years). The demographic characteristics of these patients are summarized in Table I.

Immobilization in internal rotation was performed with a sling and swathe. Immobilization in external rotation was performed with a wire-mesh splint covered with sponge and a stockinette (Figs. 1-A and 1-B). The precise method for making this immobilizer was described in our previous report[15]. The shoulder was kept in adduction and 10° of external rotation. In November 2003, we started to use a prototype brace, manufactured by Alcare, Tokyo, Japan (Figs. 2-A and 2-B). The same immobilization position was obtained with this brace, and it was easier to apply than the former splint-stockinette immobilizer.

Fig. 1-A

Fig. 1-B

Figs. 1-A and 1-B External rotation immobilizer consisting of a splint and a stockinette. **Fig. 1-A** Oblique view. **Fig. 1-B** Frontal view.

In both the internal rotation and the external rotation group, the immobilizer was supposed to be worn continuously, except when the patient took a shower, for three weeks. At the three-week examination, we asked the patients how many hours a day and for how long they had actually worn the immobilizer in order to measure their compliance with the treatment protocol. At three weeks, we instructed the patients to begin to move the arms both passively and actively. The patients were then seen on one or two more occasions to make sure that they regained a full range of motion. We advised them to avoid vigor-

Fig. 2-A

Fig. 2-B

Prototype of the external rotation immobilization brace (Alcare, Tokyo, Japan).

ous sports activities for at least three months. The patients were asked to visit us at six months, twelve months, and twenty-four months after the initial dislocation. When they were unable to do so, we interviewed them by telephone.

The primary outcome measure was a recurrent dislocation or subluxation of the shoulder. Dislocation was defined as the humeral head being completely out of the glenoid socket until a reduction maneuver was performed, and subluxation was defined as the humeral head being completely or partially out of the glenoid socket but reducing spontaneously. We asked the patients whether they had experienced any additional dislocation or subluxation after the immobilization. If they had, we asked them when and how the recurrent injury occurred and whether they had returned to preinjury sports.

Statistical Analysis

The required sample size was calculated to be forty-two in each group when alpha = 0.05 and beta = 0.2, for a ratio of effectiveness of 0.3 in the internal rotation group and 0.6 in the external rotation group. With the assumption that the follow-up rate was 80% and the compliance rate was 50%, the necessary sample size was calculated to be 105 in each group. Compliance was assessed in both groups. Those who wore the immobilizer for twenty-four hours a day, except when they took a shower, for three weeks were defined as being compliant. Both intention-to-treat and per-protocol analyses were performed. The intention-to-treat analysis included both the compliant and the noncompliant patients, whereas the per-protocol analysis included only those who were compliant. In addition, we performed sensitivity analyses first with the assumption that all of the patients who were lost to follow-up had recurrent dislocations and then with the assumption that none of them had recurrent dislocations. The rates of recurrent dislocation and of return to sports were compared between the groups with use of the chi-square test. The absolute and relative risk reductions were calculated. We also compared the recurrence rate on the basis of when the immobilization was started (the first, second, or third day). The Kruskal-Wallis test was used to compare the recurrence rates within each group. We further analyzed a subgroup of patients who were thirty years of age or younger because they were the group of patients with the highest recurrence rate and thus the most important group clinically. Significance was set at the $p < 0.05$ level.

Results

Follow-up Rate

Figure 3 shows the profile of the trial. Of 198 patients enrolled in this study, 159 (80%) were followed for a mini-

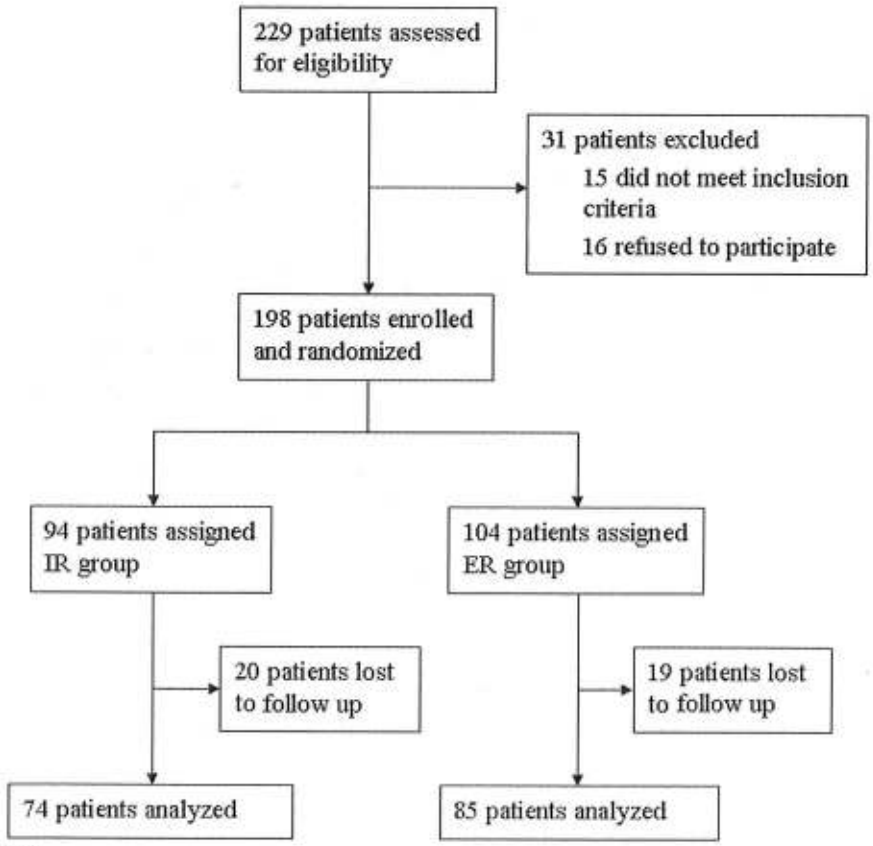

Fig. 3

Profile of the trial.

TABLE II Duration of Immobilization

	Internal Rotation Group (N = 74)	External Rotation Group (N = 85)	P Values*
<1 week	9 (12%)	4 (5%)	0.087
1-<2 weeks	11 (15%)	7 (8%)	0.19
2-<3 weeks	4 (5%)	6 (7%)	0.67
3 weeks	50 (68%)	68 (80%)	0.074
Part-time	11 (15%)	7 (8%)	0.19
Full-time	39 (53%)	61 (72%)	0.013

*Determined with the chi-square test.

mum of two years with either a direct examination or a telephone interview. The average follow-up period was 25.6 months, ranging from twenty-four to thirty months. Twenty-eight (38%) of the seventy-four patients who were followed in the internal rotation group and thirty-eight (45%) of the eighty-five who were followed in the external rotation group were examined.

Compliance

Despite our instructions, some patients discontinued the immobilization of the shoulder before three weeks (Table II). Among those who continued immobilizing the shoulder for the full three weeks, some used the immobilizer on a full-time basis (literally full time except when taking a shower), whereas others used it on a part-time basis (range, one to twenty hours a day). In total, thirty-nine patients (53%) in the internal rotation group and sixty-one patients (72%) in the external rotation group complied with the protocol. This difference was significant ($p = 0.013$).

Recurrence

The intention-to-treat analysis revealed that the recurrence rate was thirty-one (42%) of seventy-four in the internal rotation group and twenty-two (26%) of eighty-five in the external rotation group ($p = 0.033$). Immobilization in external rotation was associated with an absolute risk reduction of 16.0% and a relative risk reduction of 38.2%.

The per-protocol analysis showed that the recurrence rate was fifteen (38%) of thirty-nine in the internal rotation group and twelve (20%) of sixty-one in the external rotation group ($p = 0.039$). Immobilization in external rotation was associated with an absolute risk reduction of 18.8% and a relative risk reduction of 48.8%.

When the sensitivity analysis was performed with the assumption that all of the patients who were lost to follow-up had recurrent dislocations, the recurrence rate was fifty-one (54%) of ninety-four in the internal rotation group and forty-one (39%) of 104 in the external rotation group ($p = 0.037$). With this assumption, the absolute and relative risk reductions associated with immobilization in external rotation were 16.0% and 38.2%, respectively. With the assumption that none of those who were lost to follow-up had recurrent dislocations, the recurrence rate was thirty-one (33%) of ninety-four in the internal rotation group and twenty-two (21%) of 104 in the external rotation group ($p = 0.061$), with the absolute and relative risk reductions being 11.8% and 35.9%, respectively.

Additional detailed data were derived with the intention-to-treat analysis. The recurrence rates as documented with direct examination were thirteen (46%) of twenty-eight in the internal rotation group and ten (26%) of thirty-eight in the external rotation group. The recurrence rates as documented with a telephone interview were eighteen (39%) of forty-six and twelve (26%) of forty-seven, respectively. There was no significant difference in the recurrence rate between the patients who underwent a direct examination and those who were interviewed on the telephone in either the internal rotation group ($p = 0.54$) or the external rotation group ($p = 0.93$). Recurrence was experienced at various periods following the initial dislocation but mainly in the first year: 84% of the recurrences in the internal rotation group and 82% in the external rotation group were noted within twelve months after the injury. The recurrence rates stratified by age are shown in Table III. In the twenty-one to thirty-year-old age group, the recurrence rate following immobilization in external rotation was significantly lower than that following immobilization in internal rotation ($p = 0.037$). The recurrence rates stratified by the day on which the immobilization was initiated are shown in Table IV. With the numbers studied, there were no significant within-group differences. There was a significant between-group difference in the recurrence rates associated with immobilization on day 1 ($p = 0.024$) but not in the recurrence rates associated with immobilization on day 2 or on day 3. However, the numbers of shoulders immobilized on days 2 and 3 were small.

Nine (29%) of the thirty-one patients who experienced recurrent dislocations or subluxations in the internal rotation group and eight (36%) of the twenty-two who did so in the external rotation group eventually underwent surgical stabilization.

Return to Sports

Forty-nine (66%) of the seventy-four patients in the internal rotation group and sixty (71%) of the eighty-five in the exter-

TABLE III Recurrence Rate Stratified by Age

Age	Internal Rotation Group	External Rotation Group	P Values*
≤20 years	13/19 (68%)	11/27 (41%)	0.064
21-30 years	12/23 (52%)	7/29 (24%)	0.037
31-40 years	2/8 (25%)	1/6 (17%)	0.71
≥41 years	4/24 (17%)	3/23 (13%)	0.73
Total	31/74 (42%)	22/85 (26%)	0.033

*Determined with the chi-square test

TABLE IV Recurrence Rate Stratified by Day on Which Immobilization Was Initiated

Initiation of Immobilization	Internal Rotation Group	External Rotation Group	P Values (Between-Group)*
Day 1	22/59 (37%)	11/59 (19%)	0.024
Day 2	4/8 (50%)	5/15 (33%)	0.44
Day 3	5/7 (71%)	6/11 (55%)	0.47
P values (within-group)†	0.36	0.080	

*Determined with the chi-square test. †Determined with the Kruskal-Wallis test.

nal rotation group sustained the injury during participation in sports ($p = 0.55$). At the time of the two-year follow-up, thirty-one (63%) of the forty-nine patients in the internal rotation group and forty-three (72%) of the sixty patients in the external rotation group had returned to sports ($p = 0.35$). However, only ten (20%) of the forty-nine patients in the internal rotation group and twenty-two (37%) of the sixty patients in the external rotation group had returned to their preinjury sports activity level ($p = 0.064$).

Complications

Six (7%) of the eighty-five patients had temporary stiffness of the involved shoulder after immobilization in external rotation. This problem resolved within a month or two through the use of self-directed range-of-motion exercises. No other complications related to immobilization were reported.

Subgroup Analyses

We performed additional analyses to assess compliance, the recurrence rate stratified by the day on which the immobilization was initiated, sports participation, and shoulder stiffness after treatment in the subgroup of patients who were thirty years of age or younger. The compliance rate was seventeen (40%) of forty-two in the internal rotation group and thirty-eight (68%) of fifty-six in the external rotation group ($p = 0.007$). The recurrence rate was twenty-five (60%) of forty-two in the internal rotation group and eighteen (32%) of fifty-six in the external rotation group ($p = 0.007$). Immobilization in external rotation was associated with absolute and relative risk reductions of 27.4% and 46.1%, respectively.

In this younger subgroup, the recurrence rates were twenty (59%) of thirty-four when immobilization had been initiated on day 1, one of two when it had been initiated day 2, and four of six when it had been initiated on day 3 in the internal rotation group ($p = 1.0$); the respective values in the external rotation group were ten (25%) of forty, three of eight, and five of eight ($p = 0.11$). The difference between the internal rotation and external rotation groups was significant when the immobilization had been initiated on day 1 ($p = 0.003$) but not when it had been initiated on day 2 ($p = 0.75$) or day 3 ($p = 0.87$). Thirty-nine (93%) of the forty-two patients in the internal rotation group and fifty-three (95%) of the fifty-six in the external rotation group had a sports-related injury ($p = 0.72$). At the time of the two-year follow-up, twenty-two (56%) of the thirty-nine patients in the internal rotation group and thirty-nine (74%) of the fifty-three in the external rotation group had returned to sports ($p = 0.085$). Seven (18%) of the thirty-nine in the internal rotation group and twenty (38%) of the fifty-three in the external rotation group returned to their preinjury level of sports participation ($p = 0.039$). Two (4%) of the fifty-six patients in the external rotation group had temporary shoulder stiffness, which had resolved by the time of follow-up.

Discussion

Immobilization in internal rotation following shoulder dislocation has been performed for over 2000 years[16]. Surprisingly, there has been no evidence that this position is optimum for the healing of the Bankart lesion. The current study has demonstrated that immobilization in 10° of external rotation for three weeks reduces the relative risk of recurrence by 38.2% compared with the risk associated with conventional immobilization in internal rotation.

The recurrence rate in the external rotation group was significantly lower than that in the internal rotation group when the immobilization had been started on the day of the dislocation, but there was no difference between groups when it had been started on day 2 or 3. This suggests that the earlier that the immobilization is started, the better the results, although the numbers of patients who were initially treated on day 2 or 3 were quite small, perhaps too small to allow meaningful comparisons.

Additional analyses of the subgroup of patients who were thirty years of age or younger revealed that individuals who are younger than that age would particularly benefit from immobilization of the shoulder in external rotation after an initial dislocation. Again, when the immobilization had been on day 1, the recurrence rate was significantly lower in the external rotation group than it was in the internal rotation group. Furthermore, the proportion of patients who returned to their preinjury level of sports was significantly higher in the external rotation group. Thus, the benefit of external rotation immobilization was demonstrated in this clinically important group of young patients.

The ideal method of immobilization in external rotation has not yet been established. First, the best position of immo-

bilization needs to be determined. In this study, we immobilized the shoulder in approximately 10° of external rotation. Miller et al. measured the contact force between the Bankart lesion and the glenoid in cadaveric shoulders as the arm was rotated from 60° of internal rotation to 45° of external rotation[17]. The contact force started to be positive as the arm passed through neutral rotation and became maximum at the maximum external rotation of 45°. This study suggests that the greater the amount of external rotation, the greater the contact force. However, in our experience, the greater the amount of external rotation, the less comfortable the patient. Therefore, we chose 10° of external rotation, which according to the study by Miller et al. creates positive contact for healing, but we need to determine the minimum effective amount of external rotation in future studies.

Regarding the position of immobilization, an interesting study was reported from the United Kingdom. During arthroscopic examination, Hart and Kelly observed that external rotation improved the reduction of a Bankart lesion after an initial dislocation in 92% of the shoulders in their series[18]. However, they found that the best reduction was achieved with the arm in 30° of abduction and 60° of external rotation. Thus, the best position for immobilization, particularly in the coronal plane, needs to be studied further.

The second factor that needs to be better elucidated is the duration of immobilization. In this study, we immobilized the shoulder for three weeks according to conventional recommendations regarding the duration needed to achieve soft-tissue healing[7,19]. We thought that this would be an appropriate length of time to allow initial healing of a Bankart lesion. Kitamura and Ikuta reported that they immobilized the shoulder in external rotation for four weeks followed by two weeks of immobilization in internal rotation[20]. None of their thirteen patients had experienced a recurrence at the time of a one-year follow-up. Their report suggests that three weeks of immobilization may not be long enough. Thus, the optimum duration of immobilization also needs to be determined in a future study.

There are several limitations of the present study. First, the patients' compliance with the treatment protocol was significantly better in the external rotation group, although the patients were randomly assigned to the groups. One might wonder why the compliance rate was higher in the external rotation group when the device was much more cumbersome. This finding strongly suggests that there was some bias, as this part of the study (when the surgeons instructed the patients regarding the immobilization protocol) could not be blinded. We and the other treating surgeons might have made a stronger effort to ensure compliance with the external rotation immobilization than to ensure compliance with the internal rotation immobilization. This is a drawback of this study and one of the reasons why it was assigned a level of evidence of II. Second, the occurrence of dislocation or subluxation was the primary end point of the study. However, those without recurrence may or may not have been satisfied with the shoulder because of residual symptomatic instability. We did not include a patient-based quality-of-life assessment such as the Western Ontario Shoulder Instability Index (WOSI)[21]. Third, this was a two-year follow-up study. According to Rowe[7], 70.5% of all recurrent shoulder dislocations occur within the first two years and 18.7% occur from two to five years. Further evaluation at five years or later would be valuable.

In conclusion, immobilization in 10° of external rotation for three weeks reduces the relative risk of recurrence of a first-time traumatic anterior shoulder dislocation when compared with the risk associated with conventional immobilization in internal rotation. This treatment is particularly beneficial for those who are thirty years of age or younger. ■

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