



The position of sling immobilization influences the outcomes of anatomic total shoulder arthroplasty: a randomized, single-blind, prospective study



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Background: To date, no studies have been published that have assessed the optimal position of sling immobilization after anatomic total shoulder arthroplasty for glenohumeral osteoarthritis.

Methods: Thirty-six patients undergoing anatomic total shoulder arthroplasty for osteoarthritis were randomized to a neutral rotation sling versus an internal rotation sling. The primary outcomes assessed included the Disabilities of the Arm, Shoulder and Hand score; Western Ontario Osteoarthritis of the Shoulder score; Single Assessment Numeric Evaluation score; visual analog scale (VAS) scores for pain and satisfaction; compliance ratings; and radiographic and range-of-motion measurements. Primary outcomes were assessed at baseline and postoperatively at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.

Results: All patient-determined outcome scores for both groups revealed statistically significant improvements ($P < .0001$) from enrollment to final follow-up. There were statistically significant advantages to the neutral rotation sling group compared with the internal rotation sling group when we evaluated the improvements in (1) active external rotation (42° vs 25° , $P = .03$), (2) passive external rotation (44° vs 26° , $P = .02$), (3) passive horizontal adduction (7.7 cm vs 3.7 cm, $P = .05$), and (4) pain relief with passive adduction (VAS score, 6.2 cm vs 3.5 cm; $P = .002$). There was a trend toward greater improvements in the neutral rotation sling group when we measured (1) active horizontal adduction (8.3 cm vs 2.9 cm, $P = .06$) and (2) active internal rotation behind the back (18 cm vs 11.1 cm, $P = .09$). At 2 weeks, the neutral rotation sling group had significantly less night pain than the internal rotation sling group (mean VAS score, 18 mm vs 34 mm; $P = .047$).

Conclusions: Neutral rotation sling use after anatomic total shoulder arthroplasty resulted in statistically significant improvements in external rotation and adduction, as well as decreased night pain, compared with an internal rotation sling.

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

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Few studies have examined the role of sling immobilization for both the nonoperative and operative treatment of shoulder pathology. Most of the studies that have been published have examined the position of immobilization when treating shoulder instability in a nonoperative fashion and, at this point, are inconclusive.^{4,6,10,11,13,15,21,22} In addition, at least 2 studies have investigated the effect of the type of sling used on outcomes of rotator cuff repair.^{5,7} To date, no studies have been published that have assessed the optimal position of sling immobilization after anatomic shoulder arthroplasty for glenohumeral osteoarthritis.

There remains no consensus regarding the optimal position of postoperative immobilization, and it is not known whether the position of shoulder immobilization has an effect on motion and functional recovery.²⁵ Yin et al²⁵ demonstrated that external rotation bracing after arthroscopic shoulder stabilization is associated with a predictable recovery of range of motion and functional score improvement. However, this was not a comparative study, and they suggested that future studies comparing external rotation bracing with traditional sling use should be conducted to determine the optimal method of postoperative immobilization.

We hypothesized that sling position after anatomic total shoulder arthroplasty may affect the outcomes of this surgical procedure. Specifically, we hypothesized that sling immobilization in neutral rotation would result in (1) decreased postoperative pain, (2) decreased night pain as determined by both validated outcome scores and visual analog scale (VAS) scores, and (3) improved range of motion compared with conventional slings that maintain the upper extremity in an internally rotated position. The rationale for exploring this question is that when the glenohumeral joint is placed in the neutral position, the center of the humeral head is better aligned with the center of the glenoid and might maintain a more balanced tension across the anterior and posterior soft tissue structures (rotator cuff, ligamentous capsule) compared with maintaining the arm in a fully internally rotated position, which might over-tension the posterior and under-tension the anterior soft tissue structures.

Materials and methods

In this prospective, randomized clinical trial, all patients were recruited from the orthopedic clinic of the senior author (K.M.B.). The inclusion criteria were patients with glenohumeral osteoarthritis in whom nonoperative treatment failed and who decided to undergo anatomic total shoulder arthroplasty. The exclusion criteria were patients with rotator cuff tears or previous surgery violating the subscapularis, rotator cuff tear arthropathy, inflammatory arthritis, revision arthroplasty, arthroplasty performed for fracture, cervical spine pain, or radiculopathy and patients who were unable or unwilling to complete the patient-based outcome scores or undergo the physical examinations required for this study.

Patients were invited to enroll in this study at their clinic visit when they elected to pursue total shoulder arthroplasty. Written informed consent was obtained at that time. Patient randomization was performed using a computer-generated table of random numbers to

determine treatment allocation at that time as well. Group allocation was revealed immediately after surgery, once confirmation of meeting the appropriate inclusion and exclusion criteria had been obtained. Patients were randomly assigned to either the internal rotation sling group or the neutral rotation sling group.

All patients undergoing total shoulder arthroplasty were treated in a standardized fashion using a subscapularis tenotomy with subsequent repair and a 360° release of the capsule performed at the capsulolabral junction. Immediately after surgery, all patients were placed in a sling. The sling was worn at all times for the first 6 weeks except during showering, hygienic care, changing clothes, and physical therapy. Physical therapy was standardized for all patients. Patients were randomized to 1 of 2 groups. Half of the patients were placed in a Joslin sling (Brownmed, Boston, MA, USA) that maintained the arm in glenohumeral internal rotation and allowed for scapular protraction (internal rotation sling). The other half were placed in a Slingshot 3 sling (Arthrex, Naples, FL, USA) that maintained the glenohumeral joint in neutral rotation and attempted to maintain a neutral scapular position (neutral rotation sling).

Demographic information such as age, sex, height, weight, and hand dominance, as well as comorbidities, were collected. Radiographic imaging (anteroposterior, true anteroposterior, Y-scapular, and axillary views) was reviewed to assess the severity of osteoarthritis. Osteoarthritis severity was determined by the classifications of Samilson and Prieto,¹⁷ Kellgren and Lawrence,¹² and Walch et al.²⁰ At the initial visit, patients completed patient-determined outcome scales that assessed their perception of their preoperative function. These outcome scales included the Disabilities of the Arm, Shoulder and Hand (DASH) score⁹; Western Ontario Osteoarthritis of the Shoulder (WOOS) score¹⁴; Shoulder Activity Level²; and Single Assessment Numeric Evaluation (SANE) rating.²³ In addition, VAS scores were determined for (1) overall pain, (2) night pain, (3) neck pain, and (4) ability to sleep in a horizontal position at night. Both active and passive shoulder range of motion was measured bilaterally at enrollment, including flexion in the supine and standing positions, standing external rotation in the neutral position, supine external rotation in the 90° abducted position, supine internal rotation in the 90° abducted position, standing internal rotation behind the back, and cross-body adduction (maximal cross-body adduction was determined as the minimal distance from the antecubital fossa to the contralateral acromion when the arm was adducted horizontally across the body¹) by 1 of 2 physical therapists (R.O. and M.J.Z.). With maximal cross-body adduction, patients were asked to rank their pain on an ordinal scale from 1 to 10, with 1 being no pain and 10 being the worst pain. Subjects were clinically and radiographically evaluated postoperatively at 2 weeks, 6 weeks, 3 months, 6 months, and 12 months. Radiographs were assessed by the senior author (K.M.B.) for evidence of radiographic prosthetic loosening, narrowing of the acromiohumeral distance, fractures, or other radiographically evident complications. The investigators performing assessments at these time points were blinded to which sling the patient used.

At the 2-week time point, the subjects completed the VAS for (1) overall pain, (2) night pain, (3) neck pain, and (4) ability to sleep in the horizontal position at night. In addition, they recorded the day on which they were able to sleep in a horizontal position throughout the night. The day of narcotic cessation was determined as well.

At the 6-week time point, the subjects completed the VAS for (1) overall pain, (2) night pain, (3) neck pain, (4) ability to sleep in the horizontal position at night, and (5) compliance with sling use. The patients determined the percentage of time that they were

compliant with sling use. In addition, the patients recorded the day on which they were able to sleep in a horizontal position throughout the night. The DASH, WOOS, and SANE scores were determined. Passive supine forward elevation and passive standing external rotation in the neutral range-of-motion position were determined. The day of narcotic cessation was determined as well.

At the 12-week time point, the subjects completed the VAS for (1) overall pain, (2) night pain, (3) ability to sleep in the horizontal position at night, (4) neck pain, and (5) overall satisfaction. The day of narcotic cessation was confirmed. In addition, the patients recorded the day on which they were able to sleep in a horizontal position throughout the night. The DASH, WOOS, Shoulder Activity Level, and SANE scores were also determined. Moreover, range-of-motion measurements as described earlier were obtained.

At the 6- and 12-month time points, subjects completed the DASH score, WOOS score, Shoulder Activity Level, and SANE rating. In addition, VAS scores were determined for (1) overall pain, (2) night pain, (3) neck pain, (4) ability to sleep in a horizontal position at night, and (5) overall satisfaction. Range-of-motion assessment was performed at these time points as well.

The primary statistical hypothesis of interest was the differences in patient-determined outcomes between the different sling groups. A power analysis was modeled from a previous study that determined a 10-point difference in mean improvement in DASH scores (minimal clinically important difference [MCID]) between groups with a standard deviation of 10 points conducted at $\alpha = .05$ and $\beta = .8$.⁸ For the current study, with the assumption of a

moderate effect size ($f = 0.5$), $\alpha = .05$, and power = 0.80, the necessary sample would be 34 subjects, that is, 17 per group. The Student t test was used to determine differences between the groups. The level of significance was set at .05.

Results

Patients were recruited from the orthopedic clinic of the senior author (K.M.B.) between January 2012 and June 2015. We randomized 17 patients to the neutral rotation sling group and 19 to the internal rotation sling group (Fig. 1 shows the CONSORT [Consolidated Standards of Reporting Trials] diagram). The age of the groups was statistically similar, with a mean age of 73 years in the neutral rotation sling group compared with 68 years in the internal rotation sling group ($P = .14$). The percentage of male patients was higher in the internal rotation sling group (63%) than in the neutral rotation sling group (47%).

There was no significant difference in preoperative radiographic severity of osteoarthritis. When we used the Samilson-Prieto classification,¹⁷ the mean score was 2.94 in both groups ($P = .98$). When we used the Kellgren-Lawrence classification,¹² the mean score was 3.76 in the neutral rotation sling group and 3.63 in the internal rotation sling group

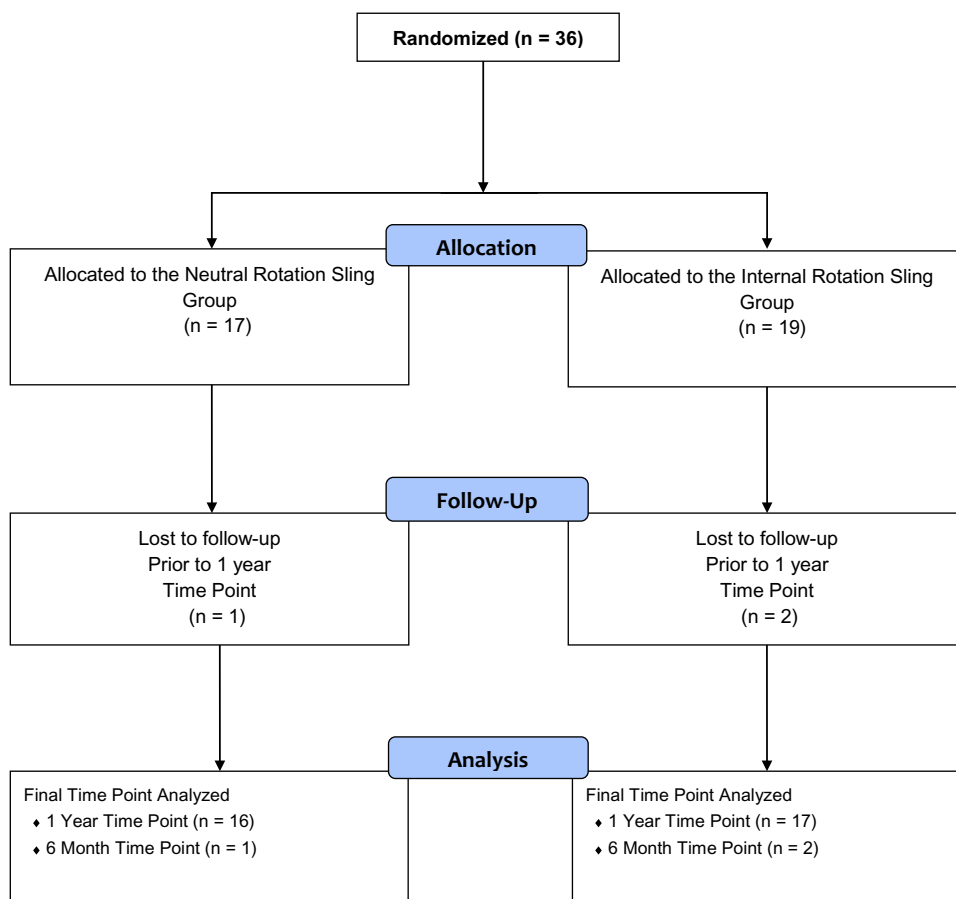


Figure 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

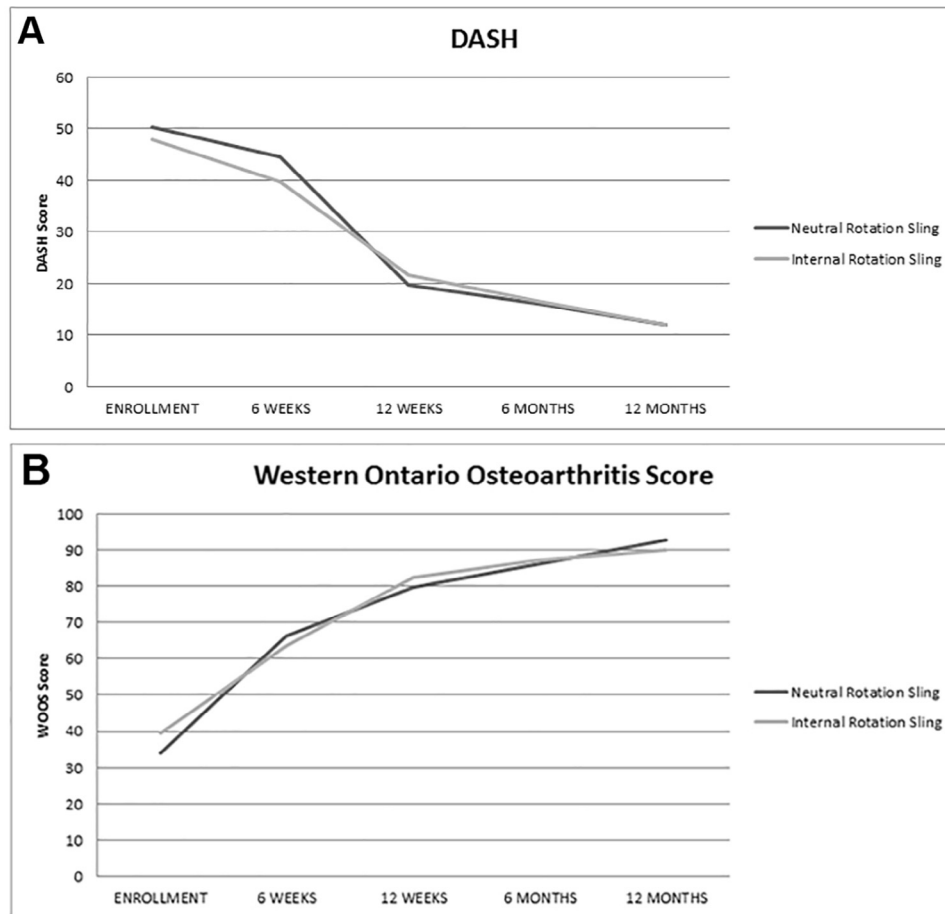


Figure 2 (A) Disabilities of the Arm, Shoulder and Hand (*DASH*) outcome scores. (B) Western Ontario Osteoarthritis of the Shoulder (*WOOS*) outcome scores. (C) Single Assessment Numeric Evaluation (*SANE*) outcome scores. (D) Shoulder Activity Level.

($P = .46$). No difference in the mean acromiohumeral distance was found between the groups (12 mm in neutral rotation sling group vs 13 mm in internal rotation sling group, $P = .38$).

We found no difference in the patient-reported VAS score for compliance with sling use ($P = .40$) or percentage of time using the sling (87% in neutral rotation sling group vs 85% in internal rotation sling group, $P = .78$). In addition, no difference in the day of cessation of narcotic use was noted between groups (23 days in both groups, $P = .96$).

All patient-determined outcome scores in both groups revealed statistically significant improvements ($P < .0001$) over time from enrollment to final follow-up except the Shoulder Activity Level ($P = .24$ for neutral rotation sling group and $P = .17$ for internal rotation sling group) (Fig. 2). Although not statistically significant, both groups had a mean 1-level improvement in the Shoulder Activity Level over time from enrollment to final follow-up. No statistically significant differences in any outcome score (*WOOS*, *DASH*, *SANE*, or Shoulder Activity Level) were noted at any time point between the 2 different sling groups.

Although not statistically significant, the change in all quality-of-life outcome scores from enrollment to final follow-up was greater in the neutral rotation sling group than in the in-

ternal rotation sling. However, this change did not meet the MCID for the *DASH* score¹⁶ or *SANE* score²⁴ and is, therefore, of questionable clinical significance (Table I).

For the neutral rotation sling group, range of motion in all planes revealed statistically significant improvements over time from enrollment to final follow-up. For the internal rotation sling group, there were statistically significant improvements in all range-of-motion measurements except active horizontal adduction of the shoulder across the body. The improvement in this measured plane did not meet the level of significance ($P = .22$) (Table II).

For the neutral rotation sling group, there was a greater degree of improvement over time compared with the internal rotation sling group for all range-of-motion measurements except the measurement of passive internal rotation with the arm abducted to 90° (16° in neutral rotation sling group vs 20° in internal rotation sling group, $P = .56$) (Table III).

Statistically significant improvements were found in the neutral rotation sling group compared with the internal rotation sling group when we evaluated improvements from baseline to final follow-up for (1) active external rotation with the arm in the neutral position (42° vs 25°, $P = .03$), (2) passive external rotation with the arm in the neutral position (44° vs

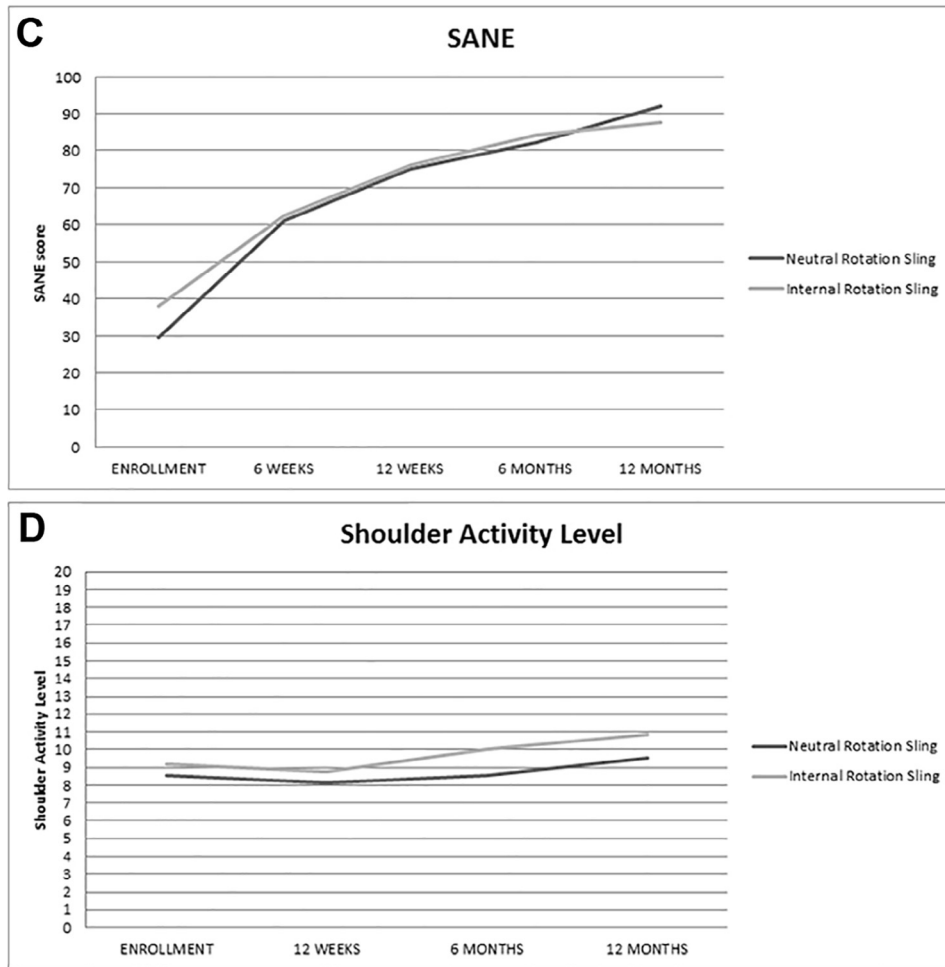


Figure 2 (Continued)

26°, $P = .02$), (3) passive horizontal adduction (7.7 cm vs 3.7 cm, $P = .05$), and (4) pain with passive adduction (6.2 cm vs 3.5 cm, $P = .002$). We also found a trend toward significant improvements in the neutral rotation sling group compared with the internal rotation sling group when we measured (1) active horizontal adduction (8.3 cm vs 2.9 cm, $P = .06$) and

(2) active internal rotation behind the back (18 cm vs 11 cm, $P = .09$). Although not statistically significant, the mean improvement in active flexion in the supine position was 12° greater in the neutral rotation sling group compared with the internal rotation sling group ($P = .16$) (Table III).

When examining the VAS outcomes, we found statistically significant improvements in both groups from enrollment to final follow-up for (1) overall pain, (2) night pain, (3) neck pain, and (4) difficulty sleeping horizontally ($P < .0001$) (Fig. 3). There was no statistically significant difference between groups for overall satisfaction determined at final follow-up with the success of the procedure (mean VAS score, 5 ± 9 mm in neutral rotation sling group vs 8 ± 12 mm in internal rotation sling group; $P = .45$; 95% confidence interval [CI], -4.6 to 10.3 mm). For all VAS scores measured, the neutral rotation sling group uniformly had greater improvements from enrollment to final follow-up than the internal rotation sling group, but these did not reach statistical significance. At 2 weeks, the neutral rotation sling group had significantly less night pain than the internal rotation sling group (mean VAS score, 18 ± 21 mm vs 34 ± 21 mm; $P = .047$; 95% CI, 0.1 - 31.7 mm), which superseded the MCID of the

Table I Improvement in outcome scores from baseline to follow-up

	Neutral rotation sling	Internal rotation sling	<i>P</i> value	95% CI
DASH score	39 ± 19	33 ± 11	.25	-5 to 17
WOOS score	58 ± 17	50 ± 19	.22	-5 to 21
Shoulder Activity Level	1.2 ± 3.9	1.3 ± 3.7	.93	-3 to 3
SANE score	63 ± 17	52 ± 22	.15	-4 to 24

CI, confidence interval; DASH, Disabilities of the Arm, Shoulder and Hand; WOOS, Western Ontario Osteoarthritis of the Shoulder; SANE, Single Assessment Numeric Evaluation.

Table II Range of motion at each time point

	Neutral rotation sling					Internal rotation sling				
	Enrollment	12 weeks	6 mo	12 mo	<i>P</i> value*	Enrollment	12 weeks	6 mo	12 mo	<i>P</i> value*
Supine active flexion, °	109	133	143	143	<.0001	117	131	139	143	.0004
Supine passive flexion, °	123	144	152	150	<.0001	129	139	150	152	.0002
Active external rotation, °	28	56	65	67	<.0001	33	47	57	60	.0003
Passive external rotation, °	35	67	75	77	<.0001	42	57	66	70	.0002
Supine active abducted external rotation, °	35	60	65	68	<.0001	34	50	60	63	<.0001
Supine passive abducted external rotation, °	43	68	77	78	<.0001	43	61	71	73	.0001
Supine active abducted internal rotation, °	35	40	43	49	.004	31	42	43	46	.006
Supine passive abducted internal rotation, °	44	50	52	58	.007	38	51	51	56	.001
Standing active flexion, °	96	110	125	130	<.0001	102	112	126	131	.001
Active internal rotation behind back, cm	50	42	36	32	<.0001	45	42	35	34	.002
Active horizontal adduction, cm	33	29	28	25	<.0001	31	28	27	27	.22
Passive horizontal adduction, cm	30	26	25	23	<.0001	27	26	25	24	.02
Pain with passive adduction on VAS, cm	7	2	2	1	<.0001	6	2	2	1	<.0001

VAS, visual analog scale.

* *P* values analyze the improvement at 12 months' follow-up compared with the measurements at enrollment.

VAS score.¹⁸ At 12 months, the neutral rotation sling group trended toward better overall pain relief compared with the internal rotation sling group (mean VAS score, 4 ± 9 mm vs 9 ± 6 mm; $P = .08$; 95% CI, -0.6 to 9.9 mm), although the difference did not meet the MCID. Finally, the neutral rotation sling group had greater improvements in the ability to sleep in the horizontal position (mean VAS score improvement, 49 ± 24 mm vs 35 ± 43 mm), but the difference did not reach statistical significance ($P = .20$; 95% CI, -10 to 36 mm) (Fig. 3).

Discussion

To our knowledge, this is the first study examining the influence of sling position on range of motion and patient-determined outcomes after anatomic total shoulder arthroplasty. This study demonstrated greater improvements with the use of a neutral rotation sling after total shoulder arthroplasty for external rotation motion, with statistically significant improvements found in active ($P = .03$) and passive ($P = .02$)

Table III Comparison of improvements in range of motion between groups from baseline to final follow-up

	Neutral rotation sling	Internal rotation sling	<i>P</i> value	95% CI
Supine active flexion, °	35 ± 20	23 ± 20	.16	-5 to 29
Supine passive flexion, °	29 ± 19	20 ± 16	.14	-3 to 21
Active external rotation, °	42 ± 24	25 ± 20	.03*	2 to 33
Passive external rotation, °	44 ± 21	26 ± 21	.02*	4 to 34
Supine active abducted external rotation, °	36 ± 22	26 ± 17	.16	-4 to 23
Supine passive abducted external rotation, °	39 ± 26	27 ± 19	.13	-4 to 28
Supine active abducted internal rotation, °	16 ± 19	15 ± 17	.85	-12 to 15
Supine passive abducted internal rotation, °	16 ± 20	20 ± 17	.56	-18 to 10
Standing active flexion, °	37 ± 23	29 ± 26	.34	-9 to 26
Active internal rotation behind back, cm	18 ± 10	11 ± 11	.09	-1 to 15
Active horizontal adduction, cm	8.3 ± 6.1	2.9 ± 7.8	.06	-0.2 to 11
Passive horizontal adduction, cm	7.7 ± 5.6	3.7 ± 4.8	.05*	0.1 to 8
Pain relief with passive adduction on VAS, cm	6.2 ± 2.1	3.5 ± 2.5	.002*	1 to 4

CI, confidence interval; VAS, visual analog scale.

* Statistically significant.

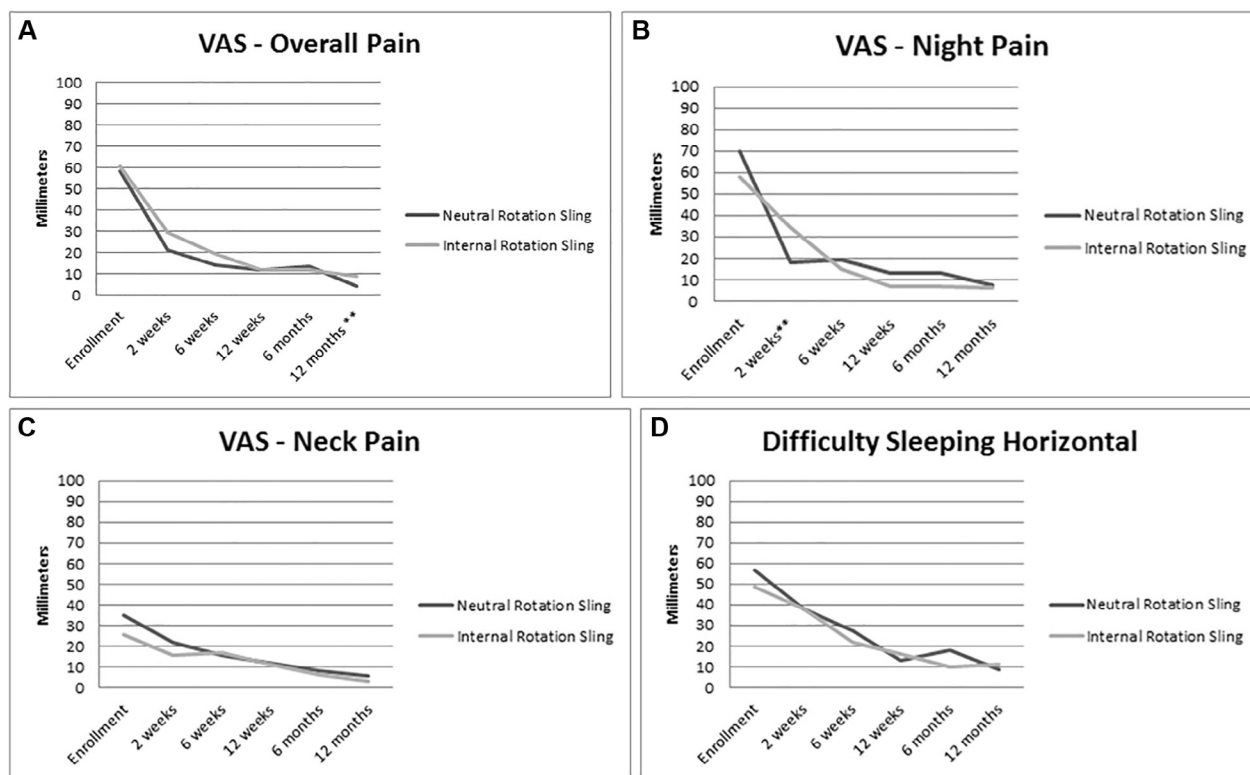


Figure 3 (A) Visual analog scale (VAS) scores for overall pain. **There was a statistical trend toward decreased pain in the neutral rotation sling group compared with the internal rotation sling group at 12 months ($P = .08$). (B) VAS scores for night pain. **There was statistically significantly less night pain in the neutral rotation sling group than in the internal rotation sling group at 2 weeks ($P = .047$). (C) VAS scores for neck pain. (D) VAS scores for ability to sleep in horizontal position.

external rotation with the arm in the neutral position. In addition, we found statistically greater improvements in passive horizontal adduction ($P = .047$) and pain with passive adduction ($P = .002$) and trends toward improvements in both active horizontal adduction ($P = .06$) and active internal rotation behind the back ($P = .09$) in patients using a neutral rotation sling after total shoulder arthroplasty. Improvements in both active flexion (difference of 12° between groups) and passive flexion (difference of 9° between groups) were greater in the neutral rotation sling group, but these did not meet the level of statistical significance.

Night pain is frequently found in patients with shoulder pain. However, the underlying cause of this night pain has not been determined.¹⁹ At 2 weeks after surgery, patients in the neutral rotation sling group had significantly less night pain than patients using an internal rotation sling ($P = .047$). A trend toward better overall pain relief at 12 months after surgery was found in the neutral rotation sling group compared with the internal rotation sling group as determined by the VAS. However, this remains of unknown clinical significance because it did not meet the MCID of the VAS.¹⁸

Fortunately, the benefits of the neutral rotation sling did not come at the cost of increased discomfort or inconvenience as determined by self-reported compliance. Both sling groups reported similar compliance rates and VAS scoring

of compliance with how patients were instructed to wear the sling.

The findings of our study had several similarities with the findings of Conti et al,³ who examined the use of a 15° external rotation brace after rotator cuff repair in a prospective, randomized, unblinded trial. Although there were no differences found in patient-determined outcome scores (DASH, Constant, and UCLA scores), this trial demonstrated significantly less pain during the early post-operative period as determined by a VAS. In addition, passive range of motion, particularly abduction and external rotation, was significantly greater in the external rotation brace group.

One limitation of this study is that it does not elucidate the mechanisms for improved relief of night pain and the greater range of motion provided by the neutral rotation sling. One might theorize that the neutral rotation sling keeps the anterior capsule and subscapularis in a relatively lengthened position compared with the internal rotation sling (Fig. 4). This theory would explain why external rotation is improved in the neutral rotation sling group because the internal rotation sling might be more likely to predispose the post-operative shoulder to an anterior shoulder contracture and thereby loss of relative external rotation.

Another limitation is that this study includes a relatively short follow-up period for studies examining the outcomes

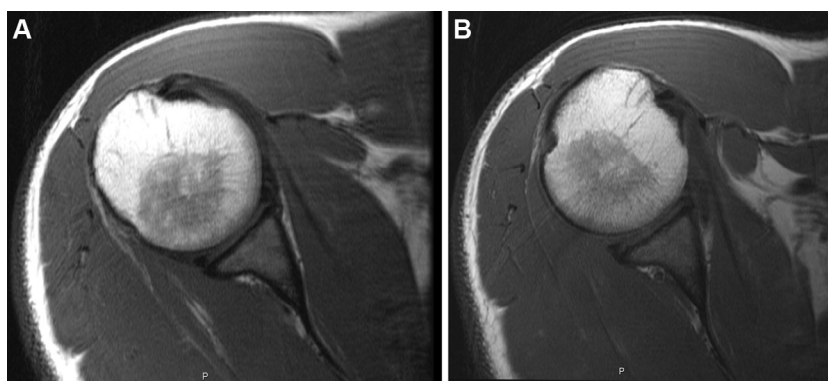


Figure 4 (A) Magnetic resonance imaging of shoulder immobilized in neutral rotation sling. (B) Magnetic resonance imaging of shoulder immobilized in internal rotation sling.

after total shoulder arthroplasty. However, it is intuitive that the final effects of the position of the sling, which is only used for the first 6 weeks after total shoulder arthroplasty, should be apparent by the end of the first postoperative year. Finally, the study only includes a small sample size, which potentially limits this study. However, clinically and statistically significant results were found even in the setting of a smaller sample size, which may decrease the concern regarding a smaller sample size.

Conclusions

Neutral rotation sling use after anatomic total shoulder arthroplasty resulted in statistically significant improvements in external rotation and adduction, as well as decreased night pain, compared with an internal rotation sling. One might consider using a neutral rotation sling rather than an internal rotation sling after anatomic total shoulder arthroplasty secondary to its superior improvements in postoperative range of motion and pain relief.

Disclaimer

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