A commentary by Rony-Orijit Dey Hazra, MD, et. al, is linked to the online version of this article.

InSpace Implant Compared with Partial Repair for the Treatment of Full-Thickness Massive Rotator Cuff Tears

A Multicenter, Single-Blinded, Randomized Controlled Trial

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Background: The purpose of this study was to prospectively evaluate the efficacy and safety of a subacromial balloon spacer (InSpace implant; Stryker) compared with arthroscopic partial repair in patients with irreparable, posterosuperior massive rotator cuff tears.

Methods: Patients ≥40 years of age with symptomatic, irreparable, posterosuperior, massive rotator cuff tears and an intact subscapularis who underwent failed nonoperative management were included in this randomized controlled trial comparing the InSpace implant with partial repair. Clinical outcome data were collected at baseline through a 24-month follow-up. The primary outcome was improvement in the American Shoulder and Elbow Surgeons (ASES) scores. The secondary outcomes included change from baseline in the Western Ontario Rotator Cuff (WORC) score, the visual analog scale (VAS) pain score, the Constant-Murley shoulder score, the EuroQol-5 Dimensions-5-Level (EQ-5D-5L) score, active range of motion, and operative time. Complications and reoperations for each group were also recorded.

Results: Twenty sites randomized 184 patients: 93 in the InSpace group and 91 in the partial repair group. Significant and clinically relevant improvements in the ASES score from baseline were noted in both groups at Month 12 and were maintained at Month 24. Overall, 83% of patients in the InSpace group and 81% of patients in the partial repair group achieved the ASES minimally clinically important difference threshold, and 82% of patients in the InSpace group and 79% of patients in the partial repair group achieved the substantial clinical benefit threshold. Forward elevation was significantly greater in the InSpace group compared with the partial repair group at Day 10 ($p = 0.04$), Week 6 ($p = 0.0001$), Month 12 ($p = 0.005$), and Month 24 ($p = 0.003$). The operative time was significantly shorter in the InSpace group ($p < 0.0001$). No device-related surgical complications were noted, and 4 reoperations after InSpace implantation and 3 reoperations after partial repair were required.

Conclusions: The InSpace implant is an appropriate alternative to partial repair in patients with irreparable posterosuperior massive rotator cuff tears and an intact subscapularis. Notable benefits include early functional recovery and pain relief combined with a shorter operative time.

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

Despite successful results for both conservative and operative treatment for partial-thickness, small, and medium-sized rotator cuff tears[1-3], surgical treatment options other than total joint replacement for painful, massive rotator cuff tears in patients without severe glenohumeral arthritis remain controversial[2,4-10]. The lack of a universally accepted

*A list of the SPACE GROUP members is included in a note at the end of the article.

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H35).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H37).

treatment algorithm for massive rotator cuff tears may explain why decision-making around the management of these patients remains so challenging[2,11,12]. Savarese and Romeo[12] described a surgical technique using the InSpace implant (Stryker) as a novel treatment option for patients with irreparable massive rotator cuff tears[2]. The implant is deployed arthroscopically into the subacromial space and is designed to act as a temporary spacer between the humeral head and the acromion, enabling smooth gliding during articulation and reducing acromiohumeral contact pressure while restoring a more anatomic glenohumeral position[13]. The implant has been used clinically for >10 years, with numerous publications demonstrating decreased operative time, decreased surgical complexity, and the ability to accelerate rehabilitation, resulting in more rapid patient recovery[14,15]. However, to our knowledge, no randomized controlled trial has previously evaluated its efficacy and safety.

The purpose of this multicenter, randomized controlled trial was to evaluate the efficacy and safety of the InSpace implant (Stryker) compared with partial repair as a primary surgical treatment for posterosuperior, massive rotator cuff tears. We hypothesized that the functional and patient-reported outcomes following InSpace implant arthroplasty would be equivalent to those following partial repair, with a shorter operative time.

Materials and Methods

Prior to study initiation, 20 enrolling sites in the United States and Canada received institutional review board approval. This study was registered at ClinicalTrials.gov (NCT02493660). Patients with posterosuperior, massive rotator cuff tears (defined as tears of ≥5 cm at the tendon insertion and ≥2 tendons involved as determined on preoperative magnetic resonance imaging [MRI] scans) were screened to determine if they met the inclusion or exclusion criteria by the investigator (Table I). Prior to randomization, subjects were stratified by sex, with blocking by site, to ensure a within-stratum-balanced subject distribution between the 2 treatment groups. An individual independent of the study team developed the randomization schedule, using a random block size of 2 or 4 (Fig. 1).

Intraoperative eligibility criteria were confirmed during the arthroscopic surgery. Subjects were included if the posterosuperior, massive rotator cuff tear was amenable to partial repair (adequate tissue quality to restore the force couple) but could not be completely repaired, the subscapularis was intact, and severe glenohumeral arthritis (International Cartilage Repair Society [ICRS] Grade 3 or higher) was not present. Eligible subjects were electronically randomized intraoperatively 1:1 to either receive the InSpace implant without partial repair (the treatment group) or undergo partial repair (the control group). Subjects were blinded to their treatment assignment throughout the study.

The implant is a biodegradable balloon spacer (poly L-lactide-co-ε-caprolactone [PLCL]) inflated with sterile saline solution to a predetermined volume after positioning in the subacromial space, and 1 of 3 sizes is selected on the basis of the intraoperative measurement (Fig. 2). Implant resorption occurs over 12 months. No rotator cuff repair was performed in the InSpace group. Patients randomized to partial repair underwent suture anchor repair (the best possible repair as determined by the operating surgeon) of the posterosuperior rotator cuff. Additional concomitant procedures were recorded for both groups. The intraoperative times documented included total operative time, skin incision to skin

TABLE I Key Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1. Male or female subject ≥40 years of age 2. Within 9 months before study enrollment, positive diagnostic imaging by MRI of the index shoulder indicating a full-thickness massive rotator cuff tear: a. Measuring ≥5 cm in diameter (Cofield classification) b. Involving ≥2 tendons 3. Functional deltoid muscle and preserved passive range of motion on physical examination 4. Documented VAS pain score >30 mm 5. Underwent failed nonoperative treatment of at least 4 months' duration (time elapsed since the initial treatment) using ≥1 of the following: a. Oral analgesics b. Anti-inflammatory medication (e.g., ibu profen, naproxen) c. Corticosteroid injection(s) d. Physical therapy e. Activity modification f. Rest (sling used)	1. Known allergy to the implant material (poly L-lactide-co-ε-caprolactone, a copolymer of poly L-lactide [PLA] and ε-caprolactone) 2. Evidence of the following conditions: a. Severe glenohumeral or acromiohumeral arthritis b. Full-thickness cartilage loss as seen on MRI c. Anterior or posterior shoulder subluxation or dislocation according to the patient history within the previous 5 years, examination, or radiographic findings d. Preexisting deltoid defect or deltoid palsy e. Major joint trauma, infection, or necrosis f. Partial-thickness tears of the supraspinatus g. Fully reparable rotator cuff tear (tear <5 cm in diameter [or <4 cm^2 in area] with a tendon that can be released and repositioned back to the tendon insertion site and can be fully repaired) h. Known neurovascular compromise i. Complete deltoid muscle palsy j. Traumatic muscle tears of the pectoralis or deltoid 3. Requirement for concomitant: a. Subscapularis repair b. Labral repair of any type 4. Previous surgery on the index shoulder in the previous 1 year, excluding diagnostic arthroscopy 5. Bilateral shoulder condition, with rotator cuff repair for the contralateral shoulder scheduled or planned to be scheduled over the course of this study 6. Current acute infection in the area surrounding the surgical site 7. Baseline WORC total score <420

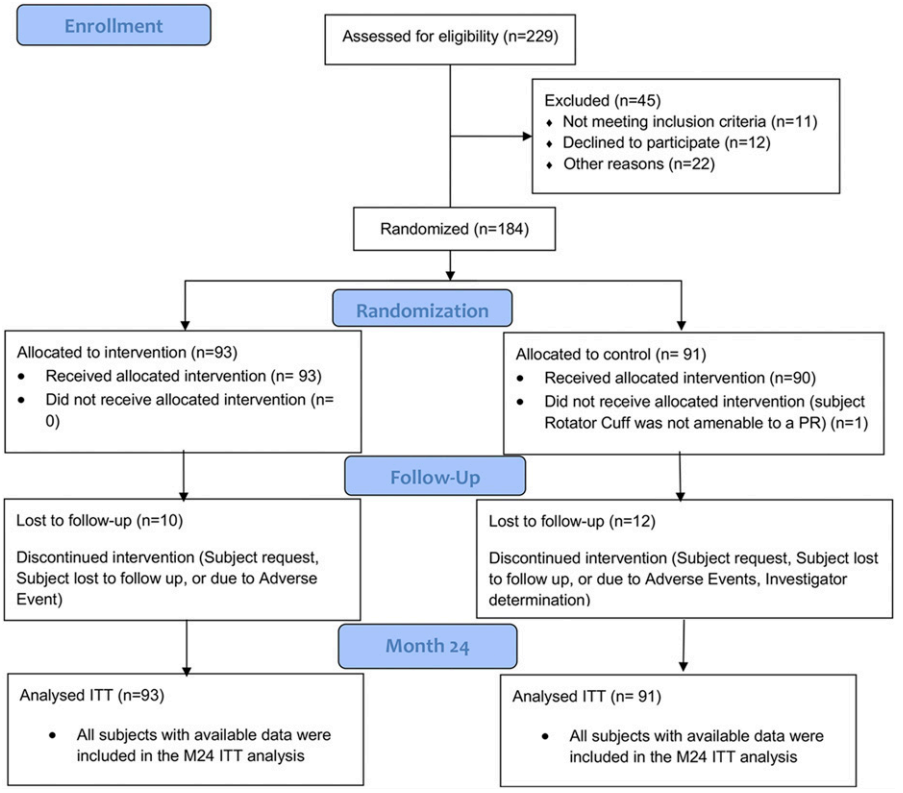

Fig. 1

Flowchart of patients. PR = partial repair and M24 = Month 24.

closure, and time for implant placement. Postoperative rehabilitation was standardized in both groups (Table II).

Follow-up visits completed at Day 10, Week 6, and Months 3, 6, 12, and 24 included shoulder examinations; review of complications, reoperations, and concomitant medications; and collection of patient-reported outcomes by an independent clinical research coordinator. The shoulder physical examination was conducted by an investigator not blinded to treatment group and included a goniometric measurement of active range of motion in forward elevation, external rotation with the arm at the side, and internal rotation reaching behind the back, as well as isometric strength testing with the arm elevated at 90° forward elevation in the scapular plane using a handheld dynamometer.

The primary outcome variable was the change from baseline to Month 24 for the American Shoulder and Elbow Society (ASES) score. The secondary outcome variables included the Western Ontario Rotator Cuff (WORC) score, Constant-Murley shoulder score, visual analog scale (VAS) for pain score, EuroQol-5 Dimensions-5 Level (EQ-5D-5L) quality-of-life score, and active range of motion. Our original study time frame for the primary end point was from baseline to Month 12, but, as this was an Investigational Device Exemption (IDE) study approved by the U.S. Food and Drug Administration (FDA), the FDA requested that we extend the time frame for our study to Month 24. Additionally, the prespecified primary end point for the IDE study was designed to assess the potential for early improvements that were maintained over time, utilizing a composite end point for patient-level success that was constructed to include 2 efficacy measures (change from baseline of ≥275 for the WORC and ≥6.4 for the ASES)[16-18], a safety measure (absence of a device-related serious adverse event), and avoidance of a subsequent secondary surgical procedure; each component was required to be met at Week 6 and to be maintained through Month 24. The composite end point was

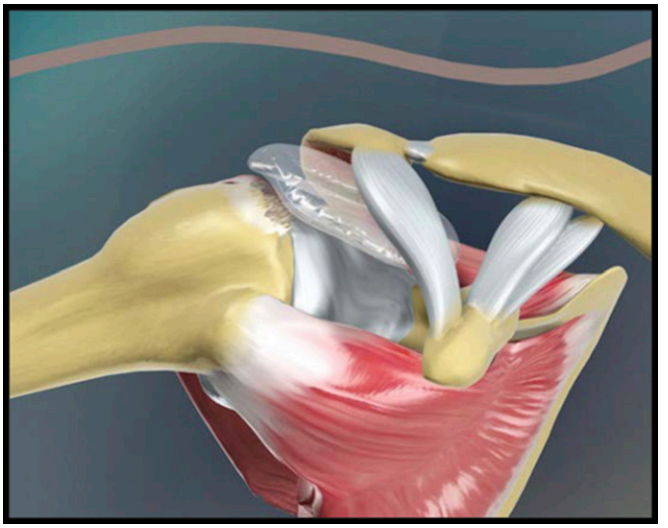

Fig. 2

Illustration of the InSpace implant in situ. (Reproduced with permission from Stryker.)

TABLE II Guidelines for Recommended Rehabilitation

Projected Timeline	Therapy Guidelines
Weeks 1 to 4*	Immobilization (e.g., sling) and passive range-of-motion exercises
	Hand pumps
	Isometric exercises with arm at side
	Passive range-of-motion exercises
	Grip strengthening
Week 5	Light passive stretching at end ranges
Weeks 6 to 12	Supine active range-of-motion exercises
	Increase range of motion as tolerated
	Advanced strengthening exercises as tolerated
	Begin with light weights up to 5 lb (2.27 kg)
	Gentle passive stretching exercises
Weeks 13 to 24	Advanced conditioning exercises
	Range-of-motion exercises using wand activities
	Strengthening exercises using tubing for active resistance

*There was no resisted motion during this phase

additionally analyzed (post hoc) by revising the prespecified ASES minimally clinically important difference (MCID) of 6.4[18] to an ASES MCID of 11.1 to align with more recently recognized thresholds, as noted below[19]. Due to the relevance to clinical practice, the prespecified end point of change from baseline for ASES is described as the primary focus for this article.

For the ASES score in patients undergoing rotator cuff repair, values have been previously described as 11.1 for the ASES MCID, 17.5 for substantial clinical benefit (SCB), and 86.7 for the patient acceptable symptom state (PASS)[19]. With a sample size of 184 subjects randomized 1:1, there was >80% power to detect a success rate improvement involving achievement of the ASES SCB at Month 24 (relative to baseline) from 80% for partial repair to 95% for the InSpace implant, and improvement involving achievement of the ASES PASS from 53% to 75%, given a 2-sided Fisher exact test and a 5% type-1 error. For the ASES measured as a continuous end point, there was >80% power to detect an effect size (ratio of the mean difference and standard deviation for the change from baseline) of 0.415, given a 2-sided unpaired t test and a 5% type-1 error; any effect size of ≥0.29 would reach a 2-sided p value of ≤0.05 according to an unpaired t test. For the composite end point, the study was designed to rule out a 10% disadvantage for the InSpace group using a noninferiority study design; the power was 80% for a 1-sided test with a 2.5% type-1 error, given the 1:1 randomization allocation.

The results of the study were analyzed using a 2-sided Fisher exact test for the percentages of subjects achieving the ASES MCID, SCB, and PASS thresholds. The intent-to-treat (ITT) population, defined as all randomized subjects, was used as the primary analysis population. Preplanned multivariable analyses were based on a logistic regression model for Month 24 success based on age (<65 years, ≥65 years), sex, and treatment as the model covariates. The effects of baseline forward elevation, extremity dominance, and the number of concomitant procedures on outcomes were also assessed as exploratory end points. Secondary outcomes and demographic data were assessed for differences with the use of standard statistical tests appropriate for the data, including an unpaired t test used to analyze mean changes from baseline for each outcome at each nominal follow-up time. All statistical analyses were performed using SAS version 9.3 (SAS Institute).

Source of Funding

This study was sponsored and funded by OrthoSpace, Caesarea, Israel (now a part of Stryker Corporation), the manufacturer of the implants in the study, and 2 of the authors are OrthoSpace or Stryker employees.

Results

Between 2015 and 2018, a total of 184 subjects were randomized: 93 to the InSpace treatment group and 91 to the control group. Of these, 89% (83) of the InSpace implant subjects and 87% (79) of the partial repair subjects had a Month 24 follow-up visit. The 2 treatment groups were similar in terms of demographic characteristics (Table III), baseline characteristics (Tables III and IV), and the mean number of concomitant procedures performed (3.4 for the InSpace group and 3.7 for the partial repair group; p = 0.21) (Table V).

TABLE III Demographic and Baseline Characteristics*

Parameter	InSpace (N = 93)	Partial Repair (N = 91)	P Value
Age† *(yr)*	66.8 ± 7.7	64.7 ± 7.9	0.068
Age category‡			0.47
<65 years	38 (40.9%)	43 (47.3%)	
≥65 years	55 (59.1%)	48 (52.7%)	
Sex‡			0.88
Male	50 (53.8%)	50 (54.9%)	
Female	43 (46.2%)	41 (45.1%)	
Race‡			0.97
White	83 (89.2%)	80 (87.9%)	
Black or African American	7 (7.5%)	7 (7.7%)	
Asian	1 (1.1%)	1 (1.1%)	
Other	2 (2.2%)	3 (3.3%)	
Body mass index† *(kg/m²)*	30.1 ± 6.4	30.1 ± 7.0	1.0
Nicotine use status‡			0.27
Yes, currently	13 (14.0%)	8 (8.8%)	
Stopped	31 (33.3%)	40 (44.0%)	
Never	49 (52.7%)	43 (47.3%)	

*Data are presented for the safety population of 184 subjects.
†The values are given as the mean and the standard deviation.
‡The values are given as the number of patients, with the percentage in parentheses.

TABLE IV Shoulder Baseline Characteristics*

Parameter	InSpace (N = 93)	Partial Repair (N = 91)	P Value†
Index shoulder‡			0.46
Left	28 (30.1%)	28 (30.8%)	
Right	65 (69.9%)	63 (69.2%)	
Bilateral shoulder pain‡			0.53
Yes	31 (33.3%)	26 (28.6%)	
No	62 (66.7%)	65 (71.4%)	
Mechanism of tear‡			0.83
Tendon degeneration associated with age	47 (50.5%)	44 (48.4%)	
Low-energy fall	19 (20.4%)	21 (23.1%)	
Other	14 (15.1%)	13 (14.3%)	
Fall from height	9 (9.7%)	9 (9.9%)	
Motor vehicle accident	3 (3.2%)	1 (1.1%)	
Cycling accident	0 (0%)	2 (2.2%)	
Motorcycle accident	1 (1.1%)	1 (1.1%)	
Time since symptom onset§ *(mo)*	37.5 ± 56.0	29.4 ± 48.7	0.37
Symptom onset for index shoulder‡			0.18
Gradual	55 (59.1%)	44 (48.4%)	
Acute	38 (40.9%)	47 (51.6%)	

*Data are presented for the safety population of 184 subjects. †All p values were not significant ($p > 0.05$). ‡The values are given as the number of patients, with the percentage in parentheses. §The values are given as the mean and the standard deviation.

TABLE V Concomitant Procedures

	InSpace* (N = 93)	Partial Repair* (N = 91)	P Value†
No concomitant procedures	2 (2.2%)	0 (0%)	0.50
Subacromial decompression	43 (46.2%)	45 (49.5%)	0.77
Biceps tenodesis	20 (21.5%)	22 (24.2%)	0.73
Biceps tenotomy	28 (30.1%)	33 (36.3%)	0.43
Rotator cuff debridement	44 (47.3%)	47 (51.6%)	0.66
Subacromial bursectomy	62 (66.7%)	63 (69.2%)	0.75
Glenohumeral debridement, major	33 (35.5%)	35 (38.5%)	0.76
Glenohumeral debridement, minor	28 (30.1%)	25 (27.5%)	0.75
Distal clavicle excision or resection	16 (17.2%)	11 (12.1%)	0.41
Acromial spur removal	4 (4.3%)	8 (8.8%)	0.27
Capsular release	5 (5.4%)	9 (9.9%)	0.28
Acromioplasty	25 (26.9%)	26 (28.6%)	0.87
Suprascapular nerve release	1 (1.1%)	3 (3.3%)	0.37
Other‡	7 (7.5%)	11 (12.1%)	0.33

*The values are given as the number of patients, with the percentage in parentheses. †The Fisher exact test was used to determine between-treatment differences. ‡For the InSpace group, "other" included extensive debridement, lysis of adhesions, rotator cuff scar release, loose body removal, chondroplasty, extensive intra-articular debridement, and labral debridement. For the partial repair group, "other" included chondroplasty, debridement, removal of old suture material, tuberoplasty, coracoacromial ligament resection, excision of ganglion cyst from acromioclavicular joint, release of bursal scar, partial synovectomy, removal of retained sutures, lysis of adhesions, and revision rotator cuff repair.

TABLE VI Study Treatment Details*

Parameter	InSpace (N = 93)	Partial Repair (N = 91)	P Value
Total duration in the operating room† *(min)*	84.3 ± 21.0	113.1 ± 37.3	<0.0001
Duration of anesthesia† *(min)*	91.4 ± 25.3	121.1 ± 37.9	<0.0001
Duration of operative procedure (skin incision to closure)† *(min)*	44.6 ± 16.9	71.2 ± 30.1	<0.0001
Duration of implant-deployer insertion† *(min)*	3.8 ± 1.9	NA	—
Size of device‡			
Small	1 (1.1%)	NA	—
Medium	29 (31.2%)	NA	—
Large	63 (67.7%)	NA	—

*NA = not applicable. †The values are given as the mean and the standard deviation. ‡The values are given as the number of patients, with the percentage in parentheses.

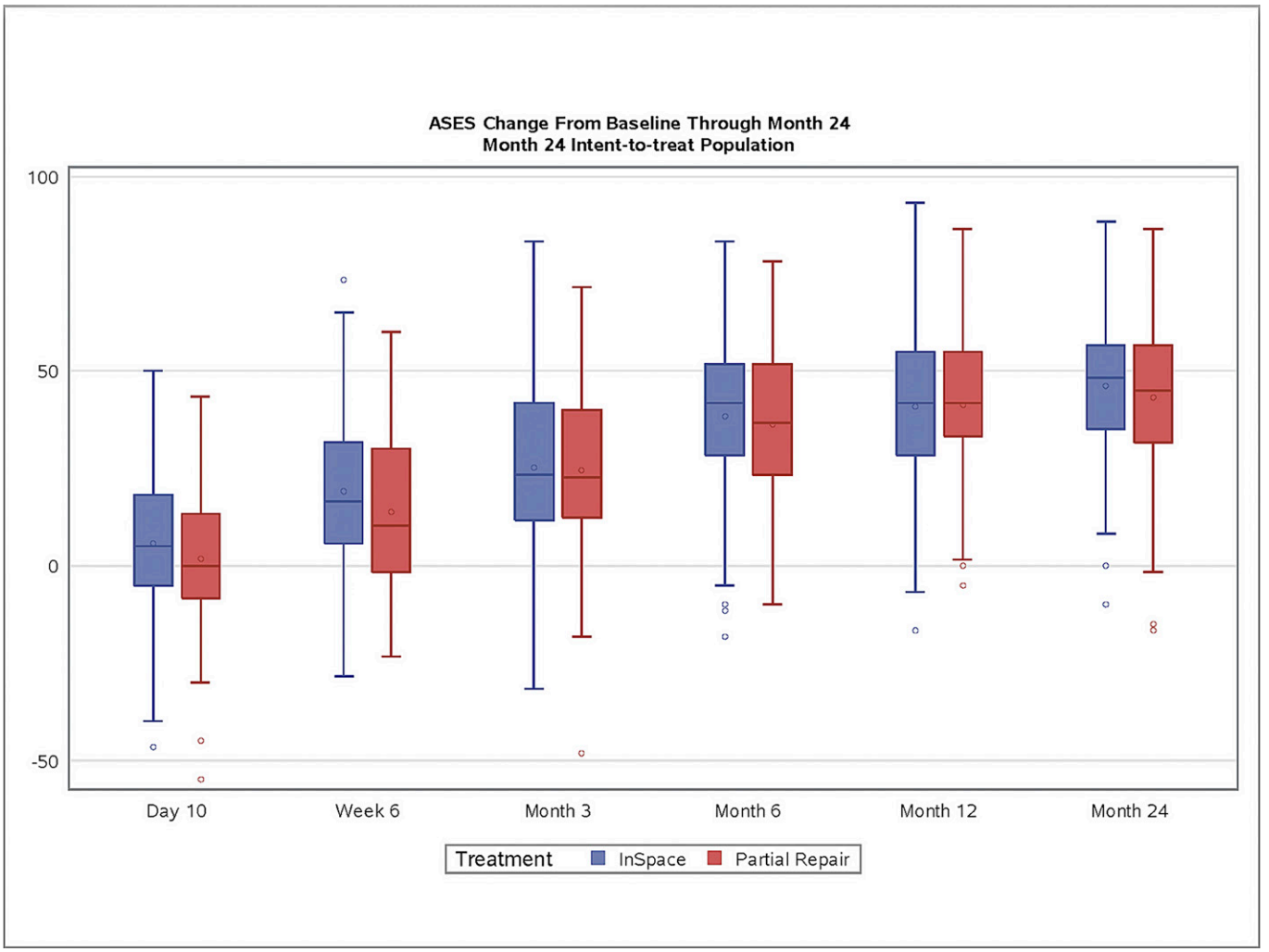

Fig. 3

Box-and-whisker plot showing the overall ASES scores, presented as the change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). The ASES score can range from 0 to 100; a higher score indicates improvement. No significant differences were found between groups, determined with an unpaired t test. The median values are indicated with horizontal lines, interquartile ranges (IQRs) are indicated with boxes, and whiskers denote data points within ±1.5 IQR. The circles indicate outliers.

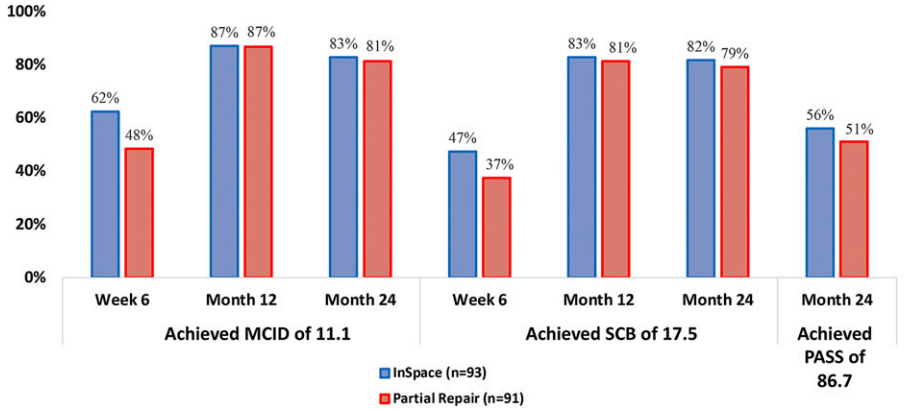

Fig. 4

The percentage of subjects meeting the ASES score thresholds for the InSpace group (n = 93) and the partial repair group (n = 91). The percentages were calculated on the basis of the number of patients who returned at each designated follow-up and had success relative to the actual number of patients enrolled in each treatment group. The patients with data numbered 92 at Week 6, 91 at Month 12, and 83 at Month 24 in the InSpace group and 90 at Week 6, 87 at Month 12, and 79 at Month 24 in the partial repair group. No significant differences were found between groups.

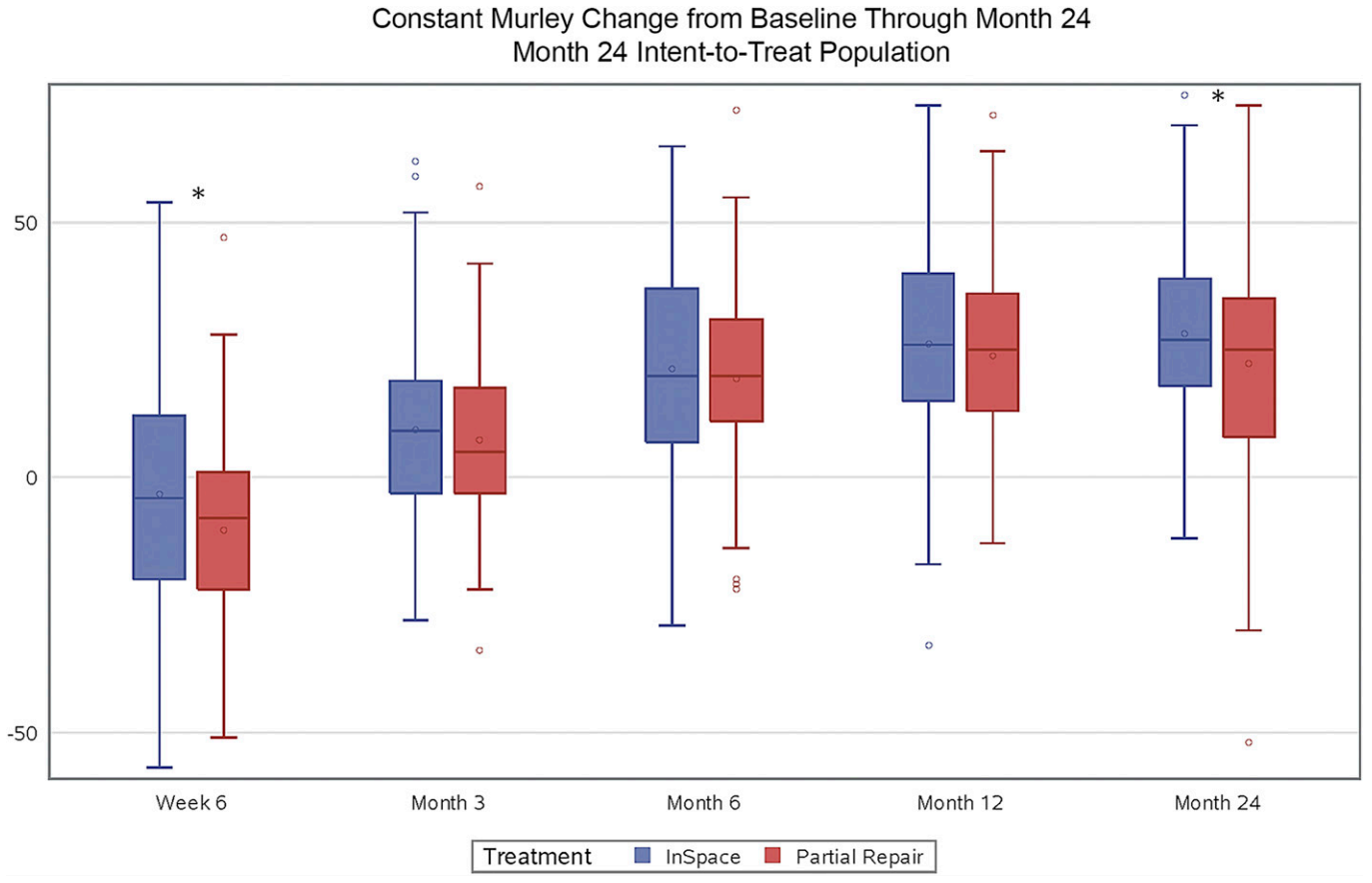

Fig. 5

Box-and-whisker plot showing the overall Constant score, presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). The Constant score can range from 0 to 100; a higher score indicates improvement. No data were available for Day 10. Significant differences were found between groups at Week 6 ($p = 0.021$) and Month 24 ($p = 0.05$), determined with an unpaired t test. The asterisk indicates significance at $p \leq 0.05$. The median values are indicated with horizontal lines, IQRs are indicated with boxes, and whiskers denote data points within ±1.5 IQR. The circles indicate outliers.

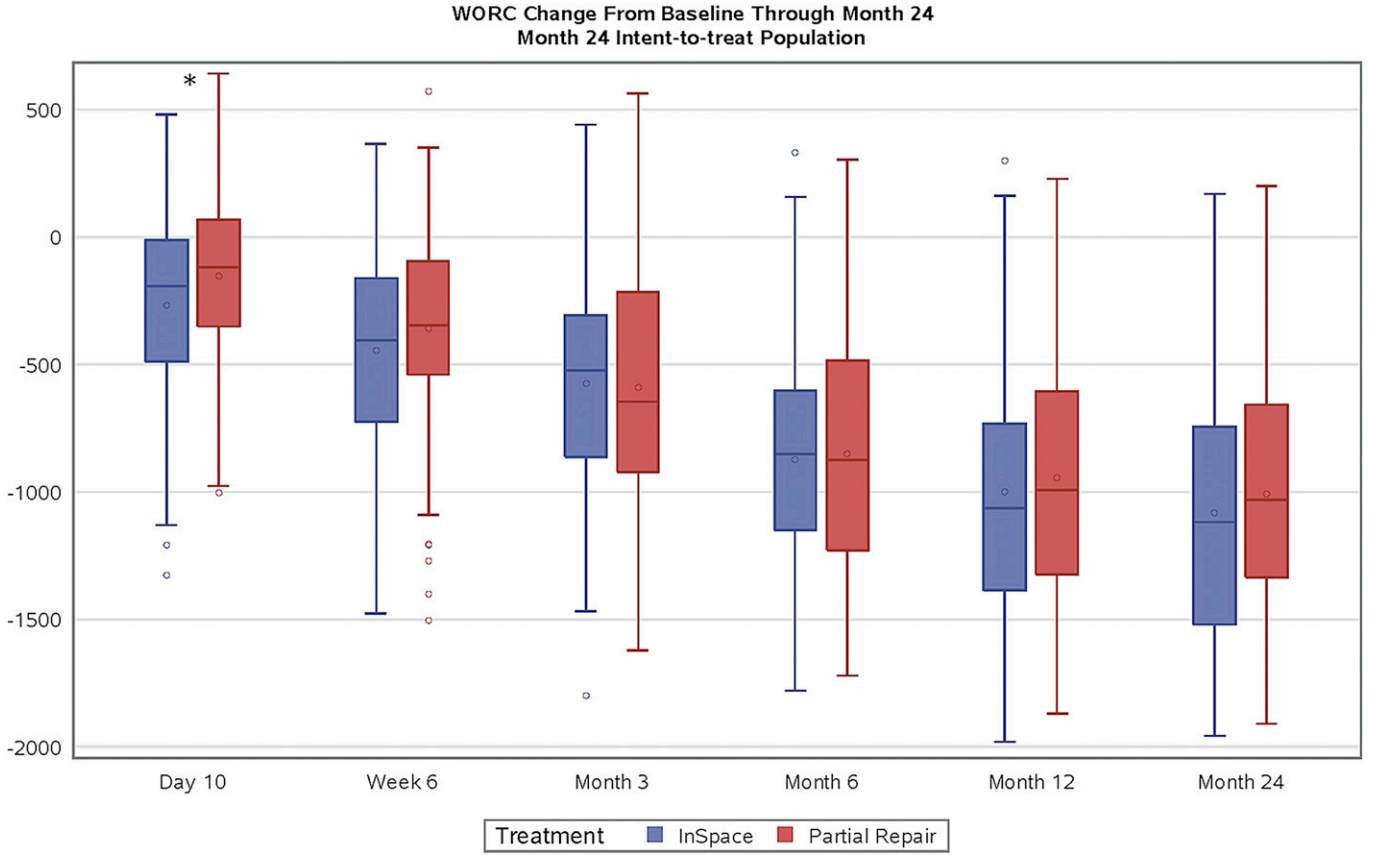

Fig. 6

Box-and-whisker plot showing the overall WORC score, presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). The WORC score can range from 0 to 2,100; a lower score indicates improvement. A significant difference was found between groups at Day 10 ($p = 0.035$), determined with an unpaired t test. The asterisk indicates significance at $p \leq 0.05$. The median values are indicated with horizontal lines, IQRs are indicated with boxes, and whiskers denote data points within ±1.5 IQR. The circles indicate outliers.

The mean operative time for the InSpace implant group (44.6 minutes) was significantly shorter ($p < 0.0001$) than for the partial repair group (71.2 minutes) (Table VI). The mean InSpace implant insertion time was 3.8 minutes (range, 1 to 13 minutes) (Table VI), with almost all subjects receiving a medium or large implant. The mean number of anchors used for partial repair was 3 (range, 1 to 5).

There were significant improvements from baseline to Month 24 in the ASES score for both the InSpace group (mean and standard deviation, 46.22 ± 20.89; $p < 0.0001$) and the partial repair group (42.53 ± 20.54; $p < 0.0001$) (Fig. 3). There was no significant difference between the InSpace and partial repair groups in the percentage of patients achieving the MCID, SCB, and PASS at Month 12 and Month 24, and most patients who achieved the MCID and SCB at Month 12 maintained them at Month 24 (Fig. 4).

With regard to secondary end points, there was a significant difference between groups in improvement from baseline in the Constant score at Week 6 and Month 24 (Fig. 5), the WORC score at Day 10 (Fig. 6), and forward elevation at Day 10, Week 6, Month 12, and Month 24 favoring the InSpace group (Fig. 7). At Month 24, 10% (8 of 82) of InSpace implant subjects reported forward elevation improvement greater than that of the greatest range-of-motion responder in the partial repair group (i.e., 94°) (Fig. 8). Additionally, for subjects with range of motion below the baseline level at Month 24 (13% [11 of 82] for the InSpace implant group and 25% [19 of 77] for the partial repair group), the mean range of motion loss was greater in the partial repair group: a change of −29° ± 30.63° compared with −16° ± 12.59° in the InSpace implant group. The external rotation and internal rotation range-of-motion outcomes were comparable between the 2 treatment groups (see Appendix). There was no significant difference in VAS pain or EQ-5D-5L outcomes (Fig. 9) or Constant score at any postoperative time point between the InSpace group and the partial repair group (see Appendix). No device-related surgical complications or device-related serious adverse events, including infection or implant removal, were noted in either group. Seven subjects required reoperation, 3 in the partial repair group (1 repeat arthroscopy for persistent pain and 2 conversions to reverse total shoulder arthroplasty [TSA]) and 4 in the InSpace group (1 arthroscopy for persistent pain, 2

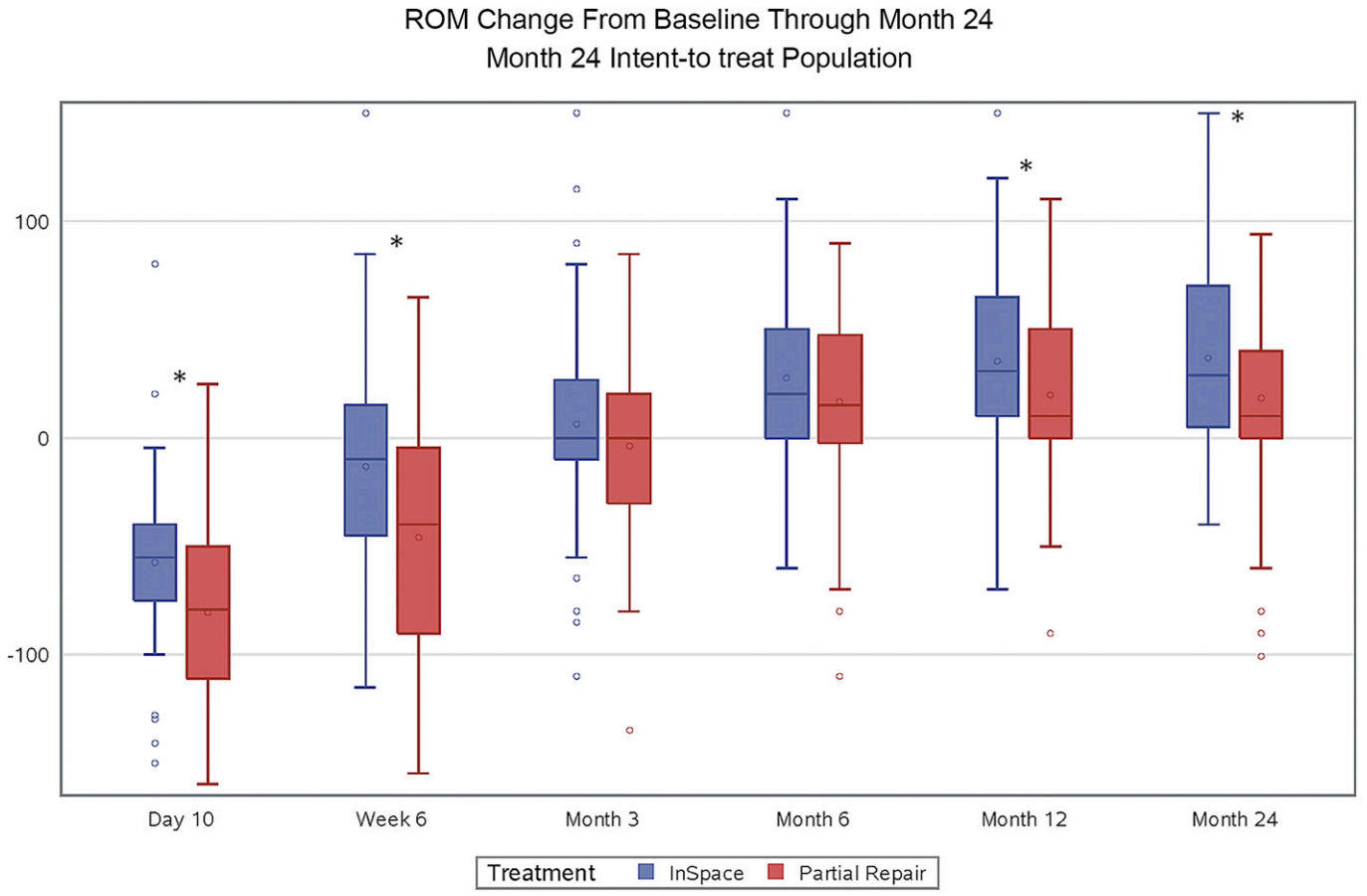

Fig. 7

Box-and-whisker plot showing forward elevation, presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). Range of motion (ROM) can range from 0° to 180°; a higher value indicates improvement. Significant differences were found between groups at Day 10 (p = 0.041), Week 6 (p = 0.0001), Month 12 (p = 0.0048), and Month 24 (p = 0.003), determined with an unpaired t test. The asterisk indicates significance at $p \leq 0.05$. The median values are indicated with horizontal lines, IQRs are indicated with boxes, and whiskers denote data points within ±1.5 IQR. The circles indicate outliers.

conversions to reverse TSA for failure, and 1 conversion to reverse TSA for fracture nonunion following a fall).

For the primary end point, baseline age, study site, treatment of the dominant extremity, and preoperative forward elevation were found to have no significant effect on the between-treatment difference. However, sex had a significant effect on the treatment outcomes at Month 24, with male patients performing better than female patients in both treatment groups. Additionally, the number of concomitant procedures (i.e., 0 to 1 procedure compared with ≥2 procedures) had no effect on outcome in either treatment group.

Finally, the composite end point for patient-level success, with early improvement (i.e., at Week 6) maintained at Month 24, demonstrated comparable results between the InSpace and partial repair groups, although the percentage of patients achieving success was 8.4% higher in the InSpace group when an ASES MCID of 6.4 was used (p = 0.0199) and 7.3% higher when an ASES MCID of 11.1 was used (p = 0.0257) (Table VII).

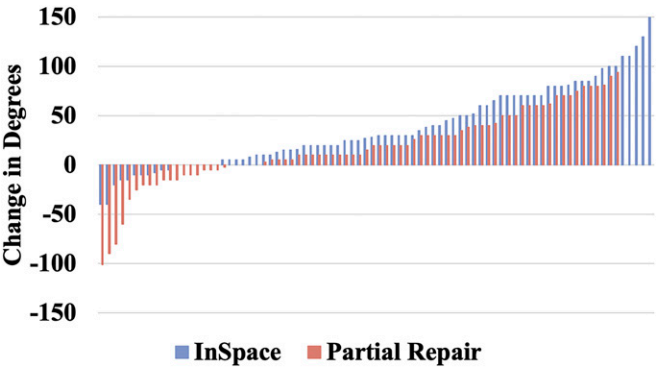

Fig. 8

A waterfall plot showing the forward elevation change from baseline to Month 24 for the InSpace group and the partial repair group. A line below the x axis indicates worsening range of motion at Month 24 relative to baseline. A line above the x axis indicates improvement at Month 24 relative to baseline.

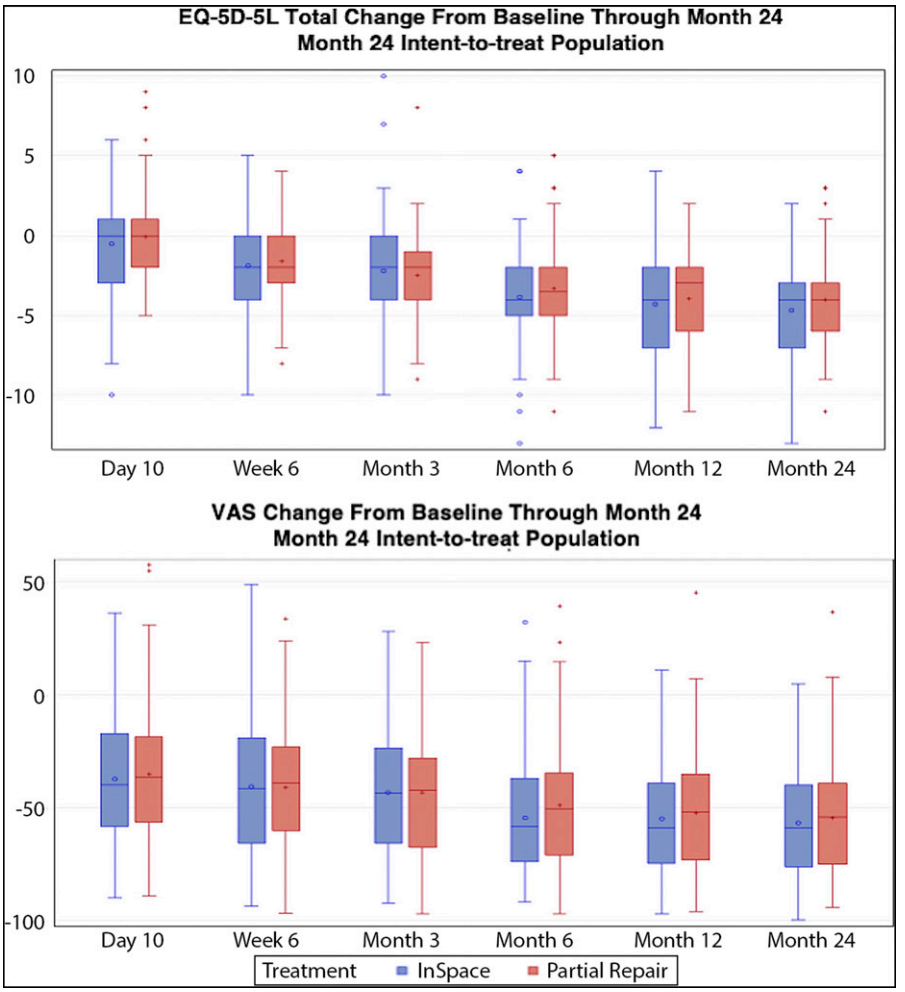

Fig. 9

Box-and-whisker plots showing EQ-5D-5L (top panel) and VAS scores (bottom panel), presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). The EQ-5D-5L can range from 1 to 5; a lower score indicates improvement. The VAS can range from 0 to 100; a lower score indicates improvement. No significant differences were found between groups for either outcome measurement, determined with an unpaired t test. An asterisk indicates significance at $p \leq 0.05$. The median values are indicated with horizontal lines, IQRs are indicated with boxes, and denote data points within ±1.5 IQR. The circles indicate outliers.

Discussion

The InSpace implant demonstrated functional and patient-reported outcomes that were comparable with those of partial repair for the treatment of irreparable, posterosuperior, massive rotator cuff tears in shoulders with an intact subscapularis by Month 12, with durable benefit maintained up to Month 24. The InSpace group had earlier recovery than the partial repair group at Week 6, characterized by improvement in the ASES, WORC, and Constant scores and range of motion. Subjects in the InSpace group reported ASES score improvements similar to those in the partial repair group at all time points and better WORC scores, range of motion, and Constant scores across multiple time points. The 2-year follow-up is well beyond the degradation profile of the implant, indicating that clinical improvement is maintained even after the implant has biodegraded. The operative time for the InSpace implant was significantly shorter than that for partial repair, and there were no complications specifically related to the implant.

Although the groups performed similarly well on all patient-reported outcomes and there was a significant between-group difference at Month 24 in improvement in the Constant score from baseline, subjects in the InSpace group were more likely to achieve success thresholds without a decrease in range of motion (87% reported no range-of-motion deterioration), indicating that these subjects were more likely to return to daily functioning with at least the same range of motion as they had preoperatively, and more commonly gained range of motion. In contrast, more subjects in the partial repair group demonstrated limitation of range of motion at Month 24 compared with their preoperative state despite achieving similar pain and function outcomes as their InSpace counterparts. The potential reasons for this finding are multifactorial, including reduced operative time, less scarring, no bone

TABLE VII Composite End Point*†

	Per-Protocol Analyzed Population at Month 24†	P Value for Noninferiority
Prespecified end point§		
InSpace (n = 82)	38 (46.3% [35.5% to 57.1%])	
Partial repair (n = 79)	30 (38.0% [27.0% to 49.0%])	
Difference	8.4% (−7.1% to 23.8%)	0.0199
Post hoc end point#		
InSpace (n = 82)	34 (41.5% [30.8% to 52.1%])	
Partial repair (n = 79)	27 (34.2% [23.4% to 45.0%])	
Difference	7.3% (−7.9% to 22.4%)	0.0257

*Results from the general linear model (Proc Mixed), with proportions estimated using normal approximations, for noninferiority with a 10% margin. †The per-protocol population consists of all subjects in the ITT population without major protocol deviations. ‡The values for the specific groups are given as the number of patients, with the percentage in parentheses and the 95% confidence interval in brackets. The values for the differences are given as the percentage, with the 95% confidence interval in parentheses. §Prespecified denotes WORC score improvement ≥275 and ASES score improvement ≥6.4 at Week 6; these improvements were maintained at Month 24 with no subsequent secondary surgical intervention and no device-related serious adverse event. The analyses of the ITT populations were consistent with the per-protocol population (achievement of ASES MCID of 6.4 in ITT population: 39 (41.9%) of 93 for the InSpace group and 31 (34.1%) of 91 for the partial repair group; p = 0.014). #Post hoc denotes WORC score improvement ≥275 and ASES score improvement ≥11.1 at Week 6; these improvements were maintained at Month 24 with no subsequent secondary surgical intervention and no serious adverse device effects. The analyses of the ITT populations were consistent with the per-protocol population (achievement of ASES MCID of 11.1 in ITT population: 34 (36.6%) of 93 for the InSpace group and 28 (30.8%) of 91 for the partial repair group; p = 0.025).

instrumentation, and less pain following the procedure, which may allow for earlier mobilization.

Prior investigations, limited primarily to case series and small prospective trials, have similarly demonstrated successful outcomes with the use of the InSpace implant[14]. Senekovic et al.[20] reported on the outcomes in 20 consecutive patients with massive rotator cuff tears and found that there was a significant increase in the Constant score at the 3-year follow-up compared with preoperatively. In a subsequent study, the same authors demonstrated sustained outcomes and implant longevity in 24 patients at a 5-year follow-up, with the Constant scores showing significant improvement over preoperative values[21]. Furthermore, 84.6% of patients maintained favorable outcomes at 5 years. Deranlot et al.[22] reported successful outcomes in a retrospective review of 37 patients (39 shoulders) undergoing subacromial spacer arthroplasty. The mean adjusted Constant score was significantly increased at a mean follow-up of 32.8 months, and the mean shoulder ranges of motion in anterior elevation, abduction, and external rotation were significantly improved compared with preoperative measures. Moreover, limited radiographic deterioration was noted, with the Hamada score advancing only a single radiographic stage in 4 patients and progressing 3 stages in 1 patient.

In contrast, in a prospective study of 15 patients, Ruiz Ibán et al.[23] demonstrated inconsistent results following InSpace implant insertion for irreparable massive rotator cuff tears, with 33% (5) of 15 patients requiring conversion to reverse TSA within 2 years and only 40% (6) of 15 meeting the criteria for meaningful improvement in the Constant score. The differences between these authors' experience and the results of the current study are difficult to reconcile. It is notable that the mean preoperative active forward elevation in the current study group was 115° compared with only 90° in the study by Ruiz Ibán et al.[23]. Furthermore, they noted that 4 patients had pseudoparalysis. This difference would suggest that preoperative range of motion may be an important predictive factor in outcomes following InSpace implant insertion.

Few studies have compared the outcomes following utilization of the InSpace subacromial spacer with those following other surgical treatments of massive rotator cuff tears. Holschen et al.[24] demonstrated that, when compared with arthroscopic techniques (including debridement, synovectomy, bursectomy, biceps tenotomy or tenodesis, and partial repair when possible [n = 11]), 12 patients who were treated with the InSpace implant had greater absolute improvements in ASES and Constant scores at the final follow-up. Patients receiving the InSpace implant entered the study with lower preoperative shoulder function scores, and Holschen et al. reported a shorter final follow-up time (due to InSpace availability at the institution) for the InSpace group (22.3 months) than the traditional group (30.6 months).

A recent systematic review of the InSpace implant identified significant improvements in patient-reported outcomes and functional recovery after InSpace implant insertion[14]. The existing studies generally had small sample sizes and consisted of Level-III and IV evidence, highlighting the importance of this Level-I randomized trial. Johns et al. also conducted a financial analysis showing InSpace to be highly cost-effective in treating patients with massive rotator cuff tears[14].

The cause of pain in patients with rotator cuff pathology remains unclear. Even more perplexing is why some patients maintain normal function in the setting of rotator cuff tears and others experience a substantial loss of active motion. It is likely that, for many patients, pain inhibits function. Pain may occur from multiple sources such as bursitis, synovitis, the long head of the biceps, the acromioclavicular joint, deltoid

dysfunction, and abnormal contact between the acromion and the humeral head. For most patients with massive rotator cuff tears, the pathoanatomy is chronic but symptoms are recent, and there is often a decompensating event that results in the onset of symptoms. The exact mechanism of action of the InSpace implant is not clearly understood. In patients who have undergone failed conservative care, it is our opinion that the implant allows for a reset in the shoulder by recentering the humeral head, temporarily eliminating contact between the humeral head and the acromion and allowing time for deltoid reeducation in a state of reduced pain, thus improving the success of subsequent physical therapy. Given that the implant resorbs over time, the durability of clinical benefit exhibited by patients in this study can only be explained by successful rehabilitation resulting in clinical benefit up to 24 months. Although the standardized rehabilitation protocol required each group to wear a sling for 4 weeks postoperatively, rehabilitation may be accelerated in clinical practice[15] because the use of the InSpace implant does not require the protection of a repair. The InSpace implant group did demonstrate a more rapid range-of-motion recovery in this study.

The most important strength of the study was its design as a randomized, single (subject)-blinded study. Moreover, subjects were followed for 2 years, facilitating an assessment well beyond the degradation profile of the implant. However, patients with subscapularis tears were not evaluated because of the strict inclusion criteria and design of the study, and further studies are needed to establish the benefits of the implant in patients with subscapularis pathology. Study limitations included the lack of standardization with respect to the concomitant procedures performed in both groups and the repair techniques in the partial repair group and evaluators of the physical examination not being blinded to treatment group, which may have been a potential source of detection bias. Although the study presents data on intermediate-term follow-up at 2 years, longer-term follow-up is warranted to evaluate the duration of benefit. Importantly, the role of the implant in patients with true pseudoparalysis unrelated to pain remains unknown and is beyond the scope of this study.

In conclusion, the outcomes of the InSpace implant were comparable with those of partial repair for the treatment of patients with irreparable, posterosuperior, massive rotator cuff tears and an intact subscapularis at Month 24. There was also earlier recovery of outcome in the InSpace implant group compared with the partial repair group, significantly shorter operative time, and no device-related surgical complications.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H36). ■

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