Sports Medicine
Literature Matters

Research Bulletin

InSpace implant compared with partial repair for the treatment of full-thickness massive rotator cuff tears

A multicenter, single-blinded, randomized controlled trial

Verma N, Srikumaran U, Roden CM, Rogusky EJ, Lapner P, Neill H, Abboud JA, on behalf of the SPACE GROUP*[1]

Top-level summary:

The purpose of this study was to prospectively evaluate the efficacy and safety of a subacromial balloon spacer (InSpace implant; Stryker) compared to arthroscopic partial repair in patients with irreparable, posterosuperior massive rotator cuff tears. Results from the study demonstrate the InSpace implant provides notable benefits including early functional recovery and pain relief combined with a shorter operative time when compared with the partial repair group. Thus, the authors concluded that the InSpace implant is an appropriate alternative to partial repair in patients with irreparable posterosuperior massive rotator cuff tears with intact subscapularis.

Methods:

Twenty sites randomized a total of 184 subjects ≥40 years of age with symptomatic, irreparable, posterosuperior, massive rotator cuff tears (defined as tears of ≥5 cm at the tendon insertion and ≥2 tendons involved) who previously underwent failed non-operative management and met all inclusion/exclusion criteria. Intraoperative eligibility criteria were also confirmed, after which patients were electronically randomized (1:1) to either receive the InSpace implant without partial repair (N=93) or undergo partial repair using suture anchors (N=91).

Following the surgery, patients attended routine in-person follow-up visits at Day 10, Week 6, and Months 3, 6, 12, and 24, which included review of complications, reoperations, and concomitant medications; and collection of patient-reported outcomes by an independent clinical research coordinator. The primary outcome variable was the change from baseline to Month 24 for the American Shoulder and Elbow Score (ASES). The secondary outcome variables included the Western Ontario Rotator Cuff Score (WORC), Constant-Murley Shoulder Score, Visual Analog Scale (VAS) for pain score, EuroQol-5 Dimensions-5 Level Quality of Life Score (EQ-5D-5L), and active range of motion. Operative times, complications, and reoperations for these two groups were also collected. The results of the study were analyzed using appropriate statistical methods to compare between the two treatment groups as well as to evaluate mean changes from baseline for subjects within each treatment group. For the primary endpoint, literature values for ASES MCID, substantial clinical benefit (SCB), and patient acceptable symptomatic state (PASS) were utilized.

A pre-specified primary endpoint was designed to assess the potential for early improvement that was maintained over time, utilizing a composite endpoint 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), and 2 safety measures (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 for patient-level success.

Results:

Both treatment groups were similar in terms of demographic characteristics, baseline characteristics, 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). Significant improvements in the ASES score from baseline were noted in both groups at Month 12 and were maintained at Month 24. Overall, similar results were achieved between both groups where 83% of patients in the InSpace group and 81% of patients in the partial repair group achieved the ASES MCID threshold, and 82% of patients in the InSpace group and 79% of patients in the partial repair group achieve the substantial clinical benefit (SCB) threshold (Fig. 1).

With regard to secondary endpoints, although both groups performed similarly well on all patient-reported outcomes, there was a significant difference between groups in improvement from baseline in the Constant Score at Week 6 and Month 24 (Fig. 2) and the WORC Score at Day 10 (Fig. 3), and forward elevation (ROM) at Day 10, Week 6, Month 12, and Month 24 favoring the InSpace group (Fig. 4). 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 degrees). Additionally, treatment with the InSpace implant was shown to result in a greater magnitude of ROM improvement in more patients than those treated with partial repair, where 13% of all patients treated with the InSpace implant and 25% of all partial repair patients did not get back to their baseline range of motion (Fig. 5).

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). The mean InSpace implant insertion time was 3.8 minutes (range 1 to 13 minutes). No device-related surgical complications or device-related serious adverse events, including infection or implant removal, were noted. 4 reoperations after InSpace implantation and 3 reoperations after partial repair were required.

Clinical relevance:

The outcomes of the InSpace implant group were comparable with those of partial repair group in the treatment of patients with irreparable, posterosuperior, massive rotator cuff tears and an intact subscapularis at Month 24. There was also earlier recovery of outcomes (characterized by improvement in the ASES, WORC, and Constant scores and range of motion at Week 6) in the InSpace implant group compared with the partial repair group, significantly shorter operative time, and no device-related surgical complications. Thus, the authors concluded that the InSpace implant is an appropriate alternative to partial repair in patients with irreparable posterosuperior massive rotator cuff tears with intact subscapularis.

Study strengths:

- Level I evidence; prospective, randomized, controlled, single-blinded, multicenter clinical study
- Patients were followed through two years, well beyond degradation time of balloon (expected degradation at one year)
- High subject retention rate (n = 184); 97% at one year and 88% at two years
- Robust data collection which included objective and subjective outcomes
- In-person follow-up at 6 timepoints post-operatively
- Well-defined extensive eligibility criteria for patient population
- Subjects blinded to treatment
- Post-operative rehabilitation was standardized in both groups

Study limitations:

- Lack of standardization with respect to concomitant procedures performed in both treatment groups
- Lack of standardization with respect to the repair technique in the partial repair group
- Physical examination evaluators not blinded to the treatment group may have been a potential source of detection bias
- Longer-term follow-up (beyond 2 years) is warranted to evaluate the duration of benefit
- The role of the implant in patients with true pseudoparalysis unrelated to pain remains unknown and is beyond the scope of the study

Figures 1–5:

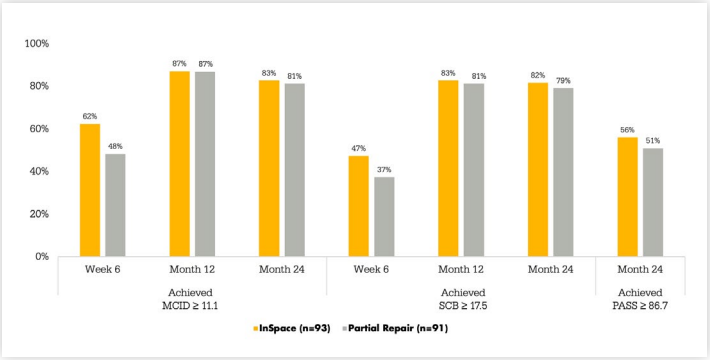

Figure 1. The percentage of subjects meeting the ASES score thresholds for the InSpace group (n = 93) and the partial repair group (n = 91). The percentages were calculated on the basis of the number of patients who returned at each designated follow-up and had success relative to the actual number of 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.

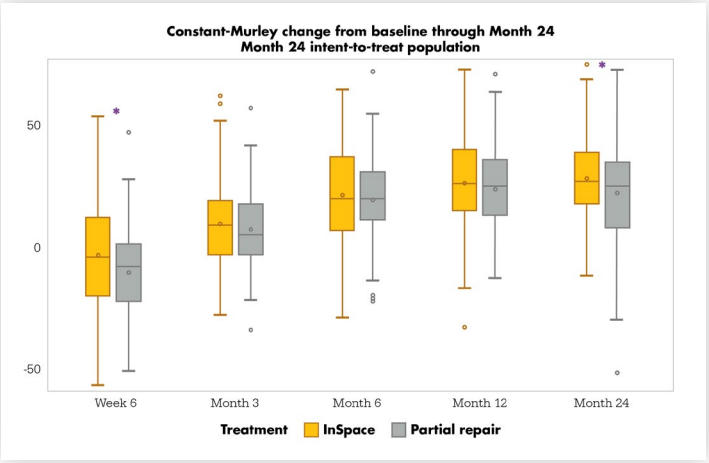

Figure 2. Box-and-whisker plot showing the overall Constant score, presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). The Constant score can range from 0 to 100; a higher score indicates improvement. No data were available 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.

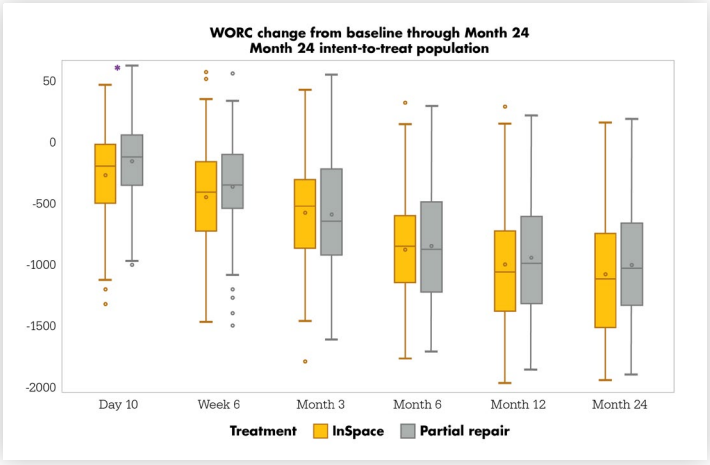

Figure 3. Box-and-whisker plot showing the overall WORC score, presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). A significant difference was found between groups at Day 10 ($p = 0.035$), determined with an unpaired t test. 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.

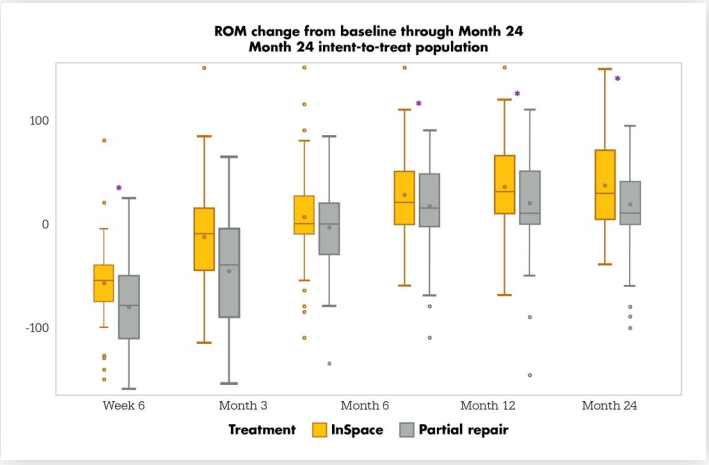

Figure 4. Box-and-whisker plot showing ROM-forward elevation, presented as a change from baseline for the ITT population, for the InSpace group (n = 93) and the partial repair group (n = 91). Range of motion (ROM) can range from 0° to 180°; a higher value indicates improvement. Significant differences 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.

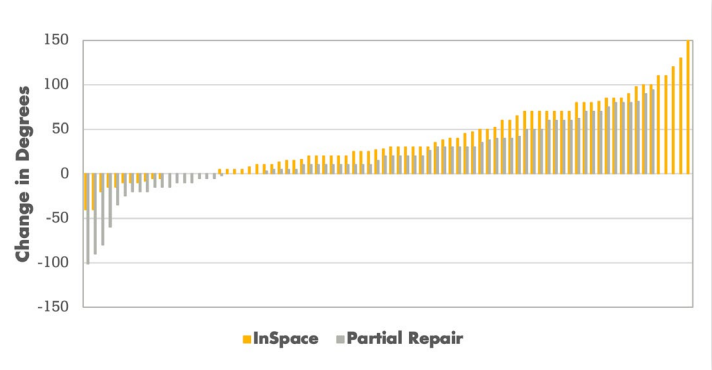

Figure 5. A waterfall plot showing the forward elevation change from baseline to Month 24 for the InSpace group and the partial repair group. A line below the x axis indicates worsening range of motion at Month 24 relative to baseline. A line above the x axis indicates improvement at Month 24 relative to baseline. Vertical bars represent individual patient data.

References:

1. Verma N, Srikumaran U, Roden CM, Rogusky EJ, Lapner P, Neill H, Abboud JA. (2022). InSpace implant compared with partial repair for treatment of full-thickness massive rotator cuff tears. J Bone JT Surg Am. Advance online publication. doi. 10.2106/JBJS.21.00667.

InSpace Indications for Use (United States): The InSpace™ Subacromial Tissue Spacer System is indicated for the treatment of patients with massive, irreparable full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age whose clinical conditions would benefit from treatment with a shorter surgical time compared to partial rotator cuff repair.

***Note:** The SPACE GROUP includes: Verma N[†], Cole BJ, Nicholson GP, Rogusky EJ, Tyndall WA, Sensiba PR, Srikumaran U, Abboud JA[†], Lapner P, Trenhaile SW, Bravman JT, McCarty EC, Higgins LD, Matzkin EG, Murthi AM, Levy JC[†], Snyder SJ, Bahk MS, Getelman MH, Burns JP, Jones GL, Bishop JY, Hasan SS[†], DiPaola MJ, O'Brien MJ, Savoie FH, Levine WN, Jobin CM, Setter KJ, Athwal GS[†], Faber KJ, Litchfield RB, Jazrawi LM, Meislin RJ, Lavin PT, Roden CM[‡], Neill H[‡].

[†]Stryker Consultant; [‡]Employee of OrthoSpace

Literature Matters pieces are intended to help to make scientific literature relevant to Stryker products more digestible by summarizing and pulling out key highlights, etc. from publications. They convey information directly from the literature and do not represent Stryker's opinions or interpretations of the publications. Literature Matters pieces are intended to be supplementary to a publication and not a substitute; readers are encouraged to fully read the covered article. They are not comprehensive of other information or published literature regarding a Stryker device; readers are encouraged to consult other literature.

Sports Medicine

Stryker
Sports Medicine
5670 Greenwood Plaza Blvd.
Ste. 200
Greenwood Village, CO 80111

t: 866 596 2022
www.sportsmedicine.stryker.com

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate Stryker's products. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

Please contact your representative if you have questions about the availability of Stryker's products in your area.

Stryker or its affiliated entities own, use, or have applied for the following trademarks or service marks:InSpace and Stryker. All other trademarks are trademarks of their respective owners or holders.

The absence of a product, feature, or service name or logo from this list does not constitute a waiver of Stryker's trademark or other intellectual property rights concerning that name or logo.

1000904172 Rev B

Copyright © 2022 Stryker