Regence

Medical Policy Manual Surgery, Policy No. 226

Subacromial Balloon Placement

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Next Review: May 2027
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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A balloon subacromial spacer is a device that can be used in the treatment of massive, irreparable rotator cuff tears and other shoulder pathologies.

MEDICAL POLICY CRITERIA

The use of subacromial balloon spacers for any indication, including but not limited to rotator cuff repairs, is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

The treatment of rotator cuff tears depends upon several factors, including the duration of symptoms, shoulder dominance, the type of tear (partial versus full thickness), and patient characteristics such as age, comorbidities, and activity level.[1] Treatment options include

surgical repair and physical therapy. To date, few randomized trials have been performed that directly compare surgical and nonsurgical management of rotator cuff tears. Of these, many trials have not demonstrated a clear benefit to surgery. Additional well-controlled, prospective trials are needed to determine the relative risks and benefits of, and appropriate patients for, each approach. Given the limited evidence, our approach to the management of rotator cuff tears, summarized in the accompanying algorithm, is necessarily based upon largely observational data, animal studies, evidence extrapolated from successful treatment of non-rotator cuff tendon tears, and our clinical experience.

REGULATORY STATUS

The InSpace™ Subacromial Tissue Spacer System by Stryker was granted De Novo Classification from the US Food and Drug Administration (FDA) in June of 2020.[2] The indications for use include “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.”

EVIDENCE SUMMARY

Systematic Reviews

Sirignano (2024) published a systematic review of 27 studies with 894 participants receiving subacromial balloon spacers.[3] The overall methodological quality was rated as fair, with a mean Modified Coleman Methodology Score of 61.4. Functional outcomes showed significant improvement over time. Constant-Murley scores rose from a baseline of 34.8 to 64.2 at 12 months and 67.9 at 24 months. ASES scores improved from 35.1 at baseline to 83.3 at 12 months and 81.8 at 24 months. Pain levels, measured by VAS, decreased from 6.6 at baseline to 2.6 at 12 months and 2.0 at 24 months. Range of motion also improved: flexion increased from 108.5° to 151.2°, abduction from 97.7° to 142.3°, and external rotation in adduction from 33.1° to 53.9° over 24 months. External rotation at 90° abduction rose from 56.3° to 83.5° at 12 months and slightly decreased to 77.1° at 24 months. The authors noted that more rigorous comparative studies showed insignificant results with small effect sizes, suggesting the need for more high-quality evidence to demonstrate long term efficacy.

Berk (2023) published a review on 28 studies including 886 patients to evaluate the clinical utility of the use of subacromial balloon spacers for the treatment of irreparable rotator cuff tears.[4] Primary outcomes in the included studies were Constant score, American Shoulder and Elbow Surgeons score, Oxford Shoulder Score, and Visual Analog Scale/Numeric Pain Raiting Scale. Mean follow-up duration was 30.4 months (range 12-56) and all patient reported primary outcomes showed improvement from baseline. Additional functional outcome measures (forward elevation, abduction, and external rotation) also improved. The authors concluded that short-term outcomes show that balloon spacers can be safe and effective in the treatment of irreparable rotator cuff tears. The review also reported significant clinical heterogeneity, use of concomitant procedures, and heterogeneity in patient selection which limit the ability to definitively conclude the procedure is effective in this patient population. Additional data is necessary to determine the effectiveness compared to other accepted treatment options and the durability of the treatment over time.

Levy (2023) published a review of 22 studies including 766 patients evaluating the clinical utility of subacromial balloon spacers in patients with irreparable rotator cuff tears. [5] The authors reported improvements in functional outcomes such as forward elevation, external rotation, and abduction in addition to improvements in patient-reported outcomes (Constant Score, ASES, Oxford Shoulder Score, and pain scores). The results suggest short-term outcomes from the use of subacromial balloon spacers show improvement in clinical and patient-reported outcomes. Heterogeneity in outcomes and patient selection were identified demonstrating the need for additional high quality, comparative long-term data.

Liu (2021) published a review on 261 patients who received surgical treatment with the use of subacromial spacers in patients with irreparable or massive rotator cuff repairs.[6] Primary outcomes included total constant score, Oxford shoulder score, American Shoulder and Elbow Society scores, and numeric rating scales at different time points. The authors concluded that the combined results showed a significant improvement in total constant score at final follow-up and that a sensitivity analysis revealed a treat towards improvement. The results of this review indicated that short term and middle term effects of subacromial spacers may be positive, however additional long term randomized trials are needed to confirm these findings.

Additional systematic reviews identified confirmed the findings of the reviews addressed in this section that there may be viable clinical utility in the short and middle term, but long term data is needed.[7, 8]

Randomized Controlled Trials

Metcalfe (2022) published a randomized controlled trial comparing arthroscopic debridement of the subacromial space with biceps tenotomy to debridement with the use of the InSpace balloon in patients with irreparable rotator cuff tears.[9] The primary outcome was Oxford Shoulder Score at 12 months post-intervention with a modified intent to treat analysis adjusted for the planned interim analysis. The mean Oxford Shoulder Score was 34.3 in the debridement only group compared to 30.3 for those who received debridement plus the InSpace balloon. The mean difference adjusted for the adaptive design was -4.2, favoring the debridement only group. There were no differences reported in adverse events between groups. The results of this trial indicate that debridement alone had a greater effect on the primary outcome and the authors do not recommend the use of the InSpace ballon for the treatment of irreparable rotator cuff tears.

Haque (2025) published two year follow up data on the Metcalfe (2022) study in a total of 99 participants.[10] At the two year mark, there was no statistically significant difference in the Oxford Shoulder Score between the two treatment groups (95% CI: -7.9 to 0.4; P = .08). However, the Western Ontario Rotator Cuff score showed a significant advantage for the group that received debridement only, with a mean difference of -10.1 (95% CI: -19.5 to -0.8; P = .04). Similarly, the Patient Global Impression of Change also favored the debridement-only group, with an odds ratio of 0.4 (95% CI: 0.2 to 0.8; P = .015). No significant differences were observed in the EQ-5D-5L scores (mean difference: -0.009; 95% CI: -0.107 to 0.088; P = .85) or in patient satisfaction (odds ratio: 0.6; 95% CI: 0.3 to -1.2; P = .14). Complication rates were comparable between the two groups over the 24-month period. Overall, participants in the debridement-only group continued to demonstrate better outcomes than those who received debridement with the InSpace balloon. Based on these findings, the authors concluded that subacromial balloon spacers are not recommended for treating irreparable rotator cuff tears.

Verma (2022) published a randomized controlled trial comparing the InSpace balloon with partial rotator cuff in patients with symptomatic, irreparable massive rotator cuff tears.[11] A total of 184 patients were randomized into the treatment (InSpace) and control (partial cuff repair) groups and the primary outcome was improvement in American Shoulder and Elbow Surgeons (ASES) scores. Secondary outcomes included additional pain and function scores, active range of motion, and operative time. The authors reported statistically and clinically relevant improvements in ASES scores from baseline to 12 and 24 months in both groups. Additionally, it was concluded that the InSpace balloon is an appropriate alternative to partial rotator cuff repair.

Nonrandomized Studies

Kishan (2024) published five year follow-up results on the effect of subacromial balloon placement for the treatment of MRC.[12] A total of 42 (out of 61) patients were monitored for an average of 83.98 ± 9.50 months. Seven participants required revisions within two years, resulting in an 83.33% revision-free survival rate. Significant improvements were observed from preoperative to latest follow-up: acromiohumeral interval decreased (7.83 to 6.56, p = 0.004), critical shoulder angle increased (36.10 to 38.24, p = 0.001), osteoarthritis grade increased (1.45 to 2.81, p = 0.001), SF-12 physical score improved (27.40 to 37.69, p = 0.001), and Constant-Murley total scores increased (26.50 to 68.69, p = 0.001). MCID for total Constant-Murley scores was 11.78 points. Among those without revisions, satisfaction rates were 11.43% excellent, 57.14% satisfied, and 31.43% dissatisfied.

Additional non-randomized, non-comparative studies have been published which suffer from significant study design limitations which renders their conclusions severely limited.[13]

Section Summary

There remains limited long-term, randomized evidence to demonstrate the safety and efficacy of the use of subacromial balloon spacers in the treatment of irreparable rotator cuff tears. The published systematic reviews suggest there may be short-term efficacy, but the included studies have significant patient and clinical heterogeneity. Two RCTs (Metcalfe and Verma) reported differing results for the use of balloon spacers for the treatment of irreparable rotator cuff tears, which demonstrates the need for additional findings in this space. Additionally, the Metcalfe study and two-year follow-up data by Haque suggest that debridement alone is superior to the use of balloon spacers and do not recommend their use. Additional high quality randomized trials using appropriate clinical comparators with long-term follow up data are needed to confirm the findings in the existing literature and demonstrate clinical efficacy for this procedure.

PRACTICE GUIDELINE SUMMARY

The 2025 American Academy of Orthopedic Surgeons (AAOS) guidelines for the management of rotator cuff injuries includes the following summary of options for patients with unrepairable tears without arthropathy:[14]

- “In the absence of reliable evidence, it is the opinion of the workgroup that physical therapy, biceps tenotomy/tenodesis, partial repair, tendon transfer, superior capsular reconstruction, arthroscopic debridement, balloon spacers, graft interposition, or graft augmentation (non-porcine) can improve patient-reported outcomes. Strength of Evidence: moderate, low; Strength of Option: consensus).”

SUMMARY

There is not enough high-quality, long-term evidence demonstrating the efficacy of subacromial spacers for rotator cuff repairs. Additional high quality randomized trials are needed to confirm the findings in the existing literature and demonstrate clinical efficacy. No clinical practice guidelines based on research recommend the use of subacromial balloons during rotator cuff repairs. Therefore, the use of subacromial balloon spacers for any indication, including but not limited to rotator cuff repairs, is considered investigational.

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CODES

Codes	Number	Description
CPT	23929	Unlisted procedure, shoulder
HCPCS	C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed

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