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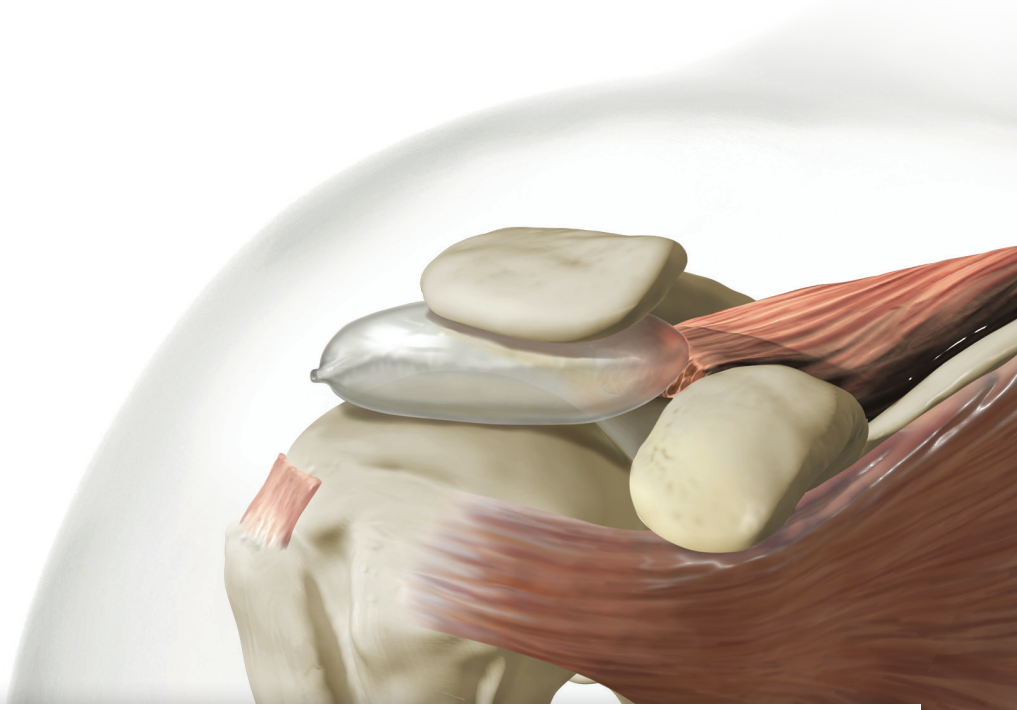

InSpace balloon implant

Key literature summary

Clinical studies

The biodegradable spacer as a novel treatment modality for massive rotator cuff tears: a prospective study with 5-year follow-up

Senekovic V, Poberaj B, Kovacic L, Mikek M, Adar E, Markovitz E, Maman E, Dekel A. Arch Orthop Trauma Surg. Jan 2017; 137(1): 95-103.

Purpose	The purpose of this study was to confirm the long-term safety and efficacy of the InSpace balloon in patients with massive reparable or irreparable RCTs.
Level of evidence	IV
Type of study	Prospective, single-armed, sponsored study
Number of subjects	24 patients
Follow up period	5 years
Safety observations	No complications or unexpected device-related adverse events were recorded
Study endpoints	Pain assessment: • Subjective Pain Score (SPS) • Relief of Shoulder Night Pain (SNP) Functional outcomes: • Total Constant Score (TCS) • Range of Motion (ROM) • Activity of Daily Living (ADL)
Summary of results	Of the participating subjects who reached the 5-year follow-up (15/24), 84.6% of the patients showed a clinically significant improvement of at least 15 points in their TCS, while 61.54% showed at least 25 points of improvement. Only 10% of the treated patients showed no improvement or worsening in the shoulder score comparing to their baseline.
Key take-aways	Study with longest follow up: 5 years

The subacromial balloon spacer for massive irreparable rotator cuff tears: approximately 3 years of prospective follow-up

Piekaar RSM, Bouman ICE, Van Kampen PM, Van Eijk F, Huijsmans PE. Musculoskelet Surg 2020; 104(2): 207-214.

Purpose	The purpose of this study was to evaluate the clinical outcome of the InSpace balloon after approximately 3 years.
Level of evidence	IV
Type of study	Prospective, single-arm, non-sponsored study
Number of subjects	44 patients (46 shoulders)
Follow up period	3 years
Safety observations	No surgical or postoperative medical complications due to implantation of the InSpace implant were reported
Study endpoints	Patient satisfaction: 3-point scale (very satisfied, satisfied, not-satisfied) Pain assessment: Numeric Rating Scale (NRS) Functional outcomes: Oxford Shoulder Score (OSS)
Summary of results	The data demonstrated that arthroscopic implantation of the InSpace balloon in the subacromial space led to significant reduction in pain, with the mean reduction in NRS at 3.5 points and 74% of patients having achieved the minimal clinically important different of 2 points by the first year. Significant improvement of functional daily activities (based on OSS and TCS) was seen in patients with irreparable RCT during 3 years of follow-up, starting postoperatively and maintained over time. 80% of patients reported that they were satisfied with their outcome.
Key take-aways	Prospective study with a 3 year follow up

Biceps tenotomy does not affect the functional outcomes of patients treated with spacer implantation

Maman E, Safran O, Beyth S, Mozes G, Dekel A, Michael B, Chechik O, Adar E. The Open Orthopaedics Journal 2017; 11: 1577-1584.

Purpose	The purpose of this study was to evaluate functional outcomes of arthroscopic InSpace balloon with or without biceps tenotomy as treatment for persistent shoulder dysfunction and pain due to an irreparable MRCT.
Level of evidence	IV
Type of study	Prospective, single-arm, sponsored study
Number of subjects	48 patients
Follow up period	1 year
Safety observations	None reported
Study endpoints	Functional outcomes: • Total Constant Score (TCS)
Summary of results	The mean TCS increased from 36 at baseline to 67 points at 12 months post implantation. Patients who underwent biceps tenotomy in addition to treatment with the InSpace balloon presented similar improvement of their shoulder function and score compared to the group that was treated with the balloon alone.
Key take-aways	Comparative study assessing the effect of concomitant biceps tenotomy on outcomes after treatment with InSpace

Biomechanical studies

The subacromial balloon spacer versus superior capsular reconstruction in the treatment of irreparable rotator cuff tears: a biomechanical assessment

Singh S, Reeves J, Langohr GDG, Johnson JA, Athwal GS. Arthroscopy 2019; 35(2): 382-389.

Purpose	The purpose of this study is to compare the InSpace balloon with superior capsular reconstruction (SCR) for the treatment of irreparable MRCT.
Level of evidence	IV
Type of study	Cadaveric
Number of subjects	8 cadaveric shoulders (male)
Study endpoints	• Shoulders were tested in four conditions: intact, irreparable rotator cuff tear (torn), InSpace balloon, and SCR • Superior humeral head migration and functional shoulder abduction force were measured at 0°, 30°, 60°, and 90° of shoulder abduction
Summary of results	In comparison to the intact condition, the torn condition resulted in a significant increase in superior humeral head migration at 0° and 30° of abduction. Insertion of the InSpace balloon and SCR restored the humeral head position such that it was not significantly different from the intact condition. No significant differences were found between the InSpace balloon and SCR in any tested condition. The InSpace balloon and SCR restored functional abduction force comparable to the intact shoulder state.
Key take-aways	Comparative study looking at the InSpace balloon and SCR

Biomechanics of biodegradable subacromial balloon spacer for irreparable superior rotator cuff tears: study of a cadaveric model

Lobao MH, Canham RB, Melvani RT, Abboud JA, Parks BG, Murthi AM. JBJS 2019; 101(11): e49.

Purpose	The purpose of this study was to investigate the ability of the balloon to restore the native glenohumeral position and joint pressure biomechanics immediately postoperatively in the setting of an irreparable rotator cuff tear.
Level of evidence	IV
Type of study	Cadaveric
Number of subjects	14 cadaveric shoulders
Study endpoints	• Shoulders were tested in four conditions: intact, small supraspinatus repair, supraspinatus repair + an InSpace balloon, and an irreparable supraspinatus tear (rotator cable-insufficient), and an irreparable tear + an InSpace balloon • Glenohumeral contact pressure, acromion-humeral interval, and deltoid load were measured using a digital sensor, a MicroScribe, and a spring scale respectively • Measurements were acquired at 0°, 30°, and 60°of humeral abduction, corresponding to 0°, 45°, and 90° of shoulder abduction, respectively, under both the balanced and the unbalanced loading condition
Summary of results	The InSpace balloon restored intact state glenohumeral contact pressures at most abduction angles, lowered the humeral head, and increased deltoid load at postoperative time 0.
Key take-aways	Comparative study looking at the InSpace balloon and surgical options for irreparable rotator cuff tears

The effect of the subacromial balloon spacer on humeral head translation in the treatment of massive, irreparable rotator cuff tears: a biomechanical assessment

Singh S, Reeves J, Langohr GDG, Johnson JA, Athwal GS. JSES 2019; 28(10): 1841-1847.

Purpose	The purpose of this study was to evaluate the InSpace balloon's ability to translate the humeral head and compare its performance with the intact shoulder, as well as after creation of a massive irreparable rotator cuff tear. Additionally, humeral head depression and translation by the InSpace balloon were addressed at varying inflation volumes.
Level of evidence	IV
Type of study	Cadaveric
Number of subjects	8 cadaveric shoulders (male)

Study endpoints	• Shoulders were tested in five conditions: intact, massive irreparable rotator cuff tear, and InSpace balloon at 3 fill volumes:
	  • 10mL – underinflation
	  • 25mL – manufacturer-recommended inflation
	  • 40mL – overinflation
	Superior humeral head migration was measured at 0°, 30°, 60°, and 90° of shoulder abduction in the scapular plane

Summary of results	The InSpace balloon is most effective in depressing the humeral head and restoring the glenohumeral joint position when inflated to 25mL.
Key take-aways	Comparative study looking at the InSpace balloon and its ability to depress the humeral head in the setting of massive, irreparable rotator cuff tears at varying inflation volumes

Systematic reviews

Subacromial spacer implantation for the treatment of massive irreparable rotator cuff tears: a systematic review

Moon AS, Patel HA, Ithurburn MP, Brabston EW, Ponce BA, Momaya AM. Arthroscopy 2018; 35(2): 607-614.

Purpose	The purpose of this paper was to perform a systematic review of the literature on clinical and radiographic outcomes associated with the InSpace balloon's use in patients with irreparable MRCT.
Level of evidence	IV (6 Level IV studies and 1 Level III study)
Type of study	Systematic review
Number of subjects	7 eligible studies including 200 patients (204 shoulders) were identified
Follow up period	Average: 19.4 months
Safety observations	A total of 6 (3%) complications were reported related to balloon spacer implantation in the included studies
Study endpoints	Functional outcomes: • Total Constant Score (TCS) • American Shoulder and Elbow Society (ASES) Score
Summary of results	Patients undergoing subacromial spacer implantation for treatment of massive irreparable rotator cuff tears have satisfactory outcomes at the 2- to 3-year follow-up with a low rate of complications.
Key take-aways	Systematic review of the InSpace balloon

Outcomes of subacromial balloon spacer implantation for massive and irreparable rotator cuff tears: a systematic review

Stewart RK, Kaplin L, Parada SA, Graves BR, Verma NN, Waterman BR. Orthop J Sports Med 2019; 7(10): 1-10.

Purpose	The purpose of this paper was to perform a systematic review of the published literature assessing outcomes after InSpace balloon implantation for treatment of irreparable MRCT.
Level of evidence	IV (10 Level IV studies and 2 Level III studies)
Type of study	Systematic review
Number of subjects	12 eligible studies including 284 patients (291 shoulders) were identified
Follow up period	Average: 22.9 months
Safety observations	A total of 6 patients (2.1%) experienced complications related to balloon spacer implantation in the included studies.
Study endpoints	Functional outcomes: • Total Constant Score (TCS) • American Shoulder and Elbow Society (ASES) Score • Oxford Shoulder Score (OSS) • University of California Los Angeles (UCLA) Shoulder Score • Patient Satisfaction
Summary of results	The authors concluded that the placement of the InSpace balloon is a minimally invasive, technically simple procedure with favorable patient-reported outcomes at limited short-term follow-up.
Key take-aways	Systematic review of the InSpace balloon

Implantable subacromial balloon spacers in patients with massive irreparable rotator cuff tears: a systematic review of clinical, biomechanical, and financial implications.

Johns WL, Ailaney N, Lacy K, Golladay GJ, Vanderbeck J, Kalore NV. Arthroscopy 2020; 2(6): e855-e872.

Purpose	The purpose of this paper was to determine the clinical, biomechanical, and financial impact of the use of subacromial balloon spacers in the surgical management of massive, irreparable rotator cuff tears (RCTs).
Level of evidence	IV (Level IV and Level III studies included in the review)
Type of study	Systematic review
Number of subjects	19 eligible studies including 337 patients (343 subacromial balloon spacers) were identified
Follow up period	Average: 33 months
Safety observations	The total complication rate was 3.14%, and included events such as transient forearm dysesthesia in the lateral cutaneous nerve of the forearm (1), infection (2), and identification of implant remnants with transformation to scar tissue in the subacromial space on MRI (1). In total, 11 of the procedures required reoperation, for reasons including InSpace Balloon migration, synovitis, and absence of clinical improvement or worsening of symptoms at various postoperative follow-up durations.
Study endpoints	Functional outcomes: • Total Constant Score (TCS) • American Shoulder and Elbow Society (ASES) Score • Oxford Shoulder Score (OSS) • Range of Motion (ROM)
Summary of results	Results from the included clinical studies indicate that subacromial balloon spacer implantation in patients with massive irreparable RCTs is cost-effective and leads to improved function (TCS and OSS) and ROM. In cadaveric studies, subacromial balloon spacers resist superior humeral head migration and reduce subacromial pressure. It is important to note that the primary limitation of this study stems from the low quality of evidence of the included studies, as the majority of the studies included are retrospective and without a control group.
Key take-aways	Systematic review of the InSpace balloon

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