Symptomatic Early Rupture of the InSpace Subacromial Balloon Spacer – a Case Report

Jack Mangan, BA1; Adam Shafritz, MD2
1Larner College of Medicine, University of Vermont, Burlington, VT; 2Department of Orthopaedic Surgery, University of Vermont Medical Center, Burlington, VT
Jack.Mangan@med.uvm.edu

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INTRODUCTION: The InSpace subacromial balloon spacer (Stryker) has recently been approved by the FDA as a novel treatment for massive irreparable rotator cuff tears that otherwise pose a significant challenge for the orthopedic surgeon.1 Given the vast array of surgical options available for the treatment of massive irreparable rotator cuff tears in conjunction with the short amount of time the InSpace product has been available for use within the United States, limited data is available regarding the clinical utility and complications of the implant.2 We present the case of a patient who underwent arthroscopic placement of the subacromial balloon spacer with subsequent early rupture and deflation of the device associated with acute onset atraumatic shoulder pain and functional limitation at three-and-a-half weeks postoperatively.

METHODS: An 82-year-old woman presented with a one-month history of left shoulder pain following a ground-level fall onto her left side. The history, physical examination, and imaging studies revealed complete tears of the supraspinatus and infraspinatus tendons with retraction to the glenoid, mild superior migration of the humeral head relative to the glenoid, and the absence of significant glenohumeral joint arthritis. After 3 months of conservative treatment including oral nonsteroidal anti-inflammatory medications and steroid injections into the glenohumeral joint, she continued to experience pain primarily with overhead function. Given her advanced age and low demand, she was interested in a low-risk procedure and elected to undergo arthroscopic debridement of the glenohumeral joint and subacromial space with insertion of a subacromial balloon spacer. A small-sized balloon was selected and placed according to the manufacturer’s protocol. After filling the balloon, it was noted to be stable and in the appropriate position. No complications were noted during the procedure or in the immediate postoperative period.

RESULTS SECTION: Two weeks after surgery, the patient was evaluated in the clinic for routine follow-up and was noted to be doing well post-operatively. She reported satisfaction with the procedure, well-controlled pain, and had started physical therapy. Three-and-a-half weeks after surgery, the patient experienced acute-onset atraumatic left shoulder pain with associated limitations in range-of-motion, primarily abduction and forward flexion. Magnetic resonance imaging of the shoulder was ordered and demonstrated deflation of the subacromial balloon spacer with mild posterior migration of the balloon under the acromion process and surrounding hemorrhaxis (Figure I). Additionally, the humeral head was superiorly elevated with a subacromial space measurement of 2 mm. During evaluation in clinic one week after hospital admission the patient reported continued pain and functional limitation. Decision was made that time to proceed with reverse total shoulder arthroplasty. During the procedure, the subacromial balloon spacer was carefully removed and inspected. Inspection revealed a tear at the seam of the balloon at the 8:00 position relative to the glenoid (12:00 position) and the balloon neck from the lateral side (6:00 position) (Figure II). The balloon was subsequently returned to the manufacturer for further evaluation.

DISCUSSION: This is the first described case of atraumatic early subacromial balloon spacer rupture associated with acute-onset severe pain. The root cause of failure of the subacromial spacer balloon in this patient is unclear. A detailed history describing the onset of this patient’s acute pain revealed no precipitating traumatic events that may have caused inadvertent rupture. Bloodwork and vital signs during hospital admission confidently ruled out infection as an explanation for her symptoms. Given thorough preoperative inspection of the balloon in association with the patient’s overall reassuring status postoperatively, a preoperative or intraoperative tear of the balloon is extremely unlikely. Removal and inspection of the balloon during the patient’s reverse total shoulder arthroplasty demonstrated a tear in the seam of the balloon. Based on the balloon positioning within the subacromial space, there was no bony contact that could have caused the split in the seam as it was anterior to the glenoid and medial in the position of the sub-coracoid recess. In addition, an anterior portal was not utilized in the insertion process, so no surgical tools contacted the balloon anteriorly. Therefore, we postulate that early failure of this specific device was secondary to inherent manufacturing defect in the seam of the balloon leading to rupture in an atraumatic setting.

SIGNIFICANCE/CLINICAL RELEVANCE: This case represents the first reported subacromial balloon rupture and deflation associated with the acute onset of pain and functional limitation in the early postoperative period. Surgeons using this product should be aware of this potential risk, and the manufacturer of the product should further investigate the root cause of this failure.

REFERENCES:

IMAGES AND TABLES:

Figure 1: Sagittal and Coronal T1W MRI at 4 weeks postop. 6 days after the onset of acute left shoulder pain. White arrows indicate deflated subacromial balloon space. Superiory elevated humeral head with reduced subacromial space measuring 2 mm. Large glenohumeral joint effusion communicating with subacromial and subdeltoid bursal space is likely due to a combination of postoperative inflammation, synovitis, and saline that was previously confined to the balloon.

Figure 2: Ruptured subacromial balloon spacer following removal during reverse total shoulder arthroplasty procedure. Dotted lines point to tear at the 8:00 position relative to the glenoid rim at the 12:00 position.

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