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“Comparing the Efficacy of a Subacromial Balloon Spacer (SBS) versus Rotator Cuff Repair (RCR) Surgery in Older Adults: a multi-centre pilot randomized control trial (RCT)”

The Problem: A rotator cuff (RC) tear is a debilitating shoulder injury that is painful and affects function. RC pathology can be an issue at any age, but over 50% of people 70+ years old will experience a RC tear. RC repair (RCR) surgery can restore shoulder function and relieve pain; however, older patients have a higher risk of re-tear after surgery. Further, the recovery period is restrictive because the shoulder is immobilized (placed in a sling) for 6 weeks after surgery. For these reasons, some older patients opt out of RCR leaving them with few treatment options. A less invasive, low risk operation that allows for more rapid mobilization postoperatively may provide considerable advantages in this population.

A Potential Solution: The subacromial balloon spacer (SBS) is an alternative treatment to RCR that requires less operative time and a shorter postoperative immobilization period. The SBS is an implant that resembles a balloon and is surgically inserted in the shoulder between two bones: the acromion and the humerus head. This location is known as the ‘subacromial space’, hence the name of the implant. Once inserted, the SBS is inflated with sterile saline solution and left in the joint. It’s made from a biodegradable material and will naturally degrade within 1 year. The SBS works to reduce shoulder pain and restore function as follows:

- it acts as a physical barrier reducing friction between the bones, which can reduce pain.
- it restores normal positioning of the humeral head, which can improve function.

Our Research: Literature suggests SBS is safe and effective, but it has not been studied specifically in older patients. Our study is the first randomized trial to compare SBS to RCR in patients 70+ years of age who suffer from full thickness RC tears. We are launching our study in two phases: Phase I-Pilot Study and Phase II-Large Trial. The purpose of our pilot study is to determine if we can recruit enough patients to make a larger trial successful, and secondly, to collect a variety of clinical and functional outcomes.