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Subacromial balloon spacer versus partial repair for massive rotator cuff tears

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Use of a biodegradable balloon spacer during massive rotator cuff tear surgery produced similar outcomes when compared to partial rotator cuff repair for patients with massive rotator cuff tears (MRCTs) at 24-month follow up, with potential for early improvement, according to research presented today at the American Orthopedic Society of Sports Medicine—Arthroscopy Association of North America Combined 2021 Annual Meeting.

Despite various treatment options, the successful management of irreparable, MRCTs remains challenging. Implantation of a biodegradable subacromial balloon spacer has gained considerable interest for the treatment of MCRTs due to its potential to recenter the humeral head within the glenoid.

"However, few studies have been completed that compare the balloon spacer implant with other surgical procedures, over a longer period of time with a significant number of patients," said Nikhil Verma, MD, an orthopedic surgeon at Rush University Medical Center in Chicago, and the Principal Investigator for the clinical study.

Dr. Verma and his colleagues completed a non-inferiority, prospective, single-blinded, multicenter, randomized, controlled, pivotal study for surgical treatment of MRCTs. Patients were 40 years of age or older with symptomatic full thickness MRCTs that had failed non-operative management. The study included follow up at day 10, week 6, months 3, 6, 12 and 24.

The safety and effectiveness of the subacromial balloon spacer were evaluated by patient reported and physician-assessed outcomes, including the American Shoulder and Elbow Society (ASES), Western Ontario rotator cuff index (WORC), Constant Shoulder Outcome Score (CS), and Range of Motion (ROM), in addition to safety observations. A total of 20 sites were included in the investigation. One hundred, eighty-four patients were randomized into the clinical study (n= 93 balloon spacer; n= 91 partial repair).

According to data presented today, patients in the balloon spacer group demonstrated similar results to patients in the partial repair group for ASES substantial clinical benefit (SCB) threshold improvement. ASES SCB has been previously defined as a change of 17.5 points. At 24-month follow up, 82% (n=76/93) of patients in the balloon spacer group, and 79% (n=72/91) in the partial repair group, had reached the SCB change from baseline threshold. Significant improvement over time relative to baseline was observed in ASES (Fig. 1) and WORC (Fig. 2) scores in both groups. Early improvements were noted in the balloon spacer group for WORC, CS, and ROM outcomes. Mean procedure duration was approximately 44 minutes for the balloon spacer group and 71 minutes for the partial repair group.

Subsequent secondary surgeries to the treated shoulder occurred in 6 patients (n=3 balloon spacer; n=3 partial repair), with two patients in each group requiring reverse shoulder arthroplasty and one patient in each group undergoing shoulder arthroscopy. One additional patient in the balloon spacer group required a subsequent reverse shoulder arthroplasty due to fracture non-union following a fall.

"Use of the balloon spacer was found to produce similar outcomes when compared to partial rotator cuff repair for patients with MRCTs at 24-month follow up," said Dr. Verma. "Early improvement was also noted in the balloon spacer group with shortened operative time

compared to partial repair."

Provided by American Orthopaedic Society for Sports Medicine