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Arthroscopic Biodegradable Spacer as a Treatment Alternative for Massive Rotator Cuff Tears: A Summary of Three Prospective Cohort Studies

Eran Maman, MD, ISRAEL
Vladimir Senekovic, MD, PhD, SLOVENIA
Boris Poberaj, MD, QATAR
Ofir Chechik, MD, ISRAEL
Enrico Cautero, MD, ITALY
Enrico Gervasi, MD, ITALY

Multicenter
Tel Aviv, Lubliana, Udine, ISRAEL

Summary:
Based on the analysis of 3 prospective cohort studies, we conclude that arthroscopic implantation of a subacromial spacer restores shoulder balance, improves deltoid function and range of motion and reduces pain in majority of treated patients with MRCT.

Abstract:

Objectives: The management of patients with massive, full- thickness, rotator cuff tears remains a challenge with no definitive treatment option or guidelines. Recently, the subacromial biodegradable spacer (SBS) has been shown to be an effective treatment option in this group of patients. This study aims to present a cumulative efficacy and safety data of three (3) prospective cohort studies that employed a subacromial biodegradable spacer to treat patients with massive rotator cuff tears(MRCT).

Methods

Three prospective cohort studies were conducted in 3 countries and 7 clinical sites. Two studies utilized arthroscopic approach (68 patients) and one study used a fluoroscopy guided implantation technique under local anesthesia (45 patients).
In all 3 studies the inclusion criteria were similar and included: 1. Radiologically confirmed massive, full-thickness rotator cuff tear of <5 cm with no severe osteoarthritis; 2. Persistent pain and failure of non-operative treatment for at least 4 months.
Patients having partial or reparable tears were excluded from this analysis.
Efficacity outcome of shoulder function was evaluated using change in Total Constant Score (CS) at each follow-up visit comparing to pre-operative/baselinescore.
Follow-up visits were scheduled according to routine clinical practice to assess safety and efficacy.

Results

A total of 113 patients (Mean age 71+9) diagnosed with MRCTs were treated by subacromial spacer implantation and followed for a mean period of 30 month (+ 24). Majority of the treated patients had either previous surgical intervention (e.g.: repair, debridement and/or tenotomy) and/or intra-articular steroid injection in the past 2 years prior to implantation. All three cohorts presented consistent results of improvement in shoulder functionality as assessed by a continues change in Total Constant Score (TCS) from a mean of 33 points (+4) at Baseline to ~60 (+5) at

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12 and 24 months post implantation. The most significant improvement was related to shoulder pain reduction which started at 2-3 weeks post implantation and enable faster post-operative rehabilitation. Device related serious adverse event was low (>2%) and rarely required additional surgical intervention for device removal (>1%).

Discussion

Based on the analysis of 3 prospective cohort studies, we conclude that arthroscopic implantation of a subacromial spacer restores shoulder balance, improves deltoid function and range of motion and reduces pain in majority of treated patients with MRCT. This procedure may be considered as a treatment option for elderly patients or for patients with multiple comorbidities complicating or contraindicating major surgery under general anesthesia. Technically easy, this technique can be an effective tool in the armamentarium of most orthopedic surgeons. Further studies with larger patient numbers and longer follow-up are warranted.