(Investigational Device Exemption Trial conducted under FDA approval)

Stemless reverse total shoulder arthroplasty for glenohumeral arthritis with massive rotator cuff tears: two-year results of a prospective, multi-center, historically controlled trial.

Introduction

Reverse Shoulder Arthroplasty (RSA) has become the most common type of shoulder arthroplasty performed in the United States.(1) Similar to anatomical Total Shoulder Arthroplasty (TSA), RSA humeral components have also evolved from standard length stems to short stems and now stemless components. Several small case studies of stemless RSA have been reported outside of the United States.(2,3) The purpose of this study is to report 24-month outcomes for a stemless RSA system in an Investigational Device Exemption study in the United States.

Material and Methods

This study is a multi-center, prospective clinical trial evaluating the clinical and radiographic outcomes of the Easytech™ Reversed Shoulder System (FX Shoulder Solutions, Dallas, TX). Surgical indications for all subjects undergoing RSA in this study included osteoarthritis, post-traumatic arthritis, and osteonecrosis in the setting of a massive and non-repairable rotator cuff tear. After surgery, subjects were evaluated at 6 weeks, and 3, 6, 12 and 24 months. Outcomes collected at those timepoints included an adjusted Constant score, QuickDASH, ASES, VAS Pain and range of motion (ROM). Radiographs were obtained at baseline, day of surgery and all follow-up intervals and evaluated by independent radiologists. Adverse events and any subsequent surgical interventions were also documented.

The primary endpoint of the study was composite clinical success (CCS) at 24 months defined as 1) adjusted Constant score of 70 or greater, 2) no continuous humeral radiolucency >2mm or humeral migration/subsidence ≥5mm, 3) no revision surgery and 4) no serious device related adverse event.

Results

Ninety (90) subjects were enrolled between December 2018 and January 2022 at 7 institutions including 61 males (67.8%) and 29 females (32.2%) with a mean age of 70.3 (± 6.1). Adjusted Constant scores improved from 42.0 (95% C.I. 39.2, 44.8) at baseline to 92.3 (88.5, 96.1) at 24 months. VAS Pain improved from 67.0 (62.6, 71.5) to 15.1 (10.5, 19.8), ASES from 32.6 (29.6, 35.6) to 80.0 (76.6, 83.5), and QuickDASH from 56.1 (52.9, 59.4) to 12.9 (9.8, 16.1) baseline to 24 months (Table 1). There were no operative complications reported with 53 procedures reporting at least one adverse event, 20 reporting serious adverse events and 2 deaths (unrelated to the device or procedure). Fifteen (15) of the adverse events were device related, and of those, 6 were serious adverse events. Independent radiographic analysis revealed no incidence of continuous radiolucency, humeral component migration or subsidence in any subjects beyond 3 months. A total of 10 secondary surgical interventions were reported including 7 revisions, 2 reoperations and 1 removal.

Discussion

Limitations of this study include a lack of randomization to a prospective concurrent control. The two incidents of implant migration/subsidence occurred extremely early in the subject's recovery window with all other subjects indicating excellent radiographic results through two years. All other surgical interventions were not related to implant failure.

This study demonstrated clinically significant improvement in all clinical outcome measures at 24 months postoperatively for this stemless RSA system. The reoperation rate was similar to prior published reports using other stemmed RSA systems.

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Table.7.Outcomes.Scores.at.Baseline?.7.year.and.8.year

	Baseline		**1 Year**		**2 years**	
	n	mean (95% C.I.)	n	mean (95% C.I.)	n	mean (95% C.I.)
Adjusted Constant Score	90	42.0 (39.2-44.8)	77	88.2 (84.3-92.1)	81	92.3 (88.5-96.1)
VAS Pain	90	67.0 (62.6-71.5)	78	12.0 (8.3-15.7)	82	15.1 (10.5-19.8)
ASES	90	32.6 (29.6-35.6)	78	82.3 (78.9-85.6)	82	80.0 (76.6-83.5)
QuickDASH	90	56.1 (52.9-59.4)	78	11.4 (8.7-14.2)	82	12.9 (9.8-16.1)