Latest RSP Clinical Follow-up Approved for Publication in the JBJS

I am pleased to announce that Dr. Frankle and his research team have received approval for their latest prospective clinical follow-up of the RSP. The article will be published in the June issue of the Journal of Bone and Joint Surgery American edition (JBJS). I have received the approved manuscript and would like to summarize the information in the article. Please note that reprints will not be available until sometime in late June or early July and an announcement will be made when they are ordered.

There are several significant findings in this article. One of the most significant parameters of the study is that it is the first prospective analysis of the RSP using both the 5.0 mm peripheral locking screws and the inferior tilt of the baseplate. Dr. Frankle's previously published clinical results included many patients that had received RSP's with the 3.5 mm non-locking peripheral screws. It is important to keep in mind when reviewing these clinical outcomes and comparing them to other devices on the market, that all of the patients in this study received either a 32 mm Neutral or a 32 mm -4 mm glenoid head. Therefore, the clinical outcomes, including the complication rate, are reflective of the most lateral centers of rotation offered in the system.

Study Parameters

- 112 patients (114 shoulders) were treated with a RSP between January 2004 and March 2005
- 94 patients (96 shoulders) were available for a minimum 2 years of follow-up (9 patients died and 9 were lost to follow-up)
- 63 patients (64 shoulders) were women
- 31 patients (32 shoulders) were men
- Average age of all patients was 72 years
- Patients were prospectively evaluated clinically using ASES score, SST, and self reported satisfaction
- Patients were also prospectively evaluated radiographically for mechanical failure, loosening, and scapular notching (reviewed by an independent observer)
- In addition, all patients were videotaped while performing a standard active range of motion protocol pre-operatively and post-operatively. This video was analyzed using a digital goniometer in a blinded fashion by three independent observers that were not involved in the treatment of the patients.

Results

- Average total ASES scores improved 30.3 to 77.6
- Average ASES pain scores improved from 15.6 to 40.9
- Average SST scores improved 1.8 to 6.8
- Blinded analysis of range of motion showed:
    - Average abduction improved 61° to 109.5°
    - Average flexion improved from 63.4° to 118°
    - Average external rotation improved from 13.4° to 28.16° (none of the patients in this study received a latissimus dorsi transfer)
- 53 patients rated their outcome as excellent (55%)
- 26 patients rated their outcome as good (27%)
- 11 patients were satisfied with their outcome (12%)
- 6 patients were unsatisfied with their outcome (6%)
- Overall 7% complication rate (9 complications in 6 patients)

- **0 instances of mechanical baseplate failure (compared to 12% in previous study)**
- **0 instances of scapular notching**

Discussion

This is the first study that analyzes only those patients that received the 5.0 mm peripheral locking screws and inferior tilt of the baseplate. The majority of the criticism aimed at the RSP is focused on the lateralization of the center of rotation of the glenoid head. However, that criticism is not backed by any biomechanical or clinical evidence. There were no baseplate failures reported for this study with an average follow-up of 27.5 months. That is compared to 7 out of 60 baseplate failures reported in the previous study, all of which occurred an average of 21.4 months after surgery. This study further demonstrates that the reliable fixation of the center screw helps to overcome any potential increase in stresses across the baseplate/glenoid interface.

Six patients experienced a total of nine complications in this study (7%). 4 of the 6 patients rated their overall outcomes as excellent or good at their latest follow-up. Of the 9 complications in this study, the most common was dislocation (4 out of 9). All studies involving any of the reverse shoulder prostheses have reported rates of dislocation higher than traditional total shoulder arthroplasty. There are a variety of factors that contribute to this, most notably the deterioration of the surrounding soft tissues of the gleno-humeral joint that would normally contribute to stability in a healthy shoulder. It is important to note that 2 of the 4 dislocations reported in this study were traumatic dislocations and 1 of the 4 was associated with a patient being non-compliant with the post-operative rehabilitation protocol.

The following is a list of strengths of this most recent RSP study that should be noted:

- The clinical findings of the RSP continue to show significant improvements in external rotation as compared to the competitive devices
- The use of the 5.0 mm peripheral locking screws has significantly reduced mechanical failure of the baseplate, even with the use of the most lateral offset glenoid head options
- The RSP continues to show no evidence of scapular notching
- The study is prospective and examines a large number of patients with a wide range of pathology
- Many efforts were made in this study to limit potential bias and make the data collection as objective as possible
    - Each patient was filmed while performing a standard protocol for range of motion
    - Three independent observers not involved in the patients' treatment digitally measured the range of motion and were blinded to the dates of the videos (they did not know if they were looking at pre-operative or post-operative video)
    - All radiographs were evaluated using an independent observer to look for mechanical failure and scapular notching
    - Results were obtained using patient reported outcomes and satisfaction that were filled out without the surgeon present

Conclusion

Reverse shoulder arthroplasty with a center of rotation lateral to the glenoid with 5.0 mm peripheral locking screws allows for improvement in patient outcomes while minimizing early mechanical failure, scapular notching, and decreasing the overall complication rate in patients with rotator cuff deficiency.

The table below summarizes some of the clinical results of reverse shoulder arthroplasty in the peer reviewed literature.

Authors	Publication	Date of Publication	Device	Abduction	Flexion	External Rotation	Complications	Re-operation	Scapular Notching	Baseplate Failure
Werner et al[1]	JBJS Am	Jul-05	Depuy Delta III	43° to 90°	42° to 100°	17° to 12°	50%	33%	96%	NR
Boileau et al[2]	JSES	Nov-06	Depuy Delta III	NR	55° to 121°	7° to 11°	24%	22%	68%	NR
Frankle et al[3]	JBJS	Oct-05	RSP	41° to 102°	55° to 105°	12° to 41°	17%	12%	0	7/60 (12%)
Frankle et al	JBJS	Jun-08	RSP	61° to 110°	63° to 118°	14° to 29°	7%	7%	0	0

1. Werner C, Steinmann P, Gilbart M, Gerber C. Treatment of painful pseudoparesis due to irreparable rotator cuff dysfunction with the Delta III reverse ball and socket total shoulder prosthesis. JBJS Am. 2005 Jul; 87: 1476:86.

2. Boileau P, Watkinson D, Hatzidakis A, Hovorka I. The Grammont reverse shoulder prosthesis: results in cuff tear arthritis, fracture sequelae, and revision arthroplasty. JSES. 2006 Sep-Oct; 15: 527-40.

3. Frankle M, Siegal S, Pupello D, Saleem A, Mighell M, Vasey M. The Reverse Shoulder Prosthesis for glenohumeral arthritis associated with severe rotator cuff deficiency. A minimum two-year follow-up study of sixty patients. JBJS Am. 2005 Aug; 87: 1697-1705.