Comprehensive® Total Shoulder System Early Clinical Outcomes

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Study Ongoing

Total shoulder arthroplasty (TSA) has been used since 1972 for treatment of osteoarthritis, fracture and other shoulder non-inflammatory issues. Biomet's Comprehensive® Total Shoulder System is an evolutionary design based on the successful clinical heritage of the Bio-Modular® Shoulder System, which has been in use clinically since 1987, and has provided excellent results (Rozing *et al*[1]; Gartsman *et al*[2] ; McCarty *et al*[3]). The Comprehensive® Total Shoulder System allows for surgeon efficiency through intraoperative flexibility, multiple humeral stem options and infinite humeral head offset possibilities in this modular system.

Historically, humeral stems have ranged in length from about 120 mm on up to very long stems used in revision cases (200 mm). In 2005, Biomet pioneered short stem technology with a mini (70 mm) stem for the Bio-Modular® Shoulder System. More recently, both mini (83 mm, introduced in 2006) and micro (55 mm, introduced in 2007) stems have been made available for the Comprehensive® Total Shoulder System. The main advantage of short stem technologies is that they provide a less invasive alternative to standard shoulder arthroplasty. Additional advantages include use in cases where there is the presence of existing humeral hardware (e.g., a proximal humeral plate or total elbow replacement) and/or a humeral mal-union or deformity in which traditional long-stem components would not fit.

While short stems have been used in total hip arthroplasty (THA) for a number of years, the use of short stems for total shoulder arthroplasty (TSA) is a relatively new concept. Recently, Jost *et al* [4] published a retrospective report on their first 49 mini-stem shoulder replacements in 47 patients for primary osteoarthritis. The stems used were the Biomet Bio-Modular® mini stem in the first 40 patients with the Comprehensive® Shoulder mini-stem used in the next 15 shoulders. At a minimum 2-year follow-up, the authors found that their results were comparable to previous outcomes achieved with conventional length humeral components, suggesting that mini-stem humeral components are an effective option for total shoulder arthroplasty.

This paper reports on early results of a Biomet-sponsored clinical study to collect survivorship and other clinical outcome data for the Comprehensive® Total Shoulder System family of products. The overall purpose of this report is to present survivorship and outcomes of the Comprehensive® Total Shoulder System at 2 to 4 years, measuring function, pain and ROM results.

Materials and Methods

Device Description:

The Comprehensive® Total Shoulder System features a broad array of sizes and offsets, potential enhanced fixation and easy-to-use instrumentation. It also offers flexibility to convert from a hemi-arthroplasty or a total arthroplasty, to a reverse shoulder and later revisions if necessary. The system consists of the Comprehensive® Humeral stems, the Versa-Dial® Humeral Head, and the Modular Hybrid® Glenoid.

The Comprehensive® Humeral Stems (Figure 1) are available in micro, mini, standard and revision lengths. The micro stem is 55 mm long, the mini stem is 83 mm long, and the standard stem is 122 mm long. All three are available in stem diameters from 4 to 20 mm, in 1 mm increments. The revision stems (194 mm long) feature a lateral fin for tuberosity repair and are available in six stem diameters from 4 to 14 mm, in 2 mm increments. The tapered geometry provides for even stress offloading and PPS® Porous Plasma Spray coating on the proximal portion for increased biologic fixation. The Fracture stem has a proximal MacroBond® coating. The reverse Morse taper provides for unobstructed preparation of the glenoid face and the option for future conversion to reverse shoulder arthroplasty. The micro, mini and standard stems have no proximal collar and are polished distally for ease of revision, if necessary. All the stems have a 45°/135° anatomic neck shaft angle. Stems may be implanted either with cement or cementless. All stems are manufactured from Ti6Al4V alloy except for the Fracture stem, which is manufactured from CoCr alloy.

Fig. 1
Comprehensive® Total Shoulder System Humeral Stems: Standard, Mini, Micro, Revision and Fracture Stems.

The Modular Hybrid® Glenoid (Figure 2) is available in small, medium and large ArCom® polyethylene. The glenoids have three outer pegs to facilitate cement fixation. It also has two types of optional center pegs: one of Regenerex® Porous Titanium Construct to allow for biologic fixation, and the other of ArCom® polyethylene with compression fit for cemented applications. These central pegs feature a titanium core for strength and modularity.

Fig. 2
Comprehensive® Total Shoulder System Modular Hybrid® Glenoid and Optional Center Pegs of ArCom® Polyethylene and Regenerex® Porous Titanium Construct.

The Versa-Dial® Humeral Head (Figure 3) allows for infinite offset options between 0.5 and 4.5 mm. It has 17 head sizes ranging from 38 to 58 mm in diameter and 18 to 27 mm in height. The design of the Versa-dial® heads and Comprehensive® stems allow the humeral head to sit virtually flush with the resection.

Study Patients:
Starting in 2007 through July 2013, one physician enrolled patients into prospective clinical study. As of July 2013, there were a total of 95 patients enrolled, with 18 bilaterals, (113 cases total). Patient demographics are provided in Table 1.

Fig. 3
Versa-Dial® Humeral Head and Taper Adapters for Use with the Comprehensive® Stems.

Table 1. Patient Demographics.

Characteristic	Value	Range/Percent
Gender Distribution: Female/Male	65/48	58%/42%
Mean Age at Surgery	70 years (±8.6 SD),	Range: 50 - 90
Mean Height	66.62 (±4.22 SD)	Range: 56 - 75
Mean Weight	183.30 (±42.47 SD)	Range: 110 - 340
Hand Dominance: Right/Left/Ambidextrous	101/10/2	89% / 9% / 2%

Primary diagnosis was osteoarthritis in 100 cases (88.5%), avascular necrosis in 4 cases (3.5%), traumatic arthritis in 3 cases (2.6%), rheumatoid arthritis in 2 cases (1.8%), recurrent dislocation/instability in 2 cases (1.8%), and one case (0.9%) received the prosthesis for each of the following primary conditions: rotator cuff arthropathy, and other (unspecified).

Previous shoulder surgery had occurred in 49% of cases: 41 cases (36%) had arthroscopy, one case (1%) had a previous hemiarthroplasty, and 21 cases (19%) had previous total arthroplasty.

Surgical details:
The surgeon used the deltopectoral approach for all cases. Mean surgical time was 62.10 minutes, with a range of 50 to 110 minutes. All cases were total arthroplasty, with no hemiarthroplasties performed.

At the time of surgery, the biceps was normal or stable in 21 cases (19%), degenerated in 74 cases (65%), ruptured in 10 (9%), and subluxed in 14 cases (12%). The deltoid was normal in 104 cases (92%) and thinned in 9 (8%). The humeral head was found to be damaged in all patients. There were 105 cases (93%) with peripheral osteophytes, 85 cases (75%) with humeral head deformity, 42 cases (37%) with segmental head erosion, and 19 cases (17%) with total head erosion. (More than one defect occurred in many of the patients; thus the percentage

reported is based on the number of patients reporting these conditions, not the number of answers.)

The surgeon found the glenoid to have normal alignment of bone stock in 12 cases (11%), to have posterior erosion in 92 cases (81%), erosion beyond the base of the coracoids in 18 cases (16%), and severe erosion to the base of the coracoids in 2 cases (2%). Osteophytes were found in 82 cases (73%). Again, more than one glenoid defect occurred in many patients; and again, the percentage reported is based on the number of patients reporting these conditions, not the number of answers.

No operative complications were reported. The stem was cemented using Biomet Cobalt™ cement in 20 cases (18%), uncemented in 3 cases (3%) and not reported in 90 cases (79%). All cases used a primary Comprehensive® Shoulder System stem (either mini or standard), with no Fracture or revision stems used.

Patient Evaluation:

Patients were evaluated prior to surgery and at 6 months, 1 year, and annually post-operatively. Patients were assessed using a Modified Constant-Murley Scoring system[5], based on points in the following categories (maximum in parentheses), for an overall maximum possible score of 100 points, which is equivalent to a normal, pain-free shoulder:

- Pain (15)
- Activity Level (10)
- Arm Positioning (10)
- Strength (25)
- Forward Elevation – Range of Motion (10)
- Lateral Elevation – Range of Motion (10)
- External Rotation (10)
- Internal Rotation (10)

Results

Patient follow-up is shown in Figure 4 below. Patient follow-up percentages were 99%, 92%, 74%, 83% and 79% at 6 months, 1 year, 2 years, 3 years and 4 years after surgery, respectively, for cases due for follow-up. Numbers shown in the graph are for the number of cases with follow-up (in blue), and due for follow-up but did not return (in red).

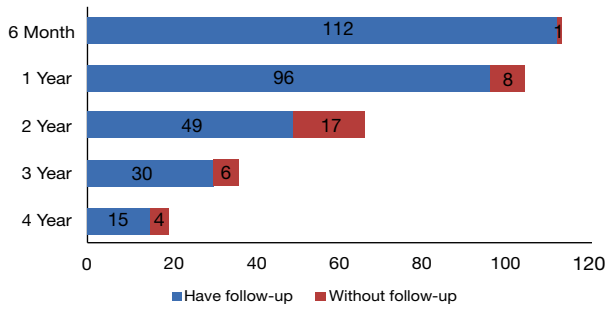

Fig. 4
Patient Follow-up at Intervals from 6 Months to 4 Years.

Before surgery, the mean Modified Constant-Murley score was 51, with a range of 17 to 83 points. For patients reporting for follow-up, at 2 years, the mean score was 90 (range 58 to 100); at 3 years, the mean score was 89 (range 63 to 100) and at 4 years, the mean score was 89 (range, 71 to 100).

Before surgery, all patients reported pain, with 27 cases (24%) reporting moderate pain with unusual activity, 64 cases (57%) reporting moderate pain at rest, and 22 cases (19%) reporting severe pain. At 2, 3 and 4 years, all patients except one (at each 2 and 3 years) reported no or only slight pain, as shown in Table 2.

Table 2. Patient Pain				
	Pre-operation	2 Years	3 Years	4 Years
None	0 (0%)	45 (92%)	23 (77%)	12 (80%)
Slight	0 (0%)	3 (6%)	6 (20%)	3 (20%)
Moderate with Unusual Activity	27 (24%)	1 (2%)	1 (3%)	0 (0%)
Moderate at Rest	64 (57%)	0 (0%)	0 (0%)	0 (0%)
Severe	22 (19%)	0 (0%)	0 (0%)	0 (0%)

All patients were able to improve their activity levels from before surgery to latest follow-up, as shown in Table 3.

Table 3. Activity Levels				
	Pre-operation	2 Years	3 Years	4 Years
Full Work	21 (29%)	48 (98%)	28 (93%)	14 (93%)
Full Recreation/ Sport	13 (18%)	45 (92%)	29 (97%)	14 (93%)
Unaffected Sleep	7 (10%)	48 (98%)	29 (97%)	15 (100%)
None Apply	41 (56%)	0 (0%)	0 (0%)	0 (0%)

Arm positioning also improved, as indicated in Table 4.

Table 4. Arm Positioning				
	Pre-operation	2 Years	3 Years	4 Years
Arm to Waist	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Arm to Chest	22 (20%)	1 (2%)	0 (0%)	0 (0%)
Arm to Neck	51 (45%)	0 (0%)	1 (3%)	0 (0%)
Arm to Top of Head	35 (31%)	5 (10%)	3 (10%)	2 (13%)
Arm Above Head	4 (3%)	43 (87%)	26 (87%)	13 (87%)

Range of Motion showed significant improvement at 2 and 3 years. Tables 5 and 6 provide the mean scores for forward and lateral elevation for pre-surgery and at each of the follow-up intervals.

Table 5. Forward Elevation				
Degrees	**Pre-operation**	**2 Years**	**3 Years**	**4 Years**
0-30	0 (0%)	0 (0%)	0 (0%)	0 (0%)
31-60	9 (8%)	1 (2%)	0 (0%)	0 (0%)
61-90	24 (21%)	0 (0%)	1 (3%)	0 (0%)
91-120	33 (29%)	0 (0%)	2 (7%)	0 (0%)
121-150	44 (39%)	5 (10%)	0 (0%)	2 (13%)
151-180	3 (3%)	43 (88%)	27 (90%)	13 (87%)

Table 6. Lateral Elevation				
Degrees	**Pre-operation**	**2 Years**	**3 Years**	**4 Years**
0-30	2 (2%)	0 (0%)	0 (0%)	0 (0%)
31-60	28 (25%)	1 (2%)	0 (0%)	0 (0%)
61-90	57 (50%)	2 (4%)	3 (10%)	0 (0%)
91-120	21 (19%)	7 (14%)	4 (13%)	4 (27%)
121-150	5 (4%)	22 (45%)	12 (40%)	8 (53%)
151-180	0 (0%)	17 (35%)	11 (37%)	3 (20%)

External and internal rotation also improved, as shown in Tables 7 and 8.

Table 7. External Rotation				
	Pre-operation	**2 Years**	**3 Years**	**4 Years**
Hand to Chest	2 (2%)	0 (0%)	0 (0%)	0 (0%)
Hand Behind Head – Elbow Forward	11 (9%)	0 (0%)	0 (0%)	0 (0%)
Hand Behind Head – Elbow Back	55 (49%)	1 (2%)	0 (0%)	1 (7%)
Hand on Top of Head – Elbow Forward	33 (29%)	8 (16%)	2 (7%)	0 (0%)
Hand on Top =of Head – Elbow Back	11 (10%)	22 (45%)	12 (40%)	6 (40%)
Full Elevation	1 (1%)	18 (37%)	16 (53%)	8 (53%)

Table 8. Internal Rotation				
	Pre-operation	**2 Years**	**3 Years**	**4 Years**
Dorsum of Hand to Trochanter	14 (12%)	0 (0%)	0 (0%)	0 (0%)
Dorsum of Hand to Buttock	23 (20%)	0 (0%)	0 (0%)	2 (13%)
Dorsum of Hand to SI Joint	39 (35%)	2 (4%)	1 (3%)	2 (13%)
Dorsum of Hand to L3-T12	25 (22%)	29 (59%)	19 (63%)	7 (47%)
Dorsum of Hand to T12-T8	11 (10%)	12 (25%)	7 (24%)	3 (20%)
Dorsum of Hand >T8	1 (1%)	6 (12%)	3 (10%)	1 (7%)

Overall patient satisfaction was high. At 2 years, patients in 46 of the 49 cases noted excellent results and 2 reported a good result (1 was unaccounted for). At 3 years, 29 of the 30 reported excellent satisfaction and 1 reported good satisfaction, while at 4 years, 14 of the 15 reported excellent results and 1 reported good results

No revisions were reported; hence survivorship at 6 months to 4 years is 100%.

Discussion and Conclusion:

This study corroborates earlier studies on the Comprehensive® Shoulder System and documents excellent clinical results. Pain and function improved for all patients with an average improvement in Constant-Murley scores of 38 points. Overall patient satisfaction was high at 93%.

References

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