Stemless shoulder arthroplasty—current results and designs

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Published online: 25 January 2016
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Abstract Stemless shoulder arthroplasty was originally introduced in 2004 by a single manufacturer. Now, over a decade later, numerous designs are available outside the USA, but as yet, only one implant has been cleared by the Food and Drug Administration (FDA) and is available for use within the USA. Often referred to as “canal sparing,” these implants are designed for metaphyseal fixation to minimize humeral bone removal, avoid intraoperative and postoperative humeral fracture complications, and to decrease morbidity associated with revision operations. Recently, the second generation of stemless arthroplasty, a convertible implant allowing use in either anatomic or reverse arthroplasty configuration, was released for use outside the USA. This paper will review the available designs, reported results, and raise potential concerns for this emerging technology.

Keywords Stemless shoulder arthroplasty · Canal sparing shoulder arthroplasty · Shoulder arthroplasty · Osteoarthritis · Arthritis

Introduction

Total shoulder arthroplasty results were first reported in 1974 [1]. Over the following 40 years, manufacturers introduced

multiple variations of stemmed humeral components, which can be broadly categorized in to four distinct generations. One aspect of this evolutionary change was the slow but distinct shortening of the humeral stem. Many manufacturers now have short stem implants, such as the Tornier Flex (Wright Medical, Memphis, Tennessee) which has stem lengths ranging from 66 to 98 mm and the Biomet Micro and Mini (Warsaw, Indiana) with stem lengths of 55 and 83 mm, respectively. These implants both have a porous plasma spray coating allowing for cementless implantation. Shortening of the stem as well as cementless application techniques have been incorporated to try and reduce humeral stem complications [2–19]. The incidence of intraoperative humeral fractures in total shoulder arthroplasty is 1.5 %, and the incidence of postoperative periprosthetic humeral fracture is between 1.6 and 2.3 % [2, 11]. For those humeral fractures that do require surgical management, conversion to a long stem component, open reduction and internal fixation, or conversion to a reverse arthroplasty can prove to be surgically challenging with sub-optimal results achieved [2, 4, 5, 15, 18, 19]. Other long-term humeral stem concerns include proximal humeral bone loss due to stress shielding, humeral stem loosening, and osteolysis [12, 13, 16]. When revision arthroplasty is indicated, removal of a well-fixed humeral stem can be difficult and results in further proximal humeral bone destruction [20, 21, 22, 23]. Ultimately, bone loss, regardless of the etiology, can limit the reconstructive options and clinical success of the revision operation [7, 20, 22, 23].

Stemless arthroplasty arose from the desire to avoid stem-related complications, provide ease of revision, and maintenance of optimal bone quality in revision operations. Not to be confused with humeral resurfacing, which relies on preservation of the majority of the humeral head making glenoid exposure and replacement difficult if not impossible, stemless arthroplasty is completed utilizing a standard humeral neck

This article is part of the Topical Collection on *Shoulder Arthroplasty*

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cut allowing for full exposure and optimal access for glenoid replacement.

Anatomic stemless shoulder arthroplasty results

The original stemless shoulder arthroplasty clinical report was published in 2010 by Huguet et al. [24••]. This paper reported results for 63 patients with 3-year minimum follow-up utilizing the Biomet TESS (Biomet, Warsaw, Indiana) implant. All patients were implanted between 2004 and 2005 for the clinical indications of osteoarthritis, posttraumatic arthritis, and osteonecrosis. This heterogeneous group of patients received 44 hemiarthroplasties and 19 total shoulder arthroplasties. At 3-year minimum follow-up, the mean group Constant score was 75, an increase of 45 points over their preoperative score. Group mean forward elevation improved 49° to 145°, and external rotation to the side improved 20° to 40° (Table 1). Final follow-up radiographs indicated no evidence of osteolysis, stress shielding, or lucent line formation surrounding the implant. Complications reported included five intraoperative fractures of the lateral humeral cortex which occurred during final seating of the stemless implant. These patients were followed with serial radiographs, and all fractures healed without further complication over the following 2 months. Over the 3-year study period, seven implants were removed. Four of the implants were removed for infection, two for massive cuff tear, and one for instability. Thus, the 3-year revision rate of the Biomet TESS implant was 11.1 %.

Three years later in 2013, Berth and Pap reported their results comparing the TESS stemless implant to the Affinis (Mathys, Bettlach, Switzerland) stemmed prosthesis [25••]. This was a prospective, randomized, longitudinal study with 2-year minimum follow-up with 82 patients involved in the study. All patients had the preoperative diagnosis of osteoarthritis and were treated with a total shoulder arthroplasty. The patients were divided equally into two groups of 41 patients, each with 14 males and 27 females. At 2-year minimum follow-up, both groups had significant improvements in Constant score, DASH score, and active range of motion (Table 1). No differences in functional outcome score or range of motion were identified between the groups. Additional factors studied included operative time, estimated blood loss, and

hospital length of stay. The mean operative time was significantly longer with the Affinis stemmed arthroplasty group (106.2 min) compared to the TESS stemless arthroplasty group (91.5 min). Of note, all stemmed components were implanted with cement, and all stemless components were implanted without cement. Estimated blood loss was significantly greater in the stemmed group (593 cc) compared to the stemless group (496 cc). No difference in hospital length of stay was identified between the groups. Radiographic analysis at 2-year minimum follow-up indicated no evidence of radiolucent lines or osteolysis surrounding any of the stemmed or stemless implants. There was one intraoperative humeral-sided complication which involved the Affinis stemmed group. The complication was a greater tuberosity fracture which ultimately healed without further treatment. There were no revision operations reported during the study period.

The most recent and largest study to date on stemless shoulder arthroplasty involves the Simpliciti shoulder system (Formerly Tornier, now Wright Medical, Memphis, Tennessee) [26••]. This study was a prospective, single-arm, multicenter study with 2-year minimum follow-up. One hundred and fifty-seven patients with the preoperative diagnosis of osteoarthritis or posttraumatic arthritis were included in the FDA Investigational Device Exemption (IDE)-approved protocol. All patients were implanted with a total shoulder arthroplasty between 2011 and 2012 at one of the 14 US sites participating in the study. The patients were evaluated postoperatively at 2, 6 weeks, 3 months, 1, and 2 years. One hundred and forty-nine of the original 157 patients (95 %) had complete follow-up data available for analysis. At 2-year minimum follow-up, significant improvement was noted in Constant, Simple Shoulder Test (SST), and American Shoulder and Elbow Surgeon (ASES) scores. Range of motion significantly improved with forward elevation improving from 103° to 147° and external rotation from 31° to 56° (Table 1). Strength testing (12.5 to 15.7 lb, $p < 0.0001$) and pain control as measured by VAS (5.9 to 0.5, $p < 0.0001$) also improved significantly. Radiographic analysis involved comparison of the 1- and 2-year X-ray images with the initial 2-week postoperative X-ray image. This was completed by three blinded independent musculoskeletal radiologists. After reviewing all radiographic images, the radiologists determined that there was no evidence of component migration,

Table 1 Comparison of stemless arthroplasty reports with 2-year minimum results

Author	Implant	Number of patients	Years of minimum follow-up	Hemi or total arthroplasty	Constant score	Forward elevation	External rotation
Huguet et al.	TESS	63	3	Both	75	145°	40°
Berth and Pap	TESS	41	2	Total	65	NR	54°
Churchill et al.	Simpliciti	149	2	Total	81	147°	56°
Habermeyer et al.	Eclipse	78	5	Both	75	140°	44°

subsidence, osteolysis, or loosening of the humeral components (Fig. 1). Three postoperative complications resulted in revision surgery: one each for infection, glenoid loosening, and subscapularis failure, for a revision rate of 2 %. In each revision operation, the Simpliciti implant was found to be stable and without signs of loosening.

The only midterm results on stemless shoulder arthroplasty were reported by Habermeyer et al. [27••]. This study involved the Eclipse stemless shoulder system (Arthrex, Karlsfeld, Germany). This prospective study involved 96 patients implanted between 2005 and 2008 for a multitude of clinical indications including primary osteoarthritis, posttraumatic arthritis, instability arthritis, and cuff tear arthropathy. Seventy-eight patients were available for review at 5-year minimum follow-up. These 78 patients were equally divided between total shoulder arthroplasty and hemiarthroplasty at 39 patients each. At 5-year minimum follow-up, significant improvements were noted in Constant score which increased from 38 to 75 and range of motion with forward elevation increasing from 114° to 140° and external rotation to the side from 25° to 44° (Table 1). Radiographic follow-up demonstrated what the authors refer to as “decreased bone density in the metaphyseal region of the humerus” in 54 % of hemiarthroplasty patients and 46 % of total shoulder patients. Specifically, 35 % of patients were noted to have “decreased density of cancellous bone in the greater tuberosity.” The radiographs included in the report show dramatic bone resorption in the regions referred to as “decreased bone density.” Analysis of the results demonstrated no clinical difference between those with or without decreased bone density in the tuberosity region. One patient had an incomplete lucent line surrounding the humeral implant, and three additional patients demonstrated partial osteolysis under the collar of the implant. Of note, two of these three patients with osteolysis under the

implant collar also had notable glenoid loosening. The overall complication rate of the Eclipse implant was 12.8 % with a revision operation rate of 9 % at 5-year minimum follow-up.

Reverse stemless shoulder arthroplasty results

In 2013, Ballas and Beguin reported 38-month minimum follow-up on the TESS reverse arthroplasty [28•]. This study included 56 patients with various preoperative conditions, massive cuff tear (20), cuff tear arthropathy (33), and primary osteoarthritis (3). At follow-up, significant improvements were demonstrated in the Constant score which increased from 29 to 62 and Oxford score which decreased from 46 to 17. Range of motion was significantly improved with forward elevation improving from 79° to 140° and external rotation from 13° to 45°. Radiographic analysis at final follow-up demonstrated no periprosthetic radiolucent lines and no migration or loosening. One patient was noted to have significant greater tuberosity osteolysis but no signs of humeral implant loosening. Five patients (9 %) had stage 1 scapular notching noted at final follow-up. One intraoperative fracture occurred during implantation of the humeral prosthesis. A crack was noted in the proximal humerus, and the implant was determined to be stable. No postoperative change in therapy was indicated, and the patient healed the fracture uneventfully. Postoperative complications included hematoma evacuation, superficial infection, subscapularis tendon rupture, and acromial stress fracture. Revision operation was required in four patients (7 %). Three patients required conversion to a stemmed reverse prosthesis, and one patient in poor health had removal of the implants.

Tiessier et al. in 2015 reported their 2-year minimum follow-up results on 91 stemless reverse arthroplasty cases [29•]. This prospective study was performed between 2006 and 2010 and also involved the TESS stemless reverse arthroplasty system. All patients had the preoperative diagnosis of either massive rotator cuff tear or cuff tear arthropathy. Clinical evaluation at 2-year minimum follow-up demonstrated significant improvement in the Constant score which increased from 40 to 68. Pain and range of motion were also significantly improved. Forward flexion improved from 96° to 143° and external rotation from 26° to 39°. Radiographic analysis at final follow-up demonstrated no evidence of humeral or glenoid component loosening; however, the authors made no mention of the presence or absence of osteolysis, lucent line formation, migration, or subsidence. Scapular notching was noted in 19 % of cases, all of which were stage 1 except a single case of stage 2 notching. There were no intraoperative complications and three postoperative complications. One patient had recurrent dislocations which required revision surgery with the addition of a thicker polyethylene spacer, one patient sustained a scapular spine stress fracture,

Fig. 1 Two-year follow-up X-ray image of a Simpliciti total shoulder implant

and one patient had a traumatic clavicle fracture which occurred after a fall. The overall reoperation rate was 1 % at 2-year minimum follow-up.

Stemless shoulder arthroplasty systems

Wright Medical—Simpliciti

Within the USA, just a single stemless shoulder arthroplasty system is available, the Simpliciti. This implant, originally developed and marketed by Tornier, now Wright Medical, began clinical use in France in 2010. It is a two-piece system composed of a humeral implant, available in three sizes, and a head implant, available in multiple diameters and thicknesses. The humeral implant has a three-fin design with a collar and female Morse taper, allowing for full access to the glenoid (Fig. 1). The undersurface of the collar and the majority of the fins are comprised of a bone ingrowth porous coating. This humeral implant is impaction implanted, which locks the male Morse taper on the head with the female Morse taper on the humeral implant. The humeral collar has nine slots aligned for osteotome insertion to aid in implant extraction. The Simpliciti stemless shoulder system obtained FDA clearance for use within the USA in March, 2015 (Table 2).

Arthrex—Eclipse

The Arthrex Eclipse stemless shoulder arthroplasty system was introduced for use in 2005. This is a three-piece system which includes a humeral head and two-piece humeral implant composed of a threaded central cage unit that is inserted over a collar. The implants have a grit-blasted coating for improved bone ongrowth. The threaded central cage has portals for bone capture. Together, the central cage and collar form the humeral implant which has a male Morse taper. The corresponding humeral head has a female Morse taper.

Of the implants currently on the market, this implant is the only threaded implant that has screw in implantation as opposed to impaction implantation. The Eclipse does not have FDA approval for implantation within the USA. An IDE clinical trial is currently underway [30] (Table 2).

Zimmer Biomet—TESS, Nano, Sidus

The original stemless shoulder arthroplasty system on the market, the TESS was first implanted in Europe in 2004. Since this time, the TESS has been redesigned with a second generation system, the Nano (Zimmer Biomet, Warsaw, Indiana) now available. The Nano is a convertible stemless design which allows the surgeon to utilize it in either anatomic or reverse configuration. The TESS system is a three-component system based upon a six-armed porous-coated metaphyseal component. This metaphyseal component is impaction implanted into the metaphyseal bone. Following this, the humeral head is inserted via a corresponding female Morse taper. The Nano humeral component is also impaction implanted; however, the Nano was designed with a female Morse taper with a corresponding male Morse taper on the humeral head implant. Both the TESS and Nano are collarless designs. The TESS and Nano do not have FDA clearance and are not approved for implantation in the USA. The Nano is currently involved in an IDE clinical trial. This trial is evaluating the Nano for use as a standard, anatomic, total shoulder system rather than for use in a reverse arthroplasty configuration (Table 2).

The Sidus (Zimmer Biomet, Warsaw, Indiana) stemless shoulder system was introduced in Europe in 2012. The Sidus is a two-piece system consisting of a metaphyseal implant and a head implant. The metaphyseal implant has a four-fin design with a rough blasted surface to promote bone ongrowth. Similar to the Affinis Short, the fins are open rather than solid. The humeral component has a male Morse taper design and is impaction implanted. Rather than a standard

Table 2 Key features of stemless arthroplasty implants

	Arthrex	Biomet Zimmer			FX Solutions	Lima	Matheys	Wright Medical
	Eclipse	TESS	Nano	Sidus	Easytech	SMR Stemless	Affinis Short	Simpliciti
Introduced	2005	2004	2013	2012	2015	2015	2008	2010
FDA approval	No	No	No	No	No	No	No	Yes
2-year minimum follow-up report	Yes	Yes	No	No	No	No	No	Yes
Fixation	Screw In	Impaction	Impaction	Impaction	Impaction	Impaction	Impaction	Impaction
Collar type	Solid	None	None	Open	Open	None	None	Solid
Bone contact area	High	High	High	Low	Low	High	Low	High
Morse taper	Male	Male	Female	Male	Female	Female	Male	Female
Component pieces	3	3	2	2	3	4	2	2
Convertible	No	No	Yes	No	No	Yes	No	No

solid collar, the Sidus has an open window collar design, a surface ring actually, that comes to rest on the humeral cut surface once implanted. The humeral heads have a female Morse taper and are available in standard sizes. The Sidus does not have FDA approval for implantation within the USA. An IDE clinical trial is currently underway [30] (Table 2).

FX Solutions—Easytech

This is one of the more recent implants, introduced to the market in 2015. It is a three-component system. Both the humeral implant and the humeral head have a female Morse taper; connecting the two is the third part of the system, a double male Morse taper. The humeral implant has a central barbed post, an open window ring collar, and five peripheral barbed posts which extend off the undersurface of the ring collar. This implant is coated to promote bone ongrowth and is seated by impaction technique. The Easytech does not have FDA approval for implantation within the USA (Table 2).

Lima SMR stemless

Also released in 2015 is the Lima Shoulder Modular Replacement (SMR) Stemless shoulder system. This is a convertible system which has four parts for anatomic configuration (humeral core component, double male Morse taper, locking screw, and humeral head) and two parts for reverse configuration (humeral core component and reverse liner). The humeral core component is composed of Trabecular Titanium designed for bone ingrowth and is seated by impaction. When utilized in reverse configuration, a metallic reverse liner is impacted into the humeral core component. This metallic liner, manufactured out of CoCrMo, then articulates with an all polyethylene glenosphere. The SMR Stemless does not have FDA approval for implantation within the USA (Table 2).

Mathys Affinis Short

The Mathys Affinis Short (Mathys, Bettlach, Switzerland) stemless arthroplasty system was introduced into the European market in 2008. This is a two-piece system involving a metaphyseal humeral implant and a humeral head. The metaphyseal implant is a four-wing design with a rough porous titanium surface for improved bone fixation. The four wings are not solid like the Simpliciti; rather, they are an open window design. The humeral implant is collarless with a male Morse taper and is impaction implanted. The corresponding humeral heads are made of ceramic and designed with a female Morse taper. The Affinis Short does not have FDA approval for implantation within the USA [30] (Table 2).

Discussion

Despite the fact that stemless arthroplasty has now been available for over 11 years, there are few literature reports with follow-up of 2 years or more. In fact, there are only three implants that have met the 2-year minimum follow-up requirement: Eclipse, Simpliciti, and TESS. The remaining implants available, Nano, Easytech, SMR Stemless, Affinis Short, and Sidus, have no 2-year minimum follow-up data available. In fact, most of these five implants have no reported results. Historically, stemmed implants in the early 1970s and 1980s all closely mirrored the original Neer stemmed implant. Thus, a lack of quality reporting at that time was virtually unnoticed. Surgeons and developers considered the stemmed implants similar enough in design that drastic clinical and radiographic differences were unlikely to occur. However, at that point in history, little was known about osteolysis, stress shielding, and polyethylene wear debris. Now, having witnessed the effects of these conditions, it is logical to raise concern regarding new implant designs. As you can see from the descriptions of the eight stemless implants available outside the USA, these designs are far from the similarity originally seen among stemmed implants.

Key features to focus on regarding stemless implant stability can be divided into four distinct categories: insertion technique, presence of a collar, surface coating, and bone contact area (Table 2). The insertion technique in seven of the implants is impaction. This allows the surgeon to press fit the implants into the prepared metaphyseal bone. The one exception to this is the Eclipse, which incorporates a threaded central post implanted by screw in application. This screw in application allows compressive force in the metaphyseal region. It is unknown whether the long-term effects of the metaphyseal bone are benefited with this compression or not. One possible concern regarding this technique is when the compression is taken to the limit and the central screw is actually threaded into, and sometimes through, the lateral cortex of the humerus. In the Habermeyer report on the 5-year minimum results of the Eclipse [27•], one radiographic image demonstrates the threaded central post through the lateral cortex of the humerus. This radiographic image also exhibited proximal humeral bone loss in the greater tuberosity region. One can theorize that this bone loss is secondary to stress shielding due to the implant engaging the lateral humeral cortex allowing for force transmission to bypass the proximal metaphyseal region as it is directly applied to the lateral humeral cortex.

The second major design difference is the presence or absence of a collar. The Eclipse and Simpliciti systems have a full, solid, collar present which rests on the proximal humeral cut surface. The Eclipse is designed to rest on the cortical rim, while the Simpliciti rests on the cancellous bone inside the cortical rim. Two other implants, Easytech and Sidus, have an open window ring collar which rests on the cancellous bone of the cut surface. The remainder of the implants is

collarless. With the literature available, it is not possible to make a definite recommendation regarding the collar feature. The Eclipse midterm results and the Simpliciti 2-year minimum results both indicate the absence of stress shielding below the implant collar. The Eclipse did have three patients with osteolysis under the collar which was seen in combination with glenoid loosening, raising the suspicion for possible infection. Whether the collar, and possibly the open window ringed collar, will more appropriately distribute stress to the proximal metaphyseal bone and avoid stress shielding is yet to be proven. If stress shielding and bone resorption does occur to the edge of the humeral implant, collared implants may provide more stability as opposed to collarless implants which could have resorption back to the level of the implant fins.

The use of surface coating, be it either ingrowth or ongrowth, is present on each of the implants. Ingrowth technology is utilized in the Simpliciti and SMR Stemless implants, while the remainder has variations of sprays and coatings allowing for bone ongrowth. At the present time, with 2-year minimum data only available on the Eclipse, Simpliciti, and TESS, no apparent differences are identifiable secondary to the implant surface coating. However, surface coatings cannot be independently considered without also correlating the fourth significant design characteristic: bone contact area. Implants can be divided into high and low bone contact area. Implants with solid collars and solid fins are easily separated from those with open window fins and collars or those without collars. Thus, high bone contact implants would include Eclipse, Simpliciti, and SMR Stemless as well as the collarless six finned TESS and Nano. The low bone contact implants are the open-windowed Easytech, Affinis Short, and Sidus implants. Without quality 2-year minimum follow-up studies demonstrating radiographic stability, caution should be exercised when implanting low bone contact implants. Due to the open window and collarless design, low bone contact implants raise concern over the initial and long-term implant strength as well as the ability of these implants to incorporate adequate bone surface growth for long-term stability.

Stemless shoulder arthroplasty has clearly demonstrated short and midterm clinical results equal to stemmed implants. However, as demonstrated throughout this article, significant differences exist between the stemless implants. Physicians should not attempt to transfer results from one specific stemless design to all stemless designs. Critical evaluation of an implant's specific design features and review of available literature results for that implant should be exercised prior to proceeding with the use of a specific implant.

Conclusions

Stemless shoulder arthroplasty has promising short and early midterm results when utilized as a primary anatomic implant.

Several well-designed studies indicate that stemless anatomic arthroplasty has equivalent clinical and radiographic results to the historical gold standard, stemmed humeral component. The various stemless implant designs available for use have significant differences. These design differences preclude one from making the general assumption that all stemless implants will be successful. Surgeons should give careful consideration as to which stemless implant they utilize. Second generation stemless implants which allow conversion from a primary to reverse application remain in early development, and use of these products should proceed with caution until further data is available.

Compliance with ethical standards

Conflict of interest Dr. R. Sean Churchill reports royalties from Tornier, Inc.

Dr. George Athwal has the potential to receive royalties from Imascap and Tornier. Additionally, he is a consultant for Depuy-Synthes.

Human and animal rights and informed consent Research involving human and animal subjects was performed in accordance with the Declaration of Helsinki and was approved by the IRB.

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