EXACTECH | **SHOULDER**

equinoxe®

Value Profile

Table of Contents

Executive Summary

INCREASING DEMAND

Increasing economic pressures are forcing hospitals to evaluate the cost drivers of procedures and implants. Hospitals need to evaluate the current and future demand for the procedure, considering factors such as patient demographics, outcomes and cost effectiveness. Part of hospitals' analysis should include implant choice since potential complications can increase cost.

Demographics

More surgeons now describe their practice as "Shoulder and Elbow Surgery"; more fellowship programs in this specialty are also now available in the United States. The number of arthroplasties performed annually in the U.S. is growing so rapidly now that the FDA has cleared reverse shoulder arthroplasty. Additionally, the debilitating nature of osteoarthritis and the number of patients affected (more than 67 million in the U.S. by 2030)[2] will lead to further demand for the procedure.

Three expanding uses will increase the demand for shoulder arthroplasty in the coming years: younger patients, fracture care and oncology/revision. Recent studies have explored the use of shoulder arthroplasty in patients younger than 70 with good results.[25] Surgeons using reverse arthroplasty in three or four complex fractures show improved function results over open reduction or hemi-arthroplasty procedures.[26] Musculoskeletal oncology and complex revisions will also increase demand for shoulder arthroplasty. Recent articles report the use of reverse arthroplasty for humeral tumor procedures, which is the third most common type in orthopedic oncology.

The average shoulder patient is 65 years old, Caucasian and female.[10] Thirteen percent of the current population is over 65 years old, and this group is expected to increase steadily over the next 25 years. Hospitals are motivated to examine the patient demographics in their treatment areas and determine the future demand for shoulder arthroplasty. A study comparing shoulder, knee and hip patients reported that shoulder patients are less likely to be Medicare patients - and they have half the complication rates.[16]

Outcomes

Hospitals need to be confident in the outcomes of shoulder arthroplasty. Knee and hip arthroplasties are the gold standard in treating end stage arthritis and are the benchmark hospitals use to compare arthroplasty options. Shoulder surgery is a technically difficult procedure, but studies show that results of shoulder replacements have been equivalent to hip and knee replacements.[16] In addition, although

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orthopedic implants do not necessarily contribute to longer life expectancy, they do improve quality of life – an important goal. Renfree reports that reverse shoulders resulted in improvements in quality of life measures, such as self-care, anxiety/depression and pain/discomfort.[18] Castracini reports that patients who received reverse shoulder five years earlier had similar quality of life when compared to healthy controls the same age.[19]

Cost Effectiveness and Cost Drivers

For hospitals, the demand and demographics of treatment areas will create an increased focus on shoulder arthroplasty. Each hospital should determine the success and efficacy of shoulder surgery compared to other gold standard treatment options. The hospital should then explore the current cost effectiveness of the procedure, as well as the cost drivers. A 2013 study of cost utility for reverse shoulder arthroplasty determined that the reverse shoulder was moderately to highly cost effective.[18] Virani reports that cost associated with anatomic shoulder replacement is $17,587 over four years (and five times the reduction in pain with nearly double the improvement in function).[30] Chalmers concluded that treatment of complex fractures with a reverse had equivalent overall cost compared to hemi-arthroplasty and open reduction and plating.[26] The higher cost reverse implant was offset by reduced physical therapy and hospital visits.

In addition to cost effectiveness of shoulder surgery, the costs of arthritis, extended hospital stays and complications of shoulder surgery factor in. In 2009, Rizzo reported that arthritis cost the U.S. $185.5 billion in direct cost.[5] Kotlarz reported that the indirect cost of absenteeism cost the U.S. $10.3 billion.[6] Readmission and additional hospital stays can significantly increase the cost of shoulder surgery. Every complication increases the risk of an extended hospital stay or readmission into the hospital. This cost driver will have an even bigger impact as the new federal guidelines administer penalties or refuse reimbursement for readmission within 30 days after initial surgery. The cost of an extra day in the hospital was higher in patients 65 years and older (a typical shoulder patient) at $12,600 a day.[24]

Complications in surgery requiring revision and removal of implants are an ongoing concern in the medical community and will continue to be a subject of discussion, with the new federal readmission penalties and reimbursement policies. A meta-analysis review of 21 studies reported an industry complication rate of 24 percent.[22] Revision surgery risks increasing cost through extended hospital stays, physical therapy, implant cost and operating room time. In the meta-analysis review the most common problem related to reverse shoulder was scapular notching, with one type of implant (Grammont-style; medial glenoid/medial humerus design) having 49.8 percent of the scapular notching issues. Glenoid lucency was the second most common problem, and the lateral glenoid/medial humerus design had twice the lucency rate as the medial/medial implant. Scapular notching and glenoid lucency create concerns with baseplate stability due to the loss of bony support around the implant. If the glenoid component fails, there can be significant impact on hospital cost due to revision surgery.

In the meta-analysis study, needing to remove the implant during a revision was the most severe complication. The most common complication was instability, at a rate of 4.5 percent; this rate can be as high as 9 percent. A common cause for instability is the secondary cuff dysfunction after a primary anatomic total shoulder procedure. Young reported that survival rates after five years were 100 percent in total shoulder but at 10 and 15 years survival rates declined (84 percent and 45 percent).[23] Traditionally cuff tear with glenohumeral arthritis is treated with a reverse total shoulder arthroplasty.

THE EQUINOXE® SOLUTION

The Equinoxe system allows for the conversion of an anatomic to reverse shoulder arthroplasty without removal of the humeral stem, saving time and money, and lessening blood loss compared to other systems, shown in a study by Drs. Crosby and Wright. They estimate that when a stem needs to be removed, the cost increases from $8,020 to $15,120.[33]

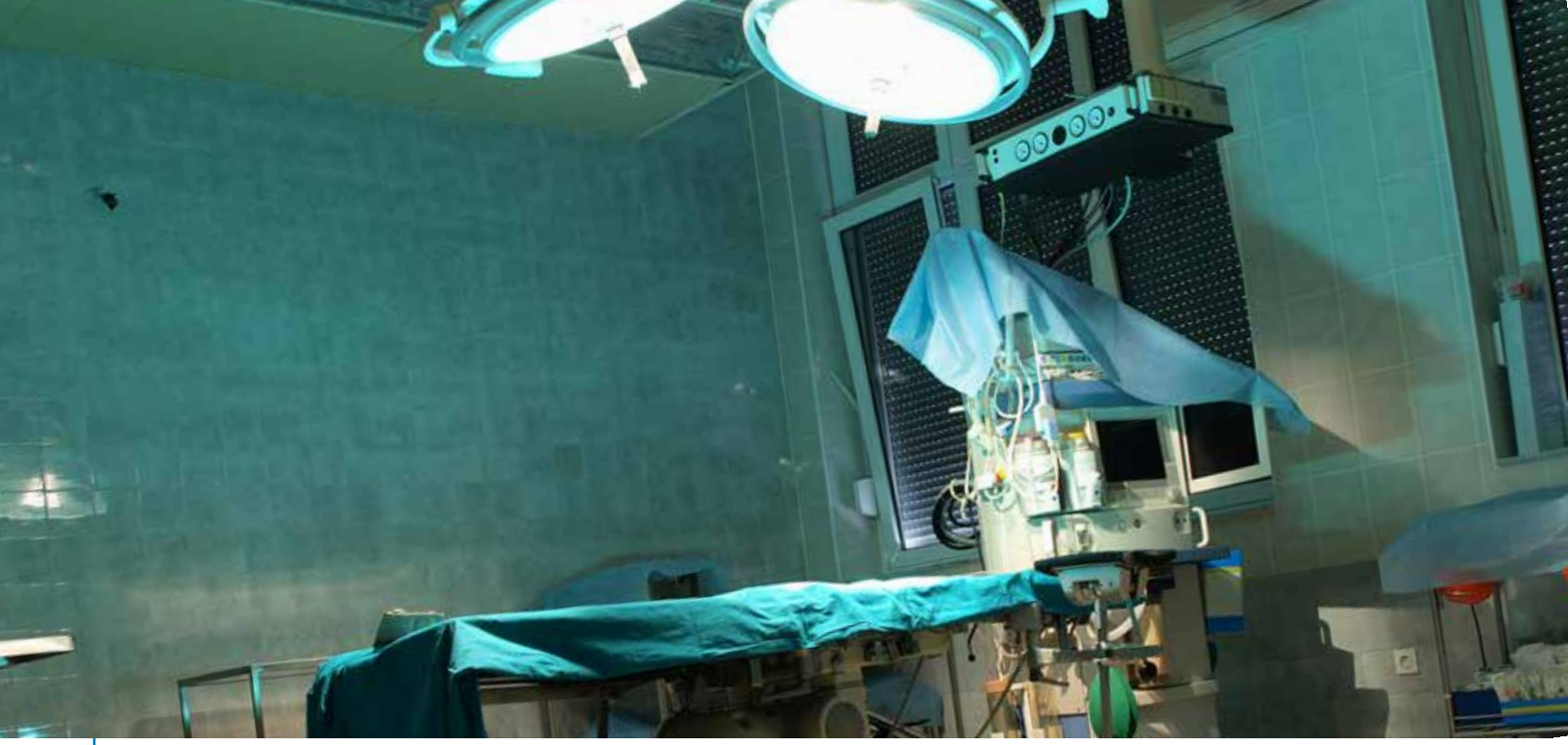
Glenoid bone loss can cause instability due to medialization of the joint space. A medialized joint causes laxity in the surrounding soft tissues that provide compression force in the joint. The standard of care for glenoid bone loss is to ream the bone even with the glenoid wear. Exactech offers augmented options that allow for restoration of the joint line and centering of the humeral head. Design surgeons have reported mixed results of other techniques.[41-43,55,58,59] Hospitals should review an implant's ability to provide reproducible results with a reduced learning curve.

Henninger reports that as the compression forces in the glenohumeral joint increase, the force required to dislocate the implant also increases.[58] The biomechanic design of the Equinoxe system addresses instability. Roche reported on the point in which the wrapping angle of the deltoid is 0 degrees in three reverse designs. When the wrapping angle of the deltoid reaches 0, the ability for the deltoid to provide compression force is neutralized. The normal shoulder lost deltoid wrapping at 48 degrees; Equinoxe (medial glenoid/lateral humerus design) lost wrapping at 40 degrees, lateral/medial design at 28 degrees, and medial/medial at 8 degrees.[59]

The glenoid component is the other significant cost driver for shoulder arthroplasty. Glenoid loosening is a concern in both anatomic and reverse designs. Many companies have design solutions for glenoid loosening as it can have a detrimental effect on the patient if it fails. The Equinoxe baseplate is designed with features that provide more options and long-term fixation.

At the time of this publication, Equinoxe is the only platform stem with 10 years of clinical results – one being a multicenter study that reported no instability and no glenoid loosening.[35] The function results were better in nearly every category as other published reports for shoulder arthroplasty. Flurin reported that the Equinoxe implant also resulted in the greatest pre-operative to post-operative improvement of external rotation.

Exactech is committed to providing the most comprehensive options and the best service for the hospital, the surgeon and the patient. Hospitals can reduce cost through use of a platform stem, revision friendly systems and designs focused on reducing complication risk.



Epidemiology: The Demand for Shoulder Surgery

Healthcare cost is a topic of much debate. It is important for every hospital to understand not only the treatment of a disease, but also its cost and any cost drivers that can arise from the treatment. Hospitals must understand the current and future demand of the procedure and how these interventions can affect the long-term profitability of the hospital. They need confidence that the intervention improves patient quality of life in a cost effective manner.

Musculoskeletal disease is a complicated and burdensome disease throughout the world. This burden combined with the aging population caused the World Health Organization to partner with 60 countries to develop the "Bone and Joint Decade" to raise awareness and conduct research in the field.[1] Arthritis is the United States' leading cause of disability, and osteoarthritis is the most common form of arthritis.[2,7] From 2007-2009, 50 percent of adults over 65 years of age reported an arthritis diagnosis, and

> By 2030, 67 million Americans will be diagnosed with arthritis[2].

it is estimated that by 2030, 67 million Americans will be diagnosed with arthritis.[2] It is well established that total knee and hip replacement is the standard of care for end stage arthritis. As the incidence and treatment of shoulder arthritis continues to increase, it is important to have confidence in the decision to treat patients with total and reverse shoulder arthroplasty.

Reasons for this growth include:

IMPROVED TECHNOLOGY

In 2004 the Food and Drug Administration cleared the reverse total shoulder and increased the scope of indications for patients who have cuff tear arthropathy. As demonstrated in **Figure 1**, surgical volumes grew substantially in the U.S. from 2000 to 2013 (Global Data Report).[44]

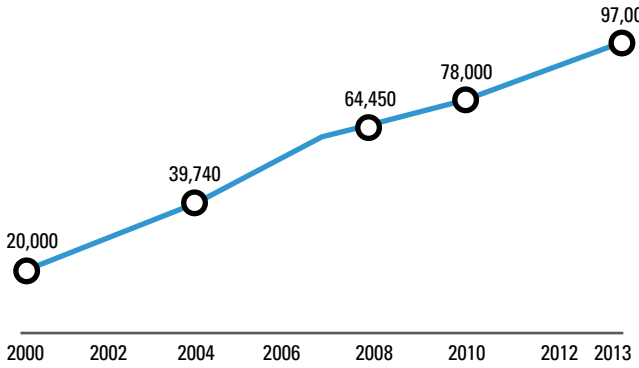


Figure 1: US Shoulder Implant Procedures

SPECIALIZED TRAINING

Training on shoulder surgery has become a priority for the orthopedic industry, demonstrated by surgeons' descriptions of their practice and by the number of fellowship programs now offered in the U.S. The American Academy of Orthopedic Surgeons (AAOS) reported an increase in the "Shoulder and Elbow Surgery" practice focus from 24 percent in 1992 to 44 percent in 2004.[8]

Expanding uses will drive future demand for shoulder arthroplasty, as more surgeons have become comfortable with the surgery and management of potential complications. The primary indication for shoulder arthroplasty is the presence of osteoarthritis in the glenohumeral joint **(Figure 2)**. This loss of cartilage leads to hypertrophic bone formation and thickening of the joint capsule. Clinically these conditions lead to pain and loss of function, which can ultimately affect activities of daily living.[3]

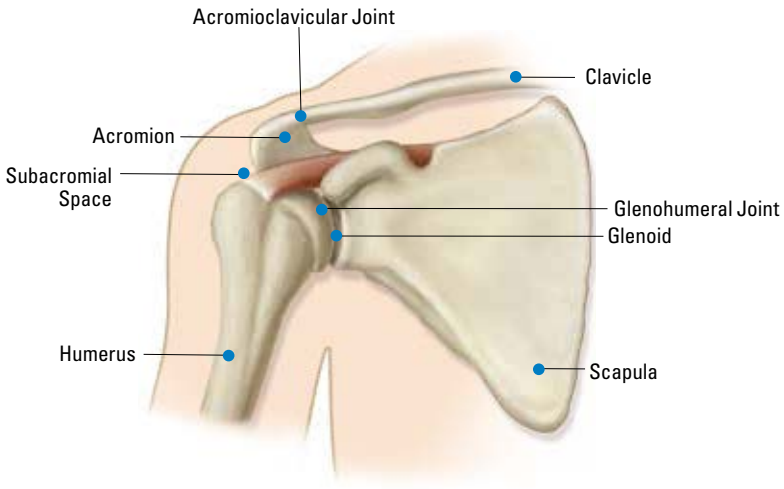


Figure 2: Bony Anatomy of the Shoulder

Contributors to Increase in Demand

Improved technology

Specialized training

Expanding market

Changing patient demographics

Improved outcomes

Cost effectiveness

TRADITIONAL CARE

- Anatomic shoulder arthroplasty is indicated in patients with glenohumeral arthritis and an intact rotator cuff.
- Reverse shoulder arthroplasty is traditionally indicated in patients with glenohumeral arthritis and irreparable rotator cuff tears. This indication usually presents with pain and loss of function.

EXPANDING MARKET

- Younger patients: The general consensus is that reverse shoulder components are indicated in patients older than 70 years of age, but that restriction has gradually declined to patients in their 60s as reverse shoulder arthroplasty procedures are increasing - with good outcomes. A recent study of 66 patients 60 years or younger, with an average follow-up of 36.5 months, showed similar functional outcomes to previously reported studies.[25]
- Fracture care: The treatment of proximal humerus fractures varies widely by physician and location, suggesting there is a lack of agreed treatment protocol for these cases. The current "standard of treatment" has many disadvantages, which has led to the use of reverse arthroplasty. Current treatment options include:
    - Open reduction and internal fixation (ORIF): This option allows for anatomic reconstruction of the humeral head; however, the risk of arthrofibrosis, fracture displacement humeral head necrosis, and screw cut-out in 16-67 percent of cases, can be detrimental to patient outcome.
    - Hemi-arthroplasty: This treatment avoids concerns of fracture displacement and necrosis of the humeral head; however, the tuberosities make this a challenging healing environment. Osteolysis of the tuberosity can cause loss of function for the patient.

  Complex three- and four-part fractures are especially difficult to treat in older patients, who typically have co-morbidities. As more surgeons understand the benefits of reverse shoulder arthroplasty, the indications have expanded to fracture care – prompting the design and development of specific implants for fractures. Chalmers retrospectively reviewed 27 patients at three facilities with minimum follow up of 12 months; they reported improvements in ROM and function scores and equivalent complications to other interventions.[26]
- Musculoskeletal oncology: This is also an expanding treatment in shoulder arthroplasty, as the proximal humerus is the third most common site for occurrence of bone tumors. Managing tumors of the proximal humerus is a complicated limb salvage procedure, and there are many techniques to restore function for these patients. In these salvage procedures, the proximal humerus and surrounding soft tissues may need to be sacrificed to fully resect the tumor. Most patients have difficulty achieving full function afterwards, but the use of a reverse shoulder for these patients has shown improved results in short-term studies.[27] Recent articles show the increased attention this procedure is receiving.[28]

Average Shoulder Patient

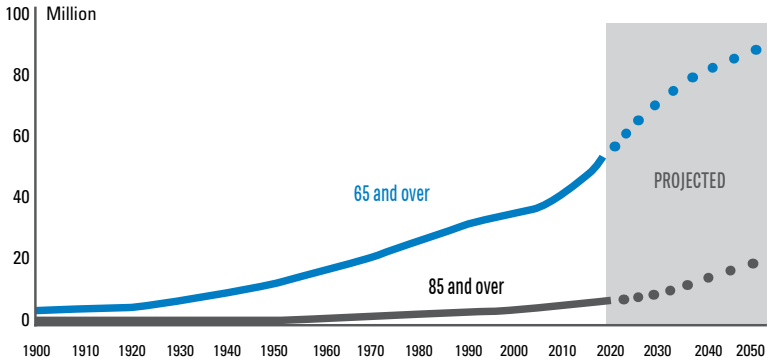
CAUCASIAN FEMALE > 64

NON-MEDICARE PATIENT

DEMOGRAPHICS

A hospital can better understand the cost and demand of a procedure by determining the patient demographics in its treatment area. The average shoulder arthroplasty patient is a Caucasian female older than 64 years of age, and more likely to be a non-Medicare patient. In the last 10 years the incidence of shoulder arthroplasty has increased in both patients older than and younger than 65 years of age, due to the development of effective prosthetic designs, the FDA's clearance of the reverse total shoulder, expanding uses, and an aging population. The number of people more than 65 years old has significantly increased in the U.S. The U.S. Census Bureau reports that the population over 65 years of age represents more than 13 percent of the total population. This population is expected to double by the year 2030 (**Figure 3**).[9]

Figure 3: Population Age 65 and Over and Age 85 and Over Selected Years 1900-2010 and Projected 2020-2050[9]

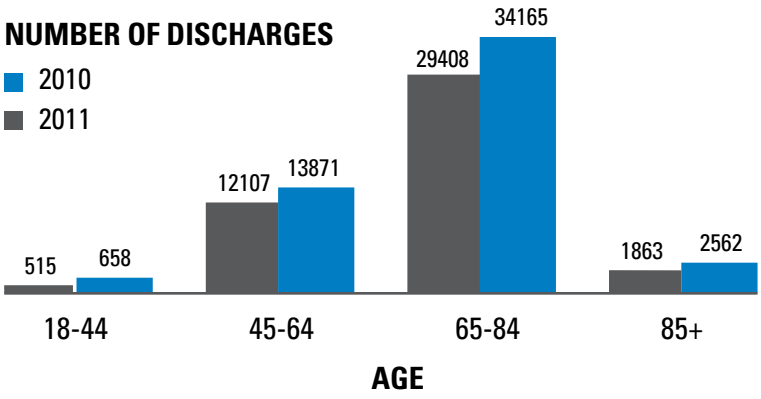


Shoulder arthroplasty tends to be performed on patients 65 years or older. Research using the HCup research software with the parameter search for 2010 and 2011 that included ICD-9 CM code 81.80 and 81.88 confirmed that.

In 2010 and 2011 the largest volume of shoulder arthroplasty cases were within 64-84 years of age[10].

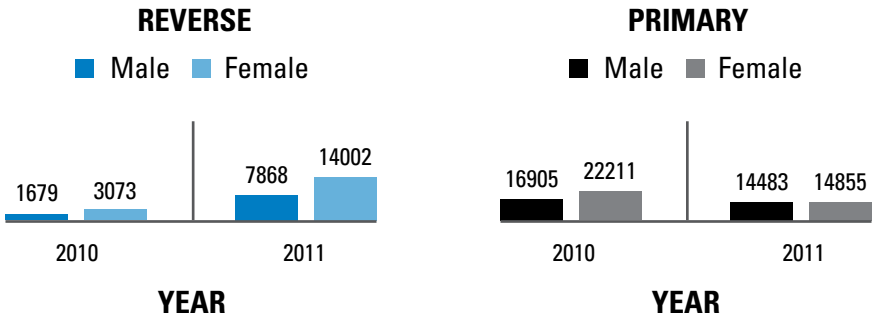
In 2010 and 2011 the largest volume of shoulder arthroplasty cases were within 64-84 years of age.[10] The distribution was similar in both the search of anatomic shoulder replacement and reverse total shoulder (**Figure 4**).

Figure 4: Age Distribution Shoulder Arthroplasty[10]



Historically, more total shoulders are performed on females. With the recent emergence of reverse total shoulder arthroplasty, the overall number of reverse total shoulders has increased significantly with a 2:1 female to male ratio (**Figures 5**), while anatomic total shoulders have declined slightly with equal male: female distribution. Recent published journal articles show an increase in shoulder arthroplasty in younger patients[11,12]; however, a significant shift in age distribution is not expected within the next five years.

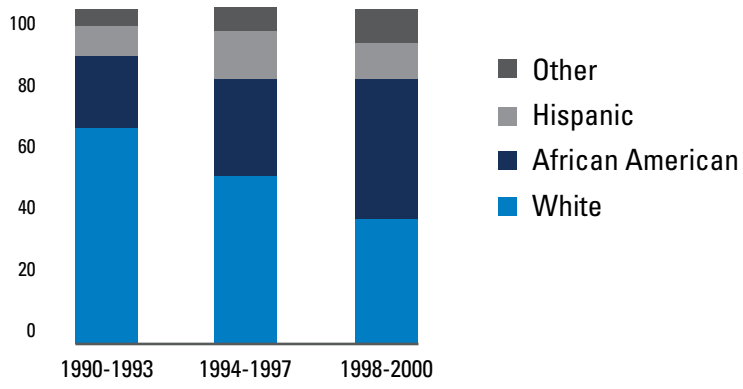
Figure 5: Gender Distribution Shoulder Arthroplasty[11-12]



Note: 2010 RTSA only includes Q4 data (FDA clearance in October 2010)

Race and ethnicity are factors to consider as well. Vegini reports that, of patients who underwent shoulder arthroplasty, 62.1 percent were Caucasian, 2.5 percent were African American, 2.5 percent were Hispanic, and 1.9 percent had other ethnicities (30.9% did not select ethnicity on patient records).[13] These results are consistent with total knee epidemiology reported by Jain in 2005 (**Figure 6**).[14]

Figure 6: Knee Epidemiology[14]



EFFICACY

Shoulder surgery is a technically demanding procedure, and although there is more complication risk with shoulder arthroplasty, studies show equivalent functional and pain relief outcomes when compared to other accepted forms of treatment for arthritis. Although shoulder arthroplasty is performed less often than knee and hip arthroplasty, it is just as successful in terms of pain relief for arthritic joints.[16] Shoulder arthroplasty was first performed in the U.S. during the 1950s but it did not reach popularity until the 1970s, when further advancements were developed. In a study that

Published results for shoulder replacement are consistent with treatment of knee and hip arthritis.

reviewed shoulder, knee and hip outcomes from 1994 to 2001, shoulder arthroplasty was viewed positively as a treatment for osteoarthritis.[16] The study revealed that total shoulder patients were less likely to be Medicare patients; the author noted this would decrease cost and increase reimbursement rates. Reported complication rates were half as much for the total shoulder group compared to the hip and knee patients.

Published results for shoulder replacement are consistent with treatment of knee and hip arthritis. In 2010, 719,000 knee replacements and 332,000 hip replacements were performed, compared to 78,000 shoulder replacements.[44,61] A study by Chalmers reported the use of reverse shoulder arthroplasty for proximal humerus fracture and showed superior results in time until active forward elevation (a predictor of patient satisfaction) and range of motion. The reverse shoulder patients had similar ASES, SST and SF-12 pain and function scores, and the reverse arthroplasty patients recovered largely without supervised physical therapy.[26] After the reverse shoulder prosthesis was cleared in the U.S., the increasingly popular procedure resulted in more medical education programs and better designs that have improved clinical outcomes.[15] Clinical success is not the only measure of efficacy in shoulder arthroplasty; quality of life improvements for the patient are important as well.

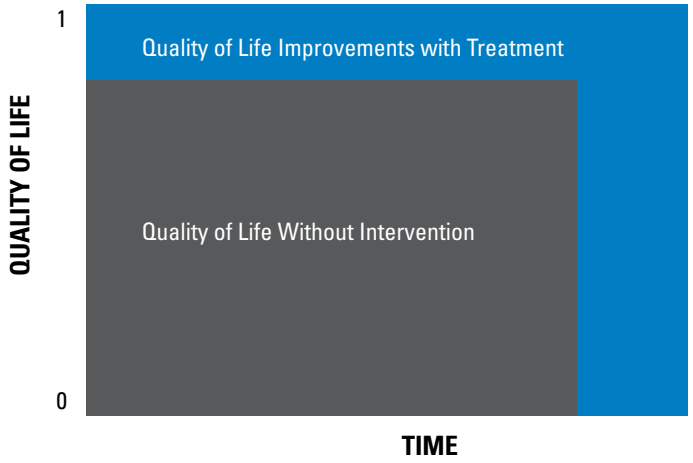
The goal of orthopedic intervention is to increase the quality of life. In a 2013 study by Renfree, reverse total shoulder surgery resulted in improvements in mobility, self-care, and anxiety/depression and pain/discomfort levels.[18] Castricini's study of health-related quality of life in reverse shoulders also reported increases in range of motion and improvements in function.[19] Castricini showed that patients who received reverse shoulders five years previously had a similar health-related quality of life when compared to healthy controls of the same age groups. Another article reviewed 20 studies and showed a quality of life improvement with significant improvements in physical function and reduction in pain.[20] These reports demonstrate that both the reverse and anatomic shoulders are highly effective interventions that improve the quality of life and function for patients.

COST EFFECTIVENESS

There is increased interest in the cost efficiency and utility of shoulder arthroplasty. The quality of life improvements and the clinical outcome results for function and pain of anatomic and reverse shoulder arthroplasty are substantial and must justify the procedure.[20,29,30] Cost utility analysis is widely considered the gold standard of cost effectiveness in the healthcare field. "Quality adjusted" life years are the standard measurement of incremental health effects of an intervention compared to its cost for each year of "quality adjusted" life (**Figure 7**). Many patients have a wide variety of health states before having surgery, so this study uses a utility score to adjust for this variation. A 2013 study that reviewed cost utility of reverse shoulder arthroplasty reported that the reverse total shoulder is a moderate to highly cost effective procedure.[29]*

*Utility scores were gathered based on the EQ-5D and SF-36 forms. Cost data was gathered from a hospital accounting database. The results were based on the threshold of less than $50,000 being considered cost effective and less than $25,000 being highly cost effective (the generally accepted U.S. measurement). The results using the EQ-5D form for quality of life adjusted yearly life resulted in $16,747 and would be considered highly cost effective; using the form SF-36 resulted in a cost utility of $26,920, resulting in almost highly cost effective results.[29] Further research by Frankle and associates showed four-year cost of $17,587, five times the reduction in pain and nearly double the improvement in function.[30]

Figure 7: Cost/Quality of Adjusted Yearly Life[29]



As applications for care continue to expand, it is important to examine the cost effectiveness of these treatment options. A prospective study by Chalmers and colleagues[26] reviewed patients who underwent reverse total shoulders for three- and four-part fractures of the humerus and compared them retrospectively with the results of patients who underwent hemi-arthroplasty, open reduction and plating. The study conducted two cost analyses: societal cost determined by Medicare data and individual cost determined by list price. The two variables of physical therapy and implant cost were combined to estimate total cost. This study showed that, combining physical therapy and operative room reimbursement, the cost for hemi-arthroplasty was an average of $6,081, open reduction averaged $5,296, and reverse total shoulder averaged $1,735. When list prices of implant and number of hospital or clinic visits were combined, the mean total cost for hemi-arthroplasty was $20,899, for open reduction $14,321 and for reverse arthroplasty the average cost was $15,352 (**Figure 8**).[26] When considering patient outcomes using cost utility, reverse shoulder is highly

Figure 8: Cost of Fracture Intervention[28]
(Combining Physical Therapy, Operative Room Reimbursement, Implant Cost, Clinic/Hospital)

HEMI-ARTHROPLASTY
$20,899

FRACTURE PLATE
$14,321

REVERSE SHOULDER
$15,352

cost effective across multiple treatments. The overall decision for a hospital to perform shoulder arthroplasty needs to be determined by the demand for the procedure, the patient demographics of the hospital, the surgeons performing the procedure, whether the procedure is successful and whether it is cost effective.

Key Cost Drivers

Hospital systems need to be aware of the cost of arthritis to determine the most appropriate way to address the social and economic impact. The cost of arthritis can be broken down into three types: direct cost, indirect cost, and intangible cost (Table 1).[4]

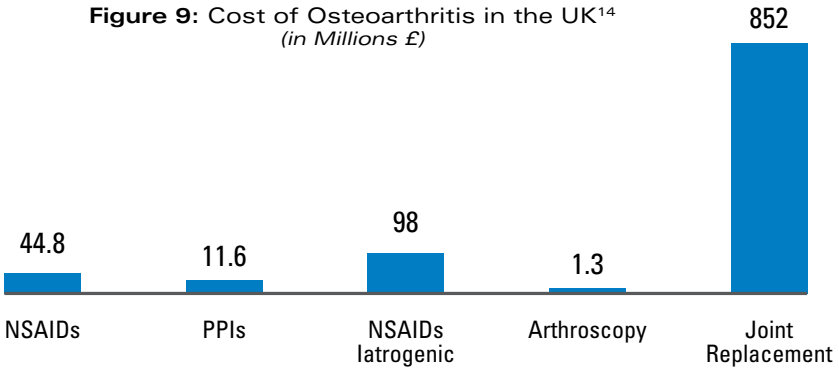
Table 1: Cost of Arthritis[4]

DIRECT COST	INDIRECT COST	INTANGIBLE COST
Hospital Resources	Loss of Productivity	Pain/Suffering
Cost of Surgery	Absenteeism	Depression/Anxiety
Pharmacy Treatment	Premature Mortality	
Physical Therapy	Quality of Life	
Cost of Side Effects	Insurance System Burden	
Research and Development	Disability Payments	
Caregiver Time	Insurance System Burden	

A 2009 study by Rizzo reported that the yearly expenditure on osteoarthritis treatment reached $185.5 billion in direct costs per year.[5] Kotlarz et al, 2010 estimated that the indirect cost related to absenteeism resulted in an annual cost in the U.S. of $10.3 billion and osteoarthritis is significantly correlated with missed time at work.[6] It is important for hospitals and medical device

manufacturers to understand the cost of osteoarthritis and its direct effect on the operating room bottom line. The operating room contributes a large part of the cost related to osteoarthritis. In an economic study of osteoarthritis in the United Kingdom on how the cost of osteoarthritis compares to worldwide costs, Chen demonstrated that joint replacement accounted for 85 percent of arthritis cost in the UK ($1.4 billion) (**Figure 9**).[4]

Figure 9: Cost of Osteoarthritis in the UK[14]
(in Millions £)



Additional hospital stays, revision procedures and longer physical therapy can increase the direct cost of shoulder arthroplasty - and new federal guidelines do not allow reimbursement for readmittance within 30 days of first surgery. Every complication or problem increases the risk of a longer hospital stay or readmittance to the hospital. A 2011 statistical brief by the Agency for Healthcare Research and Quality on cost of hospital stays quantified the cost of an extra day in the hospital, as well as the demographics of high risk patients. The aggregate cost for hospital stays in the U.S. in 2011 was $387.3 billion. The most concerning finding for hospitals treating shoulder arthritis is the distribution of age and condition as it relates to cost. Patients 65 and older represent 43 percent of hospital stay cost (**Figure 10**), and patients 65-84 represent the highest average cost per person at $12,600 (**Figure 11**).[24] The report also examined results per indication; the cost growth rate of osteoarthritis as a principle diagnosis was 7.9 percent from 1997 to 2011. Osteoarthritis also led to a per-stay cost of higher than 50 percent of the mean cost per stay -$15,400 - compared to the previously reported $10,000.[24] The age demographics of shoulder patients correlate with age groups that have higher hospital stay cost. Hospitals can help manage direct cost of hospital stays by focusing on implants and techniques that minimize the risk of extended or additional hospital stays.

Figure 10: Hospital Stays by Age Group[24]
(Distribution of Hospital Costs and Stays, %)

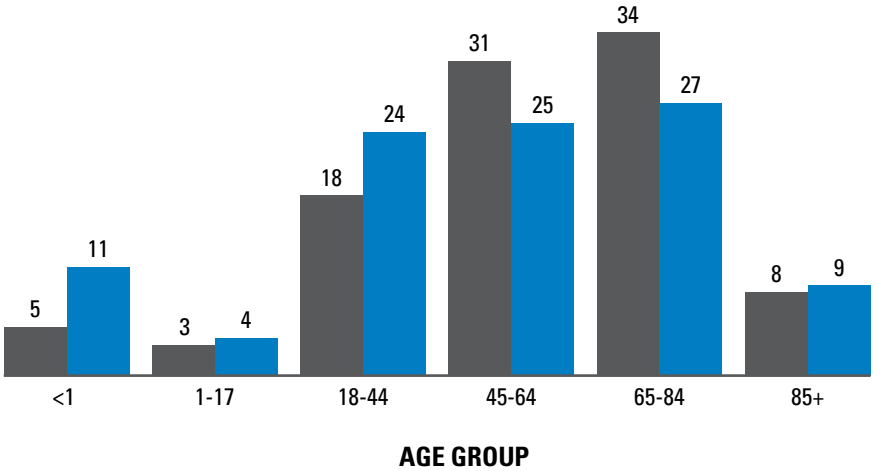
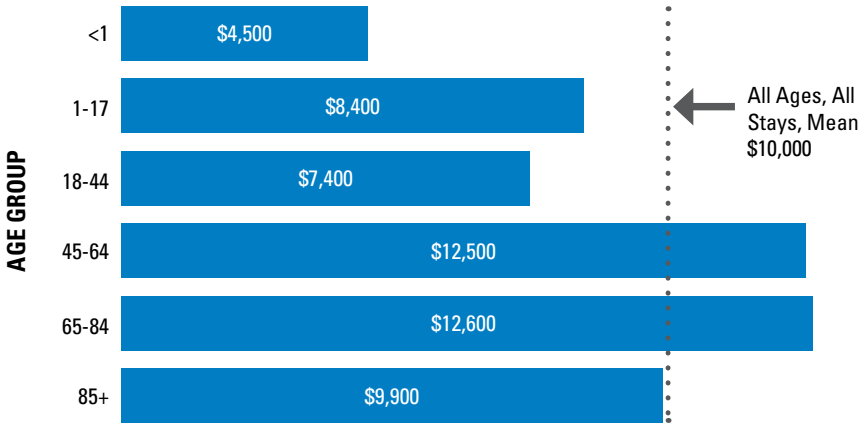


Figure 11: Hospital Cost by Age Group[24]
(Mean Cost, $)



Complications in surgery and post-surgery are an ongoing concern in the medical community and play a significant role in cost inflation per patient. The Affordable Care Act of 2010 has set policies that will reduce the Medicare reimbursement on readmissions within 30 days on selected conditions. This policy will be expanded in 2015 to include more qualified conditions, such as hip and knee replacements.[21] Federal policies that carry penalties for complications will have a greater effect on hospital profits in the future. The ability of medical device companies to offer a product that reduces the cost of readmission is critical for long-term success in this evolving healthcare reimbursement environment. Below is an overview of the problems and complications that add risk of increased cost and poor patient outcome.

The ability of medical device companies to offer a product that reduces the cost of readmission is critical for long-term success in this evolving healthcare reimbursement environment.

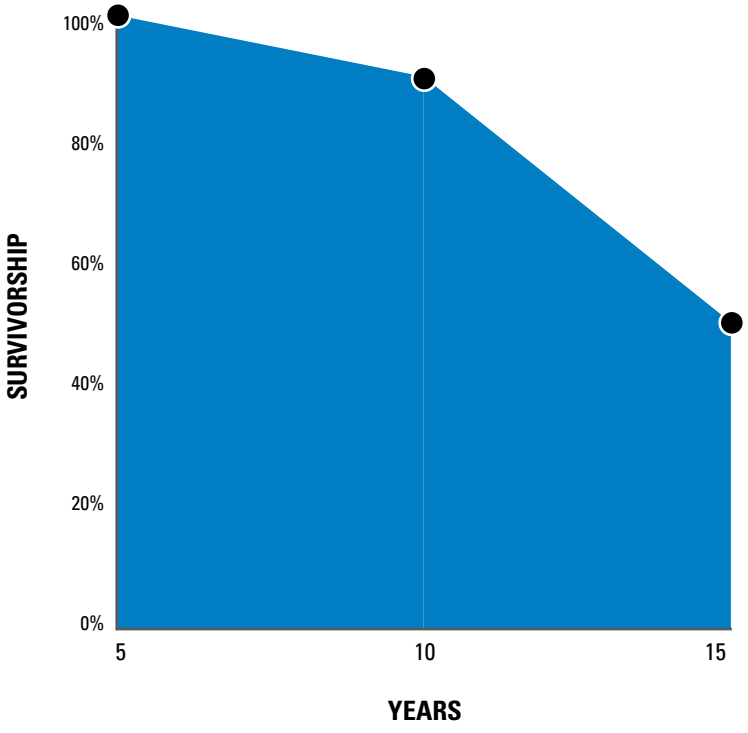
A retrospective meta-analysis that reviewed 21 studies showed a complication rate of 24 percent.[22] (It is important to note that no Exactech implant was used in the study.) The study separated less severe problems and complications with those requiring revision surgery and removal of implants.

- **Scapular Notching:** The most common problem cited was scapular notching (49.8% in the Grammont style implant). Scapular notching, also called inferior impingement, occurs when the humeral component impinges on the scapula when the arm is brought into adduction (arm to the side). This impingement causes bone loss from the contact and osteolysis from the wear of the poly component. The amount of notching is defined by four grades with "one" being the least severe and "four" the most. In this study, notching was not classified as a complication, but as a problem or clinical concern.

- **Glenoid Lucency:** The second most common problem in the literature was glenoid lucency (rate of 11.1%). Glenoid lucency is the presence of radiographic indications of early loosening. This occurrence can have significant implications to readmittance and a risk of implant failure. If implant failure occurs, the hospital is impacted by the cost of readmittance, implants and possible reimbursement penalties. Designs that lateralize the glenoids had twice the lucency rate as the Grammont style design.[22]

- **Instability:** The most reported complication in the study was instability (4.5%); the overall revision rate of the study was 10 percent.[22] Instability affects the hospital because it requires revision surgery and implant removal/re-implantation. A common cause of instability after a successful total shoulder arthroplasty is secondary rotator cuff dysfunction. This rotator cuff rupture as a secondary dysfunction can cause many issues for the patient, surgeon and hospital. The current treatment standard for cuff tear arthropathy (cuff tear with incidence of glenohumeral arthritis) is the use of a reverse shoulder. Traditional shoulder designs do not allow conversion from the anatomic shoulder prosthesis to a reverse without revision and removal of the stem. The inability to easily convert a primary or hemi shoulder to a reverse leads to a full revision of the humeral component and implantation of a new product. For the hospital this means longer operating room time, more complication risk and significant increase in cost since a new humeral stem needs to be implanted.[33] A study by Young showed that after five years, survivorship of the total shoulder is 100 percent, but after 10 years, the survivorship of a total shoulder begins to decline significantly (**Figure 12**).[23] Hospitals should be aware that many patients who receive anatomic shoulder arthroplasty will need to be revised after 10 to 15 years. This issue drove the design of the Equinoxe platform system, which facilitates conversion from a TSA to a RTSA without stem removal.[23]

Figure 12: Total Shoulder Survivorship[23]



The Equinoxe® Benefit

REDUCING COST BY REDUCING COMPLICATIONS

Platform Stem

The causes of instability are not completely understood. Some of the causes include the use of the deltoid pectoral approach, insufficient subscapularis, component malposition, and small glenoid size, but the main contributors are lack of compression forces in the glenohumeral joint and shallow socket depth.[32] Articles report instability rates as high as 9 percent.[31] The lack of compression forces in the joint after secondary cuff tear can cause a detrimental effect on outcomes and cost.[32] Traditionally, reverse and anatomic total shoulder arthroplasty use different humeral stems, and a conversion from anatomic to reverse requires removal and replacement of the stem. Although humeral stem loosening is rarely a cause for revision, representing only 1.3 percent of cases,[22] humeral stems designed by many companies have aggressive fixation coatings similar to hip stem designs, making removal difficult. The presence of a well-fixed stem in a revision setting can create excessive bone loss, intra-operative fracture and possibly the need to split the humeral shaft to remove the stem.

Mindful of the cost, time and effects of revision procedures on patients, Exactech designed a convertible platform stem. This design allows a surgeon to convert from an anatomic total shoulder to a reverse total shoulder without stem removal. Crosby and Wright conducted a study comparing the cost of revision for platform and non-platform humeral stems. This study reviewed 67 patients who underwent revision surgery; 45 had the stem removed and 22 converted from a platform stem. The study reported nine complications for traditional stems and zero for the platform stem group.[33] It also demonstrated that the platform stem used less operating room time and increased patient benefits compared to traditional systems. When the

surgeons removed the stem, they used an average of 220cc's more blood, and operating room time increased by an average of 66 minutes (**Figures 13 and 14**). The authors estimate that the total cost increase when a stem has to be replaced is between $8,020-15,120[33]. Other companies are now developing versions of the platform system; however, these systems are new to market and do not have the clinical experience or published results of the Equinoxe.

Figure 13: Average cc's Used[33]

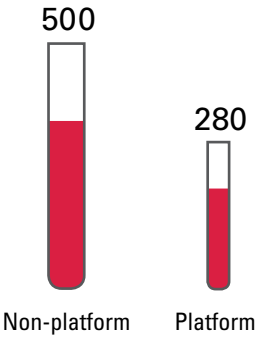
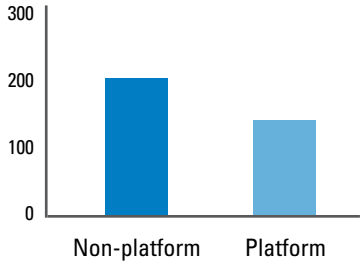


Figure 14: Operating Room Time[33]



Some companies have attempted to reduce instability through modified techniques or implant design.

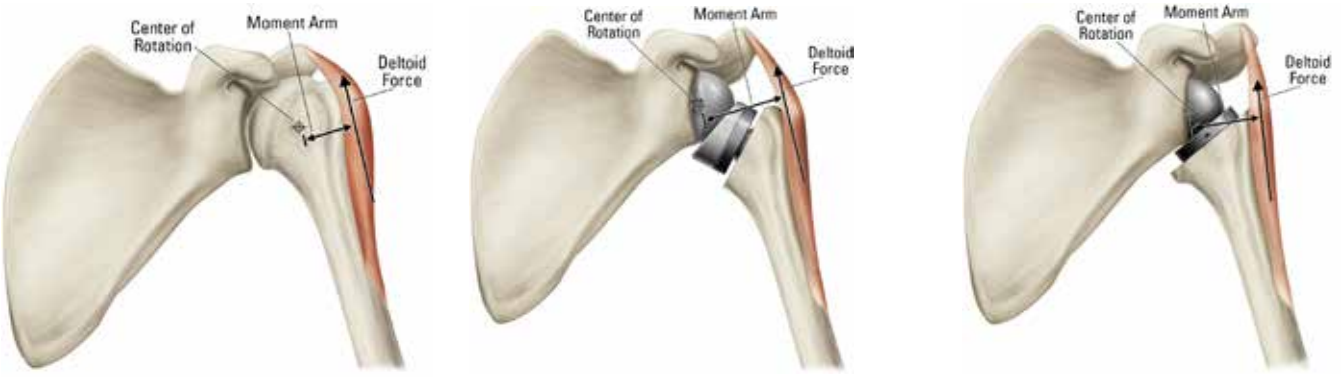
- Tornier offers a bone grafting technique to lateralize the joint; however, this technique requires bone graft to heal for the technique to be successful. The concern is that some patients may have co-morbidities that create challenges to bone healing. For instance, Pascal Boileau and Brad Edwards have conflicting results. Edwards reported only 71 percent of graft incorporation and 12 percent failure to incorporate[41], while Boileau reported 98 percent incorporation.[42]

- DonJoy Orthopedics offers a design that lateralizes through implant design. This design succeeds in lateralization and more anatomic soft tissue tension than traditional reverse shoulder designs; however, this design increases force on the glenoid face.[43,63] The reverse shoulder works on the biomechanical advantage of the deltoid moment arm; as the center of rotation is moved more laterally, the deltoid becomes less biomechanically efficient.

- Exactech's Equinoxe lateralizes the construct more than the previous two designs and keeps the center of rotation on the face of the glenoid.[43] This design allows for a mechanical advantage on the glenoid side and efficiency of the deltoid muscle; it does not require the bone healing of a grafting technique.

  Lateralization can affect stability in reverse shoulders[43,58] and creates deltoid wrapping that provides increased compression force (**Figure 15**). The anatomic shoulder loses deltoid wrapping of the humerus at 48 degrees of abduction, while the traditional Grammont type prosthesis loses wrapping at eight degrees and DonJoy Orthopedics' shoulder loses wrapping at 28 degrees. The Exactech prosthesis loses wrapping of the deltoid around the humerus at 40 degrees.[43]

Figure 15: Deltoid Wrapping



ANATOMIC SHOULDER **EQUINOXE®** **GRAMMONT**

Henninger et al. studied the effect of lateral offset and dislocation forces in the lateral and anterior plane.[58] They report that there was a stepwise increase in the forces required for dislocation (**Figure 16**). The compression forces in the shoulder are applied by the anatomic force of the deltoid and rotator cuff muscles. Roche et al.[43] report wrapping angles for three reverse shoulder implants on the market. **Table 2** shows the degree of abduction where the deltoid stops providing wrapping around the greater tuberosity and potentially how the lack of wrapping can affect compression forces within the joint.

Figure 16: Lateral Offset/Dislocation Forces

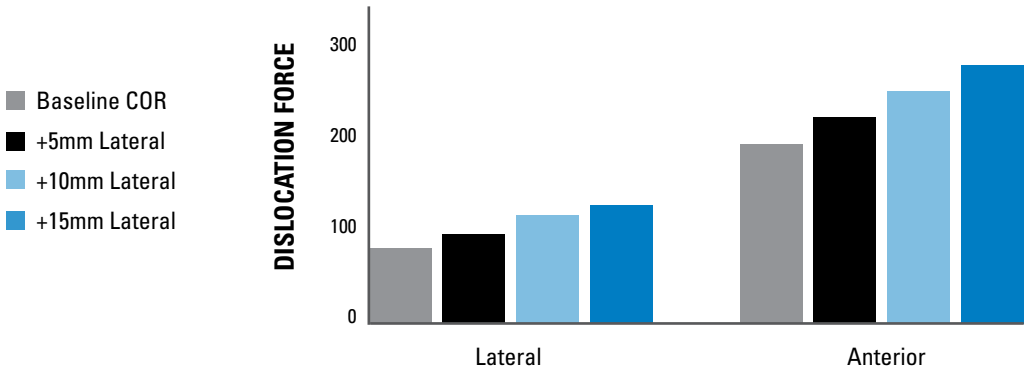


Table 2: Medial-Lateral Position of the Humerus and Its Impact on Deltoid Wrapping

	ANGLE OF ABDUCTION WHICH MIDDLE DELTOID STOPS WRAPPING GREATER TUBEROSITY
Normal Shoulder	48 Degrees
36 Grammont, 0 Degree Tilt, 20 Degree Retro	8 Degrees
36 Grammont, Lateral Graft, 0 Degree Tilt, 20 Degrees Retro	28 Degrees
32mm, RSP (DJO), 0 Degree Tilt, 20 Degree Retro	28 Degrees
38mm Equinoxe, 0 Degree Tilt, 20 Degree Retro	40 Degrees

Glenoid bone loss can also cause significant instability concerns. A soft tissue effect that causes instability can occur when there is bone loss or the inability to correct abnormal wear in the glenoid (**Figure 17**). The current "gold standard" for treating glenoid wear is to ream down the "high side" and level the glenoid with the wear surface (**Figure 17**).[59] This technique results in medialization of the joint line and rotator cuff laxity. The rotator cuff will have to contract further to provide compression forces in the joint to aid stability. Exactech offers augmented glenoids to provide a more anatomic cuff tension (**Figure 17**).[55]

Gerber reviewed reverse shoulder arthroplasty complications from most common to least common. This review showed an incidence of instability from 0-14 percent.[37] Instability is a detrimental complication because of the pain, function and revision cost associated with chronic dislocation of the glenoid humeral joint. Closed reduction has been reported as being successful about 44 percent of the time.[38]

Augmented glenoids provide more anatomic cuff tensioning[55]

Instability usually occurs within the first few months of the operation. When revision surgery is required for a reverse total shoulder to correct instability, some of the options are to change poly to a thicker construct, exchange for a constrained liner, or revise the entire implant construct:

- Renfree et al. determined that the mean cost of reverse shoulder replacement is $21,536 based on Medicare reimbursement and implant cost.[18]
- Medicare cost is determined by MS-DRG reimbursement rate DRG 483 and 484, which groups both total shoulder and reverse total shoulder within the one reimbursement (Medicare determined that the avg. cost increase for a reverse total shoulder is $2,000 and does not rate a new DRG code).[40]
- New readmittance reimbursement policies for instability can have a very large economic effect on hospitals; some may not receive reimbursement due to federal policies.

Figure 17: Rotator Cuff Tensioning

Glenoid Loosening

Reverse Baseplate:

Aseptic glenoid loosening was the historical failure mode of pre-Grammont reverse shoulder designs that utilized a lateralized glenosphere and increased torque at the glenoid fixation surface.[45-47] If the baseplate fails, a revision procedure is required. The patient would need to be readmitted for a revision procedure, which could extend operating room time and increase reimbursement issues, patient satisfaction and possibly implant cost. The Equinoxe reverse system maintains the center of rotation (CoR) near the face of the native glenoid. Further design features have been incorporated in the Equinoxe components that are designed to reduce other potential complications:

The Equinoxe baseplate is an oval 25x34mm curve-back design (**Figure 18**). It is superiorly elongated (oval shaped) in the primary loading direction to help neutralize any destabilizing action of the deltoid.

- **Surface Area:** A recent lab study evaluated eight baseplate designs and demonstrated that the Equinoxe had the largest backside surface contact area (20% larger than the next largest baseplate[24]).*
- **Screw Options:** The screw footprint is maximized by positioning the screws at the edge of an enlarged periphery and increasing the number of screw options from four to six to provide surgeons with additional intra-operative flexibility. To maximize the length of screws used to achieve fixation, poly-axial compression screws that provide 20° of angular variability are utilized and each screw is locked with a cap to prevent backing out. A recent study illustrates the importance of screw variability and additional screw options[49]. In this study, only very short screws (13 to 15mm) were able to be utilized anteriorly and posteriorly prior to bi-cortical purchase. The orientation of those screws violated the subscapularis muscle belly in 20 percent of the inferior screws, 50% of the superior screws, and 100% of the anterior screws; and most concerning, 30 percent of posterior screws damaged the suprascapular nerve or artery.[50] The ability to have more options and variable angled screws can directly impact the risk of patient complications and cost of revision and/or therapy for patients.
- **Bone Preserving:** The Equinoxe baseplate has a curved backside geometry that closely matches the native glenoid curvature, preserving cortical and cancellous bone and increasing cortical bone contact to maximize baseplate support.[48] A bench study by Roche quantified the cortical and cancellous glenoid bone removed by three different commercially-available rTSA prosthesis designs.[51] In that study, the DJO

Figure 18: Equinoxe Baseplate

RSP removed the most overall glenoid bone (3.7 cm^3) despite having the smallest baseplate, the Depuy Delta III removed the second most (3.6 cm^3), and the Exactech Equinoxe removed the least (3.3 cm^3) despite having the largest baseplate. When each prosthesis was implanted along the inferior glenoid rim, the Equinoxe had the most cortical, cancellous, and overall glenoid bone surface contact (501.3 mm^2), the RSP had the second most overall (386.0 mm^2), and the Delta III had the least overall (360.6 mm^2). Larger baseplates were also demonstrated to be advantageous in a 10mm medially worn glenoid, where the Equinoxe had the most surface contact (383.1 mm^2), the RSP was second (296.9 mm^2), and the Delta III had the least (274.1 mm^2).[51]

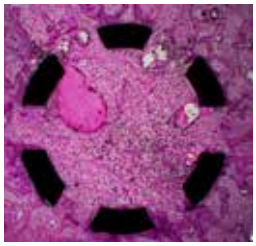
- **Fixation:** Two studies quantified the fixation of six different commercially-available rTSA prostheses in both low and high density polyurethane blocks.[52-53] These studies showed that the Equinoxe (both standard and expanded) and Delta III devices had significantly better fixation than each of the Zimmer, DJO, and BIO-RSA devices. Additionally, catastrophic failure was observed in at least one of each of the Zimmer, DJO and BIO-RSA test components during cyclic loading; no failure occurred in either of the Equinoxe or Delta III devices.[52-53] While designs with a more lateralized center of rotation generally performed worse, this was not the only factor impacting fixation. To assist in both short and long term fixation, the Equinoxe includes a cage peg designed to offer an initial press fit central peg which allows for "through growth" to achieve long-term stability (**Figure 19**). A multicenter study in France of more than 200 patients operated on by two different surgeons found no glenoid loosening.[35]

Aseptic glenoid loosening is complicated by worn glenoid patterns. Generally, surgeons eccentrically ream an eroded glenoid to correct the defect. Unfortunately, eccentric reaming medializes the joint line and removes healthy non-worn glenoid bone to correct the defect, which may compromise fixation.[33-34] To conserve glenoid bone, increase prosthesis surface contact area with cortical bone, and to better restore the native joint line when performing rTSA in eroded scapular morphologies.[26,33,35] Exactech is the first and currently only provider of augmented glenoid baseplates at this time (**Figure 18**). These augmented implants are implanted with off-axis reaming rather than eccentric reaming.[33,34]

- Superior Augment – 10 degrees superior augment glenoid
- Posterior Augment – 8 degrees posterior augment
- Superior/Posterior – A combined 10 degrees superior and 8 degrees posterior augment
- +10 mm Cage -- for medial wear, a +10mm extended cage baseplate is available to facilitate grafting of severely medially eroded glenoids

These augmented designs address both fixation and soft tissue tensioning. Glenoid loosening and instability/dislocation are two main reasons revision shoulder surgery is required, and the economic impact of working with a company that designs products to reduce these problems and complications can be substantial.

Figure 19: Equinoxe® Augmented Glenoid Baseplates



HISTOLOGY IMAGE FROM CASE STUDY

SUPERIOR AUGMENT BASEPLATE

EXTENDED CAGE BASEPLATE

POSTERIOR AUGMENT BASEPLATE

Exactech also recognizes the need for fixation and the flexibility to revise an anatomic shoulder arthroplasty to a reverse if needed. This was the impetus for the design of the cage poly glenoid (**Figure 20**). The cage glenoid leverages the experience with the Equinoxe reverse shoulder baseplates. The center cage is press fit and is designed to allow bone "through-growth." [36]

Glenoid loosening and instability/dislocation are two main reasons revision shoulder surgery is required, and the economic impact of working with a company that designs products to reduce these problems and complications can be substantial.

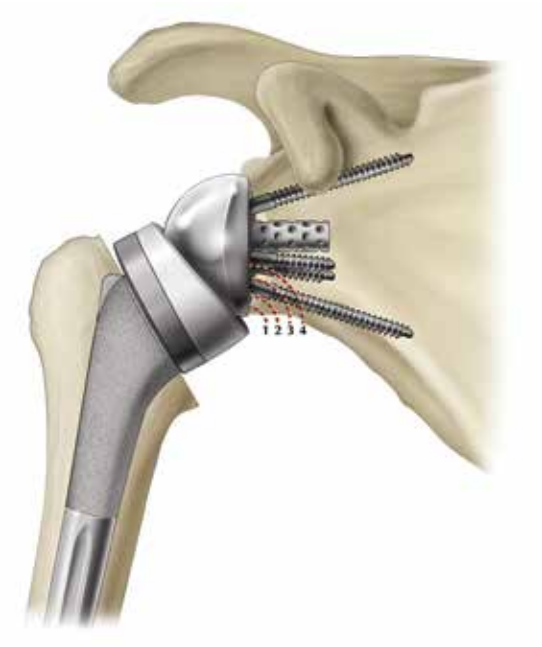
Exactech has designed an implant that complements the platform shoulder by offering a simplified revision technique. During a revision using the technique described in the instructions for use, a surgeon removed the poly with an osteotome and observed the well fixed central cage retained in the glenoid. He then used a 3.2mm drill bit to break up any bone that was present within the cage and attached an extraction device with slap hammer to remove the cage without leaving metal debris or creating a large bone void. The surgeon also reported that the use of the cage has allowed him a time savings of 5-13 minutes due to the initial press fit of the central cage while the cemented peripheral pegs harden.[36] **

Figure 20: Exactech's Cage Poly Glenoid

Notching

As noted, some of the top complications in shoulder arthoplasty are scapular notching, glenoid loosening, and instability. Scapular notching is a well recognized problem in reverse total shoulders. Reports show that between 44 percent and 96 percent of patients with implants using a medialized center of rotation have had notching.[34] The weighted average notching rates in reverse total shoulders is 68 percent.[34] Notching is classified into four grades: grade "one" being the least and grade "four" resulting in significant bone loss of the scapula (**Figure 21**).[34]

Figure 21: Notching Grade System



An Equinoxe study published in the British Bone and Joint Journal using the Equinoxe platform system reported a notching rate of only 13.2% and no notching above grade 2.[34] The reduction of notching can potentially affect the longevity of shoulder arthroplasty. A decreased risk of revision and/or failure will potentially translate into a decreased risk of surgery, and improved patient satisfaction results.

Outcomes

The Equinoxe total shoulder is the only platform stem currently on the market with published clinical outcomes. Previous sections documented cost savings with the use of the platform stem and cage glenoid. The Equinoxe System has been in use since 2004 and is the fastest growing shoulder on the market.[57] In a recent multicenter study in France, two surgeons treated 200 patients using an anatomic or reverse prosthesis with the Equinoxe implant.[35] This is the first ever head-to-head comparison of both anatomic and reverse arthroplasty. All patients demonstrated significant improvements in pain level and function. There were no reports of instability or glenoid loosing and only one instance of infection. Anatomic shoulders had better pain scores than reverse; however, reverse had a larger improvement from pre-op to post-op. As noted, both interventions had improvement in ASES and Constant scores and are compared on the following page (**Figures 22 and 23**).[35]

Figure 22: Improvement in ASES Outcome Score: aTSA vs. rTSA[35]

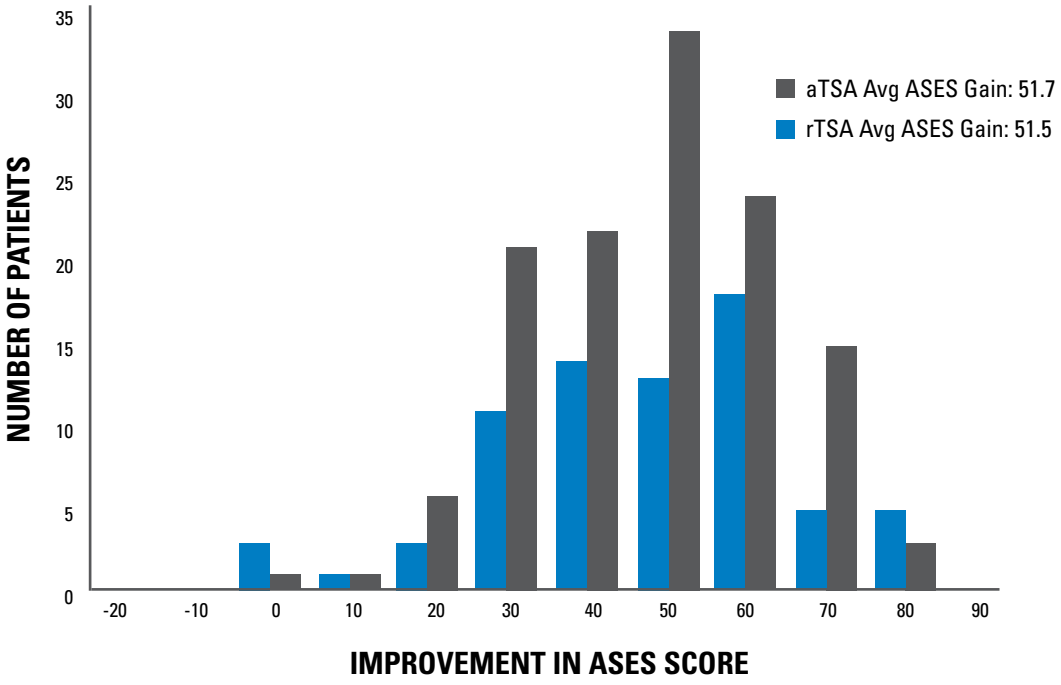
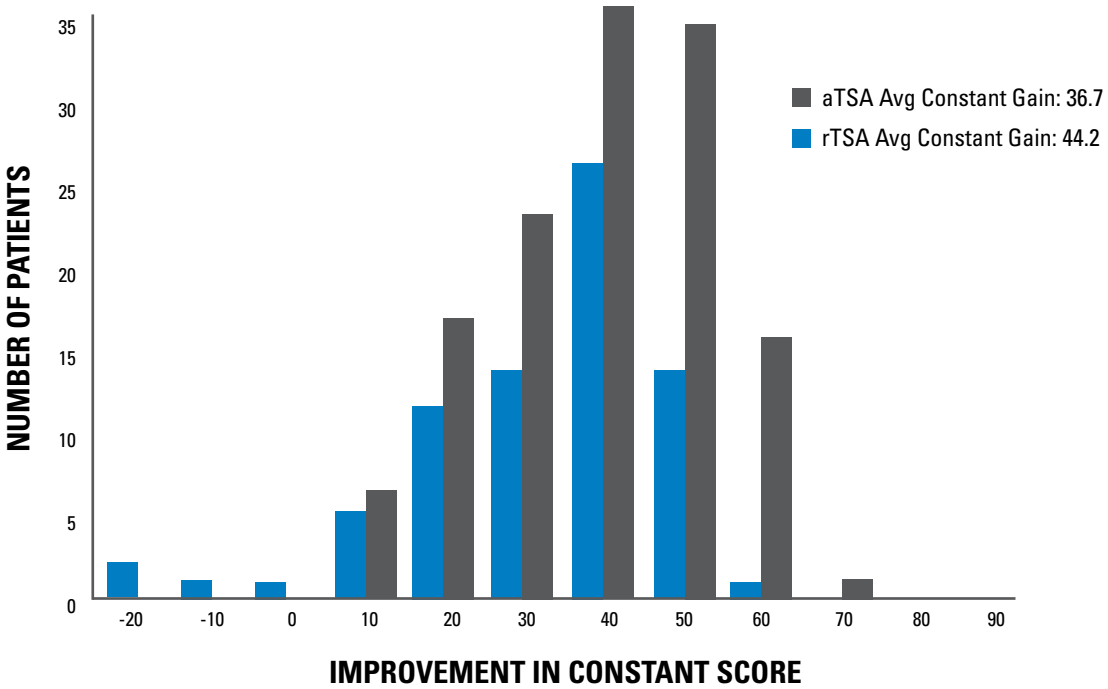


Figure 23: Improvement in Constant Outcome Score: aTSA vs. rTSA[35]



When comparing the results against previously reported literature. When dealing with reverse shoulders, one of the most significant challenges is restoring external rotation; in this study we observed an increase in external rotation when compared to previous literature (**Tables 3-6**).[35]

Table 3: Comparison of aTSA Outcome Scores Reported in Literature

STUDY	SAMPLE SIZE	AVG FOLLOW-UP (MONTHS)	PRE-OP AVG CONSTANT SCORE	POST-OP AVG CONSTANT SCORE	PRE-OP AVG ASES SCORE	POST-OP AVG ASES SCORE
Edwards 2003[1]	601	44.0	31.1	70.3	*	*
Orflay 2003[2]	37	51.6	*	*	37 (SSI)	91 (SSI)
Godeneche 2002[3]	251	30	28	71	*	*
Gartsman 2000[4]	27	35	*	*	22.7±14.4 (SSI)	77.3±18.2 (SSI)
Raiss 2012[5]	39	132	27	61	*	*
Walch 2011[6]	311	89.5	31.4±13.3	67.6[±17.6]	*	*
Present Study[35]	73	32.5±12.1	39.6±12.2	75.1±11.5	38.6±14.9	90.3±14.6

*denotes measurement not reported.

Table 4: Comparison of aTSA Shoulder Motion Data Reported in Literature

STUDY (DEGREES)	PRE-OP AVG ACTIVE FORWARD FLEXION	POST-OP AVG ACTIVE FORWARD FLEXION	PRE-OP AVG ACTIVE EXTERNAL ROTATION (ARM AT SIDE)	POST-OP AVG ACTIVE EXTERNAL ROTATION (ARM AT SIDE)
Edwards 2003[1]	91.2	144.5	7.2	41.5
Orflay 2003[2]	100	147	7	39
Godeneche 2002[3]	94	145	6	40
Gartsman 2000[4]	86	128	36 (arm in abduction)	61 (arm in abduction)
Raiss 2012[5]	84	133	11	35
Walch 2011[6]	94.9±28.2	146.6±27.1	9±16.4	35.3±19.5
Present Study[35]	115.1±31.7	157.3±18.2	1.2±17.3	37.3±16.7

Table 5: Comparison of rTSA Outcome Scores Reported in Literature

STUDY	SAMPLE SIZE	AVG FOLLOW-UP (MONTHS)	PRE-OP AVG CONSTANT SCORE	POST-OP AVG CONSTANT SCORE	PRE-OP AVG ASES SCORE	POST-OP AVG ASES SCORE
Sirveaux, 2004[7]	77	44	22.6 (4 to 50)	65.5 (34-85)	*	*
Werner, 2005[8]	44	38	29 (3 to 53) age adjusted	64 (10 to 100) age adjusted	*	*
Frankle, 2005[9]	60	33	*	*	34.3 (0 to 65)	68.2 (15 to 100)
Boileau, 2006[10]	42	40	17 (19% CI: 14 to 19)	58 (95% CI: 51 to 64)	*	*
Levigne, 2008[11]	337	47	23	58	*	*
Stechel, 2010[12]	59	48	15 (2 to 55)	55 (17 to 96)	*	*
Nolan, 2011[13]	71	24	27.5 (5 to 58)	61.8 (30 to 87)	26 (0 to 63)	76.1 (21 to 100)
Present Study[35]	127	30.8±8.0	300±11.5	74.2±8.6	35.2±10.8	86.7±10.1
*denotes measurement not reported.						

Table 6: Comparison of rTSA Shoulder Motion Data Reported in Literature

STUDY (DEGREES)	PRE-OP AVG ACTIVE FORWARD FLEXION	POST-OP AVG ACTIVE FORWARD FLEXION	PRE-OP AVG ACTIVE EXTERNAL ROTATION (ARM AT SIDE)	POST-OP AVG ACTIVE EXTERNAL ROTATION (ARM AT SIDE)
Sirveaux, 2004[7]	73	138	3.5	11.2
Werner, 2005[8]	42 (0 to 90)	100 (0 to 145)	17 (-20 to 70)	12 (-50 to 60)
Frankle, 2005[9]	55.0 (0 to 120)	105.1 (30 to 180)	12.0 (-15 to 45)	35.9 (5 to 60)
Boileau, 2006[10]	55 (95% CI: 47 to 63)	121 (95% CI: 111 to 131)	7 (95% CI: 1 to 13)	11 (95% CI: 5 to 16)
Levigne, 2008[11]	70	125	7	9
Stechel, 2010[12]	47	105	-9	19
Nolan, 2011[13]	61.2 (0 to 137)	121.3 (52 to 170)	13.8 (-35 to 60)	14.6 (-44 to 60)
Present Study[35]	85.0 ± 44.7	149.3 ± 16.9	4.5 ± 18.9	32.6 ± 13.6

Exactech Commitment

At a time when so much is changing in our industry, Exactech is holding strong to our focus on hospitals, surgeons and patient outcomes. Founded nearly 30 years ago by an orthopaedic surgeon and biomedical engineer, Exactech understands hospital and surgeon needs like no other company can. For us, it's all about working together, focusing on your clinical challenges, then engineering innovative solutions so surgeons can go work wonders. We call it the Exactech Experience. Our people are truly accessible and care about relationships. You can pick up the phone anytime and call our leadership, product managers or engineers with your thoughts or concerns. With us, you are truly heard.

Our goal is to be a partner in healthcare and operate a business that understands the cost and benefits of each intervention for the shoulder. We have designed this system with a unique understanding and commitment to shoulder surgery. We demonstrate this through our intense study of

Our people are truly accessible and care about relationships. You can pick up the phone anytime and call our leadership, product managers or engineers with your thoughts or concerns. With us, you are truly heard.

biomechanics of the shoulder, the unique design rationale that is focused on costly complications, and an understanding of how this reduction will support your financial goals.

Thank you for considering the Equinoxe Shoulder System. See the next page for additional resources that are available for better understanding of our system and commitment.

Resources

- **Exactech website:** This website is designed for both patients and medical professionals. Surgeons can find detailed product information and patients/caregivers can find high level information about treatment and disease. ***www.exac.com***
- **Medical education for surgeons:** Exactech invests in the education of medical professionals, demonstrated by the recent Shoulder Master's course in Brazil and Italy - a simultaneous intercontinental course that included live surgery, panel debate and biomechanical insight into shoulder surgery from a world renowned faculty 60. ***http://www.exac.com/medical-professionals/medical-education***
- **Operative techniques:** ***www.exac.com/shoulderoptechs***
- "**Exactech2go" app:** An app that provides techniques, white papers, videos and more. ***www.Exactech2go.com***
- **Vumedi channel:** This section includes videos and presentations of techniques and cutting edge research in shoulder surgery. ***http://www.vumedi.com/channel/exactech-2/***
- **Biomechanics animation on Exactech YouTube page:** In our commitment to educate medical professionals and patients, Exactech has released a biomechanic animation to provide a deeper understanding of shoulder surgery. ***www.youtube.com/exactechinc***
- **Surgeon visitation sites:** Exactech encourages surgeon to surgeon learning, and there are many opportunities to gain experience by visiting leaders in shoulder arthroplasty across the country.

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*_In vitro_ (bench) test results may not necessarily be indicative of clinical performance.
**These are the results of the cited study. Individual results may vary.

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