SCIENTIFIC & CLINICAL EVIDENCE

A collection of long-term outcome studies highlighting the clinical success of the Equinoxe® Platform Shoulder System.

equinoxe®

FULL ARTICLES

exactech

This year, 2022, commemorates the 20th anniversary of our collaboration with Exactech to develop the Equinoxe® Platform Shoulder System.

From the beginning, our focus has been on solving unmet clinical needs and improving clinical outcomes with shoulder arthroplasty. We're proud of that collaboration and of all the innovations that we have helped develop in our partnership with the excellent and devoted team of engineers, designers, sales and marketing professionals at Exactech. We would also like to thank each of our clinical data centers around the world for their tireless effort diligently following our patients and documenting their results.

The first product we developed was the Equinoxe anatomical total shoulder arthroplasty system, which, as the first 4th generation shoulder system, remains, "Anatomic. Redefined." We launched this new shoulder with the first surgery in Gainesville, Fla., on Nov. 17, 2004, and enrolled that patient into the Equinoxe clinical database…but more on that later.

Our next major product launch occurred on March 30, 2007, with the first implantation of our reverse total shoulder system. With this innovative new product, we demonstrated that it was possible to minimize scapular notching while simultaneously lateralizing the humerus with an onlay design[1,2] to maintain Dr. Grammont's efficient deltoid moment arm and achieve more anatomic deltoid wrapping,[3-6] all while popularizing the platform humeral stem[7] to facilitate revisions from aTSA to rTSA. The Equinoxe rTSA system is one of the most common reverse shoulders implanted worldwide and has been used to treat almost 150,000 patients.

While we are proud of all these innovations, perhaps what we are most proud of is to have worked with Exactech these past 20 years to establish the Equinoxe clinical outcomes database, which has grown to become the world's largest database of a single shoulder arthroplasty system. As of the summer of 2022, we have enrolled more than 15,000 Equinoxe patients at more than 40 different clinical sites in the U.S. and Europe.

The clinical data from the Equinoxe clinical database has been used in more than 100 peer-reviewed clinical publications, and these papers have been cited extensively in the orthopaedic literature. Additionally, this clinical evidence is the foundation for Exactech's medical education program, including the annual Equinoxe Masters Course in Shoulder Arthroplasty, which is now in its second decade. Furthermore, this clinical evidence has helped guide product development, facilitating continuous improvement of our shoulder products and helping us to identify new areas of need.

As evidence of the commitment to clinical research that we share with Exactech, this compilation of four original retrospective studies recently submitted for presentation at the 2023 Orthopedic Research Society highlights the long-term clinical success of the Equinoxe System.

We hope that you will find these original long-term clinical studies interesting and above all useful for your daily practice. Thank you for your trust and your support for the Equinoxe and its entire community of enthusiasts who have accompanied us for more than 20 years.

Sincerely,

Pierre-Henri Flurin, MD
Thomas W. Wright, MD
Joseph D. Zuckerman, MD

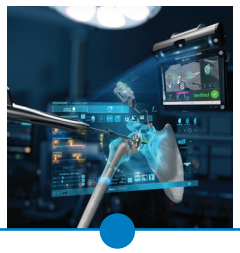
Innovations that have further improved the art of shoulder arthroplasty:

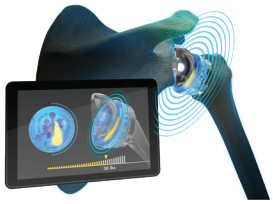
2011
rTSA glenoid augments

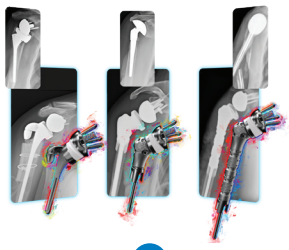
2012
rTSA prosthesis design classification system[4,5,8]

2014
ASTM standard for rTSA glenoid loosening

2015
Expanding the indications of rTSA with the Humeral Reconstruction Prosthesis to address proximal humeral bone loss







2016

GPS Shoulder – the first platform shoulder navigation system

2020

VERASENSE™ Wireless Humeral Load Sensor for rTSA, in partnership with OrthoSensor (2020) - the first commercially available load sensor in the shoulder

Predict+®, in partnership with KenSci (2020) - the first machine learning-based clinical decision support tool for the shoulder

2021

Humeral Augmented Tray (2021) – the first rTSA to address posterior proximal humeral bone loss by facilitating metallic replacement of the tuberosity

Comparison of Survivorship & Failure Modes Between Anatomic and Reverse Total Shoulder Arthroplasty Across Multiple Government Joint Registries for a Single Platform Shoulder System

Christopher Roche, MSE, MBA; Pierre-Henri Flurin, MD; Thomas W Wright, MD; Joseph D Zuckerman, MD

INTRODUCTION

The safety and efficacy of shoulder arthroplasty is well-established in the orthopaedic literature as a successful treatment option for a variety of degenerative condition of the glenohumeral joint. Historically, anatomic total shoulder arthroplasty (aTSA) has been used to treat osteoarthritis (OA) and reverse total shoulder arthroplasty (rTSA) has been used to treat rotator cuff tear arthropathy (CTA) and OA in combination with rotator cuff tears. However, recent years has seen a dramatic shift in utilization of rTSA, as it is increasingly used to treat OA in patients with an intact rotator cuff, with a corresponding decline in use of aTSA. The reasons for this shift in usage are multi-factorial, but may be due to the perceived lower risk of revision surgery associated rTSA relative to aTSA, as the quality of the rotator cuff muscles and tendon are not necessary for a functional rTSA but are pre-requisite for a functional aTSA. In order to better understand the relative differences in primary aTSA and primary rTSA usage and performance, we analyzed 2 different government joint registries for survivorship and failure modes associated with one platform shoulder system and compared usage of aTSA and rTSA over-time.

METHODS

A review of the United Kingdom (UK) and Australian national joint registries was performed for a single shoulder prosthesis from 2011 to 2021 to investigate changes in annual usage of primary aTSA and primary rTSA relative to differences in survivorship and reasons for revision for each prosthesis type. Annual enrollment between 2011 and 2021 for primary aTSA and primary rTSA patients were quantified and compared between prosthesis type and between government joint registries to assess changes in prosthesis utilization for treatment of primary shoulder arthroplasty patients in each market. Additionally, reasons for revision and the cumulative revision rate were assessed across the government joint registries to quantify and compare the performance of this platform shoulder prosthesis for primary aTSA and primary rTSA applications.

RESULTS

Between 2011 and 2021, 612 primary aTSA (95.8% OA; 303M/309F) and 3,786 primary rTSA (51.8% OA & 35.6% CTA; 1617M/2169F) procedures were performed in Australia by 162 surgeons in 148 different hospitals and 1,307 primary aTSA (92.1% OA; 423M/884F) and 3,431 primary rTSA (41.5% OA & 50.8% CTA; 950M/2,481F) procedures were performed in the UK by 232 surgeons in 143 different hospitals using the same platform shoulder prosthesis. Over the 10-year period of analysis, use of primary aTSA and primary rTSA with the platform system analyzed in this study has increased substantially in both Australia and the UK. Specifically in Australia, primary aTSA usage has grown annually by an average of 39.8% while primary rTSA usage has grown annually by 150.7%. Similarly in the UK, primary aTSA usage has grown annually by an average of 44.0% while primary rTSA usage has grown annually by 74.6%. However, as described in Figure 1, the utilization of shoulder arthroplasty in both markets has continuously shifted towards more rTSA since 2012, such that by 2020, 90% of shoulder arthroplasty patients in Australia and 80% of patients in the UK received rTSA with this platform shoulder system.

Over the past decade, the overall occurrence rate of revisions with aTSA and rTSA has been similar, where 97 of 1,919 primary aTSA (5%) and 204 of 7,217 primary rTSA (2.8%) with this specific platform shoulder prosthesis have been revised. However, as described in Figure 2, the average 8-year cumulative revision rate for primary aTSA patients was higher than that for primary rTSA patients, where 8.8% of aTSA patients were revised at 8 years (1.1% revised/year) but only 4.1% of primary rTSA patients were revised at 8 years (0.5% revised/year). The

trend for greater revisions with aTSA than rTSA was observed across the UK and Australian registries when all shoulder devices were considered, not just the single platform shoulder system analyzed in this study. Figure 3 describes the reasons for revision with primary aTSA and primary rTSA patients. The two most common reasons for primary aTSA revisions are both soft-tissue related: rotator cuff tears/subscapularis failure (n=28) and instability/dislocations (n=19), which account for approximately half of all aTSA revisions. The next most common reason for aTSA revisions is glenoid loosening (n=15), followed by infection (n=9). 4 surgical/technique errors were also reported as the cause of aTSA revision: incorrect sizing (n=3) and implant malpositioning (n=1). The most common reason for primary rTSA revision is infection (n=80), followed by instability/dislocation (n=52), then glenoid/humeral loosening (n=23), and humeral fractures (n=22). 3 surgical/technique errors were also reported as the cause of rTSA revision: implant malpositioning (n=2) and incorrect sizing (n=1). Notably, 0 revision cases out of 9,136 patients were reported for either primary aTSA or primary rTSA patients due to lysis and/or polyethylene wear.

DISCUSSION

The results of this large-scale, 10-year multi-country registry analysis of 9,136-primary shoulder arthroplasty patients with the same platform system yielded several important findings. Most significantly, the 8-year cumulative revision rate associated with this platform shoulder system is low for both primary aTSA and primary rTSA patients. However, we did observe a difference in revision rate between prosthesis types, where specifically, the 8-year cumulative revision rate with primary rTSA was less than half the 8-year cumulative revision rate of primary aTSA. The most notable difference in revision failure modes between primary aTSA and primary rTSA patients was that rTSA patients experienced zero cases of revision due to rotator cuff tears/ subscapularis failure. It should be noted that this soft-tissue quality related failure mode was the most common aTSA failure mode, and was responsible for 28 of 97 (29%) aTSA revisions since 2011. The elimination of this failure mode with rTSA is the main difference in the revision rate between prosthesis types and this factor is likely the predominant driver for the dramatic shift in utilization towards rTSA that was observed in this analysis for each market since 2012. The use of rTSA has grown so dramatically in each market over the study period that in 2020 and 2021, 90% of primary shoulder arthroplasty patients in Australia and 80% of patients in the UK received rTSA with this specific platform shoulder system. Relative to the hip and knee arthroplasty literature, it is interesting that a 10-year study of 9,136 shoulder arthroplasty patients reported 0 cases of revision due to lysis and/or polyethylene wear. Clearly the failure modes associated with shoulder arthroplasty are different than that of hip and knee arthroplasty – best explained as both aTSA and rTSA joint loading is unrelated to gait, and those loads are of lower load magnitudes and lower frequency relative to weight-bearing, large joint arthroplasty applications.

This study has several limitations. First, our registry analysis only permitted a comparison of revision rates between 2 different prosthesis types of the same shoulder system, reasons for revision are almost always multi-factorial and those details may not be considered when analyzed in aggregate. Second, while the relative risk of revision is an important consideration of prosthesis performance, it does not completely describe a patient's clinical outcome. Future work is required to compare differences in functional outcomes, range of motion, pain, and patient reported outcome measures between aTSA and rTSA prosthesis types. Furthermore, as rTSA usage continues to grow and indications for aTSA and rTSA begin to over-lap, it is important that clinical outcomes for like-diagnoses (like OA with an intact rotator cuff) be directly-compared, as different diagnoses may have different potential for improvement. Third, while some patient demographic, diagnosis, and comorbidity information was available in the registries, these registries did not specifically stratify that data for patients with revisions, so it is currently unknown if patients with revisions had any unique demographic, diagnosis, or comorbidity risk factor that may have pre-disposed failure. Finally, case-specific information related to surgical technique and implant position is limited, however, 4 cases of aTSA revision and 3 cases of rTSA revision were implied to be surgeon-induced (i.e. "incorrect size" and "malpositioning").

SIGNIFICANCE

In conclusion, this study demonstrated a dramatic shift in utilization of primary rTSA relative to primary aTSA in two different markets over the past decade. Our comparative analysis of failure modes and survivorship demonstrate low rates of failure for both aTSA and rTSA with one specific platform shoulder prosthesis, but also identified that rTSA patients had a lower revision rate and where not susceptible to the most common failure mode of aTSA: rotator cuff tears/subscapularis failure, potentially explaining the reason why so many more primary patients are now being treated with rTSA.

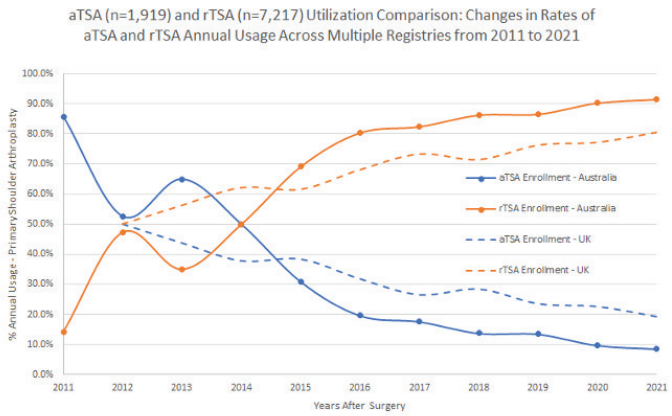


Figure 1. Comparison of Primary aTSA & Primary rTSA Annual Usage Across the UK and Australian National Joint Registries for a Single Platform Shoulder Prosthesis, 2011 to 2021

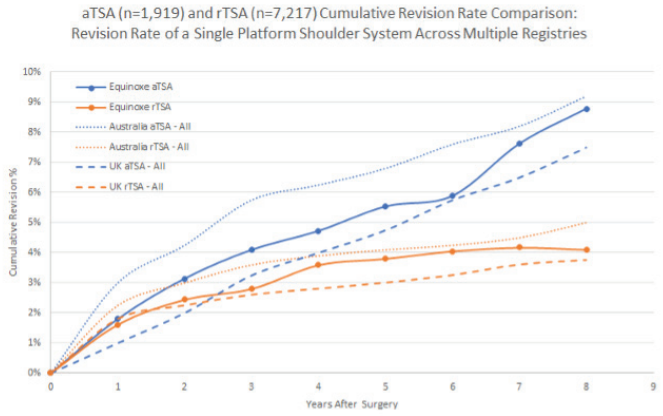


Figure 2. Combined UK and Australian National Joint Registry Comparison of Cumulative Revision Rate from 2011-2021 for a Single Platform Shoulder Prosthesis: Primary aTSA (n=1,919) vs. Primary rTSA (n=7,217)

Reasons for Revision	Primary aTSA (n=97 Revisions)	% Primary aTSA (n=1,919 Cases)	Primary rTSA (n=204 Revisions)	% Primary rTSA (n=7,217 Cases)
Rotator Cuff Tears/Subscapularis Failure	28	1.5%	1	0.0%
Instability/dislocation	19	1.0%	52	0.7%
Loosening	15	0.8%	23	0.3%
Infection	9	0.5%	80	1.1%
Implant Fracture	4	0.2%	0	0.0%
Implant Disassociation	0	0.0%	2	0.0%
Pain	1	0.1%	0	0.0%
Incorrect size	3	0.2%	1	0.0%
Malpositioning	1	0.1%	2	0.0%
Lysis/Poly Wear	0	0.0%	0	0.0%
Arthrofibrosis	2	0.1%	0	0.0%
Humeral fracture	1	0.1%	22	0.3%
Metal Related Pathology	0	0.0%	1	0.0%
Other	14	0.7%	20	0.3%

Figure 3. Comparison Primary aTSA & Primary rTSA Reasons for Revision Across the UK and Australian National Joint Registries for a Single Platform Shoulder Prosthesis

Longitudinal Analysis of Shoulder Arthroplasty Clinical Outcomes and Value: a Comparative Assessment of Changes in Improvement Over 15 Years

Christopher Roche, MSE, MBA; Richard Jones, MD; Howard Routman, DO; Yann Marczuk, MD; Pierre-Henri Flurin, MD; Thomas W. Wright, MD; Joseph D Zuckerman, MD.

INTRODUCTION

The past 20 years has seen a dramatic increase in the utilization of shoulder arthroplasty. However, there are few examples in the literature quantifying and comparing the value associated with anatomic total shoulder arthroplasty (aTSA) and reverse total shoulder arthroplasty (rTSA). The goal of this study is to conduct a controlled longitudinal analysis of aTSA and rTSA outcomes and implant cost from 2007 to 2021 to quantify changes in value, as measured by the ratio of outcomes and cost.

METHODS

An international database of a single platform shoulder arthroplasty prosthesis was analyzed for all clinical sites that have continuously enrolled cases from 2007 to 2021. To compare primary aTSA and primary rTSA clinical outcomes, we segmented patients into 3, 5-year cohorts based upon the date of implantation: 2007-2011, 2012-2016, and 2017-2021. Clinical outcomes were compared across the 5-year implantation cohorts to identify differences at defined post-operative intervals. Patients were evaluated pre-operatively and post-operatively using the SST, UCLA, ASES, Constant, and SAS scoring metrics; and using VAS pain and global shoulder function. Range of motion was quantified for active abduction, forward elevation, and internal/external rotation Revision rates were also analyzed. Finally, a value analysis was conducted for primary aTSA and primary rTSA patients across the 5-year implantation cohorts, with value measured by the ratio of each 2-3 year post-operative outcome measure and the average implant selling price each year for the US sites in constant 2007 US dollars. A Student's t-test was used to identify differences between continuous variables between 5-year cohorts and a Wilcoxon-rank-sum test was used to identify differences between ordinal variables.

RESULTS

Six clinical sites (4 in the US and 2 in France) were identified that continuously enrolled shoulder arthroplasty patients from 2007 to 2021. Primary aTSA and primary rTSA patients were segmented and compared based upon the date of implantation: 2007-2011 (aTSA: n=457; rTSA: n=507), 2012-2016 (aTSA: n=694; rTSA: n=1326), and 2017-2021 (aTSA: n=367; rTSA: n=1617). Primary aTSA patients over the past 10 years are significantly younger than aTSA patients from 2007-2011, and these patients are increasingly being treated for predominately OA diagnosis, with a significant decline in treatment of RA diagnosis and also in patients with inflammatory arthritis over the past 10 years. By comparison, primary rTSA patients over the past 5 years are significantly younger and also less predominately female as compared to rTSA patients from 2007-2011. Primary rTSA patients are increasingly being treated for predominately OA diagnosis, with a significant decline in usage for rotator cuff tear arthropathy diagnosis and also in patients with inflammatory arthritis over the past 10 years. Additionally, primary rTSA patients are increasingly being used in patients with less comorbidities. The functional status of primary aTSA and primary rTSA patients have also changed over the 15-year study period. For nearly every measure, patients over the past 5 and 10 years have more motion, more function, and higher clinical scores prior to surgery than patients in 2007-2011. After surgery, both primary aTSA (Figure 1) and primary rTSA (Figure 2) patients over the past 5 to 10 years generally have the same or better motion and clinical outcome scores at most post-operative timepoints as compared to patients from 2007-2011. Specifically at 2-3 years after surgery, primary aTSA patients since 2012 have significantly greater forward elevation and external rotation and also significantly more strength and a significantly higher Constant score than aTSA patients from 2007-2011. Similarly, primary rTSA patients since 2017 have significantly greater abduction and external rotation and also significantly more strength and a significantly higher Constant score than rTSA patients from 2016 and before. No significant differences in the revision rate were observed for aTSA patients 2 years after surgery across the 3 implantation cohorts

(2007-2011: 3.7%, 2012-2016: 3.7%, 2017-2021: 4.6%) or for rTSA patients 2 years after surgery across the 3 implantation cohorts (2007-2011: 1.8%, 2012-2016: 2.6%, 2017-2021: 1.8%).

Regarding value, the average selling price associated with primary aTSA and primary rTSA patients at the US sites analyzed in this study as well as value 2-3 years after surgery is compared between the 3, 5-year implantation cohorts in Figure 3. Comparing the average selling price of primary aTSA and primary rTSA implants demonstrates that primary aTSA implants have been less expensive than primary rTSA implants over the study period. When accounting for inflation, the average selling price of aTSA implants has been relatively stable at about $5,000 in constant 2007 US dollars over the 15-year period of analysis despite the introduction of new aTSA implant technology like augmented hybrid glenoids and 3D printed stemless humeral components. However, the average selling price of rTSA implants has significantly declined, decreasing by 15% across the 3, 5-year cohorts in constant 2007 US dollars. As a result, value, as measured by the ratio of each post-operative outcome measure and the average annual US implant cost for the 4 US sites, significantly increased over the 15-year period of analysis for primary rTSA patients for nearly every outcome measure. In comparison, value remained relatively constant for primary aTSA patients, though a few significant differences were observed. However, it is interesting to note that the magnitude of the value associated with aTSA is greater than that for rTSA for each outcome measure, regardless of the implantation timepoint.

DISCUSSION

Our longitudinal analysis of shoulder arthroplasty clinical outcomes and value at 6 high-volume clinical sites who continuously enrolled patients from 2007 to 2021 identified many interesting findings. First and foremost, our results demonstrate that primary aTSA and primary rTSA patients have achieved positive clinical outcomes that have been sustained over the 15-year period of analysis, irrespectively of the year in which the procedure was performed. Second, our results demonstrate the increasing utility of rTSA, whose use has dramatically increased over the study period. rTSA is now the dominate shoulder arthroplasty procedure at each of the 6 sites. Third, both primary aTSA and primary rTSA clinical outcomes are steadily improving with no changes in the revision rate, where patients who received shoulder arthroplasty more recently have generally better motion and higher clinical outcome scores at most post-operative timepoints relative to patients who received their arthroplasty between 2007-2011. Finally, our results demonstrate that value, as measured across multiple patient-focused dimensions, including active range of motion, pain, function, and PROMs, has continuously increased for primary rTSA patients and has been maintained at a high-level for aTSA patients over a 15-year period of analysis.

The observation that aTSA and rTSA outcomes are generally improving with implantation time is encouraging, especially considering the rapid adoption of new technologies that have occurred over the study period across the 6 clinical sites. The increase in value associated with rTSA across each of the outcome measures was driven primarily by a decline in implant selling price with a corresponding introduction of new implant technologies, such as augmented glenoid baseplates, short plasma-coated humeral stems, CT-based pre-operative planning, and intra-operative surgical navigation. One of the more interesting findings is that the relative value of primary aTSA is greater than that of primary rTSA, regardless of implantation time. These findings are increasingly relevant as the indications for rTSA continue to expand to include OA, the typical indication for aTSA. However, it should be noted that rTSA patients were observed to have a lower revision rate than aTSA patients and the cost of revision surgery was not considered in our value assessment. Future work should analyze value in aTSA and rTSA patients with the same indications and also for patient populations with an elevated risk for complications.

SIGNIFICANCE

In conclusion, our 1,518 aTSA and 3,450 rTSA longitudinal analysis of shoulder arthroplasty outcomes and value across 6 clinical sites from 2007 to 2021 demonstrated positive clinical results irrespectively of the year in which the procedure was performed. Moreover, both primary aTSA and primary rTSA clinical and radiographic outcomes are steadily improving relative to patients who received their arthroplasty between 2007-2011. These clinical improvements, in combination with steady aTSA and declining rTSA implant prices, have driven rTSA value to continuously increase while aTSA value has been maintained at a high-level over a 15-year period of analysis, even when considering the cost and adoption of new technologies.

Figure 1. Comparison of Primary aTSA Outcomes at Various Post-operative Follow-up Intervals Across the 3, 5-year Implantation Cohorts, Top Left = Average Active Forward; Top Right = Average Active External Rotation, Middle Left = Average VAS Pain; Middle Right = Average Constant Score; Bottom Left = Average ASES Score; and Bottom Right = Average SAS score

Figure 2. Comparison of Primary rTSA Outcomes at Various Post-operative Follow-up Intervals Across the 3, 5-year Implantation Cohorts, Top Left = Average Active Forward; Top Right = Average Active External Rotation, Middle Left = Average VAS Pain; Middle Right = Average Constant Score; Bottom Left = Average ASES Score; and Bottom Right = Average SAS score

	Average Implant Selling Price (2007 USD)	Active Abduction	Active Forward Elevation	IR Score	Active External Rotation	VAS Pain	Global Shoulder Function	SST	Constant	ASES	UCLA	SAS
aTSA 2007-2011	$4,998	26.7 ± 6.9	29.8 ± 7.1	1.1 ± 0.3	10.0 ± 4.0	0.6 ± 1.0	1.8 ± 0.5	2.3 ± 0.5	14.8 ± 3.6	17.8 ± 4.6	6.6 ± 1.4	16.8 ± 3.5
aTSA 2012-2016	$5,141	24.6 ± 6.0	28.6 ± 5.1	1.0 ± 0.3	10.8 ± 3.6	0.2 ± 0.4	1.7 ± 0.3	2.1 ± 0.4	14.3 ± 2.4	17.1 ± 3.4	6.2 ± 0.9	16.1 ± 2.2
aTSA 2017-2021	$5,079	25.3 ± 6.0	30.5 ± 5.9	1.1 ± 0.3	11.7 ± 3.8	0.3 ± 0.4	1.7 ± 0.4	2.1 ± 0.5	15.0 ± 2.7	17.3 ± 4.2	6.3 ± 1.2	16.7 ± 2.8
P Value (2007-11 vs. 2012-16)	**0.0005**	**0.0002**	**0.0212**	**0.0002**	**0.0280**	**<0.0001**	**0.0011**	**<0.0001**	0.0925	**0.0443**	**<0.0001**	**0.0034**
P Value (2007-11 vs. 2017-21)	0.1397	0.0674	0.4046	0.4940	**0.0003**	**0.0002**	0.0880	**0.0006**	0.5805	0.3319	0.0713	0.8394
P Value (2012-16 vs. 2017-21)	**0.0048**	0.3205	**0.0015**	**0.0218**	**0.0149**	0.1644	0.6246	0.7818	**0.0227**	0.6570	0.2377	**0.0146**
rTSA 2007-2011	$8,558	12.3 ± 2.8	16.3 ± 3.2	0.6 ± 0.2	3.7 ± 1.7	0.1 ± 0.2	0.9 ± 0.2	1.2 ± 0.3	8.0 ± 1.6	9.9 ± 1.9	3.6 ± 0.6	9.0 ± 1.4
rTSA 2012-2016	$8,068	14.6 ± 3.7	17.1 ± 3.4	0.5 ± 0.2	4.5 ± 2.3	0.2 ± 0.3	1.0 ± 0.2	1.2 ± 0.3	8.5 ± 1.8	10.2 ± 2.3	3.7 ± 0.7	9.3 ± 1.6
rTSA 2017-2021	$7,302	16.4 ± 3.7	18.9 ± 3.4	0.6 ± 0.3	5.5 ± 2.4	0.2 ± 0.3	1.1 ± 0.3	1.4 ± 0.3	9.4 ± 1.9	11.2 ± 2.5	4.1 ± 0.7	10.3 ± 1.6
P Value (2007-11 vs. 2012-16)	**<0.0001**	**<0.0001**	**0.0008**	0.0780	**<0.0001**	**0.0051**	**0.0046**	0.1925	**0.0007**	0.0669	**0.0031**	**0.0254**
P Value (2007-11 vs. 2017-21)	**<0.0001**	**<0.0001**	**<0.0001**	**0.0066**	**<0.0001**	**0.0004**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**
P Value (2012-16 vs. 2017-21)	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	0.2110	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**

Figure 3. Comparison of "Value" Between 5 Year Cohorts: Average Ratio of Post-operative Outcomes and Implant Cost (in thousands of 2007 US Dollars) for Primary aTSA and Primary rTSA Patients at 2-3 years Follow-Up

Clinical and Radiographic Outcomes of Three Different Glenoid Designs with Anatomic Total Shoulder Arthroplasty at Short-Term, Mid-Term, and Long-Term Follow-up

Richard J Friedman, MD, FRCSC; Marissa L Boettcher, BS; Sean Grey, MD; Pierre-Henri Flurin, MD; Thomas W Wright, MD; Joseph D Zuckerman, MD; Josef K. Eichinger, MD; Christopher Roche, MSE, MBA

INTRODUCTION

Anatomic Total Shoulder Arthroplasty (aTSA) is an effective treatment solution for glenohumeral osteoarthritis; however, there is some debate regarding which glenoid implant design is associated with the best results. The purpose of this study is to compare the clinical and radiographic aTSA outcomes at short-term, mid-term, and long-term follow-up for three different glenoid designs: 1) hybrid cage, 2) cemented peg, and 3) cemented keel glenoid.

METHODS

1,802 aTSA patients (981 cage, 527 peg, and 294 keel) with 2-year minimum follow-up (mean 61 months) were analyzed in this study. Patients were evaluated pre-operatively and at multiple post-operative timepoints for shoulder function, pain, active range of motion, and clinical outcome scores. Adverse events and revisions were also recorded. Finally, patients were radiographically evaluated at each post-operatively timepoint for the presence and magnitude of radiolucent glenoid and humeral lines.

RESULTS

Prior to surgery, patients with keel glenoids had a significantly higher percentage of female patients than peg (64% vs. 53%, p=0.0046) and cage (64% vs. 52%, p=0.0004) glenoids. Patients with cage glenoids were significantly younger at the time of surgery than peg (66 years vs. 67 years, p=0.0008) and keel (66 years vs. 67 years, p=0.0271) glenoids, had a significantly greater percentage of patients with osteoarthritis than peg (96% vs. 93%, p=0.0060) and keel (96% vs. 88%, p<0.0001) glenoids, and had a significantly greater percentage of patients having previous shoulder surgery than peg (19% vs. 13%, p=0.0028) and keel (19% vs. 10%, p=0.0001) glenoids. Patients with cage glenoids generally had significantly higher clinical scores and active motion prior to surgery as compared to both peg and keel glenoids. Patients with peg glenoids had significantly more comorbidities than keel glenoid and cage glenoid patients, including having a significantly greater amount of inflammatory arthritis (peg vs. keel, 18% vs. 8%, p=0.0050; peg vs. cage, 18% vs. 11%, p=0.0040) and heart disease (peg vs. keel, 18% vs. 10%, p=0.0083; peg vs. cage, 18% vs. 14%, p=0.0265, respectively). Patients with peg glenoids also had significantly greater preoperative retroversion than keel (10.8 vs. 5.6, p=0.0001) and cage (10.8 vs. 6.6, p<0.0001) glenoid patients.

To compare clinical outcomes more directly by glenoid type and understand if outcome scores are maintained over the follow-up duration, we analyzed and compared outcomes by glenoid type at different post-operative intervals of 2-3 years, 3-5 years, 5-8 years, 8-10 years, and 10+ years. The UCLA (Figure 1A), ASES (Figure 1B), Constant (Figure 1C), and SAS (Figure 1D) scores are graphically presented at each short-term, mid-term, and long-term follow-up timepoint. At latest follow-up, clinical outcomes, pain, function, and active range of motion at latest follow-up are compared between the three glenoid types. Cage glenoid patients had significantly higher outcome scores for each of the UCLA, ASES, Constant, and SAS scores compared to both peg and keel glenoid patients (all p<0.0001). 53% of cage glenoid patients achieved a 100-point ASES score, which was significantly greater (p<0.0001) than the 30% of keel glenoid patients who achieved a ceiling ASES score and significantly greater (p<0.0001) than the 32% of peg glenoid patients who achieved a ceiling ASES score. Additionally, cage glenoid patients had significantly higher global shoulder function (cage vs. peg, 8.6 vs. 7.8, p<0.0001; cage vs. keel, 8.6 vs. 7.8, p<0.0001), significantly less pain (cage vs. peg, 1.1 vs. 1.9, p<0.0001; cage vs. keel, 1.1 vs. 1.6, p=0.0002), and significantly higher active range of motion for all measures (expect internal rotation for just keel patients), compared to both peg and keel glenoid patients. Keel glenoid patients had significantly higher outcomes scores than peg patients for the UCLA (p=0.0004), Constant (p=0.0031), and SAS scores (p=0.0008), and had significantly more active forward elevation than peg glenoid patients (p<0.0001).

There were 181 reported complications which resulted in 106 revisions. Cage glenoids had significantly fewer complications (7.4%) and revisions (3.5%) than peg (13.1% complications, p=0.0003; 9.7% revisions, p<0.0001) and keel (13.3% complications, p=0.0019; 7.1% revisions, p=0.0065) glenoids. No difference in complication rate or revision rate was observed between cemented peg and keel glenoids. Aseptic glenoid loosening was the most common complication and was reported in 53 patients: 11 cage glenoid patients (1.1%), 17 keel glenoid patients (5.8%), and 25 peg glenoid patients (4.7%). Irrespective of glenoid design, aseptic glenoid loosening/glenoid failure occurred most commonly in B3 glenoids (14.3%) and least commonly in A1 (2.5%), C (0%), and D (0%) glenoids; however, patients with C (0.5%) and D (1.0%) glenoids were rarely seen and patients with A1 (48.7%) glenoids were most common. While cage glenoids had a significantly lower complication rate, revision rate, and aseptic glenoid loosening rate than peg and keel glenoids, cage glenoids were observed to experience a unique failure mode of articular surface disassociation from the titanium pegs due to failure of the locking mechanism, which occurred in 13 of 981 patients for a rate of 1.3%. This disassociation failure occurred in 8 female and 5 male patients at an average time of 52 months (range: 12-102 months). Cage glenoid patients had a significantly lower glenoid RLL rate than peg (9.9% vs. 51%, p<0.0001) and keel (9.9% vs. 37%, p<0.0001) glenoids. Figure 2 illustrates the impact of follow-up duration on the formation of RLL for each glenoid type. The presence of glenoid RLL resulted in significantly worse outcomes as compared to patients without glenoid RLL, for each glenoid design.

DISCUSSION

The results of this 1,802 aTSA patient study demonstrate significant improvements in pain and function for all 3 glenoid designs analyzed, from short-term to long-term follow-up. Some differences in outcomes between glenoid types were observed. Cage glenoid patients experienced significantly higher outcome scores, active range of motion, and less pain, and significantly lower rates of radiolucent glenoid lines, aseptic glenoid loosening, and revisions as compared to patients with cemented peg and keel glenoids. These findings provide greater evidence to suggest that hybrid glenoids are associated with superior clinical outcomes compared to cemented peg glenoids. Regarding revision surgery, cage glenoid patients were significantly less likely to require a revision than both peg and keel glenoid patients. Specifically, 7.4% of cage glenoid patients had a complication and 3.5% were revised or had a reoperation; however, it is important to note that the indication for reoperation differed between the glenoid cohorts. Patients with cage glenoids had a unique failure mode of poly-disassociation. This modular junction failure occurs due to malalignment/malpositioning when preparing the central and peripheral peg glenoid holes. Any angular divergence and/or positional deviation between drilled glenoid holes and the implant pegs, during impaction of the press-fit central peg, can cause the peripheral pegs to bend/splay as the implant is seated, which can ultimately lead to modular locking mechanism failure and articular surface dissociation. While rare, this failure mechanism highlights the importance of adequate glenoid exposure and proper surgical technique. Despite low rates of glenoid RLL with this hybrid device, it is unclear if this will decrease the incidence of aseptic glenoid loosening in the long-term, but our results, even when considering the poly-disassociation failure mode, support the ongoing use of this hybrid device.

SIGNIFICANCE

In conclusion, aTSA is demonstrated to be a reliable treatment solution for glenohumeral arthritis using all 3 glenoid designs analyzed in this study, from short-term to long-term follow-up. When compared to gold-standard cemented peg or keeled glenoid designs, the hybrid cage design was associated with significantly better outcome scores, range of motion, and pain reduction, as well as significantly lower rates of glenoid radiolucent lines, aseptic glenoid loosening, complications, and the need for revision. These results support the ongoing clinical use of hybrid glenoids, but even longer-term clinical follow-up is required given the rare but unique disassociation failure mode of these modular devices.

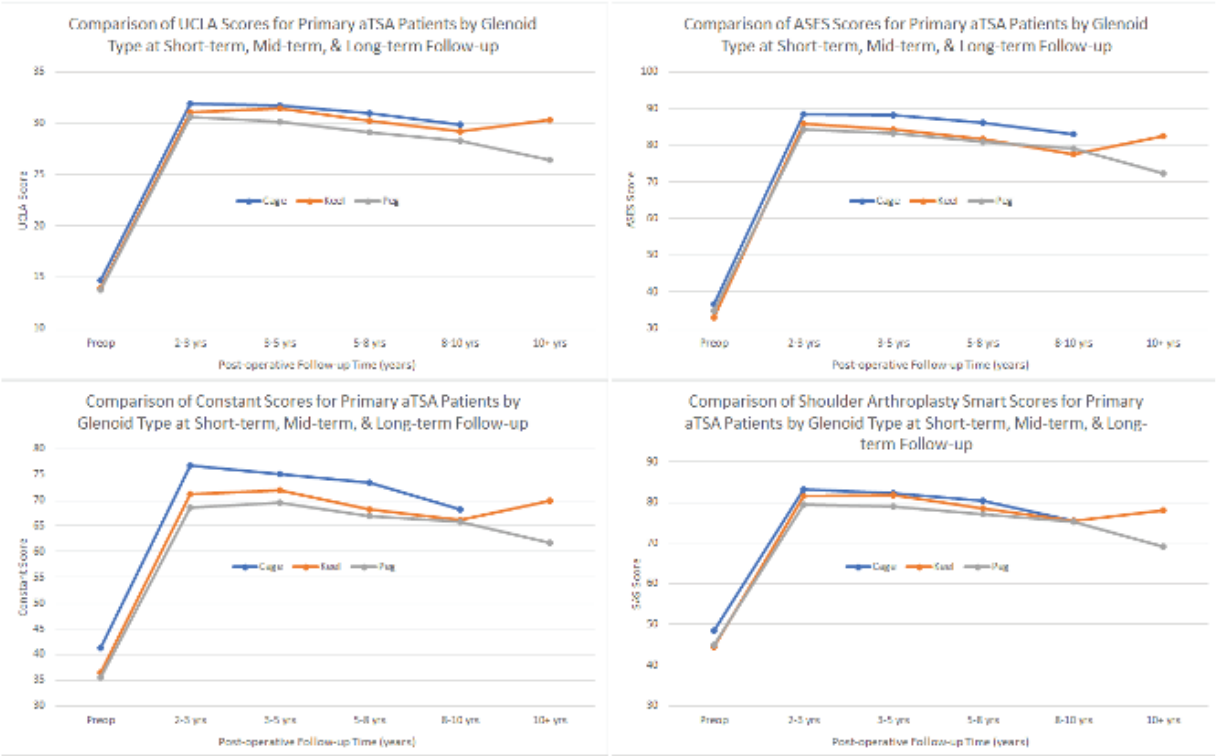


Figure 1. Comparison of UCLA (Figure 1A, top left), ASES (Figure 1B, top right), Constant (Figure 1C, bottom left), and SAS (Figure 1D, bottom right) scores at various short-term, mid-term, and long-term follow-up timepoints for cage, peg, and keel glenoids.

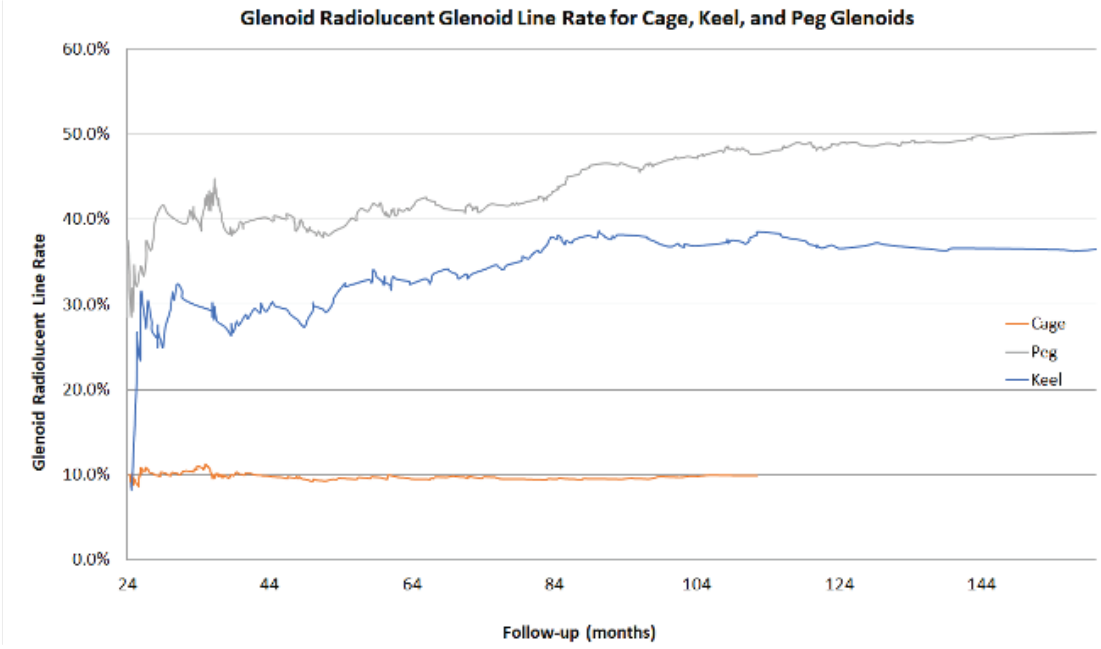


Figure 2. Comparison of Radiolucent Glenoid Line Rates by Glenoid Type over the Post-operative Follow-up Duration

Is a Lateralized Onlay Humeral Reverse Total Shoulder Prosthesis Equally Effective In Treating Patients of Shorter Height: A Comparison of Patients of Short and Average Height at Short and Long-Term Follow-up

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INTRODUCTION

Reverse total shoulder arthroplasty (rTSA) is increasingly used as the prosthesis of choice for patients with end-stage degenerative conditions of the shoulder. rTSA prosthesis designs are offered in various sizes and styles to accommodate varying patient anatomy, morphology, and wear/deformity patterns. There is some belief that more medialized humeral prosthesis design styles perform better in shorter patients than lateralized onlay humeral prosthesis designs due to relative differences in tension of the remaining musculature; there is no study that has objectively demonstrated any difference in outcomes between design styles. The purpose of this study is to analyze an international database of a single shoulder prosthesis to compare clinical outcomes associated with patients of short and average height when treated with a lateralized onlay humeral design style.

METHODS

An international database of a single shoulder prosthesis was analyzed to evaluate the impact of patient stature on clinical outcomes from short to long-term follow-up. Primary rTSA patients were included in this study if they had available demographic information related to height to classify as short or average stature as defined by Matsuki et al.1, 2-year minimum follow-up, and were treated with 38mm or 42mm glenospheres. Matsuki et al.1 defined short-stature patients as being <155cm tall and defined average-stature patients as being 162-178cm tall. Patients were excluded if 1) indicated for surgery by fracture or revision arthroplasty or 2) were outside of the specified short stature and average stature height ranges. Patients were evaluated pre-operatively and post-operatively using patient reported outcome measures (PROMs) including SST, UCLA, ASES, Constant, and SAS scoring metrics; and using VAS pain and global shoulder function. Range of motion was quantified for active abduction, forward elevation, and internal/external rotation. Revision rates were also determined. To analyze the impact of patient height on outcomes, stature cohorts were compared at latest follow-up and also at defined post-operative intervals of 2-3 years (short-term) and 8+ years (long-term) follow-up. The cohorts were compared at each timepoint using student's t-test for continuous variables and a Wilcoxon-rank-sum test for ordinal variables.

RESULTS

The clinical outcomes of 2,154 primary rTSA patients were analyzed in this study. 528 (516F/12M) primary rTSA patients were included in the short-stature cohort and 1,626 (870F/756M) primary rTSA patients were included in the average stature cohort. Several differences were observed between cohorts. Small stature patients were significantly ($p<0.0001$) older at 73.7 ± 7.9 years as compared to average stature patients who were 71.5 ± 7.7 years at the time of surgery. The cohort of small stature patients was 97.9% female, with significantly ($p<0.0001$) more female patients than in the average stature cohort, which was 53.5% female. Small stature patients had 5.5% of patients with a diagnosis of Rheumatoid arthritis (RA), which was significantly ($p=0.0002$) greater than the 2.3% of patients with RA in the average stature cohort. Interestingly, 43.8% of average stature patients had their subscapularis repaired at the time of surgery, which was significantly ($p=0.0256$) more than the 38.1% of small stature patients. Small stature patients received smaller diameter glenospheres, where 45 patients (8.5%) received a 42mm glenosphere which was significantly ($p<0.0001$) less than the 710 patients (43.7%) in the average stature cohort.

As described in Table 1, prior to surgery several differences were observed between small and average stature cohorts. Pre-operatively, small stature patients had significantly more pain ($p<0.0001$), significantly less function ($p=0.0010$), and significantly lower outcome measures as described by the SST ($p<0.0001$), Constant ($p=0.0209$), ASES ($p<0.0001$), and UCLA ($p=0.0013$) metrics. At latest follow-up, small stature patients had an average follow-up of 52.2 ± 28.4 months, which was significantly more than the average follow-up of 48.2 ± 25.9 months for average stature patients. At latest follow-up, average stature patients generally

performed better than small-stature patients as measured by each outcome measure, a trend which was also apparent in the short-term PROMs, but not ROM (Table 2). However, likely due the pre-operative differences between the two cohorts, the only significant differences in pre-to-post-operative improvement between the groups were in internal rotation (1.2 vs. 0.9, p=0.034), external rotation (20.0 vs. 16.6°, p=0.0125), and the Constant score (33.7 vs. 29.2, p=0.0004) where average stature patients experienced greater improvement in each. As shown in Table 2, no significant differences were observed at long-term follow-up between small stature and average stature cohorts as was observed at short-term and latest follow-up. However, small stature patients had a significantly (p=0.0449) lower revision rate of 0.6% as compared to the average stature patients revision rate of 1.8%. Finally, no difference in radiographic outcomes were observed, where small stature and average patients had scapular notching rates of a 10.0% and 9.8%, respectively.

DISCUSSION

The results of this study demonstrate that both small and average stature patients achieved favorable outcomes and a low revision rate out to long-term follow-up with a lateralized onlay humeral rTSA prosthesis. Some statistical differences in clinical outcomes were observed between small stature and average stature cohorts, but few differences in improvements were found. This study has several limitations. The 2 cohorts had numerous differences in pre-operative measures and surgical factors, which may have confounded our findings. Most significantly, 97.9% of the small stature cohort was female as compared to 53.5% of the average stature cohort. Additionally, the small stature cohort was significantly older and had a different distribution of diagnoses as compared to the average stature cohort, where specifically the small stature cohort had a larger percentage of patients with RA. Related to the implant choice and surgical technique, 8.5% of the small stature cohort received 42mm diameter glenospheres as compared to 43.7% of the average stature cohort; 38.1% of small stature patients had their subscapularis repaired versus 43.8%, in the average stature cohort, potentially affecting post-operative internal/external rotation capacity. These difference in gender, age, and diagnosis, implant size, and surgical technique most likely describe the observed differences in pre-operative and post-operative outcomes. Interestingly, both cohorts achieved similar levels of clinical improvement despite these differences. Future work should seek to match for age, gender, diagnosis, and glenosphere size and diameter when comparing outcomes of different stature patients.

SIGNIFICANCE

In conclusion, this large-scale clinical outcome study of 2,154 rTSA patients demonstrates that a lateralized onlay humeral rTSA shoulder prosthesis can be used to successfully treat both small stature and average stature patients with equivalent outcomes.

	Patient Height	Abduction	Forward Elevation	IR Score	Ext. Rotation	VAS Pain	Global Shoulder Function	SST	Constant	ASES	UCLA	SAS
Pre-op	≤155cm	73.8 ± 34.0	88.3 ± 40.3	3.1 ± 1.9	20.1 ± 19.9	6.7 ± 2.2	3.5 ± 2.3	3.1 ± 2.5	34.4 ± 14.1	32.1 ± 15.4	12.7 ± 4.2	44.9 ± 12.1
Pre-op	162-178cm	74.5 ± 38.2	87.6 ± 39.3	3.1 ± 1.8	18.8 ± 21.9	6.0 ± 2.2	3.8 ± 2.0	3.9 ± 2.5	36.4 ± 14.1	37.1 ± 15.8	13.5 ± 4.1	45.9 ± 12.2
Pre-op	P Value	0.6911	0.7317	0.7848	0.2819	**<0.0001**	**0.0010**	**<0.0001**	**0.0209**	**<0.0001**	**0.0013**	0.1263
LFU	≤155cm	115.7 ± 31.3	136.6 ± 29.0	4.0 ± 1.9	35.7 ± 17.4	1.5 ± 2.3	7.9 ± 2.2	8.9 ± 2.9	63.6 ± 14.3	77.9 ± 20.7	29.5 ± 5.3	73.0 ± 12.4
LFU	162-178cm	123.1 ± 31.7	141.6 ± 27.0	4.3 ± 1.8	38.2 ± 18.2	1.2 ± 2.0	8.2 ± 2.0	10.0 ± 2.6	70.0 ± 14.4	83.2 ± 18.2	30.4 ± 5.0	75.8 ± 12.2
LFU	P Value	**<0.0001**	**0.0010**	**0.0088**	**0.0115**	**0.0011**	**0.0090**	**<0.0001**	**<0.0001**	**<0.0001**	**0.0034**	**<0.0001**
Improve	≤155cm	43.8 ± 41.2	49.2 ± 43.7	0.9 ± 2.2	16.6 ± 23.1	5.2 ± 2.9	4.4 ± 2.9	5.9 ± 3.4	29.2 ± 17.9	46.0 ± 23.7	16.8 ± 6.3	28.8 ± 15.9
Improve	162-178cm	48.2 ± 41.0	53.3 ± 42.9	1.2 ± 2.2	20.0 ± 23.4	5.0 ± 2.7	4.3 ± 2.6	6.1 ± 3.4	33.7 ± 17.2	46.0 ± 21.1	16.8 ± 5.8	30.0 ± 15.0
Improve	P Value	0.0616	0.1018	**0.0341**	**0.0125**	0.0736	0.4917	0.3336	**0.0004**	0.9786	0.8039	0.2026

Table 1. Comparison of rTSA Patients of Short and Average Height, Pre-operative, at Latest Follow-up, and Pre-to-Post-operative Improvement

	Patient Height	Abduction	Forward Elevation	IR Score	Ext. Rotation	VAS Pain	Global Shoulder Function	SST	Constant	ASES	UCLA	SAS
2-3 years	≤155cm	120.2 ± 30.2	138.1 ± 27.0	4.3 ± 1.8	36.2 ± 16.5	1.3 ± 2.1	8.0 ± 2.0	9.3 ± 2.7	65.9 ± 13.1	80.0 ± 18.6	29.8 ± 4.9	74.5 ± 10.8
2-3 years	162-178cm	122.1 ± 31.2	142.5 ± 25.0	4.4 ± 1.7	38.1 ± 17.9	1.1 ± 1.9	8.3 ± 1.8	10.2 ± 2.3	70.5 ± 13.5	84.2 ± 16.8	30.6 ± 4.7	76.5 ± 11.6
2-3 years	P Value	0.3810	**0.0130**	0.1312	0.1046	0.0698	**0.0124**	**<0.0001**	**<0.0001**	**0.0002**	**0.0139**	**0.0120**
8+ years	≤155cm	100.1 ± 23.1	129.2 ± 27.3	4.5 ± 1.9	26.9 ± 21.1	1.9 ± 2.9	7.5 ± 2.5	8.3 ± 3.4	61.6 ± 16.5	73.4 ± 25.4	28.7 ± 7.0	70.6 ± 15.6
8+ years	162-178cm	106.5 ± 30.5	124.1 ± 31.6	4.2 ± 1.9	26.6 ± 20.6	1.1 ± 1.9	7.3 ± 2.4	8.4 ± 3.3	60.9 ± 18.8	76.5 ± 21.8	27.0 ± 7.3	68.3 ± 16.0
8+ years	P Value	0.1676	0.3197	0.3589	0.9254	0.3705	0.5633	0.8691	0.8199	0.3167	0.1642	0.4028

Table 2. Comparison of rTSA Patient Outcomes at Short-term & Long-term Follow-up for Patients of Short and Average Height

Abstract Summaries

The first study is a registry analysis of 9,136 Equinoxe shoulders representing the collective experience of our aTSA and rTSA system from 2011 to 2022 in the UK and Australia. It demonstrates low rates of revision and high survivorship over this 10-year period and analyzes the reasons for revision with each type of prosthesis. Regarding the reasons for revision, it is important to note that none of 1,919 aTSA cases and none of 7,217 rTSA cases were revised due to poly wear or lysis, suggesting that the failure modes with shoulder arthroplasty are different than that of hip and knee arthroplasties. Rather, the majority of failure modes with shoulder relate to the soft-tissues, highlighting the importance of patient selection, implant size selection and positioning, soft-tissue management and rehabilitation, and surgical technique.

The second study is a longitudinal analysis of the clinical outcomes achieved with the Equinoxe aTSA and rTSA over a 15-year period. This comparative study of consecutive 5-year cohorts demonstrates that positive results with the Equinoxe have been achieved for aTSA and rTSA irrespective of the year in which the implantation occurred. As developers of medical devices, we found these results to be particularly encouraging because they also demonstrated both aTSA and rTSA clinical and radiographic outcomes have been steadily improving. Interestingly, these clinical improvements, in combination with steady aTSA and declining rTSA implant prices, have driven rTSA value to continuously increase while aTSA value has been maintained at a high-level over the 15-year period of analysis, even when considering the cost and adoption of new technologies like augmented aTSA glenoids, hybrid glenoids, augmented rTSA baseplates, short humeral stems, 3D-printed stemless humeral components, and CT preoperative planning and intraoperative surgical navigation.

The third study compares the short-, mid-, and long-term clinical outcomes of 1,802 primary Equinoxe aTSA, stratified by three different glenoid designs, representing 981 hybrid cage glenoids, 527 cemented peg glenoids, and 294 cemented keel glenoids. These clinical results demonstrate that all three Equinoxe glenoid designs provide successful treatment from short- to long-term follow-up. Importantly, cage glenoid patients experienced significantly higher outcome scores, significantly more active range of motion, significantly less pain, and significantly lower rates of glenoid radiolucent lines, aseptic glenoid loosening, and revisions as compared to patients with cemented peg and keel glenoids. However, it is important to note that patients with cage glenoids had a unique failure mode of poly-disassociation relative to cemented poly glenoids. This modular junction failure occurs due to malalignment/malpositioning when preparing the central and peripheral peg glenoid holes. While rare, occurring ~1.3% of patients, this failure mechanism highlights the importance of adequate glenoid exposure and proper surgical technique. Our efforts to continuously improve have led to the recent introduction of our next-generation laser cage glenoid, which was launched in May 2022 and has substantially improved the assembly strength of this polyethylene and porous peg junction – which is associated with a 5x increase in axial pull-off strength and a 2x increase in shear strength relative to our previous generation design.[9]

Finally, the fourth study presents the short- and long-term clinical outcomes of 2,154 Equinoxe rTSAs and compares the outcomes achieved by patients of short height/stature relative to patients of average height/stature using the same lateralized onlay humeral prosthesis design. These results demonstrate that the Equinoxe rTSA prosthesis design successfully treats patients of short height/stature with equivalent levels of improvement as patients with average stature/height. Notably, no significant differences in long-term outcomes were observed between small height/stature and average height/stature cohorts, and small height/stature patients had a significantly ($p=0.0449$) lower revision rate of 0.6% as compared to the average height/stature patient revision rate of 1.8%. Finally, no difference in radiographic outcomes were observed, where small height/stature and average patients had scapular notching rates of a 10% and 9.8%, respectively.

NOTES

NOTES

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