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Eclipse stemless shoulder prosthesis vs. Univers II shoulder prosthesis: a multicenter, prospective randomized controlled trial

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Background: Total shoulder arthroplasty is an accepted treatment for glenohumeral osteoarthritis. The Arthrex Eclipse shoulder prosthesis is a stemless, canal-sparing humeral prosthesis with bone ingrowth capacity on the trunnion, as well as through the fenestrated hollow screw, that provides both diaphyseal and metaphyseal load sharing and fixation.

Methods: Between 2013 and 2018, 16 sites in the United States enrolled 327 patients (Eclipse in 237 and Arthrex Univers II in 90). All patients had glenohumeral arthritis refractory to nonsurgical care. Strict exclusion criteria were applied to avoid confounding factors such as severe patient comorbidities, arthritis not consistent with osteoarthritis, and medical or prior surgical treatments that may have affected outcomes. Patients were randomized to the Eclipse or Univers II group via block randomization.

Institutional review board approval for this study was received from multiple author institutions. All sites received institutional review board approval (Eclipse IDE Pivotal Study, no. G110128).

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Results: In total, 149 Eclipse and 76 Univers II patients reached 2-year follow-up (139 Eclipse patients [93.3%] and 68 Univers II patients [89.5%] had complete data). The success rate using the Composite Clinical Success score was 95% in the Eclipse group vs. 89.7% in the Univers II group. No patient exhibited radiographic evidence of substantial humeral radiolucency, humeral migration, or subsidence at any point. Reoperations were performed in 7 patients (3.2%) in the Eclipse group and 3 (3.8%) in the Univers II group.
Conclusion: The Arthrex Eclipse shoulder prosthesis is a safe and effective humeral implant for patients with glenohumeral arthritis at 2-year follow-up, with no differences in outcomes compared with the Univers II shoulder prosthesis.
Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Arthroplasty; shoulder; Eclipse; Univers II; stemless; arthritis; outcomes; complications

Glenohumeral arthritis is a common problem facing the increasingly aging population.[4] Patients in whom nonoperative management (exercise, lifestyle adjustment, physiotherapy, and medications) has failed and who have a functioning rotator cuff are candidates for anatomic shoulder arthroplasty.[3,7,14] Results following anatomic shoulder arthroplasty have been good to excellent in the majority of cases, with patients commonly experiencing a reduction in pain and an increase in shoulder function. [8,23] Unfortunately, there are still complications such as periprosthetic fracture, infection, and rotator cuff failure after the primary procedure, as well as late glenoid loosening, that often require removal of the humeral and glenoid components, which plague patients and shoulder arthroplasty surgeons alike.[2,23]

There have been many prosthetic designs, on both the glenoid and humeral side, for anatomic shoulder arthroplasty.[12,14,17] The humeral-sided implants are commonly broken down into long stem, short stem, stemless, and resurfacing.[17] Long-stem implants were initially designed as monobloc implants with fixed geometry.[18] Short-stem implants allow for acceptable fixation with less disruption and removal of distal humeral bone, easier removal in the setting of revision, and potentially less stress shielding of the proximal humerus. However, these short-stem components still require reaming and broaching of the humeral canal, can be difficult to remove in the revision setting without complex humeral osteotomy and compromise of the humeral diaphyseal bone, and still run the risk of periprosthetic fracture.[10,23] Recent evidence has shown very few problems with humeral fixation and humeral-sided failure in shoulder arthroplasty.[21] As such, implants that achieve acceptable fixation while preserving more humeral bone stock have been introduced.

Humeral resurfacing implants are designed to place a metal cap over the humeral head after minimal preparation and removal of humeral head bone but have limited indications as they do not address problems that compromise the bone of the humeral head and metaphysis.[13] One solution to address arthritis that affects the entire humeral head and also allows for all options with glenoid reconstruction is to resect the humeral head at the anatomic neck and then place a canal-sparing implant that can be fixed to the remaining humeral bone.[17]

The Eclipse shoulder prosthesis (Arthrex, Naples, FL, USA) (Fig. 1) was introduced in 2005 in Europe and is a stemless humeral prosthesis that minimizes the loss of humeral bone beyond the anatomic neck cut, using both cortical and cancellous bone fixation, and allows for all current methods of glenoid reconstruction including both cemented and metal-backed resurfacing implants, tissue interposition grafts, and glenoid reaming. This implant has been used extensively outside the United States but just recently received approval from the US Food and Drug Administration for use in the United States. The purpose of this investigation was to report on a non-inferiority, multicenter, prospective randomized controlled trial to compare the Eclipse shoulder prosthesis (investigational device) and Arthrex Univers II shoulder prosthesis (control device) and to report the outcomes and complications within these 2 patient cohorts. The primary endpoint was the Composite Clinical Success (CCS) score, whereas secondary endpoints including the adjusted Constant score, radiographic outcomes, and percentage of patients achieving an adjusted Constant score $\geq$ 70 points, as well as the Short Form 36 (SF-36) and visual analog scale (VAS) outcome scores. The pre-study hypothesis was that there would be no difference in clinical outcomes, complications, or reoperation rates between patients who received the Eclipse and Univers II shoulder prostheses for arthritis of the glenohumeral joint.

Methods

Sixteen separate orthopedic practice sites within the United States participated in this study between January 2013 and December 2018 (the last patient was enrolled in December 2017). The patient inclusion criteria were men or women aged >21 years with an intact or reconstructible rotator cuff and with degenerative joint disease of the shoulder due to osteoarthritis, avascular necrosis (AVN), post-traumatic arthritis, or rheumatoid arthritis. The humeral head and neck needed to have sufficient bone stock, and patients had to have an adjusted Constant score $\leq$ 50 points. Active physician-directed conservative treatment

Figure 1 Eclipse shoulder prosthesis.

(anti-inflammatory medications, physical therapy, and steroid injections) for ≥3 months was required. Finally, patients had to be physically and mentally willing and able to comply with all study procedures (including 2 years of follow-up visits and radiographic assessments) until the conclusion of the study.

Patients were excluded if they were candidates for hemihumeral arthroplasty; had AVN of the humeral head without glenoid involvement (stages 0-3); had a rotator cuff–deficient shoulder; had glenoid bone deficiency or deformity that precluded glenoid replacement; had fractures of the proximal humerus that required stem fixation for the reconstruction; had bone insufficiency (defined by the absence of cancellous bone patterning; a mature, thick cortex; and stress lines within the cancellous bone); had obvious defects in bone quality (cysts or lesions in the humeral head); had a rotator cuff that was not intact and not reconstructible; or had an irreducible 3- or 4-part proximal humeral fracture of the shoulder. We also excluded patients with a documented history of foreign-body sensitivity; those who were pregnant or lactating or who intended to become pregnant during the treatment period; those with a documented diagnosis of schizophrenia, bipolar disorder, and/or major depressive disorder defined by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; those who were radiographically skeletally immature; those at high risk of poor healing or confounding outcomes (ie, clinically significant renal, hepatic, cardiac, or hematologic disease or endocrine disease), and those receiving immune-stimulating or immunosuppressive agents. Finally, were excluded patients who had comorbidities that reduce life expectancy to <36 months; those seeking workers' compensation for shoulder injury; those weighing >158.8 kg (>350 lb); those engaged in heavy labor (eg, repetitively lifting >22.7 kg [> 50 lb]); those who underwent surgery on the affected shoulder in the past 12 months (with the exception of a diagnostic arthroscopy without any reconstruction or repair procedures); those engaged in active sports participation (eg, heavy weight lifting involving the upper extremities or involvement in contact sports); those taking medications known to potentially interfere with bone and/or soft tissue healing (eg, steroids with the exception of topical steroids and/or steroid inhalers); those who were prisoners or wards of the state; those who had a documented diagnosis of alcohol and/or substance abuse as defined by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; those with an active or chronic infection (systemic or local); those who had a pathologic fracture of the affected shoulder; those with acute trauma of the affected shoulder; and those who had osteoporosis, defined as a bone density T score < –2.5.

Overall, 418 patients were screened under the Eclipse Investigational Device Exemption study (Fig. 2). Eighty-seven patients were considered screen failures because exclusion criteria were identified prior to randomization, resulting in 331 patients who were eligible for randomization. Once a patient consented to the study, signed the informed consent form, and met all the inclusion and exclusion criteria, he or she was randomized using an Internet-based automated randomization system that ensured concealed randomization to either the Eclipse or Univers II group. A 2:1 ratio of randomization was performed so that for every 3 cases, 2 cases would be assigned the Eclipse device and 1 case would be assigned the Univers II device. After July 6, 2017, a preliminary analysis revealed that comparative results between the Eclipse and Univers II devices reached statistical significance; therefore, with US Food and Drug Administration Investigational Device Exemption oversight approval, randomization ceased and all remaining patients were assigned to the Eclipse group. This resulted in 241 Eclipse patients (including 170 randomized and 71 nonrandomized) and 90 Univers II patients (all randomized). There were 12 patients (3 with Eclipse and 9 with Univers II) who were randomized but not treated with the assigned device because of withdrawal from the study prior to surgery and 16 patients (14 with Eclipse and 2 with Univers II) who were determined to not meet all the study inclusion and exclusion criteria intraoperatively. The latter 16 patients were excluded intraoperatively because of insufficient bone quality in 10; irreparable rotator cuff tears in 3; and unavailability of the correct components, requiring the implant to be changed, in 3.

The resulting treated population comprised 303 patients: 224 Eclipse and 79 Univers II patients. After a review of protocol deviations, an additional 7 patients (6 with Eclipse and 1 with Univers II) were excluded because it was determined after surgery that the patients did not meet the enrollment criteria. The reasons for exclusion were as follows: 1 patient was taking an immunosuppressant, 1 had a history of major depressive disorder, 1 had a problem with substance abuse, 1 was receiving workers' compensation, 1 had a Constant score that was too high (51.1 points), 1 underwent ipsilateral shoulder surgery within 12 months, and 1 had a diagnosis of osteoporosis. Therefore, a total of 296 patients (218 with Eclipse and 78 with Univers II) were included (Tables I and II). Patients were seen preoperatively and postoperatively at regular intervals (3, 6, 12, and 24 months). Operative data were recorded for patients in each group (Table III). The subscapularis was managed by surgeon preference. Postoperative management was the same for both groups and was standardized. Patients were placed in a sling and began physical therapy within the first 2 weeks, focusing on passive range of motion while protecting the subscapularis repair. They progressed to active-assisted and then active motion. Once full motion was achieved, patients began strengthening, ensuring no resisted internal rotation for 12 weeks.

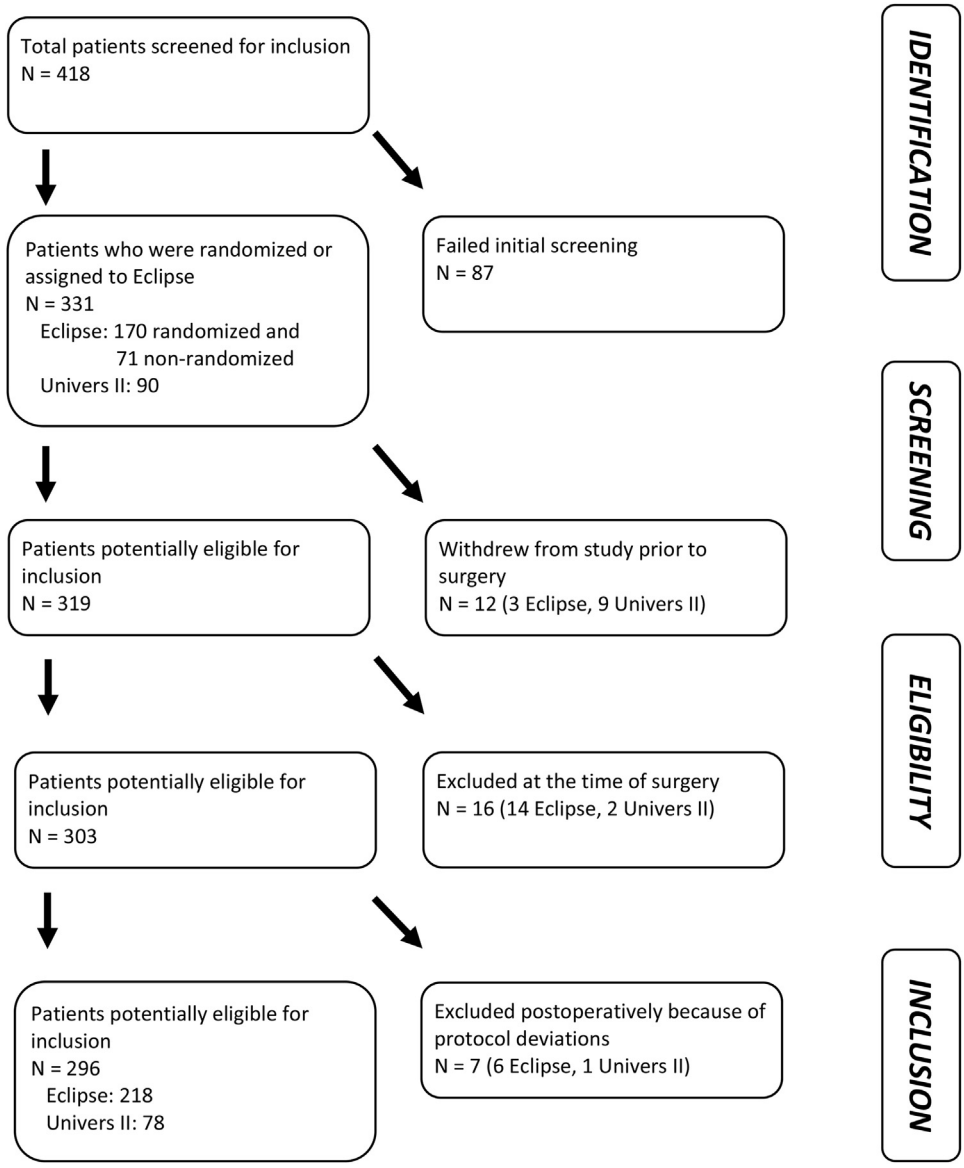

Figure 2 Flow diagram of patient enrollment.

The CCS criterion contains the following components: functional improvement (reflected by the adjusted Constant score change from baseline to 2 years), radiographic outcomes, complications, reoperations, and revision rate. The primary endpoint was the 2-year CCS score. A patient had to meet all of the following criteria to be considered to have achieved success: improvement in the adjusted Constant score (for pain, function, and range of motion) $\geq$10 points from baseline (preoperatively) to 2 years and a final adjusted Constant score $\geq$ 54 points; radiographic success defined as the absence of clinically significant humeral radiolucency, humeral migration or subsidence (relative to the 3-month time point), glenoid radiolucency, glenoid migration or subsidence (relative to the 3-month time point), device disassembly or fracture, and/or periprosthetic fracture; no reoperation, removal, or modification of any study component up to the patient's completion of the study; and no serious device-related complications up to the patient's completion of the study.

Power analysis

This study was designed as a non-inferiority study with the CCS score set as the primary outcome. The a priori non-inferiority margin was selected to be –10%. The primary null hypothesis was that the likelihood of achieving month-24 CCS would be >10% lower for the Eclipse prosthesis than for the Univers II prosthesis. The alternative hypothesis was that the likelihood of achieving month-24 CCS would be $\leq$10% lower for the Eclipse than for the Univers II. When the sample sizes in the Univers II and Eclipse groups are 98 and 196, respectively, a 2-group large-sample normal approximation test of proportions with a 1-sided significance level of .05 will have 80% power to reject the null hypothesis in favor of the alternative hypothesis assuming the true probabilities of achieving month-24 CCS were 0.88 in both groups.

Table I Demographic and baseline variables for patients included in study

	Eclipse				Univers II				Nominal significance		
	n	Med	Min	Max	n	Med	Min	Max	*t* Test*	Wilcoxon†	ES‡
All											
Age, yr	218	66.0	37.0	86.0	78	66	23	85	.676	.682	0.05
BMI, kg/m^2	218	30.3	21.5	49.5	78	31.8	19.2	43.6	.148	.090	−0.19
Height, in	218	69.0	56.0	80.0	78	69	60	75	.827	.832	−0.03
Weight, lb	218	201.5	132.0	316.0	78	201.5	130	333	.101	.287	−0.21
Male											
Age, yr	151	65.0	37.0	84.0	57	64	23	85	.676	.682	0.05
BMI, kg/m^2	151	30.0	21.5	49.5	57	31.2	19.2	43.6	.148	.090	−0.19
Height, in	151	70.0	65.0	80.0	57	70	63	75	.827	.832	−0.03
Weight, lb	151	208.0	148.0	316.0	57	206	130	333	.101	.287	−0.21
Female											
Age, yr	67	67.0	46.0	86.0	21	67	58	84	.676	.682	0.05
BMI, kg/m^2	67	30.6	22.3	44.6	21	33	23.7	40.2	.148	.090	−0.19
Height, in	67	63.5	56.0	70.0	21	63	60	68	.827	.832	−0.03
Weight, lb	67	175.0	132.0	270.0	21	190	134	257	.101	.287	−0.21
Clinical scores											
Constant score (normalized)	218	33.2	4.9	50.0	78	35	4.5	50	.501	.358	−0.09
VAS score											
Ipsilateral arm	217	54.0	0.0	100.0	78	43.5	0	98	.458	.497	0.10
Ipsilateral shoulder	217	71.0	7.0	100.0	78	70	0	100	.939	.874	−0.01
Contralateral arm	217	2.0	0.0	84.0	78	1	0	75	.167	.475	0.19
Contralateral shoulder	217	6.0	0.0	86.0	78	4.5	0	86	.166	.286	0.19
SF-36 score											
PCS	218	36.0	18.7	56.9	78	37.9	12	53.5	.981	.654	0.00
MCS	218	55.5	14.8	70.3	78	55.2	16.4	69.3	.584	.787	0.07

Med, median; *Min*, minimum; *Max*, maximum; *ES*, effect size; *BMI*, body mass index; *VAS*, visual analog scale; *SF-36*, Short Form 36; *PCS*, physical component summary; *MCS*, mental component summary.

* *P* value from nominal 2-sided pooled *t* test.

† *P* value from nominal 2-sided Wilcoxon rank sum test.

‡ Standardized ES (group difference in means divided by pooled within-group standard deviation).

Statistics

Descriptive comparisons at baseline used medians and ranges for continuous measures and counts and percentages for categorical measures. The Wilcoxon rank sum test and the χ^2 or Fisher exact test were used as aids to identify potentially important baseline group differences. Similar descriptive analyses were performed for secondary effectiveness endpoints and for safety endpoints.

There were 2 adaptations to the study design: The first was to cease randomization and to only enroll patients into the investigational device group. The second was to perform the primary effectiveness analysis prior to all patients completing 24 months of follow-up. In collaboration with regulatory reviewers, a Lan-DeMets alpha spending approach was used to account for these adaptations, with parameters set to approximate the O'Brien-Fleming alpha spending function.[16,19] The first interim analysis, supporting enrollment of only investigational device patients, was performed when approximately 37% of the projected total evaluable sample sizes had month-24 CCS outcomes. The second interim analysis, supporting the early claim for effectiveness, was performed when approximately 89% of the projected total information was available. At the first interim analysis, 0.00109 alpha was "spent." With this much alpha previously spent, at information time = 0.89, the nominal alpha remaining available to be spent is 0.03739 for this particular alpha spending function. Therefore, the 2-sided confidence level is $100 \times (1 - 0.03739) = 96.261\%$, with the corresponding 1-sided confidence interval equal to $100 \times (1 - [0.03739/2]) = 98.1305\%$. Therefore, rejection of the inferiority null hypothesis required a lower bound of the 1-sided 98.1305% confidence interval to exceed –0.10.

Results

At the time of this analysis, 149 Eclipse and 76 Univers II patients had reached 2-year follow-up. All patients who reached 2-year follow-up and were thus included in this study had been randomized. None of the patients enrolled after randomization ended had reached the 2-year time point. In addition, 4 Eclipse patients who had not yet reached 2-year follow-up but underwent a subsequent surgical intervention were included in the primary endpoint analysis. Of the patients, 143 Eclipse patients (93.5%) and 68 Univers II patients (89.5%) had complete data for 2-year follow-up and were therefore analyzed.

Table II Baseline characteristics by device group for categorical measures

	Eclipse			Univers II			Significance (*P* value)*
	N	n	%	N	n	%	
Kellgren-Lawrence scale	218			78			.169
Grade 3		92	42.2		37	47.4	
Grade 4		126	57.8		39	50.0	
NA		0	0.0		2	2.6	
AVN according to Cruess staging system	218			78			.999
Stage 4		0	0.0		2	2.6	
Stage 5		1	0.5		1	1.3	
NA		213	97.7		75	96.2	
Dominant shoulder	218			78			.854
Left		24	11.0		8	10.3	
Right		194	89.0		70	89.7	
Operative shoulder	218			78			.381
Left		102	46.8		37	47.4	
Right		116	53.2		41	52.6	
Smoker	218			78			.761
No		111	50.9		39	50.0	
Current		19	8.7		9	11.5	
Former		88	40.4		30	38.5	
Work status	218			78			.968
Working full time		75	34.4		28	35.9	
Working part time		16	7.3		5	6.4	
Not working		6	2.8		3	3.8	
Not working because of condition		10	4.6		4	5.1	
Retired or student		111	50.9		38	48.7	
Previous surgery on affected side	218			78			.782
Yes		48	22.0		16	20.5	
No		170	78.0		62	79.5	
Race and ethnicity†	218			78			
Asian or Pacific Islander		1	0.5		0	0.0	
Black		4	1.8		4	5.1	
Native or American Indian		1	0.5		1	1.3	
White		213	97.7		74	94.9	
Hispanic or Latino		4	1.8		1	1.3	
Non-Hispanic or non-Latino		182	83.5		67	85.9	
Other		1	0.5		0	0.0	

NA, not applicable; *AVN*, avascular necrosis.
* Nominal 2-sided χ^2 test or Fisher exact test when expected size was $\leq$5.
† Patients were instructed to select all potential choices that applied.

The null hypothesis that the Eclipse device was inferior to the Univers II device in terms of month-24 CCS was rejected, with 92.3% of Eclipse patients and 89.7% of Univers II patients achieving success (Table IV). By use of the O'Brien-Fleming method to correct for interim analyses, the lower bound of the 1-sided 98.131% confidence interval for the group difference was –6.4%. Because –6.4% is greater than –10%, the results from this comparison demonstrate that the study success criterion for non-inferiority was achieved, even when using a strict success criterion adjusting for interim analyses. For comparison purposes, the lower bound of the 1-sided 95% confidence interval for the group difference was –4.5%. Table IV summarizes the group differences in the individual components of the CCS score.

Adjusted Constant scores significantly improved in both groups from baseline and were not significantly different between the groups at 2-year follow-up (Tables V and VI). The percentage of patients improving by $\geq$10 points and having a final adjusted Constant score of $\geq$54 points was higher in the Eclipse group at all postoperative time points (Table VII). Although not significant, the Eclipse cohort had 5.0% more patients meeting the success criterion than the Univers II cohort at 2 years. The percentage of patients having a final adjusted Constant score $\geq$ 70 points was higher in the Eclipse group at most postoperative time

Table III Procedure characteristics by device group

	Eclipse			Univers II		
	N	n	%	N	n	%
Glenoid component type	218			77		
Keeled		34	15.6		11	14.3
Pegged		184	84.4		66	85.7
Hollow screw size	218					
Small		14	6.4			
Medium		82	37.6			
Large		94	43.1			
Extra large		28	12.8			
Anesthesia type	218			78		
General		202	92.7		75	96.2
Regional		42	19.3		15	19.2
Nerve block		173	79.4		61	78.2

Table IV Month-24 CCS score and CCS components by device group

	Eclipse			Univers II			Difference,* %	1-Sided LB, %†	
	N	n	%	N	n	%		95%	98.131%
No secondary surgical intervention‡	153	146	95.4	76	74	97.4	−1.9	−6.0	
No removal	153	147	96.1	76	74	97.4	−1.3	−5.3	
No revision	149	149	100.0	76	76	100.0	0.0		
No reoperation	153	152	99.3	76	76	100.0	−0.7	−1.7	
No serious device-related event§	149	148	99.3	76	76	100.0	−0.7	−1.8	
Overall radiographic success	136	136	100.0	66	66	100.0	0.0		
No device condition failure	137	137	100.0	67	67	100.0	0.0		
No glenoid radiolucency	136	136	100.0	66	66	100.0	0.0		
No humeral radiolucency	137	137	100.0	67	67	100.0	0.0		
No periprosthetic fracture	137	137	100.0	67	67	100.0	0.0		
Adjusted Constant score success‖	137	133	97.1	67	62	92.5	4.5	−1.2	
CCS score	143	132	92.3	68	61	89.7	2.6	−4.5	−6.4

LB, lower bound; *CCS*, Composite Clinical Success.

* Difference in proportions (calculated as Eclipse – Univers II).

† Lower bound of 1-sided 99.181% confidence interval as specified by O'Brien-Fleming method to correct for interim analyses.

‡ No reoperation, removal, or modification of any study component up to patient's completion of study.

§ No serious device-related adverse event up to day 790 following surgery.

‖ Improvement in adjusted Constant score (for pain, function, and range of motion) from baseline (preoperatively) to month-24 time point of ≥10 points and final adjusted Constant score of ≥54.

points, although this only reached statistical significance at 1 year (Table VIII). At 1 year, 10.7% more Eclipse patients than Univers II patients reported an adjusted Constant score ≥ 70 points.

Regarding radiographs, none of the Eclipse or Univers II patients exhibited radiographic evidence of substantial humeral radiolucency, humeral migration, or subsidence at any time point (Fig. 3). At 2 years, no patient in either the Eclipse or Univers II group receiving the keeled glenoid component exhibited glenoid radiolucency greater than grade 3 (Table IX). No patient in either the Eclipse or Univers II group receiving the pegged glenoid component exhibited glenoid radiolucency greater than grade 3 at 2 years (Table X). No patient in either the Eclipse or Univers II group had any evidence of glenoid migration or subsidence at 2 years. No patient in either the Eclipse or Univers II group exhibited any disassembly or fracture of the device at 2 years. No periprosthetic fractures occurred in the Eclipse group, whereas 2 intraoperative fractures occurred in the Univers II group (Table XI); these were managed with implant removal, cerclage, and reimplantation.

Subsequent surgical interventions have been performed in 7 patients in the Eclipse group (3.2%) and 3 (3.8%) in the Univers II group at 2 years (this includes all patients enrolled in the study, not just those who had minimum 2-year follow-up). The 7 reoperations in the Eclipse group

Table V Adjusted Constant scores over time by device group

	Eclipse						Univers II						Significance		
	n	Mean	SD	Med	Min	Max	n	Mean	SD	Med	Min	Max	*t* Test*	Wilcoxon†	ES‡
Baseline	218	32.4	11.1	33.2	4.9	50.0	78	33.4	11.5	35.0	4.5	50.0	.501	.358	−0.09
3 mo	209	64.4	15.3	66.0	19.3	98.9	77	63.5	17.6	65.2	20.0	97.8	.673	.822	0.05
6 mo	211	76.9	14.9	77.3	20.9	106.5	71	77.0	14.7	78.7	24.2	97.8	.988	.851	0.00
12 mo	195	83.8	14.7	85.5	14.1	111.4	72	80.7	16.3	82.3	24.2	108.4	.131	.150	0.20
24 mo	137	87.4	12.4	89.8	49.4	109.9	67	84.9	14.4	85.9	36.8	108.6	.203	.215	0.19

SD, standard deviation; *Med*, median; *Min*, minimum; *Max*, maximum; *ES*, effect size.
* *P* value from 2-sided pooled *t* test.
† *P* value from 2-sided Wilcoxon rank sum test.
‡ Standardized ES (group difference in means divided by pooled within-group SD).

Table VI Changes in adjusted Constant score from baseline

	Eclipse						Univers II						Significance		
	n	Mean	SD	Med	Min	Max	n	Mean	SD	Med	Min	Max	*t* Test*	Wilcoxon†	ES‡
3 mo	209	32.0	17.9	31.3	−15.3	76.0	77	30.0	19.7	32.6	−7.6	69.5	.414	.629	0.11
6 mo	211	44.4	17.8	44.5	−20.7	83.1	71	43.2	15.3	41.9	0.0	79.3	.598	.517	0.08
12 mo	195	50.8	18.0	52.1	−30.5	92.8	72	47.1	16.6	46.7	0.0	91.3	.133	.070	0.21
24 mo	137	54.7	16.0	53.2	13.1	94.0	67	51.2	16.7	47.9	12.6	91.3	.149	.081	0.21

SD, standard deviation; *Med*, median; *Min*, minimum; *Max*, maximum; *ES*, effect size.
* *P* value from 2-sided pooled *t* test.
† *P* value from 2-sided Wilcoxon rank sum test.
‡ Standardized ES (group difference in means divided by pooled within-group SD).

Table VII Adjusted Constant score responders over time by device group with response defined as improvement $\geq$ 10 points and score $\geq$ 54 points

	Eclipse			Univers II			Significance		
	N	n	%	N	n	%	Difference, %*	95% CI, %†	χ^2 Test‡
3 mo	209	160	76.6	77	53	68.8	7.7	−19.6 to 4.1	.184
6 mo	211	195	92.4	71	66	93.0	−0.5	−6.4 to 7.5	.881
12 mo	195	189	96.9	72	68	94.4	2.5	−8.3 to 3.3	.344
24 mo	137	133	97.1	67	62	92.5	4.5	−11.4 to 2.4	.138

CI, confidence interval.
* Difference in proportions (calculated as Eclipse – Univers II).
† Asymptotic 95% CI.
‡ *P* value from χ^2 test (2 sided without continuity correction).

were as follows: revision for infection (n = 3), conversion to reverse total shoulder arthroplasty for traumatic rupture of the rotator cuff (n = 3), and reoperation to repair a torn subscapularis (n = 1). The 3 reoperations in the Univers II group included revision to reverse total shoulder arthroplasty for rotator cuff rupture (n = 2) and mini-open distal clavicular excision (n = 1). There was no statistical difference in the number of adverse events between the groups.

Finally, regarding secondary outcome measures, no significant differences in overall VAS pain score or degree of change in VAS pain score from baseline were observed between the Eclipse and Univers II patients at any time point. Similarly, no significant differences existed between the groups regarding overall SF-36 mental health component or physical function component scores or change in SF-36 mental health component or physical function component scores from baseline.

Table VIII Adjusted Constant score responders over time by device group with response defined as score ≥ 70 points

	Eclipse			Univers II			Significance		
	N	n	%	N	n	%	Difference, %*	95% CI, %†	χ^2 Test‡
Baseline	214	0	0.0	78	0	0.0	0.0		
3 mo	209	78	37.3	77	32	41.6	−4.2	−8.6 to 17.1	.513
6 mo	211	154	73.0	71	53	74.6	−1.7	−10.1 to 13.4	.784
12 mo	195	168	86.2	72	55	76.4	9.8	−20.7 to 1.2	.056
24 mo	137	124	90.5	67	60	89.6	1.0	−9.8 to 7.9	.829

CI, confidence interval.
* Difference in proportions (calculated as Eclipse − Univers II).
† Asymptotic 95% CI.
‡ *P* value from χ^2 test (2 sided without continuity correction).

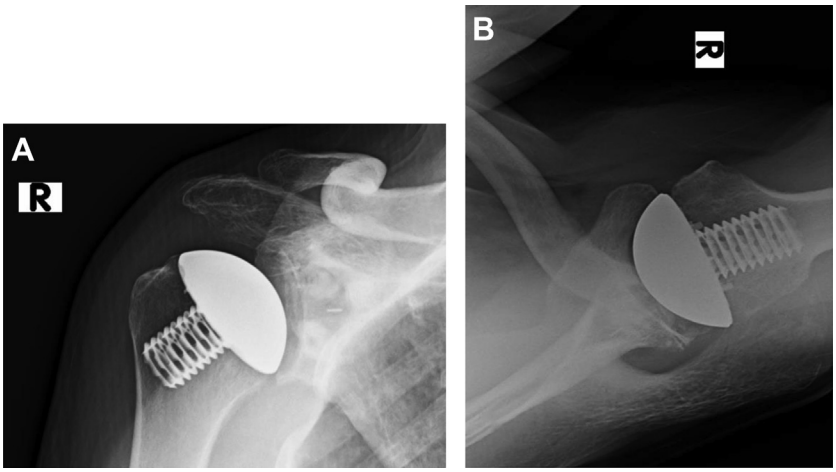

Figure 3 Postoperative Grashey (**A**) and axillary (**B**) radiographs showing excellent position of Eclipse shoulder prosthesis. Great care is taken not to overstuff the joint and to ensure that the cage screw does not engage the far humeral cortex. *R*, right.

Table IX Qualitative glenoid radiolucency grade for keeled components over time by device group

	3 mo				6 mo				12 mo				24 mo			
	Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Grade 0	28	85	9	82	23	72	8	80	20	71	7	78	11	58	8	80
Grade 1	3	9	0	0	5	16	0	0	2	7	0	0	2	11	0	0
Grade 2	2	6	1	9	4	13	1	10	6	21	1	11	5	26	1	10
Grade 3	0	0	1	9	0	0	1	10	0	0	1	11	1	5	1	10
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indeterminate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unable to assess	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Discussion

Total shoulder arthroplasty is an effective treatment option for glenohumeral arthritis. Our hypothesis was confirmed as no significant differences existed between the Eclipse and Univers II patient groups regarding clinical outcomes, complications, and reoperation rates. We found statistically reliable evidence that the likelihood of achieving month-24 CCS was not clinically inferior for the Eclipse prosthesis compared with the Univers II prosthesis. Using the Eclipse device for glenohumeral arthritis preserves humeral bone, allows glenoid reconstruction, is safe, and provides

Table X Qualitative glenoid radiolucency grade for pegged components over time by device group

	3 mo				6 mo				12 mo				24 mo			
	Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Grade 0	152	84	61	95	131	73	52	84	115	69	42	69	67	57	37	65
Grade 1	22	12	3	5	37	21	9	15	37	22	13	21	39	33	13	23
Grade 2	6	3	0	0	12	7	1	2	13	8	6	10	9	8	6	11
Grade 3	0	0	0	0	0	0	0	0	1	1	0	0	2	2	0	0
Grade 4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indeterminate	1	1	0	0	0	0	0	0	1	1	0	0	1	1	1	2
Unable to assess	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table XI Qualitative assessment of periprosthetic fractures

	Surgery				3 mo				6 mo				12 mo				24 mo			
	Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II		Eclipse		Univers II	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Absent	218	100	76	97	214	100	73	97	212	100	71	99	195	100	69	99	137	100	67	100
Present	0	0	2	3	0	0	2	3	0	0	1	1	0	0	1	1	0	0	0	0
Indeterminate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unable to assess	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Two fractures occurred in the Univers II group intraoperatively, both of which healed by 24 months' follow-up. Both fractures in the Univers II group were still visible on radiographs at 3 months of follow-up, whereas only 1 was visible at 6 months and 1 year of follow-up.

objective and patient-related outcomes that are equivalent to those of standard humeral stem arthroplasty.

Stemless humeral components have been proposed as an alternative to traditional, stemmed implants as they preserve humeral bone stock; allow for implant placement in a wide range of version and/or inclination angles to match the patient's anatomy; reduce humeral preparation time in the operating room; lower the risk of intraoperative humeral shaft fracture; and possibly reduce overall blood loss and postoperative pain, facilitating outpatient management. Furthermore, stemless designs are not affected by posttraumatic deformity whereas stemmed implants may not be implantable without humeral osteotomy or removal of part of the stem intraoperatively, and the dissociation of the humeral articulation orientation from the humeral shaft axis may force a non-ideal path in patients with significant deformity. One of the obvious advantages of stemless implants is a reduced risk of intraoperative humeral fracture owing to the absence of humeral diaphyseal preparation and bone removal. The incidence of intraoperative humeral fractures in total shoulder arthroplasty is approximately 1.5%, whereas the incidence of postoperative periprosthetic humeral fracture following total shoulder arthroplasty is between 0.7% and 2.3%.[1,15,20] This study found no intraoperative or postoperative humeral fractures in the Eclipse group. However, there were 2 humeral fractures in the Univers II group that occurred intraoperatively. This finding illustrates the benefit of a stemless implant in decreasing the risk of intraoperative periprosthetic humeral fracture. These results are similar to those of previous studies outside the United States that have examined the Eclipse implant.[9,22] Uschok et al[22] reported on 40 patients who underwent shoulder arthroplasty (20 with the Eclipse implant and 20 with a stemmed implant) and found no periprosthetic fractures in the Eclipse group whereas 1 patient in the stemmed implant group sustained a greater tuberosity fracture.

Radiolucent lines have been reported as a potential issue with humeral implants in total shoulder arthroplasty and have been a concern with some stemless implant designs. Collin et al[5] reported the results of 47 patients who underwent implantation of a stemless humeral component for osteoarthritis, fracture sequelae, and AVN. Of these 47 patients, 17 (36%) showed radiolucent lines on radiographs, especially superior and lateral to the humeral implant. These lines did not increase over time and did not lead to any revision surgical procedures for the humeral component. Our study found no evidence of significant radiolucent lines on postoperative radiographs in the Eclipse group at any time point; this degree of radiolucency is slightly less

than has been previously reported with this implant.[22] This finding may be secondary to the length of follow-up and/or implantation technique, as well as the highly selective inclusion criteria, providing an ideal group of patients for humeral fixation and bone metabolism during shoulder arthroplasty. It is important to note that in a 9-year follow-up study of the Eclipse implant in Europe, only 1 of 43 patients showed an incomplete radiolucency, and there were no revisions related to countersinking of the humeral implant or loosening.[11] Finally, a recent study looking at a 3-dimensional finite element model predicted that the Eclipse design would lead to significant bone loss.[6] However, the calculations used in this study have already proved to be wrong by the actual performance of the implant at 9 years because the investigators failed to take into consideration the impact of cortical bone fixation, which is a critical part of load sharing and an underlying explanation for the fact that the actual, not artificially calculated, risk of adverse bone reaction was a 2% incidence of incomplete radiolucent lines at 9 years using the Eclipse system.

Although radiographic parameters following shoulder arthroplasty are important, clinical outcomes remain a greater priority. This study found significant improvements in the CCS score, with 95.5% of patients in the Eclipse group and 88.7% in the Univers II group achieving success. Similarly, improvements in the adjusted Constant score, VAS score, and SF-36 score were seen in both groups, with no significant differences in these scores between the groups. These findings are similar to or better than those of previous studies performed in Europe with this implant.[9,22] Again, the strict inclusion criteria, including total shoulder arthroplasty only, as well as minimal patient comorbidities and factors than can affect bone fixation, most likely favored outstanding outcomes when compared with the use of the device in more heterogeneous populations. Gallacher et al[9] performed a retrospective review of 100 patients who received the Eclipse implant for the treatment of glenohumeral osteoarthritis between 2009 and 2015. They found significant improvements in clinical outcome scores as well as range of motion following surgery. Moreover, they reported a prosthetic revision rate of 4%, which is similar to that in our study.

This study confirms that the Eclipse prosthesis is as safe and as effective as the traditional stemmed device, the Univers II prosthesis, which is important as the advantages of the stemless design are its preservation of bone stock, ability to match the patient's anatomic head anatomy without the need to be compatible with the humeral diaphysis, ease of removal if needed, and lack of periprosthetic fracture. As demonstrated in this study, the clinical results among patients receiving the stemless implant are non-inferior to those among patients receiving the stemmed implant regarding clinical and radiographic outcome parameters, which provide benefits that outweigh those of a stemmed implant. Finally, the number of reoperations at 2 years was similar between the Eclipse and Univers groups (3.2% and 3.8%, respectively). These results indicate that the Eclipse humeral prosthesis is a safe and effective alternative to a stemmed implant and suggest that if fixation of the stemless device is possible, it should replace the need for a stemmed device.

Limitations

This study is not without its limitations. Range of motion was not consistently assessed with an objective device either preoperatively or postoperatively in our patients, so it is unclear whether the Eclipse provides a superior, equivalent, or inferior amount of shoulder range of motion following implantation. The surgeons who participated in this study and performed the surgical procedures were mostly higher-volume, experienced, fellowship-trained shoulder arthroplasty surgeons, so these results may not be generalizable to orthopedists who perform shoulder arthroplasty less frequently and/or have less experience and training. Strict inclusion and exclusion criteria were followed for this study. Patients who do not meet the inclusion and exclusion criteria may not have the same outcomes as patients in this study. Finally, this study presents 2-year results. These patients will continue to be followed up to provide mid- and long-term data on the Eclipse stemless prosthesis in the United States. Fortunately, longer-term data with favorable outcomes have already been published using this device in countries outside the United States.

Conclusion

The Arthrex Eclipse shoulder prosthesis is a safe and effective humeral implant for patients with glenohumeral arthritis at 2-year follow-up, with no differences in outcomes compared with the Univers II shoulder prosthesis.

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