A commentary by Peter A. Cole, MD, is linked to the online version of this article at jbjs.org.

Reverse Shoulder Arthroplasty Is Superior to Plate Fixation at 2 Years for Displaced Proximal Humeral Fractures in the Elderly

A Multicenter Randomized Controlled Trial

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Background: Almost one-third of patients with proximal humeral fractures are treated surgically, and the number is increasing. When surgical treatment is chosen, there is sparse evidence on the optimum method. The DelPhi (Delta prosthesis-PHILOS plate) trial is a clinical trial comparing 2 surgical treatments. Our hypothesis was that reverse total shoulder arthroplasty (TSA) yields better clinical results compared with open reduction and internal fixation (ORIF) using an angular stable plate.

Methods: The DelPhi trial is a randomized controlled trial comparing reverse TSA with ORIF for displaced proximal humeral fractures (OTA/AO types 11-B2 and 11-C2) in elderly patients (65 to 85 years of age). The primary outcome measure was the Constant score at a 2-year follow-up. The secondary outcome measures included the Oxford Shoulder Score and radiographic evaluation. Results were reported as the mean difference with 95% confidence interval (CI). The intention-to-treat principle was applied for crossover patients.

Results: There were 124 patients included in the study. At 2 years, the mean Constant score was 68.0 points (95% CI, 63.7 to 72.4 points) for the reverse TSA group compared with 54.6 points (95% CI, 48.5 to 60.7 points) for the ORIF group, resulting in a significant mean difference of 13.4 points (95% CI, 6.2 to 20.6 points; p < 0.001) in favor of reverse TSA. When stratified for fracture classification, the mean score was 69.3 points (95% CI, 63.9 to 74.7 points) for the reverse TSA group and 50.6 points (95% CI, 41.9 to 59.2 points) for the ORIF group for type-C2 fractures, which yielded a significant mean difference of 18.7 points (95% CI, 9.3 to 28.2 points; p < 0.001). In the type-B2 fracture group, the mean score was 66.2 points (95% CI, 58.6 to 73.8 points) for the reverse TSA group and 58.5 points (95% CI, 49.6 to 67.4 points) for the ORIF group, resulting in a nonsignificant mean difference of 7.6 points (95% CI, −3.8 to 19.1 points; p = 0.19).

Conclusions: At a 2-year follow-up, the data suggested an advantage of reverse TSA over ORIF in the treatment of displaced OTA/AO type-B2 and C2 proximal humeral fractures in elderly patients.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Proximal humeral fractures are among the most common fractures in the elderly. The incidence increases with age, more than two-thirds of patients with these fractures are female, and most patients live at home at the time of the injury. Proximal humeral fractures are the cause of considerable disability and societal costs, with expensive treatment and patients
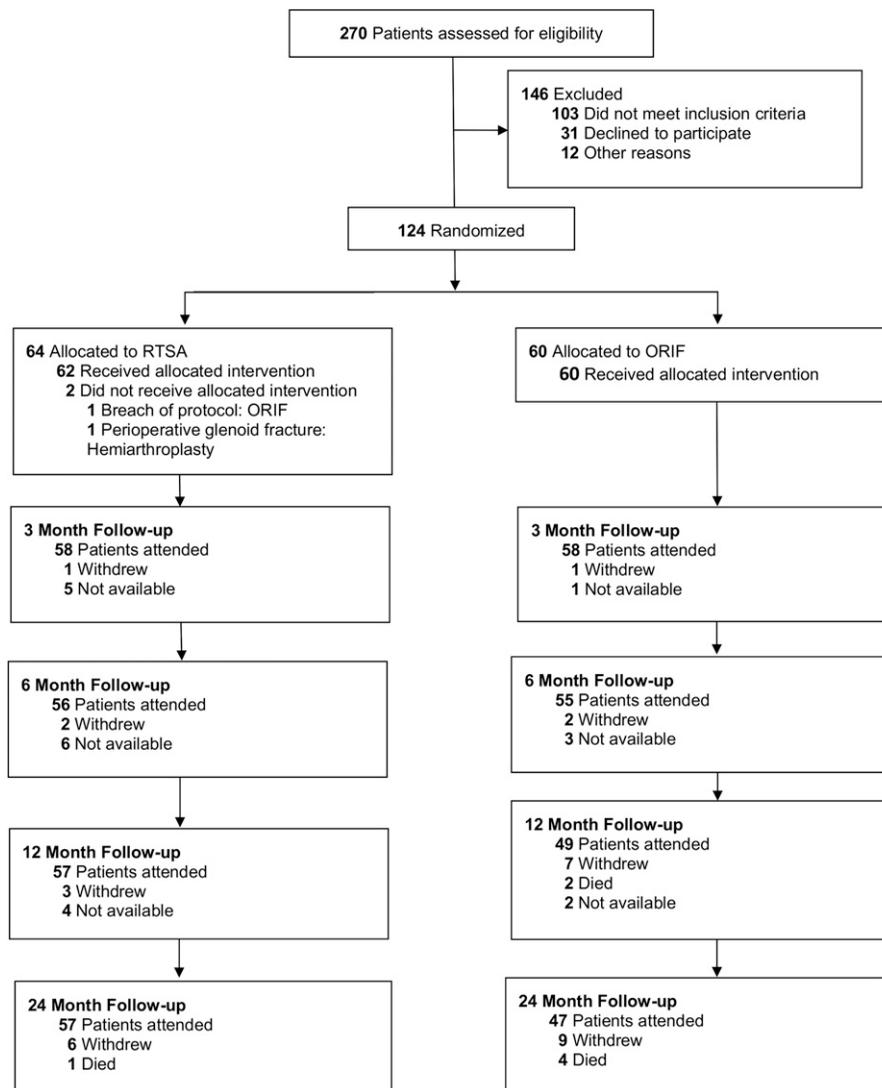
Fig. 1

The flowchart of patients in the DelPhi study. There were 270 patients with OTA/AO type-B2 or C2 fractures in the age group of 65 to 85 years assessed for eligibility. In this study, 146 patients were excluded and 124 patients were included and were allocated to either reverse TSA or ORIF. Missing data due to patients withdrawing from the study or death are shown as the cumulative value at each time point. Some patients were not available for follow-up at certain time points but were included in the analysis if they were available for testing at other time points.

needing increased support after injury[1-3]. The majority of proximal humeral fractures are treated conservatively, and up to 33% are treated surgically[4]. To our knowledge, no studies have yet proven that surgical treatment is superior to conservative treatment; simple fractures with little displacement seem to perform equally well, and displaced 3 and 4-part fractures perform equally poorly[5-10]. Even so, compliant patients with displaced fractures are more frequently being treated surgically[11,12].

Surgical treatment of displaced proximal humeral fractures remains controversial. Numerous implants are available, mainly different types of plates and screws, intramedullary nails, hemiarthroplasties, and reverse arthroplasties, and little evidence supports one method over another[13]. Open reduction and internal fixation (ORIF) with angular stable plates has gained excellent postoperative radiographs and was consequently subject to initial optimism in the orthopaedic trauma community. It is still a widely used surgical treatment, although later studies have shown that up to 30% of patients require secondary procedures[7,9]. Reverse total shoulder arthroplasty (TSA) was initially developed for treatment of cuff-tear arthropathy. In the last decade, there has been a shift toward reverse TSA as a primary operative solution for displaced proximal humeral fractures in the elderly, and it is now widely accepted as standard treatment[14].

In the present DelPhi (Delta prosthesis-PHILOS plate) trial, we included displaced proximal humeral fractures of OTA/AO types 11-B2 and 11-C2, because these are the

TABLE I Baseline Characteristics		
	Reverse TSA Group (N = 64)	ORIF Group (N = 60)
Sex*		
Male	5 (7.8%)	8 (13.3%)
Female	59 (92.2%)	52 (86.7%)
Age *(yr)*		
Mean†	75.7 ± 6.1	74.7 ± 6.5
Median‡	75.5 (65.3 to 85.8)	73.6 (64.8 to 85.8)
Age group		
65 to 74 yr		
No. of patients	27	33
Mean† *(yr)*	69.6 ± 2.8	69.5 ± 2.5
Median‡ *(yr)*	69.1 (65.3 to 74.4)	69.6 (64.8 to 74.3)
75 to 85 yr		
No. of patients	37	27
Mean† *(yr)*	80.2 ± 3.3	81.2 ± 3.2
Median‡ *(yr)*	81.3 (75.3 to 85.8)	81.1 (75.4 to 85.8)
Living situation*		
Home	63 (98.4%)	58 (96.7%)
Institution	1 (1.6%)	2 (3.3%)
Diabetes*		
Yes	8 (12.5%)	1 (1.7%)
No	56 (87.5%)	59 (98.3%)
Smoking*		
Yes	2 (3.1%)	4 (6.7%)
No	62 (96.9%)	56 (93.3%)
ASA class†	2.2 ± 0.5	2.2 ± 0.7
Time from injury to operation† *(days)*	6.0 ± 2.9	4.8 ± 2.9
OTA/AO fracture type*		
B2	26 (40.6%)	29 (48.3%)
C2	38 (59.4%)	31 (51.7%)
Injured arm*		
Right	35 (54.7%)	32 (53.3%)
Left	29 (45.3%)	28 (46.7%)
Dominant arm*		
Right	63 (98.4%)	52 (86.7%)
Left	1 (1.6%)	8 (13.3%)
Type of injury*		
Fall indoor	31 (48.4%)	20 (33.3%)
Fall outdoor	25 (39.1%)	36 (60.0%)
Sports	3 (4.7%)	2 (3.3%)
Not reported	5 (7.8%)	2 (3.3%)

*The values are given as the number of patients, with the percentage in parentheses. †The values are given as the mean and the standard deviation. ASA = American Society of Anesthesiologists. ‡The values are given as the median, with the range in parentheses.

proximal humeral fractures in the most common demographic group in which the treatment modality is most controversial. We aimed to fill some of the knowledge gap concerning operative treatment by comparing reverse TSA with ORIF using angular stable plate fixation, and our hypothesis was that reverse TSA yields better clinical results.

Materials and Methods

Study Design and Eligibility Criteria

The DelPhi trial is a multicenter, single-blinded, randomized controlled trial (RCT), comparing 2 operative methods for treating displaced proximal humeral fractures in the elderly. Patients were included from orthopaedic departments at 7 hospitals within the Norwegian public health service.

Between January 1, 2013, and June 1, 2017, patients who were 65 to 85 years of age and presented with a severely displaced proximal humeral fracture of type B2 or C2 (OTA/AO 2007 revision)[15] were eligible for the study. The 2007 version of the OTA/AO classification[15] for proximal humeral fractures was used in this study. We are aware that there is an updated OTA/AO classification from 2018[16] available; however, this classification cannot be directly applied to our study. Severe displacement was defined as >45° valgus or >30° varus in a true anteroposterior projection, >45° angulation in a scapular Y projection with the arm in neutral rotation, or >50% displacement of the humeral head against the metaphysis. The degree of tubercle displacement was not critical for inclusion.

Exclusion criteria were previous injury or illness of the injured or contralateral shoulder, concomitant injury to the ipsilateral or contralateral upper extremity, alcohol or other substance abuse, dementia or neurological disease, non-Norwegian-speaking patients, glenoid fracture or deformity,
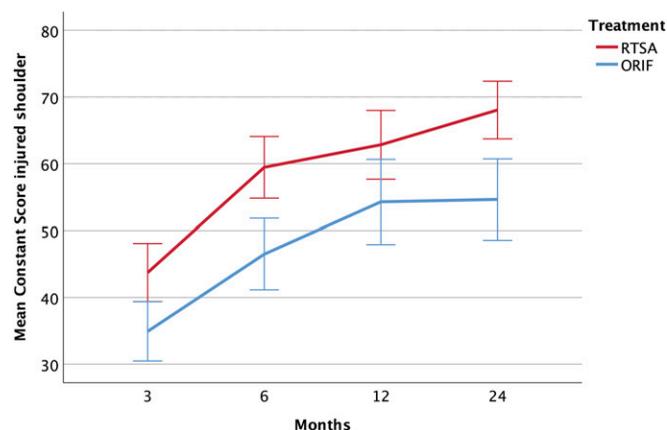

Fig. 2

The overall mean Constant score for the reverse TSA (RTSA) group and the ORIF group. The error bars indicate the 95% CIs. The Constant score ranges from 0 (worst) to 100 points (best) and consists of 4 dimensions of shoulder function: pain, activities of daily living, range of motion, and strength.
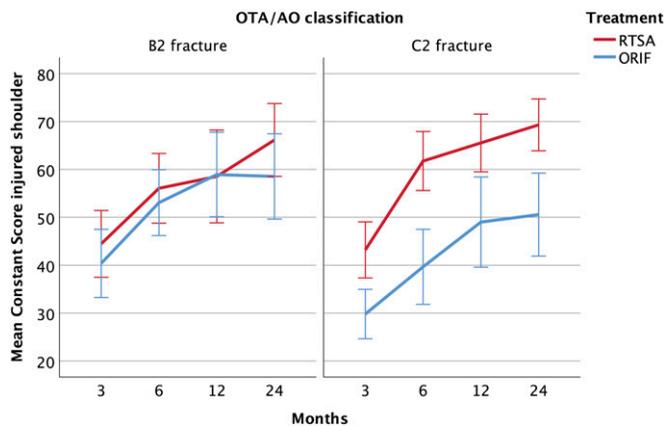
Fig. 3

The mean Constant score for the reverse TSA (RTSA) group and the ORIF group stratified by the OTA/AO fracture classification. The error bars indicate the 95% CIs.

or patients who were deemed noncompliant to rehabilitation. Head-split fractures, fracture-dislocations, and high-energy trauma were not included.

Preoperative radiographs and computed tomographic (CT) scans were examined by a dedicated orthopaedic surgeon at the attending hospitals and were verified by the coordinating orthopaedic surgeon at Oslo University Hospital. Eligible patients received oral and written information about the trial before giving written consent.

The DelPhi trial was approved by the Regional Ethics Committee of Research, South-East Health Authority, Oslo, Norway on November 6, 2012 (Reference 2012/1606). The study was registered with ClinicalTrials.gov (NCT01737060). The study protocol was published in 2014[17].

Randomization and Blinding

Patients were randomized using a secured web solution, NTNU WebCRF, and were allocated to reverse TSA or ORIF with an angular stable plate. The trial was single-blinded; the allocated treatment was known to the patients and surgeons, but not to the physiotherapists responsible for functional scoring.

Interventions

Patients were allocated to reverse TSA with the Delta Xtend Reverse Total Shoulder Arthroplasty (DePuy Synthes) (6 hospitals, 52 patients) or the Promos Reverse Prosthesis (Smith & Nephew) (1 hospital, 12 patients), or to ORIF with a PHILOS angular stable plate (DePuy Synthes). All surgical procedures were performed in the beach-chair position, using a deltopectoral approach. A detailed description of both operative techniques is featured in the methods section of the published protocol[17]. Postoperatively, all patients received a standardized rehabilitation program according to the allocated group. To secure uniform treatment, follow-ups, and functional scoring, all physiotherapists took part in workshops before the start of the trial. The attending surgeons were all consultant orthopaedic surgeons with expertise within

fracture surgery and shoulder injuries and experienced with both reverse TSA and plate fixation. The surgeons attended meetings on technical standardization of the procedures, and the senior author (T.F.) took part in the first operations in the attending hospitals. Patient information, surgical technique, and physiotherapy routines were available on the DelPhi web site[18].

Data Collection and Outcome Measures

Data collection was performed at each hospital and transferred to Oslo University Hospital. Baseline characteristics and adverse events were reported. Functional testing by dedicated physiotherapists, patient-related outcome measures, and radiographic examinations were conducted at 3 and 6 months, 1 year, and 2 years. Data-gathering included Health-Related Quality of Life 15 Dimensions (HRQoL 15D), which will be presented in a separate health economic article. The primary outcome measure was the Constant score[19] at 2 years, with a minimal clinically important difference (MCID) of 10 points[20]. Subgroup analyses of the Constant score were performed with regard to the fracture type and age groups. The secondary outcome measure was the Oxford Shoulder Score[21]. In addition, we examined radiographic measurements.

Postoperative Rehabilitation and Physiotherapy

The physiotherapy training protocol differed between the 2 groups during the first 6 weeks after the surgical procedure (see Appendix 1). Both groups started standardized patient exercises and supported physiotherapy during the first 3 postoperative days. Patients who underwent a reverse TSA underwent physical therapy with active-assisted exercises for the first 6 weeks and restrictions concerning the external rotation of the shoulder. Activating the deltoid muscle with assisted physiotherapy was equally important[22,23]. For patients treated with ORIF, exercises were started immediately after the surgical procedure, with limitations of resistance exercises in the first 6 weeks.
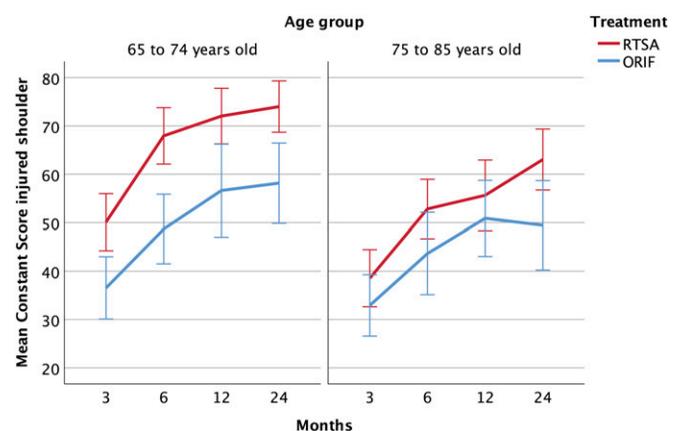

Fig. 4

The mean Constant score for the reverse TSA (RTSA) group and the ORIF group stratified by age groups. The error bars indicate the 95% CIs.

TABLE II Subscores of the Constant Score*					
Subcategory†	Time *(mo)*	Reverse TSA Group‡	ORIF Group‡	Mean Difference§	P Value
Pain					
Pain (15)	12	11.0	10.7	0.3 (−1.1 to 1.7)	0.7
	24	11.9	10.9	1.0 (−0.3 to 2.3)	0.12
Activities of daily living					
Work (4)	12	3.0	2.9	0.06 (−0.3 to 0.4)	0.73
	24	3.3	3.0	0.26 (−0.1 to 0.6)	0.14
Recreation (4)	12	3.2	3.0	0.15 (−0.2 to 0.6)	0.44
	24	3.4	3.2	0.17 (−0.2 to 0.5)	0.32
Sleep (2)	12	1.7	1.7	0.03 (−0.1 to 0.2)	0.69
	24	1.8	1.7	0.13 (−0.002 to 0.27)	0.053
Movement (10)	12	8.6	7.2	1.3 (0.4 to 2.2)	0.004
	24	9.2	7.2	1.9 (1.1 to 2.7)	<0.001
Range of motion					
Flexion (10)	12	6.7	4.7	1.9 (0.9 to 2.9)	<0.001
	24	7.0	5.2	1.8 (0.9 to 2.7)	<0.001
Abduction (10)	12	6.4	4.6	1.8 (0.8 to 2.8)	<0.001
	24	6.7	4.7	2.1 (1.1 to 3.0)	<0.001
Internal rotation (10)	12	5.0	5.8	−0.7 (−1.8 to 0.3)	0.17
	24	5.9	5.7	0.1 (−1.1 to 1.3)	0.85
External rotation (10)	12	6.6	4.6	2.0 (0.8 to 3.4)	0.002
	24	7.0	4.4	2.6 (1.3 to 3.9)	<0.001
Strength					
Strength (25)	12	12.2	9.3	2.9 (0.1 to 5.8)	0.045
	24	11.8	8.8	2.9 (0.05 to 5.8)	0.046
Total score					
	12	62.8	54.3	8.6 (0.5 to 16.6)	0.037
	24	68.0	54.6	13.4 (6.2 to 20.6)	<0.001

*The Constant score ranges from 0 to 100 points, in which 0 points is worst and 100 points is excellent shoulder function. Pain represents 15 points; range of motion represents 40 points, in which flexion, abduction, internal rotation, and external rotation represent 10 points each; strength represents 25 points; and activities of daily living represent 20 points. Measurements of strength were performed with the arm at 60° in the plane of the scapula with a strap over the elbow joint. The highest of 3 measurements was registered. †The values in parentheses are the number of points. ‡The values are given as the mean in points. §The values are given as the mean in points, with the 95% CI in parentheses.

Radiographic Evaluation

All radiographic images were examined at Oslo University Hospital by a dedicated radiologist (A.C.K.) and the first author (A.N.F.) in cooperation. The radiographs were obtained as true anteroposterior and scapular Y projections. Preoperative CT scans were obtained for all patients to ensure that the OTA/AO classification was assessed as accurately as possible. An interobserver analysis was performed with regard to OTA/AO fracture classification, and the kappa value was calculated to be 0.67[24].

Statistical Analysis

Sample size was estimated from the primary outcome, the Constant score, using the mean values from the injured shoulder in a similar population after proximal humeral fractures and a standard deviation equaling 18 points according to clinical experience[5,25]. The MCID was set to 10 points, and the level of significance (α) was 0.05. To achieve a power (β) of 0.80, the number of patients required for each group was 52. Because of a predicted loss to follow-up, we aimed to include 62 patients in each group.

Statistical analysis was performed with SPSS version 25 (IBM). The mean outcome of the respective allocation groups was compared using independent sample t test, and linear mixed model analyses for repeated measurements using a random intercept for each patient were used for subgroup analyses with regard to fracture type (OTA/AO types B2 and C2) and age group (65 to 74 and 75 to 85 years). The results were reported as the mean difference with 95% confidence interval (CI) between the 2 allocated treatment groups. The intention-to-treat principle was applied for crossover patients.
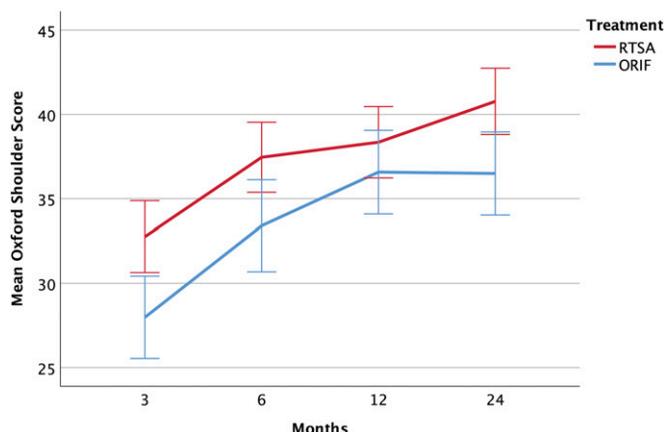
Fig. 5

The overall mean Oxford Shoulder Score for the reverse TSA (RTSA) group and the ORIF group. The error bars indicate the 95% CIs. The Oxford Shoulder Score consists of 12 questions concerning shoulder pain, shoulder function, and activities of daily living and ranges from 12 points (worst) to 60 points (best).

Results

In this study, 270 patients with OTA/AO type-B2 or C2 fractures between 65 and 85 years of age were assessed for eligibility; 124 patients (46%) were included in the trial and 146 patients (54%) were excluded (Fig. 1). There were 103 patients (38%) who did not meet the inclusion criteria, 31 patients (12%) who declined, and 12 patients (4%) who were excluded for other reasons. The excluded patients had a mean age of 75 years, 85% were female, and 48% of the patients presented with a C2 fracture. In comparison, the mean age of the included patients was 75 years, the female proportion was 90%, and 56% of the patients had a type-C2 fracture. The baseline characteristics of the 124 included patients are shown in Table I. Sixty-four patients were allocated to reverse TSA and 60 patients were allocated to ORIF; the difference was due to the electronic block randomization system.

The randomization was considered successful, and the baseline characteristics seemed to be well balanced between the 2 groups.

Primary Outcome

The patients in the reverse TSA group scored significantly better (p < 0.001) than the ORIF group at 2 years in the overall comparison of the Constant score (Fig. 2). At 2 years, the Constant score was 68.0 points (95% CI, 63.7 to 72.4 points) for the reverse TSA group compared with 54.6 points (95% CI, 48.5 to 60.7 points) for the ORIF group, which demonstrated a significant mean difference of 13.4 points (95% CI, 6.2 to 20.6 points; p < 0.001) in favor of reverse TSA.

When the Constant score was stratified by fracture classification (Fig. 3), the mean score was 69.3 points (95% CI, 63.9 to 74.7 points) for the reverse TSA group and 50.6 points (95% CI, 41.9 to 59.2 points) for the ORIF group for the C2 fractures, which yields a significant mean difference of 18.7 points (95% CI, 9.3 to 28.2 points; p < 0.001). In comparison,

in the B2 fracture group, the mean score was 66.2 points (95% CI, 58.6 to 73.8 points) for the reverse TSA group and 58.5 points (95% CI, 49.6 to 67.4 points) for the ORIF group, resulting in a nonsignificant mean difference of 7.6 points (95% CI, −3.8 to 19.1 points; p = 0.19). Furthermore, the Constant score stratified by age indicated that both age groups profited from reverse TSA (Fig. 4). The younger group (65 to 74 years) had a Constant score of 74.0 points (95% CI, 68.7 to 79.3 points) for reverse TSA and 58.2 points (95% CI, 49.8 to 66.5 points) for ORIF, a mean difference of 15.9 points (95% CI, 6.1 to 25.6 points). In the older group (75 to 85 years), the Constant score was 63.0 points (95% CI, 56.7 to 69.4 points) for reverse TSA and 49.5 points (95% CI, 40.2 to 58.7 points) for ORIF, with a mean difference 13.6 points (95% CI, 3.1 to 24.1 points). The subscores of the Constant score (Table II) illustrated that the benefit of reverse TSA was mainly due to better range of motion and strength, and the patients in the reverse TSA group scored universally better except for internal rotation.

Secondary Outcome

The overall comparison of the Oxford Shoulder Score (Fig. 5) demonstrated a consistent trend of the reverse TSA group scoring higher; at 2 years, the mean Oxford Shoulder Score was 40.8 points (95% CI, 38.8 to 42.7 points) for the reverse TSA group compared with 36.5 points (95% CI, 34.0 to 39.0 points) for the ORIF group, a significant mean difference of 4.3 points (95% CI, 1.2 to 7.4 points; p = 0.007). When stratified by fracture classification (Fig. 6), the mean Oxford Shoulder Score for the C2 fracture group at 2 years was 41.2 points (95% CI, 38.6 to 43.8 points) for the reverse TSA group and 34.6 points (95% CI, 30.9 to 38.4 points) for the ORIF group, a mean difference of 6.5 points (95% CI, 2.2 to 10.8 points; p = 0.004). The B2 fracture group showed no difference at 2 years, with a mean score of 40.2 points (95% CI, 36.9 to 43.4 points) for the reverse TSA group and 38.2 points (95% CI, 34.9 to 41.6 points) for the ORIF group, resulting in a mean difference of
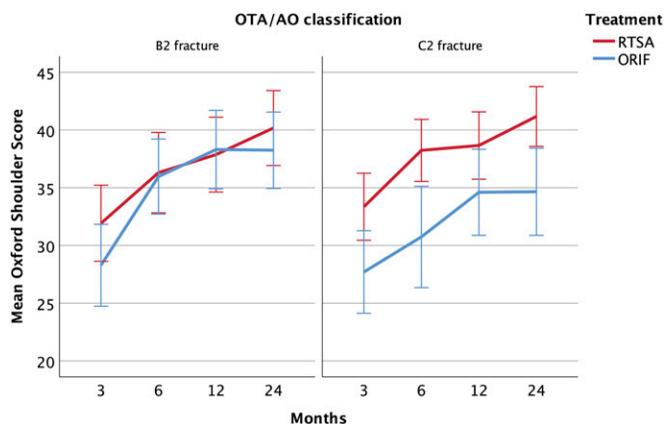

Fig. 6

The mean Oxford Shoulder Score for the reverse TSA (RTSA) group and the ORIF group stratified by the OTA/AO fracture classification. The error bars indicate the 95% CIs.
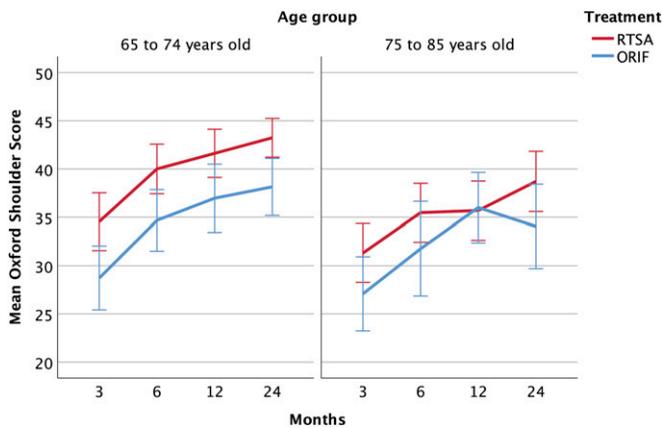
Fig. 7

The mean Oxford Shoulder Score for the reverse TSA (RTSA) group and the ORIF group stratified by age groups. The error bars indicate the 95% CIs.

1.9 points (95% CI, −2.6 to 6.4 points; p = 0.4). When stratified by age group (Fig. 7), the younger patient group (65 to 74 years) had a mean score of 43.2 points (95% CI, 41.2 to 45.2 points) in the reverse TSA group and 38.1 points (95% CI, 35.2 to 41.1 points) in the ORIF group, which yields a mean difference of 5.1 points (95% CI, 1.5 to 8.6 points; p = 0.006). In the older group (75 to 85 years of age), the mean Oxford Shoulder Score was 38.7 points (95% CI, 35.6 to 41.8 points) for the reverse TSA group and 34.0 points (95% CI, 29.7 to 38.4 points) for the ORIF group, resulting in a mean difference of 4.7 points (95% CI, −0.4 to 9.8 points; p = 0.073). Radiographic measurements are presented in Appendices 2, 3, and 4.

Adverse Events

Adverse events are summarized in Table III. In the reverse TSA group, there were 7 adverse events and 4 patients had a secondary surgical procedure. Twelve adverse events were reported in the ORIF group. Seven of these patients had a secondary surgical procedure; 4 patients were converted to reverse TSA and 3 patients had implants removed.

Discussion

The DelPhi study is a multicenter, single-blinded RCT comparing 2 surgical methods, reverse TSA and ORIF, for treating the most complex proximal humeral fractures in elderly patients. The main outcome was the Constant score at the 2-year follow-up, and the Oxford Shoulder Score and radiographic findings were secondary outcomes. There were 124 patients with B2 and C2 fractures between the ages of 65 and 85 years allocated to either reverse TSA or ORIF, and 104 patients (84%) completed 2-year follow-up. In the overall comparison of the Constant score between the 2 groups (Fig. 2), the reverse TSA group scored significantly higher than the ORIF group. The 2-year results show that the Constant score was 68 points in the reverse TSA group compared with 55 points in the ORIF group, a significant mean difference of 13 points in favor of reverse TSA, which is higher than the MCID.

To our knowledge, no previous RCTs have compared reverse TSA with ORIF. Sebastiá-Forcada et al.[13] compared reverse TSA with hemiarthroplasty in a prospective trial with 62 patients with 3 and 4-part proximal humeral fractures and found a mean Constant score of 56 points in the reverse TSA group, which is significantly lower than in our current study, maybe because of differences in the postoperative training regime. Even so, the Constant score for reverse TSA was significantly higher than for hemiarthroplasty, and the range of motion was superior with reverse TSA except for rotation.

Other authors have compared conservative treatments with surgical treatments, including for a wide variety of fractures and operative treatment modalities. Olerud et al. compared locking plates with nonoperative treatment in patients with 3-part proximal humeral fractures and found no significant difference in the Constant score (61 compared with 58 points) at 2 years[7]. When comparing hemiarthroplasty with nonoperative treatment in patients with 4-part proximal humeral fractures, no significant difference in the Constant score (48 compared with 50 points) was found[8]. Both trials showed low functional scores in both conservative and operative groups, comparable with our ORIF group but much lower

TABLE III Adverse Events		
	Reverse TSA Group (N = 64)	ORIF Group (N = 60)
No. of patients with adverse events	7	11
No. of adverse events	7	12
Type of adverse event		
Nerve injury, transient	2	
Screw penetration (implant problems)		9*
Deep wound infection	2	
Periprosthetic fracture or fracture distal to plate	2†	1
Nonunion		1
Other	1‡	1§
Revision surgery		
Change components	2	
Plate to arthroplasty		4
Implant removal or refixation		4
Other revision surgery	2	

*Of the 9 patients who presented with screw penetration, 6 presented with radiographic osteonecrosis and 1 had nonunion at 2 years. Seven of these patients required a second surgical procedure, and the patient with nonunion had 2 reoperations involving refixation and implant removal. A total of 3 patients had implant removal and 4 underwent conversion to reverse TSA. †Two patients sustained a periprosthetic fracture: 1 patient was treated operatively and the other patient was treated with an orthosis; both patients healed without incident. ‡One patient sustained a perioperative glenoid fracture and underwent a primary hemiarthroplasty and later underwent conversion to reverse TSA. §Rotator cuff rupture.

than our reverse TSA group, with a mean Constant score of 68 points.

Cuff and Pupello[26] retrospectively compared reverse TSA with hemiarthroplasty in 47 patients and reported high patient-reported outcome scores for reverse TSA and similarly good range of motion except for rotation. The study showed 8% adverse events and no revision surgical procedures in the reverse TSA group. In our study, 11% of adverse events occurred in the reverse TSA group, and 6% needed a second surgical procedure.

Since the initiation of the DelPhi trial, the Cochrane report of 2015 indicated moderate to high evidence in favor of conservative treatment for proximal humeral fractures in the elderly[27]. The main reason for this change of recommendations was the impact of 1 large pragmatic clinical trial (ProFHER [Proximal Fracture of the Humerus Evaluation by Randomization]) that concluded there was no difference between conservative and operative treatments of proximal humeral fractures[9]. That trial differed substantially from the DelPhi trial with regard to patient selection and surgical interventions: its pragmatic design allowed for the exclusion of patients who were thought to profit from operative treatment, included both younger and elderly patients, and did not differentiate between the different operative modalities included in the trial. Only 9 patients with intracapsular (type-C) fractures were included in this trial, and none were treated with reverse TSA, the main focus of the DelPhi trial.

We have made our best efforts to reduce the limitations of the trial. Even so, there was a possibility of diverse practices, that is, differences in inclusion, operative technique, or follow-up between institutions. To secure conformity in operative technique and follow-up, all attending surgeons participated in educational meetings, physiotherapists attended workshops, and the physiotherapists conducting the testing were blinded to the treatment received. Instructional treatment protocols have been readily accessible on the DelPhi home page[18].

A 2-year follow-up is considered short for an arthroplasty, although sufficient for plate fixation. We therefore plan 5-year follow-up intervals[16]. Also, the study was not statistically designed or sufficiently powered for subgroup analyses, indicating that the stratified results should be interpreted with some caution. Even so, we consider the subgroup findings relevant for displaying trends that may have clinical importance.

The strengths of the study include its randomized design and utilization of a web-based randomization system to prevent allocation bias. Furthermore, the study included functional testing, patient-reported outcome measures, and radiographic measurements, and eligible patients who were not recruited to the trial were registered for external validity analysis.

In conclusion, at the 2-year follow-up, the data suggested an advantage of reverse TSA over ORIF in the treatment of displaced OTA/AO type-B2 and C2 proximal humeral fractures in elderly patients.

Appendix

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