Retrospective and Prospective Clinical Outcomes Study of the Zimmer® Nexel® Total Elbow Annual Report 2019

Introduction

The Nexel Total Elbow System is a treatment option for subjects who require replacement of their humeroulnar (elbow) joint. This system replaces the articulating surfaces to restore motion to the elbow joint.

The objectives of this study are to monitor safety and performance of the device when used in primary and revision total elbow replacement by analysis of outcome measures, radiographs, and adverse events. The safety of the device will be monitored using the prevalence and incidence of adverse events. The performance of the device will be evaluated by assessing the pain and functional performance, survival of the device, and radiographic success of the implant.

As of May 2019, 57 subjects have undergone surgery in this study among nine global investigational sites.

Materials/Methods

Subjects qualifying for primary or revision total elbow arthroplasty with one or more of the study device's cleared indications were offered enrollment in the study.

All prospective subjects are scheduled for pain and functional evaluations at the preoperative visit, 6-week, 6-month, 1-year, 2-year, 5-year, 7-year, and 10-year postoperative intervals. These evaluations include the QuickDASH Outcome Measure (QuickDASH) and Mayo Elbow Performance Score (MEPS).

In addition to the functional evaluations, follow-up surveys are conducted at 3 years and 8 years postoperatively to help reduce the potential for loss to follow-up and collect any possible adverse event information. Institutional Review Board (IRB)/Ethics Committee (EC) approval was obtained at each clinical site prior to starting enrollment of subjects.

Those subjects who are enrolled retrospectively join the study at the current interval and all attempts are made to retrospectively collect all relevant demographic, surgical, and outcome measure data collected as standard of care prior to entering the study.

Statistical analysis was completed separately for subjects enrolled for primary surgery versus revision surgery. The F-test was used to assess the difference of variances between two groups and the t-test was used to determine mean group differences. The Satterthwaite adjustment or pooled t-test statistic was employed based on the F-test outcome. All statistical tests were evaluated with a Type I error of 0.05 and no p-values were adjusted for multiplicity.

Device Description

All subjects taking part in the study received the Nexel Total Elbow. This device is a total elbow prosthesis designed for use with bone cement. It is available in three sizes and in left and right configurations. The ulnar and humeral components are manufactured from a Ti-6Al-4V alloy (Tivanium®) and have a Ti-6Al-4V plasma spray porous coating. The axle-pin and humeral screws are manufactured from a Co-Cr-Mo alloy (Zimaloy®) and the bearings are made of vitamin E highly cross-linked ultra-high molecular weight polyethylene (Vivacit-E®).

Results: Primary Group

Demographics

45.5% (n=20) of enrolled primary subjects had primary diagnoses of advanced rheumatoid arthritis, 18.2% (n=8) had post-traumatic arthritis, 13.6% (n=6) had post-traumatic lesions, and 13.6% (n=6) had acute articular fractures. 79.5% (n=35) of enrolled subjects are female. All subjects identified themselves as non-smokers and 70.5% (n=31) identified themselves as non-drinkers. **Figure 1** shows a demographic summary of all enrolled subjects who underwent primary elbow surgery.

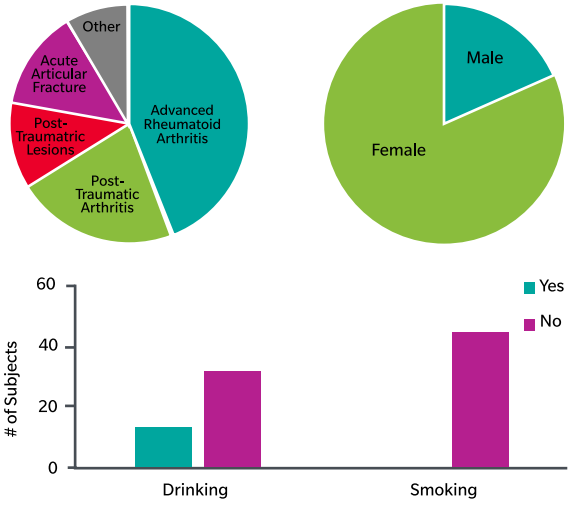

Figure 1: Demographic Summary for Primary Subjects

Hospital Stay/Mobilization

The average length of hospital stay for primary subjects was 2.1 days ± 1.4 days. Mobilization of the operative joint occurred within 24 hours for 50% of the primary subjects.

QuickDASH Score

The average QuickDASH score was 62.7 preoperatively (n=40) compared to 48.0 at 6 weeks (n=34), 35.7 at 6 months (n=24), 31.9 at 1 year (n=19), and 31.5 at 2 years (n=7). When compared to the average pre-operative QuickDASH score, the average QuickDASH scores at each visit interval showed significant improvements ($p < 0.05$). These details are shown in **Figure 2**, where red markers (•) indicate significant improvement compared to pre-operative data.

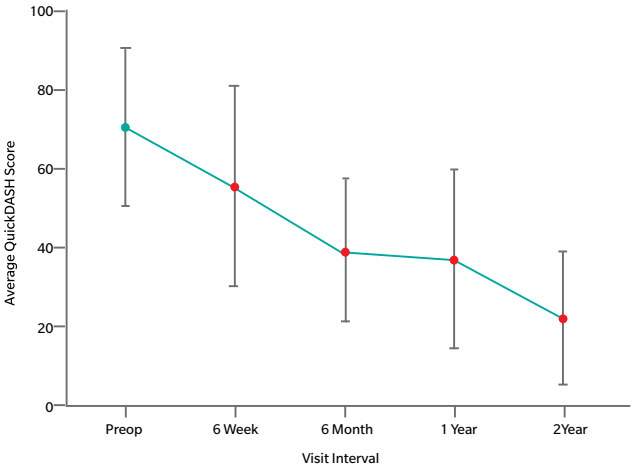

Figure 2: Average QuickDASH Score by Visit Interval

MEPS Score

The average MEPS score preoperatively was 40.7 (n=41) compared to 74.6 at 6 weeks (n=34), 84.0 at 6 months (n=24), 84.2 at 1 year (n=19), and 94.3 at 2 years (n=7). When compared to the average pre-operative MEPS score, the average MEPS scores at each visit interval showed significant improvements ($p < 0.05$). These details are shown in **Figure 3**, where red markers (•) indicate significant improvement compared to pre-operative data.

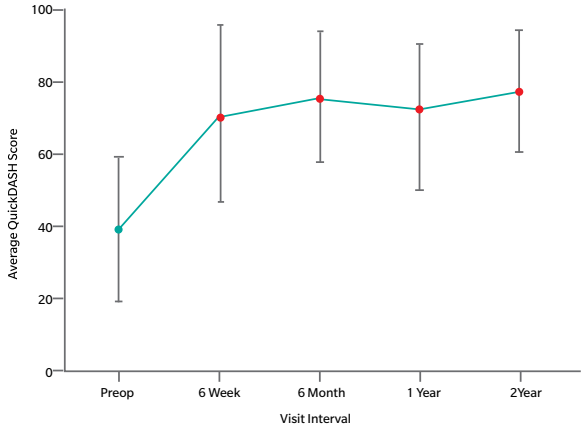

Figure 3: Average MEPS Score by Visit Interval

Survivorship

At this point in the study, the survival for the Nexel Elbow implant is 96.9% at 1 year. Literature reports survivorship of 94.9% calculated from a systematic review of national registries and clinical studies[1]. All reoperations and/or device removals were considered revisions for this analysis. There was a revision at the 2-year follow-up; however, there are not enough cases at risk to estimate survivorship after 1 year. Kaplan-Meier survivorship estimates are shown in **Table 1.**

Table 1: Kaplan-Meier Survivorship Estimates for Primary Subjects

Follow-up Years	# of Cases at Risk	# of Cases Revised (Cumulative)	Survival Estimate
1	44	1	96.9%
2	18	2	N/A
3	10	2	N/A
4	4	2	N/A

The predicted revision rate per 100 observed component years (OCY) is 4.2 for the study device. Literature reports a mean value of 5.08 revisions per 100 OCY calculated from a systematic review of national registries and clinical studies[1]. OCY survivorship estimates are shown in **Table 2.**

Table 2: Observed Component Year Survivorship Summary for Primary Subjects

Total OCY Years	N Revised	N Cases	Revision Rate per 100 OCY	Raw Survival Rate
47.6	2	44	4.2	95.5%

Radiographic Data

Radiographic data is collected during the 6-week, 6-month, 1-year, 2-year, 5-year, 7-year, and 10-year follow-up visits. There has been one case of humeral implant loosening since the start of the study. The case of humeral loosening occurred 1 year after the subject's total elbow arthroplasty. This subject had no prior elbow surgeries and ultimately underwent revision surgery in November 2017 where a periprosthetic ulna fracture and ulnar nerve neurolysis were repaired. The patient had the study device removed as part of this procedure.

In addition, heterotopic ossification in radiographic zones 19, 26, and 27 was noted in three subjects. Other radiographic findings included cortical penetration, fracture of humeral epicondyle, and radiolucency.

All radiographic zones are shown in **Figure 4**, where the highlighted zones in teal are associated with reported findings for primary subjects.

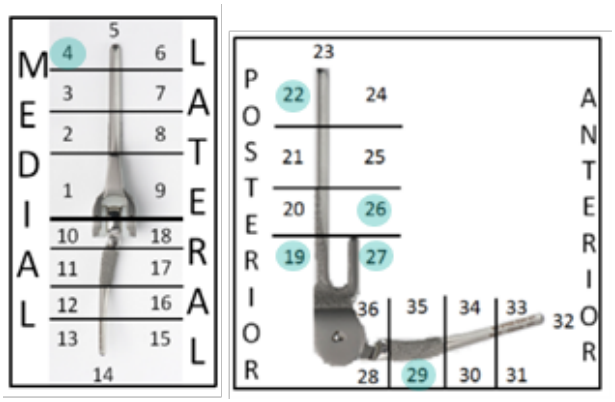

Figure 4: Elbow Radiographic Zones

All radiographic findings for subjects who underwent primary elbow surgery are summarized in **Table 3**.

Table 3: Radiographic Findings Summary for Primary Subjects

Finding	Exam Period	Zone(s)	# of Subjects
Heterotopic Ossification	6 Week	27	3
	6 Month	26	
	1 Year	19, 26, 27	
	2 Year	19	
Radiolucency	1 Year	4, 24	2
	2 Year	29, 35	
Fracture of Humeral Epicondyle	6 Week	1 (x2)	2
Cortical Penetration	1 Year	22	1
	2 Year	22	
Humeral Implant Loosening*	1 Year	20, 26, 28, 36	1

Adverse Events

The primary group had no adverse events directly related to the study device; however, three subjects had adverse events that may be related to the study device. As discussed in the Radiographic Data Section, it was found that a subject had humeral implant loosening at their 1-year visit and was later revised. Another subject had an intraoperative posterior humeral crack, but was resolved with a cerclage. An additional subject complained of pain and a periprosthetic fracture of the olecranon was found. This subject was later revised and the study device was removed.

Another subject had drainage from the surgical site approximately a month after surgery, which resulted in a reoperation and a bushing exchange.

Other adverse events that were classified as being not related to the study device by the investigator included hematoma, seizures, heterotopic ossification, swelling, olecranon fracture, and humeral fracture.

Results: Revision Group

35.3% (n=6) of enrolled revision subjects had revision diagnoses of advanced rheumatoid arthritis, 17.6% (n=3) had post-traumatic arthritis, and 17.6% (n=3) had degenerative arthritis. Revision surgeries were categorized as a subject that previously underwent an ipsilateral elbow surgery such as hemi-arthroplasty, total arthroplasty, or a device implantation and/or removal. 70.6% (n=12) of enrolled subjects are female. 88.2% (n=15) subjects identified themselves as non-smokers and 35.3% (n=6) identified themselves as non-drinkers.

The average length of hospital stay for revised subjects was 2.5 days ± 1.6 days. Mobilization of the operative joint occurred within 24 hours for 44.4% (n=8) of the revised subjects.

When compared to pre-operative outcome measure scores, the average outcome measure scores (QuickDASH and MEPS) for subjects who underwent revision surgery statistically improved ($p < 0.05$) at the 6-month, 1-year, and 2-year visit intervals. A summary of outcome measure scores are shown in **Table 4.**

Table 4: Average Outcome Measure Scores for Revision Subjects

Visit Interval	N	Average QuickDASH Score	Average MEPS Score
Pre-Operative	14	73.5	32.9
6 Week	11	66.1	62.3*
6 Month	9	42.9*	72.8*
1 Year	9	44.7*	63.3*
2 Year	5	15.0*	88.0*

*Significant improvement from pre-operative score ($p < 0.05$)

The revision group has not reported additional revisions or reoperations in this study.

Two (2) revision subjects report ulnar implant loosening. Of these subjects, one had loosening in radiographic zones 11, 17, and 29 at their 1-year visit, but the subject tolerated the complication. The other subject had loosening in radiographic zones 10-18 and 28-36 at their 6-month and 1-year visits.

Three (3) revision subjects display radiolucency. Of these subjects, one subject had radiolucencies in multiple radiographic zones at their 6-month and 1-year visits, but this subject tolerated the complication. It was noted that there was no shift or loosening of the study device. Another subject had radiolucency around the humeral implant in radiographic zones 1 and 10 at their 2-year visit, but without loosening of the implant. Another subject had radiolucency in radiographic zones 1 and 9 at their 6-week visit.

Other adverse events and radiographic findings included contracture, nerve deficit, swelling, stress shielding osteolysis, and ulnar pain.

Conclusion

The primary total elbow arthroplasty survival for the Nexel Elbow implant is 96.9% at 1 year. Literature reports survivorship of 94.9% calculated from systematic review of national registries and clinical studies[1]. Additionally, the revision rate for the Nexel Elbow implant is 4.2 per 100 OCY. Literature reports a mean value of 5.08 revisions per 100 OCY calculated from a systematic review of national registries and clinical studies[1].

For the primary group, the average QuickDASH and MEPS scores at all follow-up visits have shown significant improvements compared to the average pre-operative score. A primary subject required revision surgery after the 1-year visit to repair a periprosthetic ulna fracture and ulnar nerve neurolysis. Additionally, another subject was re-operated on due to post-operative drainage and infection.

For the revision group, the average QuickDASH and MEPS scores at follow-up visits after the 6 months visit have shown significant improvements compared to the average pre-operative score. There were no additional revisions reported for these subjects.

Reference

1. Labek, G., et *al.* "*Revision Rates after Total Joint Replacement*." The Journal of Bone and Joint Surgery. British Volume, 93-B, no. 3, 2011, pp. 293–297., doi:10.1302/0301-620x.93b3.25467.

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