Mid-long term survivorship of the cemented, semi-constrained “Discovery” total elbow arthroplasty.

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Mid-long term survivorship of the cemented, semi-constrained “Discovery” total elbow arthroplasty.

Short form title: Survivorship of the Discovery elbow prosthesis

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IRB approval: This study reports on data routinely collected during standard care without the acquisition of new information for the purposes of the study. It was subsequently classed as ‘Service Evaluation’ by the United Kingdom National Institute for Health Research (NIHR), and therefore did not require formal ethics approval.
Abstract

**Background:** The incidence of total elbow arthroplasty (TEA) is increasing and improved understanding of elbow kinematics and biomaterials have driven advances in implant design. In modern practice, cemented semi-constrained devices are most frequently utilized. The Discovery TEA has demonstrated promising early results, though there is a paucity of follow-up studies and no dedicated mid-long term series. We therefore present the longest, most complete such study to date.

**Methods:** A prospectively maintained local joint registry was interrogated to yield a consecutive series of Discovery TEA performed at a single non-design center. Minimum follow-up was set at 5 years. Revision procedures and TEA performed for acute trauma were excluded. Primary outcome was survivorship of the implant. Secondary outcomes included clinical, radiographic, and patient-reported outcomes.

**Results:** Sixty-seven TEAs in 58 patients were identified for inclusion at a mean 98.5(+/−20.4) months from surgery. Four (6%) were lost to follow-up and implant survival censored accordingly. The implant was revised in 14 cases (20.9%). Implant survivorship was 76.8% at 119 months by the Kaplan-Meier method. There was a significant difference in survival between dominant and non-dominant elbows (Breslow test p=0.012), with elbow dominance conferring a 4.5-fold increased risk of revision (relative risk 4.5 [95% CI 1.1-18.5]). Pooled clinical outcomes (70.9% follow-up at minimum 60 and median 77.8 months) are also presented.

**Conclusions:** We present the longest-term and most complete single-center follow-up study of the Discovery TEA to date. Further long-term survival studies are required to elucidate the performance of this implant compared to more established designs. We have also demonstrated differences in implant survivorship due to hand dominance for the first time.
Total elbow arthroplasty (TEA) has become an accepted strategy for end-stage degenerative disease of the elbow refractive to conservative therapy. The incidence and indications for TEA are expanding: as the incidence of TEA for inflammatory arthritis decreases secondary to the efficacy of contemporary medical management, an increasing number are performed for osteoarthritis, post-traumatic sequelae, and acute trauma\textsuperscript{17,28}.

Advances in the understanding of elbow kinematics, implant design, and biomaterials have led to an increasing number of marketed prostheses. Early fully-constrained designs were associated with high failure rates secondary to overconstraint, and have subsequently been superseded by semi-constrained and non-constrained designs\textsuperscript{22,28}. Non-constrained devices, whilst experiencing low incidence of loosening, exhibit increased dislocation risk due to their reliance on surrounding soft-tissue structures of the elbow. They subsequently have limited value in the context of ligamentous insufficiency or poor bone stock and have fallen out of favor at many centers as a result\textsuperscript{13}.

Modern semi-constrained prostheses allow a degree of coronal and axial plane laxity at the hinge- the so-called “sloppy hinge”- mirroring the native kinematics at the elbow. Many
upper limb activities take place in a degree of shoulder abduction which subsequently imparts a varus moment at the elbow. The laxity at the hinge allows load sharing between the prosthesis and soft tissues, thus minimizing the force transmitted to the bone cement interface and reducing the risk of loosening\textsuperscript{4,14}. Semi-constrained devices offer stability and good functional outcomes and are consequently the most commonly used implant type in modern practice\textsuperscript{4}.

The Discovery Elbow System (DES; Lima, Udine, Italy) is the second most commonly used TEA prosthesis in the United Kingdom, both electively and in the context of trauma\textsuperscript{29}. Data from a recent systematic review and meta-analysis demonstrated promising results in the short- and medium-term (including early results from our own center\textsuperscript{16}) but highlights a definite paucity of long-term results for the DES\textsuperscript{27}. We also note many existing series include both elective and non-elective indications, in addition to both primary and revision TEA, which can limit their external validity. We therefore aim to present the mid-long term survivorship and clinical outcomes of a large series of elective primary DES TERs from a non-design center.

**Materials and Methods**

A prospectively maintained local joint registry was interrogated to yield a consecutive series of TEA performed by four dedicated upper limb surgeons at our center. Minimum follow-up for the cohort was set at 5 years from primary surgery. Further inclusion criteria included use of the Discovery TEA system. Exclusion criteria comprised revision procedures, TEA performed for acute trauma, and use of a different implant. This study reports on data
routinely collected during standard care without the acquisition of new information for the purposes of the study. It was subsequently classed as ‘Service Evaluation’ by the United Kingdom National Institute for Health Research (NIHR), and therefore did not require formal ethics approval.

The registry database is populated and maintained by a dedicated musculoskeletal physiotherapist. Patients are reviewed at intervals with patient-reported outcome measures (Mayo Elbow Performance Score and Oxford Elbow Score) and clinical assessment. Range of motion is formally assessed using a goniometer. Where patients are unable or unwilling to attend annual review in person, telephone contact is maintained where possible.

The primary outcome of the study was defined as survival of the implant at a minimum 5 years follow-up. Secondary outcomes included patient-reported outcome measures, range of motion, triceps function, and radiographic review at minimum 5 years follow-up.

Radiographs were reviewed for radiolucency at the cement-prosthesis and bone-cement interfaces and recorded in binary format as present or absent. Location was recorded as unipolar (humeral), unipolar (ulnar), or bipolar. When present, progression was determined by comparison between the final radiograph and the radiograph on which the lucency was first appreciable.

Statistical analysis was with the SPSS software package for Windows (IBM Corp., Armonk, NY, USA). Continuous data were tested for parametricity using the Shapiro-Wilks test and descriptive statistics and statistical tests selected accordingly. The Kaplan-Meier method was used for survival analysis with revision of the humeral and/or ulna component as the end point.
point. Further analysis with revision procedure inclusive of implant retention is also presented. Survival statistics are given at the point the total number at risk dropped to 10% of the study cohort in order to minimize bias from the increased statistical uncertainty beyond this point. The Breslow test was utilized to assess differences in survival between groups. Categorical data were compared with the Chi Square or Fishers exact tests as appropriate. Groups were compared using the Mann-Whitney test. Paired data were compared with the Related-Samples Wilcoxon Signed Rank test.

All procedures were performed or directly supervised by one of four upper limb surgeons (AAT, MPE, TC, DIC). All cases were undertaken within laminar flow theatres in a dedicated orthopedic theatre complex and utilized double skin preparation and antibiotic prophylaxis prior to incision. Three surgical approaches are employed at our institution according to surgeon preference: para-tricipital, modified Gschwend, and triceps-reflecting Mayo approaches. Standard practice includes excision of the radial head and release of the ulnar nerve. Cementation is with antibiotic-impregnated cement: either Palacos R&G (Heraeus Medical, Wehrheim, Germany) or Simplex (Stryker, Mahwah, NJ, USA), again according to surgeon preference. Postoperatively the limb remains bandaged for 2 weeks and unrestricted early range-of-motion dictated by patient comfort permitted thereafter. Triceps function is restricted to ‘against gravity’ for 6 postoperative weeks, with return to functional activities and progressive loading up to a maximum of 3kg thereafter.

**Results**

Sixty-seven TEAs in 58 patients were identified for inclusion at a mean 98.5 months from surgery (standard deviation [σ] 20.4; range 62-141). All procedures took place between...
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August 2008 and March 2015. Patients were female in 42 (62.7%) of cases, and had a median age at surgery of 67 years (interquartile range [IQR] 54-71). The most common indication for surgery was inflammatory arthropathy in 43 (64.2%), followed by osteoarthritis in 17 (25.4%) and post-traumatic arthritis in 7 (10.5%).

Primary Outcome - Survivorship

There were 14 implant revisions (20.9%). Revision surgery was indicated for aseptic loosening in 7 (50% of revisions; 10.4% of cohort), infection in 5 (30.8%; 7.5%), periprosthetic fracture in 1 (7.1%; 1.5%), and component failure with disassociation of the pin in 1 (7.1%; 1.5%). Median time from primary arthroplasty was 56.5 months (IQR 21-68).

Further detail is given in table I. Eleven cases died at a median 62 months from surgery (IQR 12-84) of which none of which were revised. Implant survivorship was 76.8% (standard error 0.056) at 119 months by the Kaplan-Meier method (figure 1 and table II).

There were four cases (6%) lost to follow-up. Of these four cases, one has relocated and implant survivorship has correspondingly been censored at the date of last contact with the department. The remaining three remain within the hospital catchment but have not presented for revision. To minimize the resultant risk of bias a theoretical model of worst-case survivorship is also presented (figure 1, table II).

Re-operation without revision of the implant took place in four cases. In 2 (3%), early infection was successfully treated with débridement, antibiotics, irrigation, and retention (DAIR). One of these patients went on to formal revision for loosening 61 months later. As subsequent biochemistry and aspiration was negative, patient presentation and interoperative
findings were not clinically suspicious for infection, this has been treated as revision for aseptic loosening for the purposes of the survival analysis. One case was treated with débridement for gross synovitis causing mechanical symptoms through interposition (1.5%). A single case of triceps failure was treated with reattachment and graft jacket augmentation (1.5%).

Data pertaining to hand dominance was available in 63 cases (94%) and in all of the revised cases. There was a statistically significant difference in survival between dominant and non-dominant elbows (7.4% vs 33.3%, p=0.014). Expressed as relative risk this demonstrated a 4.5-fold increase in risk of revision (relative risk 4.5 [95% CI 1.1-18.5]). The difference in survival is well demonstrated by the survival curve in figure 2 (Breslow test p=0.012). Use of the theoretical ‘worst-case’ scenario continues to demonstrate this difference in survivorship (Breslow test p=0.013). There were no differences in age (69 vs 66.5, p=0.355), indication for surgery (18:6:3 vs 22:10:4, p=0.877) or gender (16:11 vs 22:13, p=0.708) between dominant and non-dominant groups. There was no difference in survivorship between genders (p=0.962), different indications for primary arthroplasty (p=0.569), or operating surgeon (p=0.348).

Secondary Outcome- Clinical Outcomes

Five patients died and 7 were revised prior to 60 months from primary surgery. This left 55 patients in whom minimum 5-year clinical outcomes would have been possible. Of these, those with a full complement of clinical outcomes beyond 60 months were included and those with incomplete data excluded. This left a cohort of 39 (70.9% follow-up) at a mean clinical
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Follow-up of 77.8 months (σ 16.9; range 60-119). Baseline demographics did not differ significantly from that of the larger survival cohort and are demonstrated in table III.

Median flexion-extension arc was from 25-140 degrees and pronosupination from 75-75 degrees. Median Mayo Elbow Performance Score and Oxford Elbow Score were 95 (IQR 80-100) and 40 (IQR 34-47) respectively. The difference in clinical range of motion compared to preoperative values is demonstrated in table IV, though preoperative data to support this analysis were only available in 29 (74%). There were insufficient preoperative MEPS and OES data to support paired statistical analysis. Triceps function was intact (defined as sufficient to lift greater than 3 kilograms against gravity) in 30 (76.9%). It was considered mildly impaired (sufficient to lift between 1 and 3kg) in a further 5 (14.1%). Triceps function was impaired in the remaining 3 cases: in 2 cases (5.1%) the arm could be extended against gravity in the absence of resistance and in a single case the arm could only be extended with gravity eliminated. Triceps function at final follow-up did not differ between the approaches used in our cohort (p=0.529).

Secondary Outcome- Radiographic Outcomes

Two further patients were excluded from radiographic analysis. In one, this was due to the incidental finding of component failure on the 5-year radiograph which subsequently prompted revision. In the second, due to inadequate radiographic follow-up of 58 months. Thirty-seven cases therefore underwent radiographic review at median 75 months (IQR 64-92).
There was evidence of radiolucent lines in 22 (59.5%). Lucency first appeared at median 15 months postoperatively (IQR 9-37) and was associated with the humeral component in 16 (43%), was bipolar in 4 (10.8%), and isolated to the ulna in 2 (5.4%). In 17 (77.3%) there is evidence of progression taking place over a median 60.5 months (IQR 40-63.5).

Radiographic signs of implant loosening were present in 4 (10.8%). Of these, 2 were revised for aseptic loosening as described in the primary outcome analysis. The remaining 2 cases involved the same rheumatoid patient with bilateral loosening: however, due to acceptable functional outcome (minimal discomfort, 105 and 95 degree flexion-extension arcs, OES 37, MEPS 85) this is presently being managed expectantly.

**Discussion**

We have reported what we believe to be the longest-term survivorship and largest and most complete dedicated mid-long term follow-up study of the Discovery elbow arthroplasty. Larger series with broader inclusion criteria and shorter follow-up have been published\(^1,10\). We describe a 20.9% revision rate at mean 98.5 months (range 62-141 months) follow-up, equating to 76.8% ten-year survivorship (119 months) by the Kaplan-Meier method.

The raw revision rate reported in our series is higher than the 13.8% reported for linked prostheses in a systematic review of TEA failure, though the weighted mean follow-up of this study was shorter by 2 years making direct comparison difficult\(^23\). It is however similar to the
8-year revision rate of 18% reported in a large Australian registry study\(^2^6\). Though our reported survival is also lower than the 85.5% at 7.8 years across all semi-constrained TEAs in a recent systematic review, our clinical results compare favorably\(^2^7\). Our series reports greater flexion (140 degrees vs 128), pronosupination (75-75 vs 69-67), and MEPS (95 vs 85.6)\(^2^7\). This is despite a relatively high incidence of radiolucent lines at final radiographs, of which 77.3% demonstrate slow progression over a median 5 years but only infrequently progress to frank loosening.

Taking a 5-year survivorship figure allows for comparison with shorter-term studies pertaining specifically to the DES implant. Five-year Kaplan-Meier survivorship in our study was 89.6%, comparable to series describing 90% survival at 4.5 years\(^1^9\) and 91.3% at 4.1 years\(^1^2\) but slightly lower than the 95.6% reported elsewhere\(^1^0\) and 95.4% described in a registry study including 190 Discovery elbows\(^1^5\). A small series of cementless DES arthroplasty has also reported 100% survivorship at mean 5 years\(^6\).

The most common indications for revision of TEA in contemporary practice are aseptic loosening, followed by infection, then periprosthetic fracture\(^2^3,2^9\). This relationship is upheld in our own series. Of note however, our series reports a relatively high revision rate for infection of 7.5%. We have not been able to identify a unifying explanation or etiology, and recognize that this may simply be a function of the relatively small sample size amplifying small changes in the number of infections with respect to a percentage figure.

Multiple technical factors influence revision rates and implant survival. These can be considered as implant and surgical factors. Surgical factors include technical considerations.
such as implant positioning, quality of cementation and adequacy of soft tissue balancing. Implant factors comprise the implant design and wear properties of the materials used. One key consideration is constraint: as aforementioned, modern implants utilize a semi-constrained design which allows a degree of out-of-plane motion. Wear and failure at the polyethylene bushing is consequently common. This underpinned the hemispherical bearing design of the Discovery, which both allows simple bearing exchange where required and increases articular congruence under load. The papers by Hastings give a thorough review of the design features which we have not repeated in full.

In addition to the implant and surgical factors a number of patient-associated factors have been associated with poorer outcomes from TEA, including diabetes, obesity, age, instability, preoperative deformity, smoking status, and underlying diagnosis. A putative association with activity level is also described. This is thought to underlie the improved survival described in patients undergoing revision for inflammatory arthritis, who are typically low-demand. Though intuitively linked to increased activity, to our knowledge an association between hand dominance and implant survivorship had not been formally demonstrated prior to this study.

There are a number of limitations to our study. The data is a retrospectively analyzed case series, though the prospective maintenance of the database ameliorates the resultant risk of bias to an extent. The series is small to support formal statistical analysis, though remains to our knowledge the largest single-center series of the DES at such follow-up. We were also unable to correct for confounding comorbid conditions. This imparts a degree of fragility to our statistical analyses and necessitates caution in comparing our results to much larger series.
from other designs, or to pooled data. It also prevents us from adjusting for covariates such as age, indication for surgery, and gender when describing our observed association with hand dominance and failure rate. Though dominance remains the only significant covariate in a binary logistic regression model including age, indication, gender and hand dominance with revision as the end point (odds ratio 6.0, 95% CI 1.2-31.3, p=0.031), concerns about the validity and robustness of such a model prevent us from including this in our formal analysis. Finally, as patient-reported scores were a later addition to our registry, limited preoperative scores are available to support paired analysis. We nonetheless describe our clinical results at final follow-up for the purposes of comparison to pooled similar data, or future inclusion in the same.

Conclusion

We present a dedicated mid-long term survivorship study of the Discovery total elbow arthroplasty at between 5 and 12 years follow-up, demonstrating 76.8% survival at 119 months by the Kaplan-Meier method. We believe this to be the longest term, most heterogenous study of its type. Range of motion and patient reported outcome scores at a minimum 5 years follow-up are also reported and compare favorably to the literature. Inferior implant survivorship is demonstrated in TEA of the dominant versus non-dominant elbow, which confers a 4.5-fold relative risk of revision.

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Table and Figure Legends

Table I: Descriptive summary of revision indication and baseline demographics.

Table II: Survival characteristics of the implant survivorship and theoretical worst-case scenarios, calculated using the Kaplan-Meier method.

Table III: Baseline demographics between the smaller ‘clinical’ cohort and the full cohort. a- Mann-Whitney test, b- Chi Square test. IQR = interquartile range.

Table IV: Range of motion values at a mean 6.5 years follow-up versus preoperatively. a – Related Samples Wilcoxon Signed Rank test. IQR = interquartile range.

Figure 1: Kaplan-Meier survival curve of implant survivorship at a mean 8.2 years from surgery, with worst-case scenario assuming all patients lost to follow-up were revised at the date of last contact also presented.

Figure 2: Kaplan-Meier analysis demonstrating significant difference in survivorship between dominant and non-dominant elbows.
<table>
<thead>
<tr>
<th>Revision Number</th>
<th>Age at primary (years)</th>
<th>Gender</th>
<th>Time to revision (months)</th>
<th>Indication for revision</th>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>59</td>
<td>F</td>
<td>8</td>
<td>Infection (2 stage)</td>
<td>Staph. Epidermidis</td>
</tr>
<tr>
<td>2</td>
<td>61</td>
<td>F</td>
<td>19</td>
<td>Aseptic Loosening</td>
<td>n/a</td>
</tr>
<tr>
<td>3</td>
<td>67</td>
<td>M</td>
<td>21</td>
<td>Aseptic Loosening</td>
<td>n/a</td>
</tr>
<tr>
<td>4</td>
<td>74</td>
<td>F</td>
<td>21</td>
<td>Infection (2 stage)</td>
<td>Staph. Epidermidis</td>
</tr>
<tr>
<td>5</td>
<td>68</td>
<td>F</td>
<td>45</td>
<td>Periprosthetic Fracture</td>
<td>n/a</td>
</tr>
<tr>
<td>6</td>
<td>51</td>
<td>F</td>
<td>45</td>
<td>Aseptic Loosening</td>
<td>n/a</td>
</tr>
<tr>
<td>7</td>
<td>60</td>
<td>F</td>
<td>50</td>
<td>Infection (2 stage)</td>
<td>P. Acnes</td>
</tr>
<tr>
<td>8</td>
<td>69</td>
<td>M</td>
<td>63</td>
<td>Component Failure</td>
<td>n/a</td>
</tr>
<tr>
<td>9</td>
<td>66</td>
<td>F</td>
<td>64</td>
<td>Infection (2 stage)</td>
<td>Staph. Epidermidis</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
<td>M</td>
<td>65</td>
<td>Aseptic Loosening</td>
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<tr>
<td>11</td>
<td>57</td>
<td>M</td>
<td>68</td>
<td>Aseptic Loosening</td>
<td>n/a</td>
</tr>
<tr>
<td>12</td>
<td>74</td>
<td>F</td>
<td>74</td>
<td>Infection (2 stage)</td>
<td>Staph. Epidermidis</td>
</tr>
<tr>
<td>13</td>
<td>63</td>
<td>M</td>
<td>90</td>
<td>Aseptic Loosening</td>
<td>n/a</td>
</tr>
<tr>
<td>14</td>
<td>63</td>
<td>M</td>
<td>92</td>
<td>Aseptic Loosening</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Table I: Descriptive summary of revision indication and baseline demographics.
Table II:

<table>
<thead>
<tr>
<th></th>
<th>Number of cases</th>
<th>Number of events (revisions)</th>
<th>Number censored</th>
<th>Mean Implant survivorship (months [95% Confidence intervals])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Survivorship</td>
<td>67</td>
<td>14</td>
<td>53 (79.1%)</td>
<td>121.1 (111.7-130.6)</td>
</tr>
<tr>
<td>Theoretical ‘Worst-case’ Scenario</td>
<td>67</td>
<td>18</td>
<td>49 (73.1%)</td>
<td>115.1 (105.1-125.1)</td>
</tr>
</tbody>
</table>

Table II: Survival characteristics of the implant survivorship and worst-case revision scenario, calculated using the Kaplan-Meier method.
Table III: Baseline demographics between the smaller ‘clinical’ cohort and the full cohort. a- Mann-Whitney test, b- Chi Square test. IQR = interquartile range.

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Clinical Cohort</th>
<th>Full Cohort</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, median [IQR])</td>
<td>66 (54-70)</td>
<td>65.5 (52-70)</td>
<td>p=0.91 a</td>
</tr>
<tr>
<td>Dominance (non-dominant:dominant)</td>
<td>16:19</td>
<td>27:36</td>
<td>p=0.79 b</td>
</tr>
<tr>
<td>Body Mass Index (median [IQR])</td>
<td>27 (21-29)</td>
<td>27 (22-31)</td>
<td>p=0.50 a</td>
</tr>
<tr>
<td>Gender (F:M)</td>
<td>24:15</td>
<td>42:25</td>
<td>p=0.91 b</td>
</tr>
<tr>
<td>Indication (Inflammatory arthropathy: Osteoarthritis: posttraumatic arthritis)</td>
<td>24:12:3</td>
<td>43:17:7</td>
<td>p=0.78 b</td>
</tr>
</tbody>
</table>
Table IV: Range of motion values at a mean 6.5 years follow up versus preoperatively. * – Related Samples Wilcoxon Signed Rank test. IQR = interquartile range.

<table>
<thead>
<tr>
<th></th>
<th>Range of motion at minimum 5-year follow-up (degrees; median [IQR])</th>
<th>Pre-operative range of motion (degrees; median [IQR])</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>140 (140-150)</td>
<td>120 (110-135)</td>
<td>p&lt;0.001 *</td>
</tr>
<tr>
<td>Extension</td>
<td>-25 (-15 - -30)</td>
<td>-40 (-40 - -30)</td>
<td>p=0.002 *</td>
</tr>
<tr>
<td>Supination</td>
<td>75 (65-80)</td>
<td>65 (45-80)</td>
<td>p=0.01 *</td>
</tr>
<tr>
<td>Pronation</td>
<td>75 (65-80)</td>
<td>75 (45-80)</td>
<td>p=0.30 *</td>
</tr>
</tbody>
</table>