



Arthroplasty as primary treatment for distal humeral fractures produces reliable results with regards to revisions and adverse events: a registry-based study



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Background: Primary prosthetic replacement has become an accepted method for the treatment of complex distal humeral fractures. The present study investigated implant survival and adverse events related to this procedure based on available Swedish registries and examined the completeness of the Swedish Elbow Arthroplasty register.

Materials and methods: Patients treated in Sweden with a primary elbow replacement due to a distal humeral fracture between 1999 and 2014 were identified through 3 different registries: The Swedish Elbow Arthroplasty Register, National Board of Health and Welfare inpatient register, and local registries of all orthopedic departments. Prosthetic survival was examined using Cox regression analysis with Kaplan-Meier plots. Adverse events, defined as medical treatment of the affected elbow besides revision, were analyzed separately. The study included 406 elbows in 405 patients, and no register was complete.

Results: Implant survival at 10 years was 90% (95% confidence interval, 85%-96%), but only 45 patients had an observation time of 10 years or more because 46% of the patients had died, resulting in a mean observation time of 67 (standard deviation, 47) months. An increase in the use of hemiarthroplasties and a proportional decrease of total elbow arthroplasties was detected. There were 18 revisions (4%), and 26 patients (6%) experienced an adverse event, of whom 16 (4%) required surgery. The completeness of the Swedish Elbow Arthroplasty Register regarding primary arthroplasty was 81%.

Conclusion: Primary arthroplasty as treatment of distal humeral fractures produces reliable results with regards to revisions and other adverse events.

Level of evidence: Level IV; Registry Case Series; Treatment Study

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The use of elbow arthroplasty as a primary treatment of complex distal humeral fractures has become an established method, particularly in the elderly with osteoporotic bone and with an increasing incidence of more complex fractures.²⁷ Several studies have presented medium-term results of the use of total elbow arthroplasty for primary fracture treatment

and, in recent years, also the use of hemiarthroplasty.^{11,12,17,19,31} Primary joint replacement as treatment for intra-articular distal humeral fractures in the elderly has increased, and considering this trend, it is important to investigate the long-term results.^{4,15,25,26}

A few case series with long-term follow-up (>10 years) have reported good functional results but also additional surgery in up to 27% of the patients and a 10-year implant survival rate of 76% to 92%, the lower rate in patients with rheumatoid arthritis.^{3,23} Previous registry-based studies of total elbow replacement have presented results regarding survival and complication rates, but these have included no or only few patients treated due to an acute distal humeral fracture.^{8,15,22,30}

The indications for the use of elbow arthroplasty as primary treatment for a distal humeral fracture are not clearly defined, and regarding the elderly population, avoiding secondary surgery might be at least as important as range of movement and functional outcome as assessed by commonly used scores. The aims of this study were to investigate the number of prosthetic replacements performed for distal humeral fractures in Sweden, the survival of the implants used, and any adverse event related to the arthroplasty. A further aim was to examine the completeness of the reporting rate of elbow arthroplasty as fracture treatment in the Swedish Elbow Arthroplasty Register.

Materials and methods

This is a registry-based study of the use of elbow arthroplasty as primary treatment of distal humeral fractures in Sweden between 1999 and June 2014. We found 3 sources to which patients operated on with an elbow replacement due to a fracture could have been reported: the Swedish Elbow Arthroplasty Register, the registry of the National Board of Health and Welfare, and patients files at all the Swedish orthopedic departments performing elbow arthroplasty. All people who lawfully reside in Sweden have a unique identity number based on the date of birth, and by using this number, the output from the 3 registries could be compared.

The Swedish Elbow Arthroplasty Register

The Swedish Elbow Arthroplasty Register was started in 1999. It includes details of implants used and information concerning revisions and secondary surgery and their respective cause. Reported primary arthroplasties performed between January 1999 and the end of June 2014 due to an acute (within 3 weeks) distal humeral fracture were collected. The observation time for a secondary operation were extended to March 31, 2016.

Swedish Board of Health and Welfare (Socialstyrelsen)

The Swedish Board of Health and Welfare keeps a register of all patients receiving care, both as outpatients (Öppenvårdsregistret) and inpatients (Slutenvårdsregistret). We identified patients who had been admitted due to a distal humeral fracture and treated with arthro-

plasty using the International Classification of Diseases 10th Revision (ICD10) codes for distal humeral fracture (open or closed injury) and the procedure codes for primary or revision elbow arthroplasty (Nordic Medico-Statistical Committee Classification of Surgical Procedures 96). Based on this selection of patients, a second search was performed for any readmission to an orthopedic department under any ICD10 code. The time periods used were the same as for the search in the Elbow Registry.

Local registries

All Swedish orthopedic departments providing acute trauma care were contacted, first by mail and later, if necessary, by telephone, and asked to search their own local records for patients treated with an arthroplasty due to a distal humeral fracture. Approximately 60 hospitals were providing acute trauma care, but the number varied and decreased slightly during the observation time. The same ICD and procedure codes were used as when searching the National Board of Health Registry. The respective departments were asked to report the type of implant used and whether there had been any revisions, other secondary surgery, or any adverse events defined as medical treatment, other than revision, related to the elbow with prosthetic replacement.

The output from these 3 sources was compared. Patients who were accounted for in all 3 registries under the correct diagnosis and surgical procedure were included directly. In case of discrepancies, the respective orthopedic department was contacted to check patient files or x-ray images, or both, to verify the diagnosis and treatment. A list of the patients only included in the Swedish Elbow Arthroplasty Registry or local registries was sent to the National Board of Health and Welfare to investigate under which diagnosis or surgical procedure the patients had been registered. In the event of any contradictions, the patient files were checked once more.

Readmission to an orthopedic department under any ICD10 code recorded in the National Board of Health register led to examination of the respective patients' files to check for reasons possibly related to the elbow arthroplasty. The output from the 3 registries was then compared, and patient files were checked again if necessary. Revision surgery was recorded, and readmission for other reasons concerning the elbow procedure was also recorded and defined as an adverse event.

Statistical analysis

Implant survival was defined as no recordings of revision or management of mechanical failure of the implant in any of the registries. With prosthetic survival as the dependent variable, the potential relation of patient age and sex or design of the implant was examined using Cox regression analysis with Kaplan-Meier plots. Subgroup analysis of different ages and arthritic diseases was done using the Kaplan-Meier method. Proportional hazard was tested with Schoenfeld residuals, and the assumption was fulfilled. Comparison of implant survival between hemiarthroplasty and total elbow arthroplasty was performed for the Latitude system (Tornier, Montbonnot-Saint-Martin, France) because this was the predominant system used for both modalities. Analyses were performed using SPSS 23 software (IBM, Armonk, NY, USA). Results are presented as mean and standard deviation (SD) if not stated otherwise.

Infections not necessitating revision of the arthroplasty, periprosthetic fractures, and secondary surgery due to instability or

stiffness were reported as separate adverse events. The statistical analysis omitted 2 patients because they had received an implant reported only once each in the registries.

Results

Between January 1, 1999, and June 30, 2014, 327 patients treated with a primary prosthesis due to a distal humeral fracture were reported in the Swedish Elbow Arthroplasty registry. Another 343 patients were found by a search of the Swedish Board of Health inpatient register, and the local registries finally yielded 383 patients.

When the 3 registers were compared using the unique personal identification number, we found 406 distal humeral fractures treated with primary arthroplasty in 405 patients receiving care at 29 hospitals, of which 14 had treated 10 or more patients. The mean age at surgery was 75 (SD, 10) years (range, 18-95 years), there were 365 women (90%) and 40 men, and 89 patients (22%) had been diagnosed with a previously affected joint (eg, rheumatoid arthritis, osteoarthritis). The mean observation time (until death or March 31, 2016) was 67 (SD, 41) months, and 186 patients (46%) had died during that period. Whether any of the deaths were related to the operation or complications from surgery or the implant was not investigated. We found 57 patients in the Swedish Elbow Register that were not included in the register of National Board of Health and Welfare. Common reasons for this were wrong diagnosis (proximal humeral fracture) or the surgical procedure was set as shoulder arthroplasty.

We found 44 patients (11%) who sustained an adverse event or required revision, 22 of whom were reported to the Elbow Registry and an additional 22 were in the Swedish Board of Health registry. No additional patients were found in the local registries of the respective orthopedic departments. The completeness of the Swedish Elbow Register was 81% regarding arthroplasty for distal humeral fractures related to the total sum of all identified patients.

Table I Overview of implants and demographics

Implant type	No.	Mean age (yr)	Male sex (No.)	Years used
Coonrad-Morrey	144	77	12	1999-2014
Discovery	79	76	10	2005-2014
GSB	36	75	6	2000-2012
Kudo				
Total	25	73	2	1999-2008
Hemi	9	78	0	2004-2009
Latitude				
Total	33	72	4	2008-2014
Hemi	78	72	6	2008-2014

*Coonrad-Morrey (Zimmer, Inc., Warsaw, IN, USA); Discovery (Biomet, Inc., Warsaw, IN, USA); GSB (Zimmer); Kudo (Biomet); Latitude (Tornier, Montbonnot-Saint-Martin, France).

Implants

Seven implants had been used: Coonrad-Morrey (Zimmer Inc., Warsaw, IN, USA), Discovery (Biomet Inc., Warsaw, IN, USA), Kudo (Biomet), Latitude, GSB (Zimmer), Souter (Stryker, Rutherford, NJ, USA), and Capitello-Condylar (Johnson & Johnson Orthopaedics Inc., Raynham, MA, USA). The latter 2 had only been used in 1 patient each and were therefore not included in the statistical calculations or described in the tables or graphs (Table I).

Between 2010 and 2014, the overall number of primary arthroplasties used as treatment of distal humeral fractures did not increase but remained steady at approximately 40 elbows per year. The number of elbow hemiarthroplasties (mainly Latitude) had increased from approximately 10% in 2005 to more than 40% in 2014, and the number of total elbow arthroplasties decreased proportionally (Fig. 1).

At the end of the observation time, the use of Kudo and GSB had decreased, and between 2012 and 2014,

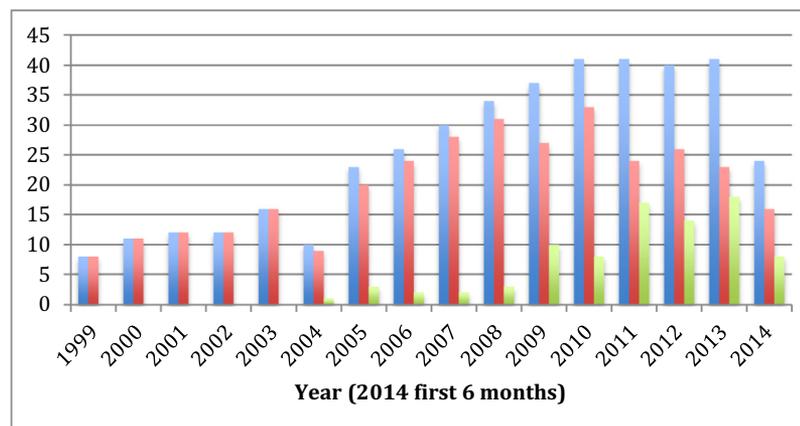


Figure 1 Total number of primary arthroplasties (blue), total elbow arthroplasties (red), and hemiarthroplasties (green) for treatment of distal humeral fractures. Note that data for 2014 are only for the first 6 months.

3 implants predominated: Latitude, Coonrad-Morrey, and Discovery.

Survival

The overall cumulative 5-year survival rate was 99% (95% confidence interval, 98%-100%), and the 10-year rate was 90% (95% confidence interval, 85%-96%). Notable is that 46% of the patients had died during the observation time. Within 5 years, 23% had died, and within 10 years, 40%. Only 45 patients were observed 10 years or longer after the initial procedure.

Increasing age reduced the risk of revision by 4% per year ($P = .008$). Survival of implants with regards to different age groups is reported in Table II. GSB had a 7.5 increased age-adjusted risk of revision compared with Latitude as a reference ($P = .014$). No other statistically significant differences were found between the different implants (including comparison between hemiarthroplasty and total arthroplasty), sex, or number of procedures performed. There was no significant difference in implant survival between patients with or without previous arthritic disease (Table II). The Kaplan-Meier plot of the 5 most frequently used implants is shown in Fig. 2. Hemiarthroplasty and total arthroplasties are not separated.

Revisions

There were 18 revisions in 18 patients, 16 in total arthroplasties and 2 in hemiarthroplasties. Of these, 7 were because of aseptic loosening of 1 or both components, 3 due to a periprosthetic fracture, 4 related to mechanical (not further specified) failure of the arthroplasty, and deep infection in 4. Both revised elbow hemiarthroplasties were changed to a total arthroplasty. One of the revisions due to infection was secondary to a deep infection of the humeral component of a shoulder arthroplasty.

Table II Survival of implants in patients of different age groups and related to previous arthritic changes to the affected elbow

Subgroup	No.	Observation time	
		5 years % (95% CI)	10 years % (95% CI)
Age, yr			
10-19	1	—*	
40-49	3	—	67 (13-100)
50-59	28	95 (90-100)	64 (31-97)
60-69	77	98 (96-100)	86 (80-92)
70-79	141	99 (98-100)	95 (89-100)
80-89	133	—†	—†
≥90	21	—†	—†
Arthritis	87	99 (98-100)	82 (75-89)
No arthritis	317	99 (98-100)	93 (88-98)

CI, confidence interval.
 * Observation time was 31 months.
 † No revisions were performed in patients aged older than 80 years at time of surgery.

There were 2 revisions (4%) in hospitals that had performed fewer than 10 procedures (a total of 54 arthroplasties) and 16 revisions (5%) in hospitals having done 10 or more procedures (a total of 350 arthroplasties). Six of the patients revised had rheumatoid arthritis. Revisions with regards to implant are summarized in Table III.

Adverse events

An adverse event was defined as a readmission to the hospital due to reasons related to the elbow implant or the elbow procedure but not necessitating revision surgery of the prosthetic components. We used this definition rather than the more commonly used term “complication” because the latter has

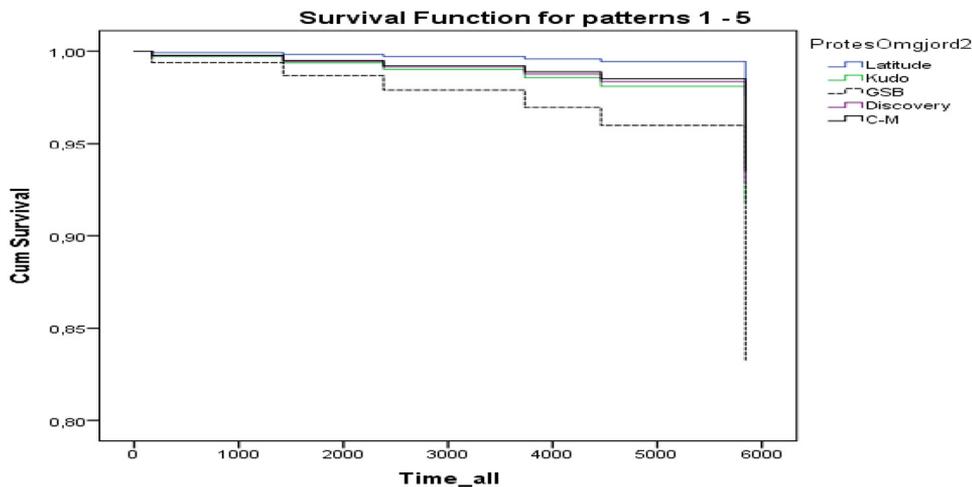


Figure 2 A Kaplan-Meier plot for the 5 most common brands of implants. The x-axis shows the number of days. Latitude (Tornier, Montbonnot-Saint-Martin, France); Kudo (Biomet, Inc., Warsaw, IN, USA); GSB (Zimmer, Inc., Warsaw, IN, USA); Discovery (Biomet); C-M, Coonrad-Morrey (Zimmer).

Table III Revisions

Implant type*	Implants (No.)	Observation time Mean (SD), mo	Revision (No.)	Aseptic [†] (No.)	Infection [†] (No.)	Fracture [†] (No.)	Mechanical [†] (No.)
Coonrad-Morrey	144	70 (40)	6	1	3	1	1
Discovery	79	61 (32)	4	3	0	1	0
GSB	36	75 (46)	3	0	0	1	2
Kudo							
Total	25	130 (48)	2	1	0	0	1
Hemi	9	90 (47)	0	0	0	0	0
Latitude							
Total	33	47 (26)	1	0	1	0	0
Hemi	78	48 (22)	2	1	1	0	0

SD, standard deviation.

* Coonrad-Morrey (Zimmer, Inc., Warsaw, IN, USA), Discovery (Biomet, Inc., Warsaw, IN, USA); GSB (Zimmer); Kudo (Biomet); Latitude (Tornier, Montbonnot-Saint-Martin, France).

[†] Reason for revision.

Table IV Adverse events that did not lead to revision surgery

Implant type*	Implants (No.)	Observation time Mean (SD), mo	Infection (No.)	Fracture (No.)	HO/stiffness (No.)	Instability (No.)
Coonrad-Morrey	144	70 (40)	2	2	2	0
Discovery	79	61 (32)	2	1	1	0
GSB	36	75 (46)	1	0	0	0
Kudo						
Total	25	130 (48)	0	0	1	0
Hemi	9	90 (47)	0	1	0	0
Latitude						
Total	33	47 (26)	2	1	2	0
Hemi	78	48 (22)	1	2	4	1

SD, standard deviation; HO, heterotopic bone formation.

* Coonrad-Morrey (Zimmer, Inc., Warsaw, IN, USA); Discovery (Biomet, Inc., Warsaw, IN, USA); GSB (Zimmer); Kudo (Biomet); Latitude (Tornier, Montbonnot-Saint-Martin, France)

no clear definition and may vary between publications. There were 17 patients (5%) with a total arthroplasty and 9 (11%) with a hemiarthroplasty who sustained an adverse event or required secondary surgery. Eight early deep infections were treated with wound revision(s) and antibiotics retaining the prosthesis. Seven periprosthetic fractures occurred, of which 5 were treated with internal fixation using plates and screws. Secondary surgery was performed in 10 patients because of stiffness or heterotopic bone formation and in 1 patient due to instability. Seven of the patients had previous affection to the joint (rheumatoid arthritis, osteoarthritis). Adverse events related to the different implants are presented in [Table IV](#).

There were 5 (9%) adverse events in patients treated at hospitals that had performed fewer than 10 procedures and 21 (6%) at hospitals that had performed 10 or more.

Discussion

In this registry-based study investigating the use of primary arthroplasty as treatment of distal humeral fractures, we found

that the overall implant survival rate for fracture treatment at 5 and 10 years was good compared with results in previous studies reporting implant survival for any diagnosis. Fevang et al⁸ presented a 92% survival rate at 5 years and 85% at 10 years in their study from the Norwegian Elbow Registry of all elbow arthroplasties between 1994 and 2006. The 10-year survival rate from the Finnish registry among patients with rheumatoid arthritis was 83%,³⁰ and Plaschke et al²² reported similar results. A recent meta-analysis of elbow arthroplasties reported an overall survival rate of 79.2% at 11.1 years and an 11.8% revision rate.³⁴

In patients treated with primary arthroplasty caused by fracture, Prasad et al²³ reported 19 patients with a 10-year survival rate of 89.5%, and Barco et al³ reported 76% survival in 15 patients with rheumatoid arthritis and 92% in 29 previously healthy elbows (no statistically significant difference). Jenkins et al¹⁵ reported a 98% survival rate at 10 years but did not present the number of censored cases.

Regarding registry completeness, we found that 81% of the arthroplasties performed for a distal humeral fracture had been reported to the Swedish Elbow Registry between 1999

and 2014. We could confirm an under-reporting as suspected by the registry. The use of arthroplasty as primary treatment in fractures increased during the period, and there were more hospitals ($n = 30$) performing arthroplasty as the primary procedure in fractures compared with the number of hospitals that regularly performed elective arthroplasties ($n = 18$ in 2013).²⁴ A number of hospitals and surgeons are therefore not used to reporting to the registry, and this might explain the under-reporting.

Seven different implants were used during the observation time. Two implants (Souter and Capitello Condylar) were used only once each. These 2 systems were also used relatively less frequently according to the Swedish Elbow Registry and have not been implanted since 2010, regardless of indication. GSB and Kudo have not been used in the trauma setting since 2012 but until 2014 were still used for other diagnoses, particularly GSB.²⁴ GSB had a higher risk of revision compared with Latitude, but the total number of GSB used was relatively small.

As of now, the hemiarthroplasties have had a low revision rate, but the observation time is still short, and no publications have presented long-term results. There may be a bias in the selection of patients receiving hemiarthroplasty, because the procedure has reportedly been primarily used in fairly active patients who have been considered to benefit without the load restrictions that some surgeons advocate after a total elbow arthroplasty.^{19,28} This probably explains the increased proportion of hemiarthroplasties during the observed period but might infer a risk of increasing number of revisions in the long term.

The mean observation time in the present study is relatively short, partly because 46% of the patients had died during the period studied and only 45 patients were observed 10 or more years after the index procedure. Long-term survival of the implant might therefore not always be relevant to an elderly population. Reduction in adverse events, which may lead to additional surgery, might be of more value to this population rather than durability of the implants, and arthroplasty may therefore be compared to other methods of treating distal humeral fractures. Ideally, any kind of procedure should yield a functional and pain-free elbow during the patient's remaining life without a need of revisions or secondary surgery.

Reoperation rates range from 7% to 49% in the literature regarding internal fixation of distal humeral fractures.^{6,7,9,14,16,17,20,29} According to Helfet et al,¹³ revision surgery using internal fixation yielded improved functional results, but 29% of the patients still required additional surgery. Reports on long-term outcome after primary total arthroplasty have reported rates of revision and additional surgery in 8% to 27% of elbows.^{3,23} Additional surgery was performed in 8% in the present study, and the rate is close to the lower limit of complications requiring secondary surgery in previous publications investigating other methods of treatment.

Another aspect in treating complex distal humeral fractures in the elderly is that the results of secondary elbow

arthroplasty after failed internal fixation have reportedly worse outcome than other indications for arthroplasty.³³ According to Fevang et al,⁸ fracture sequelae had a 5.8-times increased risk of revision compared with arthroplasties due to arthritic disease. The corresponding number in a publication by Plaschke et al²² was 1.9.

Conservative treatment may also be an option among the elderly, but comparisons are difficult because conservative treatment is often chosen in low-demand patients with severe comorbidities unfit for surgery and is not considered an option in healthier individuals.^{1,18}

There are several reports on the functional outcome after arthroplasty as primary treatment for a distal humeral fracture both hemiarthroplasty and total elbow arthroplasty. Mayo Elbow Performance Score results do not differ markedly from elbow arthroplasties used for other joint diseases or fractures treated with internal fixation, especially not in the elderly population.^{2,5,9-11,21,31,32,34}

This study has several limitations. There might be patients who were treated due to an infection admitted to a department of infectious disease but without undergoing a surgical procedure. We also do not know whether some patients declined secondary surgery for any reason, and register data do not record functional outcome. The main benefits of register data are the large numbers of observed individuals, the long-term observation related to implant performance, and the possibility to identify treatment trends.

Conclusion

With support of the present data, we conclude that elbow arthroplasty as the primary treatment for distal humeral fractures produces reliable results in terms of an acceptable rate of revisions and secondary surgery due to adverse events. Arthroplasty should be an available option when treating complex distal humeral fractures in the elderly. The role of hemiarthroplasties in the long term is yet to be determined.

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