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A registry study on radial head arthroplasties in the Netherlands: Indications, types and short-term survival

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Abstract

Background: This study aims to use the Dutch Arthroplasty Register data to report an overview of the contemporary indications and implant designs, and report the short-term survival of radial head arthroplasty.

Methods: From the Dutch Arthroplasty Register, data on patient demographics, surgery and revision were extracted for radial head arthroplasties performed from January 2014 to December 2019. Implant survival was calculated using the Kaplan–Meier method.

Results: Two hundred fifty-eight arthroplasties were included with a median follow-up of 2.2 years. The most common indication was a fracture of the radial head (178, 69%). One hundred thirty-nine (68%) of the prostheses were of bipolar design, and the most commonly used implant type was the Radial Head System (Tornier; 134, 51%). Of the 258 included radial head arthroplasties, 16 were revised at a median of six months after surgery. Reason for revision was predominantly aseptic loosening (9). The overall implant survival was 95.8% after one year, 90.5% after three years and 89.5% after five years.

Discussion: For radial head arthroplasties, acute trauma is the most common indication and Radial Head System the most commonly used implant. The implant survival is 89.5% after five years.

Keywords

Radial head, arthroplasty, registry, indication, implant design, outcome, survival

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Introduction

The radial head acts as a secondary stabilizer in the elbow joint and provides valgus resistance, along with the medial collateral ligament which acts as the primary stabilizer.[1,2] In case of radial head fractures, open reduction and internal fixation (ORIF) is the primary treatment option. However, in comminuted fractures with more than three fragments, ORIF is associated with relatively poor results due to non-union, malunion and avascular necrosis.[3] Alternatively, the radial head can be resected to restore elbow motion.[4] However, this does not restore the biomechanical load transfer of the radiocapitellar joint and fails to restore elbow stability, especially in case of concomitant fractures, ligament injury or dislocation of the elbow joint.[5] Radial head arthroplasty aims to restore elbow function and stability by replacing the original fractured head with a prosthesis in case of fractures which are not amendable to a stable osteosynthesis. Radial head arthroplasty can be used in an acute setting, or for late posttraumatic

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deformities, such as failed previous fracture surgery, non-union, malunion, or secondary osteoarthritis.[1,2,6]

Due to the low incidence of radial head arthroplasty, large cohorts are sparse. To our knowledge, the largest study reporting clinical outcomes of radial head arthroplasty included 77 patients.[6] Additionally, cohort studies and systematic reviews are prone to selection or publication bias. Data on larger cohorts may be reported using national registries, hereby diminishing selection bias and avoiding publication bias. However, to date, no studies using registry data regarding radial head arthroplasty specifically are published. Registries that include radial head arthroplasties separately (Australia, Norway, Sweden and the United Kingdom) publish annual reports on the frequency of radial head arthroplasties but do not include any further analysis.[7–12] Since 2014, the Dutch Arthroplasty Register includes radial head arthroplasties and collects demographic, surgical and revision data of radial head arthroplasties.

Radial head prostheses are available with several specific features and designs. Firstly, different materials are available. Soft silicone prostheses do not sufficiently resist against load transfer and valgus forces and have a high failure rate, whereas metal or pyrocarbon prostheses provide sufficient stability.[1,13] Secondly, there are several fixation methods; press-fit (uncemented) stems, cemented stems and 'intentional loose fit' stems.[14] The advantage of the cemented stems is that their position can be adjusted in the cement mantle. However, if revision surgery is required, the whole cement mantle has to be removed, often with great difficulty. Uncemented stems circumvent this problem; however, the fixation relies on osteointegration and is more prone to revision due to implant loosening.[15] Third, there are implants of uni- or bipolar designs; the unipolar designs consist of a radial head implant fitted firmly on a shaft implant, resulting in an anatomical position, where the radial head is fixed to the radial shaft. A theoretical downside of this design is that a minor incongruence during movement in the radiocapitellar joint might eventually cause painful erosions of the capitellum. The bipolar designs include a mobile head, allowing the radial head to articulate with the radial shaft implant, diminishing friction between the implant and capitellum. This design might seem more prone to dissociation; however, a systematic review found no difference in dissociation rate between unipolar and bipolar designs (Figure 1).[16] Implants can consist of a single piece (monoblock) or of separate modules (modular), which allows for more accurate selection of stem and head size.[17,18] Apart from silicone prostheses showing inferior results, systematic reviews have not proven the superiority of one specific design.[13,18,19] Different surgical approaches to the radial head are described, including the lateral extensor split approach, with or without takedown of the lateral collateral ligament (LCL), and the posterior approach, with the option of dissecting or leaving the triceps intact, with or without an osteotomy of the insertion of the LCL complex and annular ligament.[20–24] There is currently no consensus on the superiority of one specific surgical approach. Considering the lack of conclusive evidence, an overview of the current use of radial head arthroplasty may prove useful in determining the best practice.

In this study we analysed the Dutch Arthroplasty Register data in order to (1) report an overview of the contemporary indications, fixation techniques, implant designs and surgical approaches that were used for radial head arthroplasties in the Netherlands from January 2014 to December 2019, and (2) report the short-term revision rate of radial head arthroplasty.

Methods

In cooperation with the Dutch Arthroplasty Register (Landelijke Registratie Orthopedische Implantaten: LROI) data on radial head arthroplasties were extracted from the register. The register collects data on elbow arthroplasties since January 2014, and data collection is encouraged by the Netherlands Orthopaedic Association (Nederlandse Orthopaedische Vereniging), but is not mandatory. Trauma surgeons are also encouraged to report to this register. Data collection occurs using a standardized form for all elbow arthroplasties, which is completed after surgery (Supplemental Material). This form is available as a paper questionnaire, on which the stickers of the used implants can

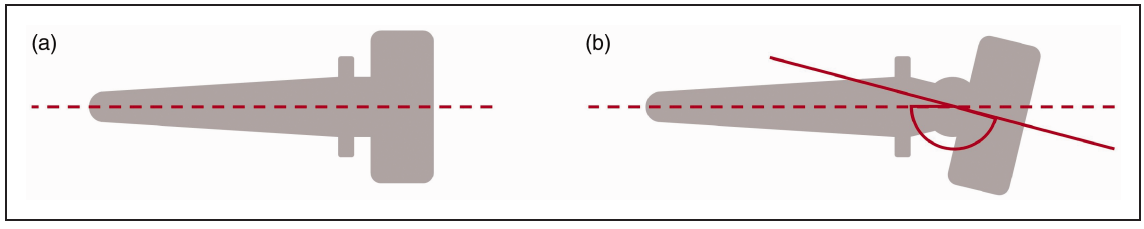

Figure 1. Schematic illustration of a unipolar (a) and bipolar (b) design.

be attached, or a digital form which requires scanning the barcodes of the implant stickers. Since 2014, this form has undergone one change in 2015 to specify the posterior approaches. The form includes demographic data (gender, age, side, American Society of Anesthesiologists classification, smoking habits, body mass index, indication for surgery and whether previous surgeries have been performed) and surgical data (used implant, surgical approach, fixation method). Additionally, the register reports deceased patients and revised implants. The data were delivered anonymously to the researchers in a way that the cases cannot be traced to a specific patient, surgeon or hospital.

Analysis

Demographic, surgical and outcome data are described using means and standard deviations (SD) for continuous variables with a normal distribution, and medians and interquartile ranges (IQR) for skewed data. Number and percentages are used for categorical variables. Implant survival is calculated using the Kaplan–Meier method from the time of surgery until the time of data collection, death (censored) or implant revision (event). Furthermore, the association of explanatory variables (indication, implant type, fixation method and surgical approach) with implant revision is assessed using Fisher's exact tests for dichotomous variables, chi-square tests for categorical variables, Student's *t*-tests for continuous variables in the case of a normal distribution, and Mann Whitney *U* tests for skewed continuous variables. The level of significance is set to $p < 0.05$.

Results

The Dutch Arthroplasty Register registered 258 primary radial head arthroplasties from January 2014 to December 2019 (2014: 22, 2015: 41, 2016: 45, 2017: 41, 2018: 53, 2019: 56). All surgeries were performed by orthopaedic surgeons. The mean age at surgery was 58 years (SD: 14 years). The female to male ratio was 184:74, and left to right ratio was 127:131. Median follow-up was 2.2 years (IQR: 0.98–3.87 years). The most common indication for radial head arthroplasty was a fracture of the radial head (178, 69%), followed by posttraumatic sequelae (64, 25%). One hundred thirty-nine (68%) of the prostheses were of bipolar design, and the most commonly used implant type was the Radial Head System (Tornier; 134, 51%), followed by the ExploR (Zimmer-Biomet; 54, 21%), Anatomic Radial Head (Acumed, 10, 4%), CRF (Tornier; 3, 1%) and rHead (Stryker; 2, 1%, Table 1).

Of the 258 included radial head arthroplasties, 16 were revised at a median of six months (IQR: 4–18 months) after surgery. Reason for revision was predominantly aseptic loosening (9 patients, 56% of revisions), followed by instability (4 patients, 25%). For three patients the reason for the revision was not reported. Of the revised implants, 10 were of bipolar design (7% of all bipolar implants) and three of unipolar design (5%), 10 of the revised implant types were Radial Head System (7%), two were ExploR (4%) and 1 was an Anatomic Radial Head (10%). For three revised implants the type was unknown. Of the revised implants, 11 (5%) were uncemented and 5 (9%) were cemented, 13 were placed via a lateral approach (6%) and three via a posterior approach (18%).

The overall implant survival was 95.8% after one year, 90.5% after three years and 89.5% after five years (Figure 2). None of the explanatory variables correlated with implant revision ($p > 0.15$).

Discussion

This study includes 258 patients from the Dutch national register that received a radial head arthroplasty between 2014 and 2019, with a median follow-up of 2.2 years. The most common indication for radial head arthroplasty was an acute radial head fracture, and the most commonly used implant was the Radial Head System. We report an implant survival rate of 95.8% after one year, 90.5% after three years and 89.5% after five years.

In the Netherlands, an acute fracture was the most common indication for radial head arthroplasty (69%), followed by posttraumatic sequelae (25%). Four other national registries collect data on elbow arthroplasties (Australia, Norway, Sweden and the UK).[7,10,25–27] From the annual reports of the registers, comparative data can be gathered. Indications for radial head arthroplasty are similar in Norway (acute fracture: 77%, post-trauma: 15%) and the United Kingdom (UK, acute fracture: 79%, post-trauma: 14%). In the Australian register, trauma was summarized in a single category, which accounted for 91%. The Swedish register did not record indications for radial head arthroplasty.

In the current study, the Radial Head System (51%) was the most commonly used implant, followed by the ExploR (21%). In contrast, Anatomic Radial Head was most common in Norway, Sweden and the UK (32, 60, and 53%) followed by rHead (22%) in Norway, Mayo Radial Head (18%) in Sweden and Evolve in the UK (19%). In Australia, the Ascension Modular Radial Head (Integra) was most commonly used (33%), followed by the Anatomic Radial Head (24%). Furthermore, 68% of the implants in the Netherlands were of bipolar design. Similarly, this was 62% in Norway. However, in the UK and Australia, 5% of

Table 1. Patient and surgery characteristics.

$n = 258$			
Patients		Surgery	
Follow-up time in years, median (IQR)	2.2 (0.98–3.87)	Right elbow, *n* (%)	131 (51)
Age in years, mean (SD)	58 (14)	Prosthesis design, *n* (%)	
BMI, mean (SD)	28 (5)	Bipolar	139 (68)
Female sex, *n* (%)	184 (71)	CRF	3 (1)
ASA, *n* (%)		rHead	2 (1)
I	86 (33)	Radial head system	134 (51)
II	135 (52)	Unipolar	64 (32)
III or IV	34 (13)	ExploR	54 (21)
Smoking, *n* (%)	24 (9)	Anatomic radial head	10 (4)
Diagnosis, *n* (%)		Unknown	55 (6)
Acute fracture	178 (69)	Cemented, *n* (%)	57 (22)
Osteoarthritis	1 (0)	Approach, *n* (%)	
Osteonecrosis	8 (3)	Lateral (LCL release)	71 (28)
Posttraumatic sequelae	64 (25)	Lateral (LCL intact)	160 (62)
Other	5 (2)	Olecranon osteotomy	1 (0)
Previous surgery	54 (21)	Posterior triceps-off	5 (2)
		Posterior triceps-on	11 (4)
		Other	7 (3)

ASA: American Association of Anesthesiologists classification; IQR: interquartile range; LCL: lateral collateral ligament; SD: standard deviation.

implants were bipolar. In congruence with previous literature, we found no difference in revision rates between implant brands[13,15] or bipolar versus unipolar designs.[28–30] However, with 16 revisions, our cohort is too small to draw definite conclusions. The discrepancy between regions is likely caused by the surgeon's preference, availability, cost and local contracts with manufacturers.

The majority of the prostheses in the current study were uncemented (78%), and the lateral approach leaving the LCL intact was most common (62%). We found no differences in revision rates between the techniques, which is congruent with the majority of previous literature.[13,16,29] In contrast, two meta-analyses identified a higher reoperation rate in uncemented prostheses compared to cemented prostheses.[15,31] However, the authors attributed this to the greater difficulty in removing a cemented implant and the consequential hesitancy for surgeons to revise these implants. To our knowledge, there are no clinical studies directly comparing the outcomes of different fixation methods or surgical approaches for radial head arthroplasty.

Our results show a survival rate of 91% after three years and 90% after five years, which is congruent with previous studies reporting three-year survival rates ranging between 72% and 100%,[32–40] and five-year survival rates ranging between 71% and 100%.[19,41–43] Furthermore, studies reporting survival data after eight years or more report survival rates ranging from 75% to 100%.[6,44–48] The majority of revisions occur within the first three years after arthroplasty,[6,15,44,48] which was also found in the current study. The majority of revisions in the current study were due to aseptic loosening (56%), suggesting that when the implant is placed firmly and remains in a solid position in the first years of follow-up, the long-term outcomes are favourable. In contrast,

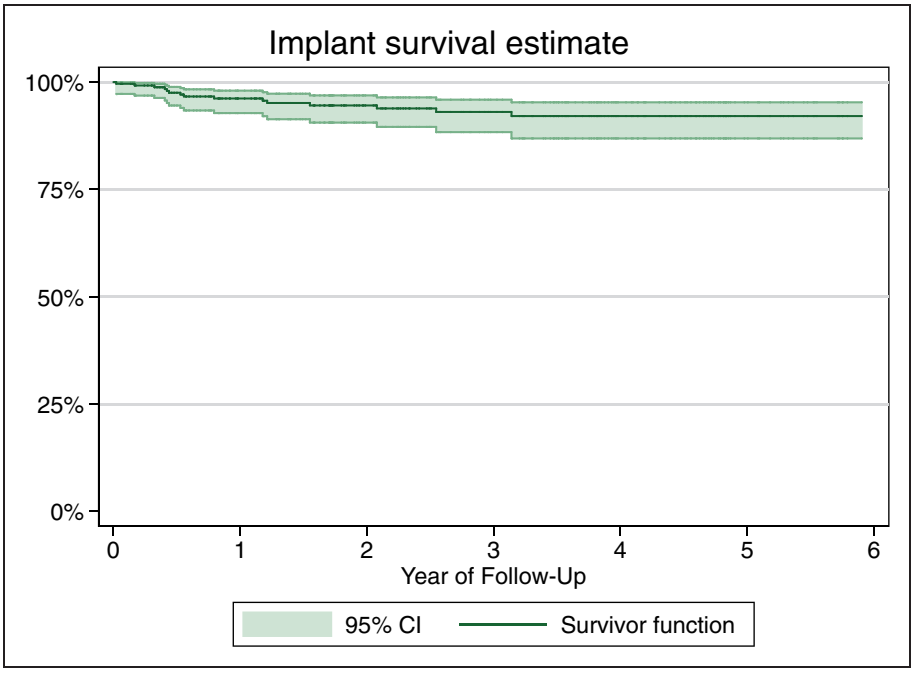

Figure 2. Implant survival estimate.

a recent systematic review including 30 studies showed that the predominant reason for revision was heterotopic ossification (47%), followed by stiffness (42%), pain (19%) and loosening (16%).[15] It is possible that the former is not recorded as an implant revision in the national register, the discrepancy might also be explained by the relatively high number of uncemented and bipolar prostheses in the current study.

It is the senior authors' experience that aseptic loosening in uncemented prostheses is often related to insufficient bone ingrowth of the prosthesis because of too much freedom of motion due to undersizing of the implant. Despite oversizing, and overlengthening in particular, potentially leading to implant loosening and capitellar wear as well, it appears from experience that undersizing is more commonly seen in failed cases. It is also hypothesized that in unipolar prostheses, micromotion of the implant in the medullary canal leads to loosening. However, previous literature shows no significant difference in loosening rates between uni- and bipolar designs.[16] Other causes of loosening in both uncemented and cemented prostheses include malpositioning and low-grade infections. Proper sizing, positioning and antiseptic measures are crucial to the success of radial head arthroplasty. The number of revisions is too low for a statistically meaningful sub-analysis in our study.

The results of this study need to be interpreted in light of its limitations. First, in collecting data through the national register, the study relies on completeness and accuracy of reporting by third parties. Reporting to the register is not mandatory, but the completeness of the register is checked using individual hospital records, and the LROI reports 89% completeness in 2018 with regards to elbow arthroplasties.[49] Nonetheless, some information is lost. For example, we were unable to define 'posttraumatic sequelae' precisely but relied on the clinical judgement of the reporting parties when selecting this option in the form. Second, the outcome data collected in the register are limited to implant revision; we were unable to assess other outcomes of radial head arthroplasty such as range of motion, pain, or patient-reported outcome scores. Third, data collection from the national register allowed for a cohort of patients from different regions, hospitals and surgeons. This may decrease the internal validity, but increases the generalizability of the results. However, there is a large variation between countries in used implant designs. Therefore, our results are not directly applicable to other geographical regions. Furthermore, due to the low incidence of implant revision, we were unable to perform meaningful sub-analyses of different implant types, indications, or fixation types. However, by using national data, we were able to include one of the largest cohorts available. Last, the register started including elbow arthroplasty in 2014, resulting in a maximum follow-up of six years in this cohort. Consequently, we are to date unable to assess long-term survival.

Conclusions

For the radial head arthroplasties performed in the Netherlands between 2014 and 2019, acute trauma

was the most common indication, Radial Head System the most commonly used implant and the majority of the implants was uncemented. The implant survival was 95.8% after one year, 90.5% after three years and 89.5% after five years.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: DE reports consultancy for Lima corporates, has given paid presentations for AO and Stryker and received institutional support from Matthys, Zimmer-Biomet and Stryker. IO and KK received institutional support from Zimmer-Biomet and Stryker. AM, AP, AS and BT declare no conflicts of interest.

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Supplemental material

Supplemental material for this article is available online.

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