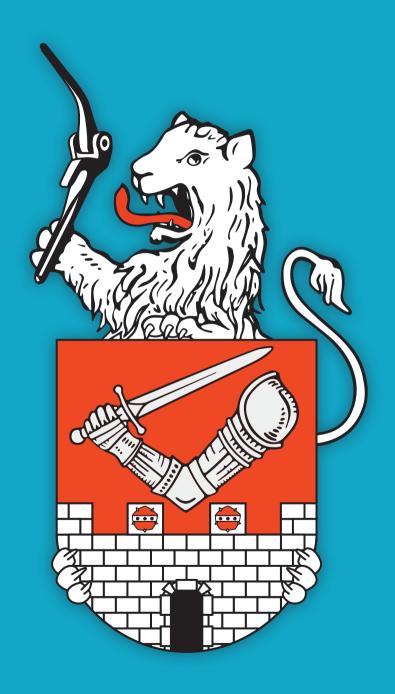
ADVANCEMENT IN TOTAL ELBOW ARTHROPLASTY CARE



Ante Prkić

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General introduction

General introduction

The elbow joint is a multi-axle joint that enables the human arm to be functional in daily life. A well-functioning elbow is of high importance in everyday activities[1, 2]. Because of changing needs in daily life, such as the use of mobile phones and computers, the need for greater range of motion of the elbow has arisen in the last decades[1–3]. Impairment of elbow function causes disability, ultimately leading to the diminishment of quality of life.

As the elbow is a complex joint, which consists of three bones that ingeniously fit together, its construction and location in the upper extremity make it prone to traumatic damage with forthcoming malalignment or degeneration[4, 5]. On the long term, osteoarthritis is seen in up to 80% of patients with an elbow fracture[6, 7]. Repetitive injuries and progressive degeneration may lead to such impairment, that normal functioning in daily life becomes compromised. Moreover, several pathological processes of degeneration may impair elbow function[4, 5]. Inflammatory diseases such as rheumatoid arthritis are better treated nowadays with biologicals with the forthcoming benefits of less joint destruction[8–10].

The simplest solution to elbow joint malfunction is to adapt activities to a lower level of functioning, which would imply the acceptance of a worse functioning joint. However, the patient usually would not accept such adjustments, thus requests treatment. A difference should be made between foremost loss of range of motion, instability and pain, as these three problems need a different management. Range of motion can be addressed by an (arthroscopic) debridement with good results[11]. Instability is usually a result of injuries to the medial and/or lateral collateral ligaments, potentially worsened by loss of congruency of the joint. Pain however, is more difficult to solve, especially when the aforementioned problems have been addressed. When activities as eating, drinking and personal care become impossible, an attempt to reconstruct the joint is needed.

Such a reconstruction is possible with an arthroplasty; when both the humerus and ulna are replaced, the prosthesis is called a total elbow arthroplasty. Unfortunately, the implant survival of elbow arthroplasties is less satisfying than hip and knee arthroplasties[12–14]. Over the years, the indications for a total elbow arthroplasty are changing from rheumatoid arthritis, to foremost posttraumatic osteoarthritis and comminuted fractures[9].

To understand the contemporary arthroplasty models, it is important to understand the historical background. During the twentieth century, component design and fixation methods have changed. Concept-changing interventions, such as non-anatomical replacement of the joint to regain function, have led to better clinical results and total elbow prosthesis being a regularly accepted intervention. Through trial and error, different fixation mechanisms have been tested and dismissed, such as screw fixation of the

implant. Linked and non-linked designs, as well as restrained and non-restrained designs have diverse indications for use, as learned from the past.

Nowadays, a variety of implants and surgical approaches are available when opting for total elbow arthroplasty. The literature is inconclusive with regard to the choice of a 'best' prosthesis and a 'best' surgical approach. The choice is therefore often dependent on the surgeons' skills and preferences, and last but not least, patient characteristics.

Aims and outline of this thesis

The overall aim of this thesis is to improve the in-hospital care and provide objective assessment tools for follow-up of total elbow arthroplasty patients. To propose improvements for the future, the current and historical practices have to be understood and critically analysed.

To reach these goals, this thesis consists of three parts. **Part 1** provides an overview on the historical and surgical proceedings of total elbow prostheses. Unfortunately, the outcomes of total ebow arthroplasty, in terms of complication rates and revision rates, are still behind the results of total knee and hip arthroplasty[15, 16]. Therfore, an analysis on complications and their clinical impact, as well as modes-of-failure, is provided in **Part 2**.

Finally, based on the outcomes of **Part 1 and 2**, suggestions for possible improvements of the current treatment for patients who are in need of a total elbow prosthesis are discussed in **Part 3**. As optimization of cost-effectiveness in health care is essential, the peri-operative process of total elbow replacement can be improved as well. A shorter stay in hospital and accelerated return to self-care are important steps in this process. Safety analysis of a proposed rapid recovery program is an important first step. Assessement of the possibility to monitor (long-term) outcomes using patient reported outcomes is the second step. The use of online collected patient reported outcomes will moreover probably reduce the number of (physical) outpatient clinic visits.

Part 1

Different concepts, models and fixation methods have been described in total elbow arthroplasty during the past 70 years. In Figure 1, an illustration of some concepts is provided, with constrained, unconstrained, fixed hinged and loose hinged designs. **Chapter one** discusses the developmental path the elbow prostheses has taken in the twentieth century, regarding materials, designs, linkage and fixation.

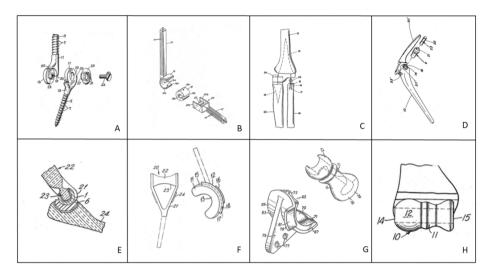


Figure 1. Historical, distinctive types of total elbow arthroplasties. A; Prevo (1954). B; Schlein (1974). C; Harmon (1978). D; Pritchard (1976). E; Arnold (1975). F; Dee (1974). G; Amis (1981). H; Stevens (1970)[17].

Different surgical approaches for total elbow artoplasty have been described in the past[18]. One of them is the 'triceps on' approach, in which the triceps is left intact. Another option is the 'triceps flap' approach; the triceps tendon is detached and fixated[18, 19]. The latter option has a higher risk of triceps insufficiency; usually the rehabilitation process does not allow immediate weightbearing of the triceps[20, 21]. Traditionally, reports in literature are institution-based, possibly leading to investigator bias and reporting bias. Often one specific comparison is analysed and a broad overview is provided from other specific studies from the literature. Concerning the surgical approach for total elbow arthroplasty, the surgeon's skills, preferences and many other aspects influence the choice of approach. When another surgical approach is started, often a learning curve is observed and this in turn could lead to bias as well. In **Chapter two** we use the data from the Dutch Arthroplasty Register to get insight into the surgical approaches used for total elbow arthroplasty in the Netherlands.

Chapter three describes a less commonly used surgical technique step-by-step along with an instructional video to illustrate another possible surgical approach. An osteotomy of the medial epicondyle is showed in detail as an alternative approach for in elbow arthroplasty to increase the overview during the surgical procedure as seen in Figure 2.



Figure 2. Video still, showing the osteotomy of the medial epicondyle [22, 23].

Part 2

A systematic review on total elbow arthroplasty 2003 by Carr and coworkers showed a revision rate of 13% after 5 years, and differences in failure modes between linked and unlinked arthroplasty models [16]. Worldwide some disagreement exists on the optimal patient reported outcomes to be used these patients. There is no consensus on the type of questionnaires, and on the best way to register complications (as infection, ulnar nerve dysfunction and implant loosening). **Chapter four** discusses the more recent literature on failure modes of total elbow arthroplasty.

As complications are defined as undesired outcomes, analysis is essential to improve future patient care. For instance, ulnar nerve dysfunction is often regarded as a relatively benign, most often self-limiting complication. However for patients the loss of sensibility and loss of fine motor skills in the affected hand is very disabling. To gain more insight in the effect of complications on the patients' reported outcomes, **chapter five** focusses on the perceived influence of complications on the most often used patient reported outcome measures; the Oxford Elbow Score and the Mayo Elbow Performance Index.

Part 3

As a multitude of prosthetic models are (and have been) in use as described in **Chapter one**, recognition of the model is a challenge. In case of a total revision, with removal of the failed prosthesis and reconstruction with a new implant, it is not very important to recognise the failed implant. However, with partial revisions it is essential to know wich implant is in situ in order to be well prepared for revisions surgery. **Chapter six** evaluates

the effectiveness of a proposed flowchart with implant-specific features that can be identified on plain radiographs[24–26].

Optimal implant sizing might also aid in improving implant survival rates[27]. Therefore, pre-operative radiographs can be made with a calibration tool, and with special software, the optimal implant size can be determined with pre-operative templating (Figure 3) In **Chapter seven**, the more modern, digital version of this templating process on one particular arthroplasty model is investigated.





Figure 3. Anterior-posterior and lateral view of a templated total elbow arthroplasty[28].

As described in **Part 1**, the surgical approach for total elbow arthroplasty is either triceps-sparing or triceps-reflecting in nature. The triceps strength after arthroplasty is an objective parameter for success after surgery[18, 29, 30]. However, there is no single established method of measuring the triceps strength and no known relation between triceps strength and patient satisfaction. A relation between dominant and non-dominant sides could serve as a reference when no pre-operative measurement is possible. **Chapter eight** investigates the most usable position of triceps brachii force testing during outpatient visits.

In the light of both the social impact of hospital stay to the patient, as well as the economic use of hospital resources, reducing the length of stay could be beneficial for both patients and hospital. **Chapter nine** reports and analyses the complication rates, length of stay and patient-reported outcomes before and after omitting a post-operative cast and functional discharge criteria.

Finally, the follow-up after arthroplasty is important for monitoring the patients and evaluating their results. One aspect of follow-up is detecting complications as described in **Part 2**. However, no minimum duration of follow-up has been determined yet. It is imaginable that complications on the short term are related to surgery, and the long-

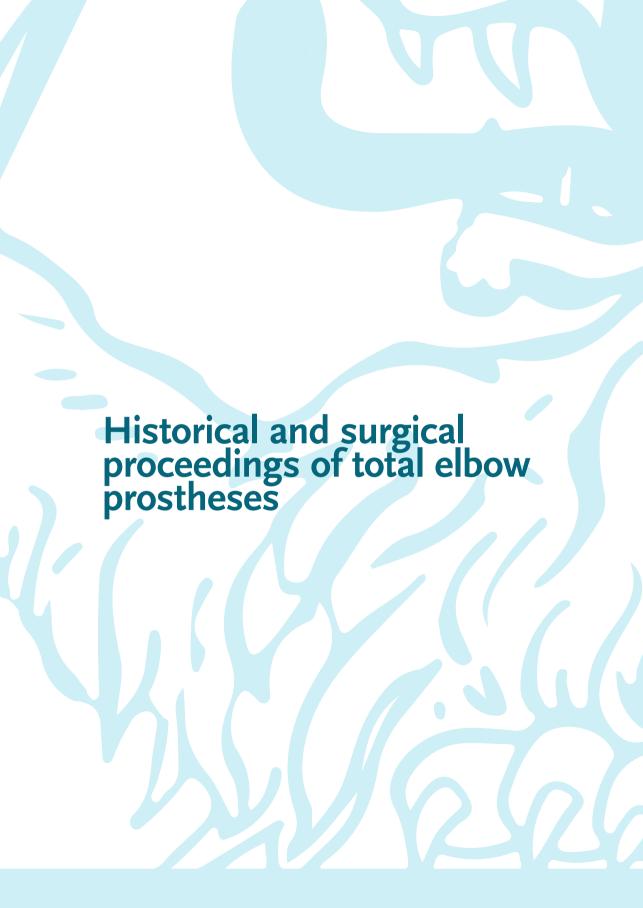
term complications such as loosening of the implant and wear of the bushing occur after time. In **Chapter ten** the outcomes and radiographic changes are described and a recommendation for follow-up duration is made to detect long-term complications.

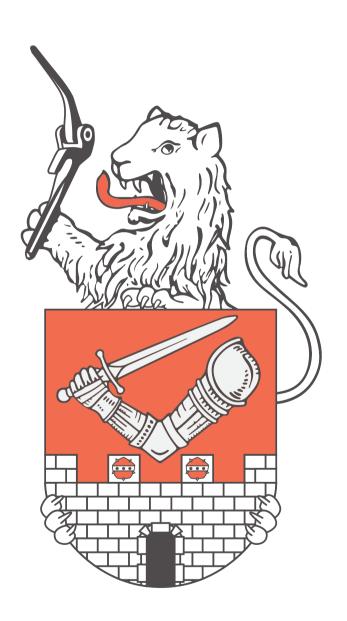
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Part one





Chapter one

Total elbow arthroplasty is moving forward; review on past, present and future

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Abstract

The elbow joint is a complex joint, which, when impaired in function, leads to severe disability. In some cases however, an arthroplasty might be an appropriate treatment. In the past four decades, large steps have been taken to optimize this treatment in order to achieve better post-operative outcomes.

To understand these progresses and to discover aspects for upcoming improvements, we present a review on the past developments, the present state of affairs and future developments which may improve patient care further.

Introduction

From an anthropologic point of view, the upper extremity in humans has evolved into an instrument capable of achieving a large range of motions in order to perform highly complex tasks. This 'open kinetic chain' demands different anatomic structures in comparison to the 'closed kinetic chain' of the lower extremity.

Consequently, pathological conditions differ between the two extremities. Pathology of the lower extremity generally result in reduced mobility of the patient. In the upper extremity however, pathologies here restrict the patient from performing simple activities in daily life. In this situation, the problem cannot be managed by the help of external aids (e.g. wheelchairs or crutches)[1].

The elbow is a complex joint, consisting of three independent joints which cooperate together to move in multiple axes while maintaining a high level of stability[2]. The humero-ulnar joint permits a flexion/extension motion and is additionally stabilized by the olecranon and coronoid process in extreme flexion and extension. The combination of the proximal and distal radio-ulnar joint allows a pronation/supination movement, which is restricted by ligaments to a certain degree. The flexion of the elbow is important in allowing the hand to reach above and at the level of the head in order to achieve simple, yet important day-to-day activities, such as eating and the washing of hair and face. The combination of these movements, as well as shoulder rotations, allows versatile positioning of the hand in space and is a prerequisite for the fulfillment of complex tasks.

A decreased range of motion in the elbow joint can be directly due to pathology, i.e. primary osteoarthritis, or trauma. Pain, usually secondary to pathology such as rheumatoid arthritis, is another factor that may restrict elbow function as well. A Total Elbow Arthroplasty (TEA) can improve the range of motion and can also relieve pain in selected cases. Therefore, TEA can considerably improve function of the upper limb and increase the quality of life.

Though the use of TEA has almost doubled between 1998 and 2011 in the US, it is still a relatively uncommon orthopedic procedure. It is performed more often in women than in men[3] and is also used in relatively young patients[4, 5]. The number of of TEA performed annually is 1.4 in 100.000 of the population, considerably less than the 70 to 99 in 100.000 of the population for total hip replacement[4, 6].

The expanding practice of TEA leads to a new field in orthopedic surgery. We believe it is necessary to understand the history of the development of TEA in order to accomplish further improvements. In this review we will focus on the evolution of the elbow arthroplasty, from a historic overview to the present and address issues that could improve the clinical outcome in today's practice.

The past

The first salvage surgery by excising infected humeral and ulnar bone was performed by Ambroise Pare in the sixteenth century to prevent amputation due to an infected elbow joint[7]. In the nineteenth century, as more advanced surgical and post-operative care could be provided, creating a pseudoarthrosis by resecting the distal humerus became an option for incapacitating elbow disease. Following the developments in hip surgery, instead of resecting the joint, the idea of replacing the diseased elbow joint became a concept. It resulted in two streams; the anatomical arthroplasty, aimed to recreate native anatomical structures, and the functional arthroplasty, which covers the functionality of the elbow joint but does not resemble normal anatomical structures.

In 1925, the first attempt to replace an elbow joint by prosthetic materials was documented, when Robineau inserted an anatomically correct elbow prosthesis, consisting of metal and vulcanized rubber. In 1941, Boerema used a hinged non-anatomical prosthesis completely made of metal[7].

In 1952, Venable published a case-report of a custom-made anatomical prosthesis after a comminutive fracture of the distal humerus which was not amendable for proper osteosynthesis. A short-term follow-up of 15 months was reported with a good outcome[8].

The promising results of experimental elbow surgery led to a rush on patents for elbow arthroplasties by several inventive doctors. In 1954, a functional prosthetic elbow joint was patented by Prevo[9], but did not reach a widespread use due to frequent loosening. In 1972, Dee reported his treatment of 12 patients using a functionally designed TEA[10]. This publication initiated an increase in various TEA models in the 1970's, ranging from stemmed devices to anatomy-resembling resurfacing models[9, 11–17]. However, overall post-operative complication rates including loosening, deep infection, and ulnar nerve neuropathy were high; ranging up to 57%[18].

It has been a challenge to design a TEA, which copies the native function and stability of all three articulations in the elbow joint. A drawback of anatomical arthroplasties was the lack of intrinsic stability. The anatomical, unlinked resemblance requires the integrity of ligaments and muscles. However, these structures often become insufficient in long-standing disease such as rheumatoid arthritis. Therefore, the unlinked anatomical design has lead to a high dislocation rate [19, 20].

During flexion and extension of the elbow, some degrees of valgus and varus laxity is normal [21]. However, the linked 'first generation' TEA's did not offer this laxity, which resulted in frequent loosening due to stress at the implant-bone transition[18]. This

problem was overcome by the 'second generation' TEA, introducing sloppy hinges, which allow some varus-valgus laxity due to their semi-constrained design.

Fixation of the prosthesis proved to be challenging too, resulting in the application of a wide range of methods: Prevo designed screw-threaded stems, Stevens a slide-on self-locking resurfacing arthroplasty, Schlein, Pritchard and Dee used smooth cemented stems, Roper used a cemented humeral component and Amis used screw fixation for the ulnar component[9, 11, 13–17]. Harmon used two rings as a radiocapitellar joint[12]. These models are presented in Figure 1.

Beside improvements in materials and models, different operative techniques have arisen, each with their own advantages. In general, two approaches can be distinguished; the triceps sparing and non-triceps sparing approach. The non-triceps sparing approach, entails the triceps tendon to be split longitudinally or reflected from its insertion at the olecranon and at the end of surgery, needs to be repaired, yielding good results[22].

In the triceps sparing approach, a Chevron osteotomy of the olecranon is performed, distal to the triceps insertion, which is turned aside en-bloc with the triceps tendon attached. After insertion of the TEA this Chevron osteotomy is repaired. A study showed the triceps-sparing approach may result in better range of motion and a lower chance of infection compared to the triceps-detaching approach [23].

The human factor of gained experience on TEA surgery, together with improved materials, have led to positive results regarding clinical outcome and revision rates. Also larger trials and level 4 follow-up data coming from registries have enabled more thorough research on TEA, contributing to evidence-based patient care.

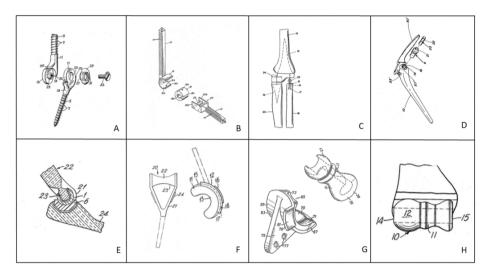


Figure 1. Historical, distinctive types of TEA. A; Prevo (1954). B; Schlein (1974). C; Harmon (1978). D; Pritchard (1976). E; Arnold (1975). F; Dee (1974). G; Amis (1981). H; Stevens (1970).

The present

In today's practice, the indications for elbow arthroplasty include all kinds of incapacitating elbow diseases, such as primary osteoarthritis, post-traumatic osteoarthritis, rheumatoid arthritis, comminutive elbow fractures, post-traumatic deformities and oncologic disease. However, unlike in hip and knee arthroplasty, the main indication is not primary osteoarthritis. In 1997, the main indication for TEA in the State of New York, USA, was rheumatoid arthritis. However, in 2006 a shift was seen to trauma as the main indication for TEA[5].

Today, both the linked sloppy hinged and unlinked TEA's are available. Fixed hinge models are not used contemporarily. According to the patient's pathology and surgeons' preferred choice of the type of implant is often made pre-operatively. A 'third generation' type of TEA is currently available, which allows the surgeon to decide during surgery to place a linked or unlinked implant.

Survival rates of different types of TEA have improved in the past four decades to around 90% after 5 years[24, 25]. Cumulative revision rates after four to five years for fixed-hinge models is 13%, for sloppy hinge models 11%, and for unlinked models 13%[25]. In the short term, the main cause of failure is infection, while in the long term, the main cause is aseptic loosening by prosthetic wear[25, 26]. When compared per group, the fixed-hinge models have a loosening rate of 11%, the sloppy hinged models 5% and the unlinked TEA's 10%[25].

Deep, periprosthetic infection is a serious complication in arthroplasty surgery, since it requires aggressive treatment in order to preserve the implant without removing it, as well as other problems to patients. To counter the infection rate, the use of peroperative antibiotics has become standard and maximum aseptic measures are taken during surgery, such as double gloving and laminar flow[27]. Use of antibiotic-containing bone cement has lowered the deep infection rate to around 8%[4, 28].

The use of bone cement might play a role in the aseptic loosening rate. A comparative study of cemented and uncemented ulnar components showed a lower rate of loosening in cemented components[29]. To avoid the use of bone cement and still achieve a firm bone-implant interface, several prosthetic coatings are available. These use the concept of bone ingrowth or osseointegration. The prosthesis is coated with hydroxyapatite, the molecular equivalent of bone. Human osteoclasts can dissolve the coating and attract osteoblasts to replace the coating with human bone[30]. A different concept is the ability to host osteoblasts in an optimal environment to enhance the intertwining of bone and implant. This can be accomplished with tantalum mesh or titanium beads[31–33].

To prevent metallosis, which might occur in metal-on-metal articulations, and to minimize shear stress between components, a plastic inlay is used. Depending on the type of arthroplasty, the inlay is either a polyethylene layer between unlinked components (iBP) or a bushing (Discovery, Coonrad-Morrey). These inlays are made of different materials, which aim to minimize wear of the prosthesis.

Wear debris can trigger 'particle disease', which in turn leads to arthroplasty component loosening and eventually failure[34]. Analysis of loosened TEA's showed presence of wear debris (predominantly bone cement, polyethylene and metal) in surrounding tissue, due to wear of the polyethylene interface[35]. The inlay wear can be lowered by either crosslinking the polymers or adding substances, such as vitamin E[36, 37]. However, no long-term follow-up results are published for elbow arthroplasty.

Patient-reported outcome scales nowadays have a more prominent role in assessing elbow function. Outcome measures have shifted from solely surgeon-opinion, to patient-oriented questionnaires, which focus on activities of daily life[38]. In a review on outcomes after TEA, the patient-reported outcomes were good or excellent in 78% of cases[25]. The function assessed by improvement of range of motion, was better in fixed-hinge models and sloppy hinged models (38 degrees and 35 degrees, resp.) than for unlinked models (20 degrees)[25].

The future

Considering the present issues of aseptic loosening and infective complications of elbow arthroplasty, there is obvious room for improvement. Ongoing insights in elbow kinematics might guide implant designers in refining TEA, not only by design but also by choice of material[21]. The previously mentioned third generation TEA models might provide a good choice when a pre-operative decision on linked or unlinked TEA is not yet clear. Also, restoring the radiocapitellar joint by inserting a radial head prosthesis is possible.

Because of the increasing use of elbow arthroplasties, an inevitable problem occurs; revision arthroplasty. Because of good results, orthopedic surgeons may perform TEA's with less difficulty in incapacitated patients than several decades ago. Besides, treatment of systemic diseases, such as rheumatoid arthritis has improved, with an overall increase in the quality of life, exposing TEA to a longer period of use. Results on TEA revision are promising; in a recent study revision led to pain relief and improved range of motion after failure of primary TEA[39].

The improved overall results might also question the need of post-operative functional restrictions, such as restricted lifting activities. These movements lead to shear distracting forces on the bone-implant junction and are therefore theoretical risk factors for implant loosening. In linked TEA types the pulling forces during lifting are transferred more to the humeral component than in unlinked TEA, since unlinked TEA requires ligaments and muscles to remain stable in this situation and is not connected to the ulnar component. However, no studies on post-operative rehabilitation are published, yet high-demanding patients show worse overall implant survival compared to low-demanding patients [40]. Therefore, research on post-operative management should be conducted to determine both mechanical factors influencing implant survival and optimal functional improvement.

Furthermore, several aspects on TEA research itself should be addressed. By setting up large implant registries, trends in the long-term can be studied. In Scotland, Sweden, Norway, the Netherlands and New Zealand, data on elbow arthroplasties are reported on a routine basis[4, 40, 41]. If this could be expanded to more countries, larger cohort studies with better follow-ups are possible[42]. Large registries also raise the possibility to assess practical questions, for example, a recommended minimum of annual cases to retain optimal surgical results. The Scottish and Finnish arthroplasty registers show that high-volume specialized centers yield better implant survival [4, 40].

Use of pre-operative plain radiographs allows to plan implant size on beforehand, to optimize concordance between the pre-operative native elbow joint and the arthroplasty. Concerning the planning of the implant size, a radiograph-based planning tool is available,

with good results in hip and knee arthroplasty. However, even though the intra-observer variability is good, the predictive value of this form of planning is insufficient[43]. A three-dimensional planning tool would possibly give more accurate information on TEA placement and sizing[44].

Another question is the use of three-dimensional guiding. Creating three-dimensional structures can be seen in two ways, creating the implant itself or re-creating the diseased elbow. Firstly, unlike Venable described in 1952, patient-specific implants could be made without preceding surgery, according to preoperative CT-scans. However, on a large scale, this might be too labor-intensive to plan and too expensive to fabricate. Therefore, patient-specific implants could be used in cases, where usual implants are insufficient.

Secondly, re-creating the diseased elbow could be of beneficial use in complex cases with severe deformation, e.g. the surgeon practicing on a model beforehand. This is already a method used in maxillofacial surgery[45]. In knee arthroplasty, patient-specific cutting guides, based on pre-operative CT-scans, are available for difficult cases, with good results[46].

Conclusion

The knowledge on elbow arthroplasty has improved greatly in the past seven decades. With more encouraging results and a more widespread awareness, further improvements can be made. By setting up databases on implants, a structured analysis on adverse factors can be made to identify further improvable factors. Advances in materials and technical aids, such as three-dimensional printers, might improve postoperative outcomes.

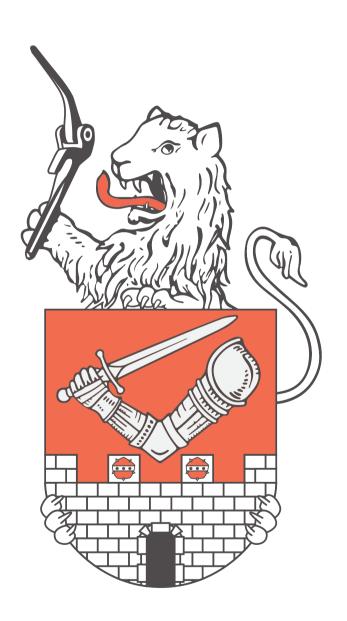
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Total elbow arthroplasty is moving forward; review on past, present and future



Chapter two

Surgical Approaches for Total Elbow Arthroplasties According to the Dutch Arthroplasty Register

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Abstract

Total elbow arthroplasty (TEA) is a relatively infrequently performed procedure. Therefore, nationwide databases help to provide more insight into factors that might influence implant survival, as for example the surgical approach used. Using data of the Dutch Arthroplasty Register, we aimed to reveal whether high-volume centers use different approaches compared to low-volume centers and whether the approach is implant-specific.

Using data from 2014 to 2017, we compared the surgical approaches used between high-volume and low-volume centers, as well as for the two most frequently used types of TEA using chi-square tests.

We analyzed 276 procedures. In 2016 and 2017, when posterior approaches were further specified, the triceps-on approach is used most frequently in the high-volume center (27/42, 64%) and the triceps-flap approach is most often used in the low-volume centers (48/84, 57%) (p <0.001). For the two most frequently used types of TEA, the Coonrad-Morrey and Latitude EV arthroplasties, surgical approach did not differ. When the high-volume center is compared to the low-volume centers, implant choice differs with the Coonrad-Morrey being most often used in the high-volume center and the Latitude EV in the low-volume centers.

In conclusion, the posterior triceps flap approach is the most frequently used surgical approach in primary TEA in the Netherlands, yet the triceps-on approach is used more often in the high-volume center. Surgical approach did not differ between two most frequently used types of TEA in the Netherlands.

Introduction

A multitude of approaches to the elbow joint are described in literature, each with their own advantages and disadvantages, usually concerning the triceps brachii muscle and tendon ^{7,9,12}. The triceps handling is of importance during rehabilitation; when the continuity of the muscle fibers and tendon is impaired, elbow extension strength has to be moderated to prevent a triceps tendon rupture. Studies comparing surgical approaches generally are single-center studies, covering a particular case series and comparing the outcomes to other approaches or narrative reviews 1,8.

Possible surgical approaches include a triceps-split posterior approach, where the triceps brachii muscle is incised and split longitudinally for intra-articular access ^{1,7,8}. A triceps-flap approach entails the creation of a triceps tendon flap which will be reflected during surgery, and afterwards this flap is refixated to the triceps fascia ^{1,6–8}. A triceps-on approach keeps the triceps muscle intact, which means less direct intra-articular view, yet less triceps muscle fiber interruption ^{1,7,8}. An olecranon osteotomy with flipping over of the complete triceps keeps the muscle fibers intact as well, yet is associated with non-unions of the osteotomy ^{1,8}. Other approaches are possible as well, such as the medial epicondyle osteotomy and the triceps split-and-snip ^{9,12}.

As TEA is a relatively infrequently performed procedure, nationwide databases could help to provide more data than single-center studies. In New Zealand, Sweden and the UK the surgical approach of total elbow arthroplasties is already reported. However, no analyses on the use of different approaches are published yet. The New Zealand Joint registry is the sole register to report data on approaches in their yearly report 10,13–15. These approaches are categorized as posterior, lateral and medial 14. Unfortunately, no further analysis of these data has been performed with regard to TEA model or differences between high- and low-volume centers.

The aim of this study is to provide an overview on the surgical approaches used for primary TEA in the Netherlands, whether these approaches differ between high- and low-volume centers and whether the approach is implant specific using population-based Dutch Arthroplasty Register data.

Materials and Methods

The Dutch Arthroplasty Register (Landelijke Registratie Orthopedische Implantaten, LROI) prospectively collects data on primary and revision arthroplasties. In 2014 the registration of TEA was initiated with almost complete coverage of Dutch hospitals. The LROI contains patient characteristics such as age, gender, ASA score, previous surgery on the affected joint, body mass index, smoking habit and diagnosis. Furthermore, procedure and prosthesis characteristics like date and hospital of surgery, surgical

approach, prosthesis used, fixation technique used, linkage type, ulnar nerve handling, and use of bone grafts are collected in the LROI 16. For this cross-sectional study we included all primary TEAs performed in the period 2014 until 2017.

Table 1. Demographics of all patient who underwent TEA in the period between 2014 and 2017 in the Netherlands.

	2014 (n = 72)	2015 (n = 78)	2016 (n = 67)	2017 (n= 59)	Overall (n = 276)
Age (mean, range)	64 (22-90)	63 (28-85)	69 (42-85)	66 (33-91)	65 (22-91)
Females (%)	74	69	73	85	75
ASA score					
1	8 (11)	10 (13)	7 (10)	4 (7)	29 (11)
II .	49 (68)	52 (67)	42 (61)	30 (51)	171 (62)
III-IV	15 (21)	16 (20)	19 (29)	25 (42)	75 (27)
Smoking (n (%))	15 (21)	29 (26)	7 (11)	3 (5)	45 (16)
BMI (mean, standard deviation)	29 (5.5)	27 (4.7)	26 (5.7)	27 (5.0)	27 (5.2)
Previous surgery (n, (%))					
Yes	45 (62)	38 (49)	30 (45)	26 (44)	139 (50)
Osteosynthesis	14 (19)	12 (15)	13 (19)	12 (20)	51 (19)
Osteosynthesis removal	4 (6)	7 (9)	9 (13)	8 (14)	28 (10)
Lateral Arthrotomy	24 (33)	18 (23)	15 (22)	11 (19)	68 (25)
Medial arthrotomy	5 (7)	4 (5)	5 (8)	3 (5)	17 (6)
Posterior Arthrotomy	16 (22)	9 (12)	8 (12)	9 (15)	42 (15)
Ulnar decompression	-	-	5 (8)	7 (12)	12 (4)
Ulnar transposition	-	-	-	2 (3)	2 (1)
Arthroscopy	3 (4)	3 (4)	3 (5)	1 (2)	10 (4)
Arthrodesis	1 (1)	-	-	-	1 (1)
Other	7 (10)	11 (14)	10 (15)	4 (7)	32 (12)
Diagnosis (n, (%))					
Rheumatoid arthritis	27 (38)	29 (37)	25 (37)	18 (31)	99 (36)
Primary osteoarthritis	13 (18)	21 (27)	10 (15)	11 (19)	55 (20)
Secondary osteoarthritis	20 (28)	18 (23)	18 (27)	19 (32)	75 (27)
Fracture	3 (4)	7 (9)	9 (13)	9 (15)	28 (10)
Hemophilic arthropathy	1 (1)	-	-	-	1 (1)
Inflammatory arthritis	1 (1)	-	1 (2)	-	2 (1)
Osteonecrosis	2 (3)	1 (1)	-	-	3 (1)
Metastasis/tumor	1 (1)	-	1 (2)	1 (2)	3 (1)
Other	2 (3)	2 (3)	2 (3)	1 (2)	10 (4)

Surgical approach was categorized as lateral, posterior, posterior triceps-flap, posterior triceps-on, posterior triceps-split, olecranon osteotomy, and "other". In 2014 and 2015 only the option 'posterior' was possible. This category was specified to 'triceps-on', 'triceps-flap' and 'triceps split' since 2016. Therefore, representative comparison of approaches is only possible in surgeries performed since 2016. High-volume centers were defined as centers with 10 or more TEA procedures performed per year in the period of 2014 to 2017 ⁴.

Demographic data and amount of surgical approaches were described using descriptive statistics. The approaches and types of TEAs used in high- or low-volume centers were compared using the Chi-square test. Due to a multitude in TEA models, we analyzed the two most common prostheses. Analyses were performed using SPSS 24 (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.).

Results

In the Dutch Arthroplasty Register 276 primary TEAs are registered from 2014 until 2017 (2014: 72, 2015: 78, 2016: 67, 2017: 59). Completeness increased from 69% in 2014 to 91% in 2017 16. Overall, the mean age at surgery was 65 years (range, 22-91) and 75% of patients were female. The main diagnoses for surgery were rheumatoid arthritis (36%), secondary osteoarthritis (27%) and primary osteoarthritis of the elbow joint (20%) (Table 1).

Any posterior approach is used in the large majority of procedures (262/276, 95%). When specified since 2016, the triceps-flap is the most often used approach in the Netherlands (61/126, 48%), followed by the triceps-on approach (47/126, 37%) and the triceps-split approach (12/126, 10%) (Table 2).

Table 2. Procedure and prosthesis characteristics

	2014 (n = 72)	2015 (n = 78)	2016 (n = 67)	2017 (n= 59)	Overall (n = 276)
Approach (n, (%))					
Lateral (LCL)	-	-	-	2 (3)	2 (1)
Posterior	25 (35)	24 (31)	-	-	49 (18)
Posterior, triceps flap	37 (51)	33 (42)	31 (46)	30 (51)	131 (48)
Posterior, triceps on	6 (8)	11 (14)	27 (40)	20 (34)	64 (23)
Posterior, triceps split	2 (3)	4 (5)	6 (9)	6 (10)	18 (7)
Olecranon osteotomy	-	1 (1)	-	-	1 (1)
Other	2 (3)	5 (6)	3 (5)	1 (2)	11 (4)
Model prosthesis (n, (%))					
Linked					
Discovery	4 (6)	6 (8)	1 (2)	6 (10)	17 (6)
Latitude	13 (18)	-	-	-	13 (5)
Latitude EV	10 (14)	32 (41)	27 (40)	11 (19)	84 (30)
NES	3 (4)	9 (12)	7 (11)	5 (9)	24 (9)
Coonrad Morrey	21 (29)	23 (30)	27 (40)	25 (42)	96 (35)
Unlinked					
iBP	10 (14)	2 (3)	-	-	12 (4)
K Elbow	-	2 (3)	3 (5)	3 (5)	8 (3)
Latitude	1 (1)	-	-	-	1 (1)
Latitude EV	2 (3)	2 (3)	-	-	4 (1)
Other/unknown	8 (11)	2 (3)	2 (3)	9 (15)	21 (8)
Radial head implant (n, (%))					
Latitude	9 (13)	11 (14)	11 (16)	5 (9)	31 (11)
Ulnar nerve handling (n, (%))					
Decompression	2 (3)	9 (12)	51 (76)	36 (61)	98 (36)
Transposition	3 (4)	6 (8)	14 (21)	19 (32)	42 (15)
Unknown	67 (93)	63 (80)	3 (4)	4 (7)	136 (49)

The median amount of procedures reported per center was 8 in the four years registered with a range of o to 23 per center per year, and 1 to 83 during the entire period (Figure 1). From the 22 reporting hospitals that performed TEA, one center was defined as a high-volume center (>10 TEAs per each year). One hospital performed more than 10 procedures annually in 2014 and 2015, but has not reported in the last two years and was therefore not considered as a current high-volume center in further analyses. In the high-volume center a total of 83 TEAs have been performed predominantly using the

triceps flap approach (45/83, 55%). The low-volume centers also predominantly use the triceps-flap approach (86/193, 45%) (Table 3). When performing the Chi-square test using the data from 2016-2017, the triceps-on approach is used most frequently in the high-volume center (27/42, 64%) and the triceps-flap approach most often in the low-volume centers (48/84, 57%) (p <0.001).

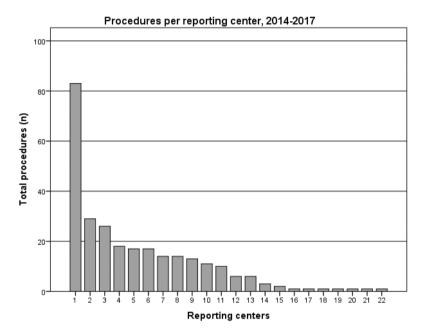


Figure 1. Number of primary total elbow arthroplasties per hospitals as reported to the Dutch Arthroplasty Register between 2014 and 2017.

The assessment of the two most often used types of TEA in 2016 and 2017 and their surgical approach resulted in the comparison between the Coonrad-Morrey (n = 50) and Latitude EV (n = 36) TEAs. Their posterior approaches did not differ significantly (p = 0.691). Ulnar nerve handling using decompression was used in 61-76% of procedures in 2016-2017.

Table 3. Comparison of approaches and implant models as registered in the Dutch Arthroplasty Register, divided into high-volume and low-volume centers.

	High volume (1 hospital) (n = 83)	Low-volume (21 hospitals) (n = 193)	<i>p</i> -value
Approaches 2014-2017			0.000
Lateral (LCL)	-	2	
Posterior	-	49	
Posterior, TC flap	45	86	
Posterior, TC on	35	29	
Posterior, TC split	2	16	
Olecranon osteotomy	1	-	
Other	-	11	
Posterior approaches 2016-2017			0.000
Posterior, TC flap	13*	48*	
Posterior, TC on	27*	20 [*]	
Posterior, TC split	2*	10*	
Type of total elbow prosthesis			0.000
Linked			
Discovery	-	17	
Latitude	-	13	
Latitude EV	_*	80*	
NES	-	24	
Coonrad Morrey	80*	16*	
Unlinked			
iBP	-	12	
K Elbow	-	8	
Latitude	-	1	
Latitude EV	-	4	
Other/unknown	3	18	

^{*} p-value of < 0.001 when compared between high-volume and low-volume centers.

Discussion

Based on population-based registry data from the LROI the posterior approaches, which require triceps handling, were used most frequently (95%) for TEA. When further specified since 2016, the triceps-flap was the most often used approach in the

Netherlands, followed by the triceps-on approach and the triceps-split approach. The triceps-on approach was used most frequently in the high-volume center and the triceps-flap approach most often in the low-volume centers.

As the different approaches do have their specific advantages and disadvantages, rehabilitation also differs accordingly ⁷. The most often used triceps-flap approach requires moderation of elbow extension during rehabilitation as the triceps muscle has been interrupted, to prevent the serious complication of a triceps rupture ^{2,6}. A triceps-on approach does not necessarily need the moderation of elbow extension force, which may be beneficial in gaining range of motion earlier in the rehabilitation process ^{2,3,9}. However, the surgical exposure for the triceps-on approach is different to the triceps-flap and triceps-split techniques as direct vision into the intramedullary canal of the ulna is more difficult, what could be the reason the triceps-on approach is used more often at centers with more experience ^{1,8}.

This study is the first using the Dutch Arthroplasty Register data on TEA, and shows a difference in surgical approaches between high- and low-volume centers. As the specification of posterior elbow approaches is in use since 2016, a more valid comparison between centers was possible. Nevertheless, the triceps-on technique is used most frequently in these last two years (27 of 50 cases in the high-volume center, 20 of 78 in the low-volume centers). This could be explained by implementation of newer surgical techniques with the advantage of keeping the triceps muscle and tendon intact, and therefore theoretically less restrictions on elbow extension force ^{2,7}. No comparison to other national registry outcomes is possible as no data considering the approaches is available in literature or national registries' reports.

Data from the Scottish arthroplasty register shows less complications when 10 or more TEAs are performed per center on a yearly basis ⁴. Regarding the median amount of two primary TEAs implanted per center per year in the Netherlands, centralization of surgery could possibly provide better patient care. Of note is that revision arthroplasties are not taken into consideration in the current data on primary TEA, and therefore centers now labeled as 'low volume' could have more experience with TEA care. Therefore, further research based on Dutch TEA data should be performed to examine this in the Netherlands.

Data gathering and data completeness is essential for meaningful arthroplasty research. Dutch orthopedic surgeons and their teams are requested to register their arthroplasty procedures into the LROI. The LROI has already reached a completeness of 91% for 2017 when cross checked with hospital data, which is high for a relatively new national database ⁵. Presumably, when more feedback is provided to the registering surgeons using personal feedback using a personal digital 'dashboard' hopefully will reach the almost full completeness of hip and knee arthroplasty registration ¹¹.

In this study, only primary procedures were selected for homogeneity of the study population. Revision procedures like the conversion of a radial head arthroplasty to a TEA were excluded, which might give the orthopaedic surgeon additional experience on TEAs. Although, in revision TEA the approach used for the primary surgery may play a confounding role, especially when complications have occurred, such as triceps tendon insufficiency. We have therefore chosen to analyze primary surgery only, as probably less non-reported surgical considerations are of importance than in revision surgery.

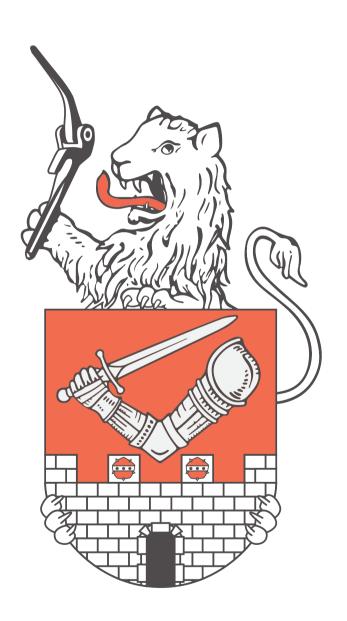
The number of procedures per surgeon cannot yet be retrieved from the LROI. Therefore, the volume of TEA per hospital was used to categorize hospitals based on their TEA volume instead of per surgeon, which may produce bias as the surgeon-volume now remains undetermined. A future analysis using the surgeon-data could provide more information, which then should be performed with caution as two surgeons can cooperate during one surgery. Also implementation of functional follow-up scores would be of great scientific value to monitor the results after total elbow arthroplasty.

Conclusion

The posterior triceps flap approach is the most frequently used surgical approach in primary TEA in the Netherlands based on population-based registry data. Surgical approach did not differ between two most frequently used types of TEA in the Netherlands, the Coonrad-Morrey and Latitude EV arthroplasties. Type of TEA differed between the high-volume compared to low-volume hospitals in the Netherlands, with the Coonrad-Morrey being most often used in the high-volume hospital and the Latitude EV in the low-volume hospitals. In addition, the triceps-on approach is used more often in the high-volume center.

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Chapter three

Total Elbow Arthroplasty; why and how

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Introduction

Elbow arthroplasty is a relatively infrequent orthopedic procedure. In the Dutch Arthroplasty Register 408 elbow arthroplasties are registered, compared to over 280.000 hip arthroplasties and 216.000 knee arthroplasties. The surgery can be performed in multiple ways according to the type of the prosthesis and needs of the individual patient.

The planned patient-specific approach includes the decisions which implant will be used and how to handle the triceps muscle and tendon during the approach. Firstly, the implant choices are based on stability and extensiveness; unlinked implants with less intrinsic stability or linked implants with more intrinsic stability, and ulnohumeral joint replacement with or without radiocapitellar joint replacement. For example, in heavily deteriorated rheumatic elbows with insufficient ligamentous stability most often a linked prosthesis is chosen. Secondly, to allow proper visualization, the triceps tendon can be split, reflected or lifted using an ulnar osteotomy². After removal of the diseased cartilage and preparation of the ulna, humerus and radius, the implants are implanted according to implant-specific guidelines.

As with all arthroplasties, rehabilitation is necessary. The elbow joint is prone to develop contractures, which have to be prevented by avoiding longstanding inactivity or casting.

Indications and Contraindications

The indication for an total elbow arthroplasty is pain at rest, or nocturnal pain uncontrolled by analgesia, NSAIDs or bracing.

Indications

- Primary osteoarthritis
- Post-traumatic osteoarthritis
- Trauma (unreconstructable intra-articular distal humeral fractures)
- Post-traumatic conditions (non-union of fractures, persistant dislocations in the elderly)
- Inflammatory arthritis (rheumatoid, psoriatic)
- Tumour reconstruction

Contraindications

- Systemic infection
- Local infection
- Inability to participate in post-operative rehabilitation
- High physical demands after arthroplasty
- Age under 50

Step 1: Positioning

The patient is positioned in a lateral decubitus position with the arm draped allowing for easy manipulation of the elbow joint during the procedure.

- Place the patient in a lateral decubitus position with the contralateral arm in 90 degrees anteflexion in the shoulder and 90 degrees of flexion in the elbow with the forearm pointing towards the floor. Secure solid patient positioning with a bean bag or pelvic supports.
- Put the arm on a padded support in such a way so only the most proximal part of the arm is supported, leaving ample room for the elbow to be manipulated.
- Prevent the arm holder form pushing the neurovascular structures towards the operating field.
- After sterile draping of the arm, a silicone ring tourniquet is applied, placing it as
 proximal as possible allowing for proximal extension of the posterior incision if
 required.

Step 2: Incision

The local bony landmarks, ulnar nerve and incision are palpated and marked. A posterior incision is made to allow a 360 degree access to the elbow joints as well as allowing decompression or transposition of the ulnar nerve.

- Mark the radial head, medial and lateral epicondyle, central band of the triceps muscle and olecranon.
- Mark the incision starting at least 8 cm proximal to the elbow joint, making a slight curve just lateral to the olecranon tip, and extending it 8 cm distal to the elbow joint.
- Incise the skin as marked.
- Prevent the incision from running over the olecranon tip, as this might give postoperative wound dehiscence and irritation of the scar.

Step 3: Approach – superficial layer

The superficial approach may include a decompression of the ulnar nerve, as well as proper visualization of the triceps tendon attachment on the proximal ulna and both epicondyles.

- Develop an ulnar flap separating the subcutaneous layer from the fascial and muscular layer deep to it. The medial epicondyle is now in view.
- Locate the ulnar nerve and decompress it. Then prepare the nerve as for an anterior transposition. A vessel loop can be used as a visual aid to keep it from harm during the remainder of the procedure.
- Use a stay suture to keep the ulnar flap to the ulnar side.

• Develop the radial flap in a similar fashion, keeping it as thick possible, revealing the lateral epicondyle, and secure the flap temporarily with another stay suture.

Step 4: Approach – deep layer

The triceps is mobilized to allow visualization of the articular surfaces of ulna, humerus and radius. Care has to be given to protect the ulnar nerve.

- For a triceps-on approach multiple options are possible. Firstly, a chevron osteotomy of the ulna can be made on the proximal part of the ulna, distal to the attachment of the triceps muscle. This allows the triceps to be lifted off and the articular surfaces to be visualized. When using this approach, we advise to 'point' the chevron osteotomy distally, to maximize bone stock of the central band of the triceps tendon. Secondly, the triceps can be reflected medially or laterally according to the needs during surgery. This approach has a relatively high amount of failures because of non-union of the ulnar osteotomy².
- For a triceps-split approach, dissection lateral to the triceps muscle is performed, which allows room for dislocation of the elbow joint. This approach does not interfere triceps muscle fiber integrity, yet care has to be given not to provide traction on the ulnar nerve².
- For a triceps-off approach, the central band of the triceps has to be palpated. An incision around the central band is performed to create a triceps-tongue and the tendon is sharply dissected to divide the tendon off the muscle³. Then, incision of the triceps muscle allows visualization of the articular surfaces. The lateral side of the triceps, to which the intermuscular septum is attached is kept untouched.
- To allow movement between the humerus, radius and ulna, the ligamentous structures can be released by osteotomies. An osteotomy of the supinator tuberosity of the ulna, to which the lateral collateral ligament and annular ligament are attached, allows a disarticulation of the elbow joint and direct vision to all joint surfaces.
- To allow even better visualization, release of the medial collateral ligament is performed. We advise the use of an osteotome to create a humeral bone block with the insertion of the medial collateral ligament, which can be refixated during closure with transosseous sutures or bone anchors.

Step 5: Preparing the osseous structures

Depending on type of prosthesis the humerus and ulna are prepared conform the technique that is described for the prosthesis. During preparation care is taken to restore the anatomical flexion-extension axis of the elbow.

• When an implant that also allows placement of a radial head component is chosen, standard preparation of the radius should be performed as well.

- Usually a guide pin is inserted into the medullary canal of the humerus and ulna, to determine the axis of the bones and joint surfaces. This needs meticulous assessment, as improper alignment might result in excessive wear of the prosthesis⁴.
- The guide pin is replaced by reamers to open the cortex, prepare the medullary canal and to determine implant sizes.
- The trial components are inserted.

Step 6: Placement of the prosthesis

When all trial components are in place, reduction of the joint is performed to test the stability of the elbow.

- The elbow joint with the trial prosthesis is reduced and the function and stability of the elbow joint is tested, using varus and valgus stress in 30 degrees of flexion of the elbow.
- When a convertible prosthesis is implanted, the trail component can be linked to asses the influence on the stability of the elbow.
- The trial prosthesis is removed and in case of a cemented prosthesis the cement plugs are inserted to the proper depth into the ulnar and/or humeral shaft.
- Excessive lavage of the ulna and humeral shaft, and when indicated of the radial shaft, is performed. This will lead to the best cement fixation possible.
- Depending on the type of the prosthesis the definite components are assembled.
- All components of the elbow prosthesis are cemented at the same time or separately, depending on the type of the prosthesis and the surgeons' preference.
 During cementation the care is taken to maintain the proper depth and rotation of the components. It is useful to extend the elbow at this moment, so longitudinal pressure over the arm can be given.
- Depending on the stability of the elbow during trial reduction and after reduction of the definite prosthesis a convertible prosthesis can be linked at this moment.
- We advise to document per-operative range of motion in order to evaluate rehabilitation success during recovery.

Step 7: Closure of the elbow

When all the definitive components of the total elbow arthroplasty are in place, the surgical wound is closed in layers as anatomy is restored.

- After placement of the prosthesis the elbow is thoroughly rinsed with a saline solution to wash out any debris, in order to prevent heterotopic ossification.
- When released during the approach, the ulnar and radial collateral ligaments are refixated to provide additional stability to the total elbow arthroplasty.

- When the triceps has been released from the olecranon, for example to create a
 triceps flap, it is refixated with vicryl sutures. A thick suture is recommended, as
 the triceps muscle provides large pulling forces at this point during extension and
 proper fixation is necessary.
- Leaving a drain in the surgery area is an option, yet it might pose a possible source of infection. We therefore suggest only to leave a drain when the patients uses therapeutic anticoagulants or in case of excessive blood loss during surgery.
- The vessel loop is removed from the ulnar nerve and the nerve is either replaced in the sulcus or transposed. Pre-operative ulnar nerve complaints might guide the decision to transpose.
- Closure of the subcutaneous layers is performed with vicryl sutures and the skin is closed with transcutaneous sutures or staples. A continuous intracutaneous suture is not recommended, as in case of an infection the whole wound will be opened.

Step 8: Post-operative care

After surgery, a wound dressing is applied and physical rehabilitation is started to maximize the functional outcomes after total elbow arthroplasty.

- After surgery, but before the tourniquet is removed, a compressive wound dressing is applied. According to local standards, the dressing is left on for 24-72 hours.
- As no clear scientific evidence exists on when to start with physical rehabilitation, immediately after surgery of after several days of rest, and the use of continuous passive motion, these choices are made according to the preference of the surgeon.
- Adequate pain relief is mandatory in the first weeks during exercises and might consist of an anaesthetic interscalene block for the first two to three days. Deterrence of range of motion has to be prevented by physical therapy.

Results

As for all practical interventions, preparation and rehearsal of the procedure is paramount. We do not advise one certain approach, yet we do advise to be conscious of different methods to choose the most fitting in individual cases. The success of total elbow arthroplasty is forthcoming from the large improvement experienced by the patient, which is measured in objective more range of motion and subjectively in pain reduction. In general, total elbow arthroplasty has a 10-year survival of approximately 85 to $90\%^{5-7}$.

Pitfalls & Challenges

• Do not incise the skin over the olecranon tip; this is might lead to more wound problems as patients do apply more pressure on this point of the elbow and less soft tissues are present.

- When incising the deeper layers, take care of the ulnar nerve. In a fair amount of patients (10%) the ulnar nerve shifts out of the sulcus during flexion and extension. This is best assessed before incision by palpating the ulnar nerve in the sulcus.
- The central band of the triceps tendon provides the most force transmission to the ulna and should be left untouched as most as possible. A proximal transverse incision provides the most traction resistance in our opinion and is therefore recommended.
- During elbow disarticulation for articular exposure, stay aware of the neurovascular structures on the ventral side of the elbow joint and do not force the disarticulation.
- Pre-operative implant size planning is possible, yet the most implants come in a selected amount of sizes, which makes pre-operative implant sizing less useful than, for example, in hip surgery.
- In our opinion, the use of a drain is controversial, since the integrity of the skin is compromised and therefore might be more prone to infections, yet the prevention of haemarthros might be beneficial in post-operative rehabilitation.

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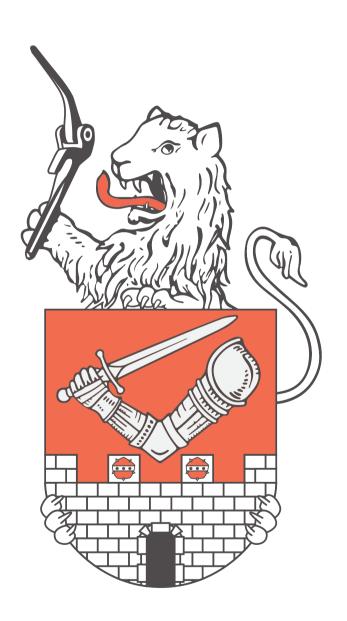
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Total Elbow Arthroplasty; why and how.

E

Part two

Complications and their impact on outcomes



Chapter four

Why does total elbow arthroplasty fail today? A systematic review of recent literature

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Abstract

Background

Total elbow arthroplasty is a relatively uncommon type of arthroplasty, which has undergone several design changes in the past four decades. However, research on improvement requires knowledge of failure mechanisms that can be addressed. Therefore we conducted a systematic review on modes of failure of total elbow arthroplasty.

Methods

We conducted searches on PubMed/Medline, Embase and Cochrane databases to identify studies describing modes of failure of primary total elbow arthroplasties. The results were coupled per type of total elbow arthroplasty and individual arthroplasty models.

Results

A total of 70 articles were included in this systematic review. 9.308 individual total elbow arthroplasties were identified with 1.253 revisions (13,5%). Aseptic loosening was the most prevalent reason for revision (38%), followed by deep infection (19%) and periprosthetic fractures (12%).

Conclusion

Revision rates have been found similar to a systematic review published in 2003. Aseptic loosening remains the most frequent cause for revision of primary total elbow arthroplasty. Therefore, more research on the occurrence, progression and risk factors of aseptic loosening should be performed and lead to higher implant survival.

Introduction

During the past forty years, total elbow arthroplasty has evolved into an established treatment for a wide range of pathological conditions. At the beginning of the 20th century elbow arthroplasty was highly experimental and only used as a last resort in devastated tuberculous and rheumatic elbows[1]. Since then, many alterations in design and materials have been tried, and today total elbow arthroplasty is a fair option in trauma of the elderly and a fair option in post-traumatic arthritis[2, 3]. In the last decade, incidence of elbow arthroplasty for rheumatoid arthritis has declined, and is mostly used in primary and secondary osteoarthritis and trauma[4, 5]. Despite all improvement of the implants and surgical techniques, survival results still seem to be less favorable than in hip and knee arthroplasty according to a systematic review in 2003[6, 7].

Therefore, a systematic review of literature was performed, to establish whether total elbow arthroplasty implant survival has changed and to gain insight into failure modes in recent years.

Materials and methods

To identify relevant articles on primary total elbow arthroplasty, PubMed/Medline, Embase and Cochrane databases were searched using 'elbow prosthesis' and 'arthroplasty', 'joint prosthesis' and 'elbow' as MESH-terms. To detect articles that did not yet have MESH-terms assigned, a second search was performed using 'elbow' and 'replacement', 'prosthesis' or 'arthroplasty'. Limitations were set to English, German and Dutch language, concerning humans and publication after 2003, as then a previous systematic review was conducted[7].

All included articles were deduplicated using RefMan reference manager (Thomson Reuters, version 12.0.1. Titles and abstracts were screened to establish relevance by one of the authors and a collegue (CW, Kaj Lambers). When judged to be potentially relevant, articles were read in its entirety. Articles reporting a follow-up of at least one year and with a minimum of 5 patients were included. In case of duplicate patient cohorts, the longest follow-up or case-series was included. Articles discussing only revisions and those not mentioning modes of failure were excluded. Articles reporting the results of interposition arthroplasties, fully constrained hinged prostheses, distal humerus hemiprosthesis, and radial head prostheses were excluded. Surgical technique articles, review articles and expert opinions were also excluded.

Information was extracted on duration of follow-up, cohort size and demographics (e.g. age at time of implant and gender), arthroplasty model (linkage and brand), revision rates and failure modes (e.g. aseptic loosening, infection, polyethylene wear, dislocation/instability, periprosthetic fracture, disassembly, material failure/breakage, and

malposition). Failure modes mentioned in the original papers were used, as no control on multiple failure modes in one patient could be checked (e.g. polyethylene wear in an aseptic loosened elbow). The information was analyzed using Microsoft Excel 2010 and divided into four groups: overall, linked arthroplasties with a sloppy hinge, unlinked arthroplasties and a non-distinctive group when no clear distinction on arthroplasty model could be made from the text nor tables or graphs provided.

To evaluate results for different indications, we have grouped well-defined original cohorts into groups of rheumatoid arthritis, trauma, post-traumatic arthritis, primary osteoarthritis and haemophilia as these could be derived from the original articles.

Follow-up and age was weighted accordingly to the review of Little et al. for group size. Cohort size was multiplied by follow-up in months or age in years, divided by the total amount of arthroplasties to calculate a weighted mean. When mentioned in the article, revisions were categorized into groups of within one-, five-, ten-, fifteen- and over-fifteen-year failures. To distinguish between acute postoperative infections and non-surgical postoperative infections an arbitrary demarcation of one year was used.

Revision was defined as operative extraction (and usually replacement) of a primarily implanted arthroplasty component. Modes of failure were defined and divided into several categories. Revision due to aseptic loosening was extracted as such from the original publications. Symptomatic and asymptomatic radiological loosening without revision were left out of our analysis. Revision due to infection consisted of all reported infections, followed by revision. Debridement, lavage and other implant-retaining interventions were not scored as revision cases. Dislocation of prosthesis components, periprosthetic fractures and polyethylene wear were originally used terms in the original articles and analyzed as such. Material failure was defined as all component breakage. Disassembly of arthroplasties with intact components was not considered as material failure but as disassembly.

To evaluate for statistical differences between the linked and unlinked totale elbow arthroplasty revision rates, the chi-square test was used. We used a significance level of p < 0.05.

The chi-square test was also used to identify statistical differences between indications for total elbow arthroplasty and for modes of failure. Here a significance level of p < 0.005 was stated as significant as more than ten tests on the same subject were performed.

Results

Articles

The PubMed/Medline search yielded 719 results, of which 16 were duplicates. The Embase search yielded 373 results, of which 190 matched PubMed results. The Cochrane review search yielded seven duplicate reviews. In total 886 studies were screened for eligibility.

After screening of abstract and title 781 articles were excluded. After excluding cohort duplicates, articles focusing on surgical technique and only regarding revisions, 70 of 105 articles were included in our systematic review (Figure 1).

Results of implant registries were from California, Denmark, Finland, Norway and Scotland [4, 8–11].

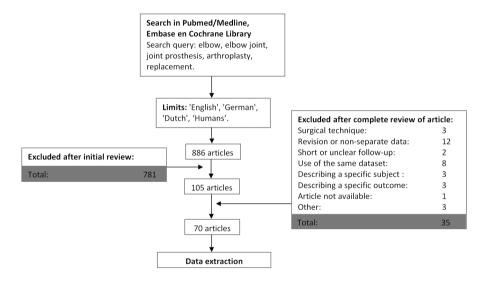


Figure 1. Flowchart of PubMed, Embase and Cochrane database search and article assessment.

When split into linked or unlinked designs, 39 cohorts of linked arthroplasties in 37 studies were identified and 40 cohorts of unlinked arthroplasties in 30 studies. Nine cohorts in nine studies could not be divided into these categories due to use of multiple implants and use of overall results. General characteristics are shown in Table 1.

Table 1. Demographic data per total elbow arthroplasty group and model.

	Cohorts (n)	Elbows (n)	Age (weighted mean)	Gender (female, %)
Overall	70	9308	60	77
Linked -all	39	2211	62	76
Coonrad Morrey	21	1260	63	75
GSB III	7	459	59	76
Discovery	4	111	69	69
Baksi	1	41	58	59
Solar	1	13	63	92
Unlinked -all	40	2764	59	81
Kudo 3/4/5	14	547	59	81
Souter Strathclyde	12	1457	59	83
iBP	3	140	62	75
NES implavit	2	225	61	80
Acclaim	2	36	64	62
STABLE	1	13	61	93
JACE	1	34	60	93
Sorbie-QUESTOR	1	51	52	50
SKC-1	1	54	59	95

Overall

A total of 9.308 individual total elbow arthroplasties were identified with 1.253 revisions (13,5%) during follow-up periods ranging from 0 months to 352 months (weighted mean follow-up was 81 months). Aseptic loosening was the most prevalent reason for revision (478/1.253, 38%), followed by deep infection (243/1.253, 19%), periprosthetic fractures (147/1.253, 12%). Reasons and rates of revisions are shown in Table 2.

Linked arthroplasties

In 36 studies a total of 39 cohorts and 2.211individual arthroplasties in 2.039 patients were identified (range, n=6-723, median n=25 arthroplasties)[2, 8, 10, 12–44]. During a weighted mean follow-up of 75 months (range, 0-352 months) 304 revisions were reported (13,8%). Modes of failure are shown in Table 2. The weighted average age was 63 years (range, 28-80 years). Arthroplasties were performed in 1.548 women (76%) and 490 men (24%).

Unlinked arthroplasties

In 30 studies 40 cohorts reported on 2.764 unlinked arthroplasties (range, n=9-522, median n=36 arthroplasties)[2, 8, 10, 34, 45-69]. Follow-up had a weighted mean of 97 months (range, 0-156 months) and a total of 451 revisions were reported (16,3%). The modes of failure are shown in Table 2. Weighted average age was 59 years (range, 42-73). Arthroplasties were performed in 2.000 women (81%) and 466 men (19%).

Linked and unlinked arthroplasties

Eight cohorts in eight studies that could not be clearly split into TEA linkage type, were discussed in this separate category of 4.333 arthroplasties [4, 9, 11, 70–74]. Included were three large registry studies, consisting of 4.128 total elbow arthroplasties in this category[4, 9, 11]. Weighted follow-up was 77 months (range, 0-216 months), with an overall revision rate of 11,4% (553/4.838). Weighted mean age was 58.8 years.

Indications for primary total elbow arthroplasty

From the original articles, 60 cohorts with a specified diagnosis could be extracted. The most frequent diagnosis for primary total elbow arthroplasty was rheumatoid arthritis, followed by trauma and post-traumatic arthritis. The revision rates are shown in Table 3.

Short-term and long-term failure modes

In total, 26 articles mentioned failures in a well-defined timeframe[11, 13–19, 25, 30, 33, 35, 37, 40, 45, 46, 48, 51, 52, 54, 57, 66, 67, 69–71]. These articles covered 506 revisions in 3.853 elbow arthroplasties, of which 8843 revisions could be sub-analyzed in follow-up-categories. However, due to heterogeneity in reporting, no exact numbers per reason for revision could be calculated. Therefore, overall numbers of revision are shown in Table 2. In twelve articles deep infection within one year was stated as the reason for revision of 31 arthroplasties[2, 14, 15, 27, 28, 32, 38, 40, 51, 65, 66, 68]. Aseptic loosening appeared to be a long-term problem, while periprosthetic fractures tended to occur at all moments, usually due to trauma [4, 9, 10, 14, 17, 18, 31, 33, 34, 37, 38, 40, 48, 53, 59, 65, 67–69, 75].

 Table 2.
 Failure rates per mode of failure for total elbow arthroplasty groups and models.

	Elbows (n)	Follow-up (weighted mean, range)	Revision (n, % of total)	Aseptic loosening (n)	Infection (n)	Infection Polyethylene Dislocation/ (n) wear Instability (n) (n)	Dislocation/ Instability (n)	Periprosthetic Disassembly Material fracture (n) failure/ (n) Breakage (n)	Disassembly (n)	Material failure/ Breakage (n)	Malposition (n)
Overall (70 articles)	9308	81 (0-352)	1253 14	478	243	39	103	147	34	22	6
Linked -all (39 cohorts)	122	75 (0-352)	304* 14	*16	8 9	38∵	<u>*</u>	43\$	24∵	33 <u>†</u>	₩
Coonrad Morrey (n=21)	1260	67 (0-300)	172 14	52	4	28		24		27	-
GSB III (n=7)	459	92 (0-352)	71	41	Ε	4	_	∞	22	9	7
Discovery (n=4)	E	42 (21-96)	13	_	6	1		8			1
Baksi (n=1)	4	56 (12-88)	3 7,3	_	7			1		1	•
Solar (n=1)	13	101 (48-151)	7 54	4	_	7	1	1	1	ı	1
Unlinked -all (40 cohorts)	2764	77 (0-324)	451* 16	279*	56≎	÷	÷19	30%	<u>⊹-</u> ∞	151	☆
Kudo 3/4/5 (n=14)	547	85 (6-161)	65	35	15		7	-	-	2	-

Why does total elbow arthroplasty fail today? A systematic review of recent literature.

 Table 2.
 Failure rates per mode of failure for total elbow arthroplasty groups and models. (continued)

	Elbows (n)	Elbows Follow-up (n) (weighted mean, range)	Revision (n, % of total)	Aseptic loosening (n)	Infection (n)	Polyethylene wear (n)	Dislocation/ Instability (n)	Infection Polyethylene Dislocation/ Periprosthetic Disassembly Material (n) wear Instability fracture (n) Failure/ (n) (n) (n) (n) (n)	Disassembly (n)	Material failure/ Breakage (n)	Malposition (n)
Souter Strathclyde (n= 12)	1475	109	260	183	27		34	4-		_	
iBP (n=3)	140	38 (26-96)	4 0	7			7		2		
NES implavit (n=2)	225	93	31	22			Ω		7	4	
Acclaim (n=2)	36	4 ¹ (24-49)	2 5,6		-	-					
STABLE (n=1)	13	60 (16-104)	23	6							
JACE (n=1)	34	56 (21- 104)	9 29	2	8		-				1
Sorbie- QUESTOR (n=1)	51	100 (2-148)	15	7	6			4			
SKC-1 (n=1)	54	48 (32-69)	. 0								

*: significant difference in favor of linked arthroplasties †: significant difference in favor of unlinked arthroplasties ‡: no significant difference between linked and unlinked models.

Statistical analysis

When the revision rates of linked and unlinked prostheses were compared, the linked group had a significantly lower revision rate (p = 0.015). Total elbow arthroplasty for rheumatoid arthritis had a significantly higher revision rate than for trauma (p < 0.001) and for post-traumatic osteoarthritis (p = 0.003). Trauma and post-traumatic osteoarthritis did not differ significantly (p = 0.83)

For linked implants, less aseptic loosening and dislocation was seen than for unlinked implants (p < 0,005). However, linked implants had more disassembly, material failure and PE wear than unlinked implants (p < 0,005). Infection, periprosthetic fractures and malpositioning were not statistically different (p = 0,02, p = 0,01 and p = 0,05, respectively).

Table 3. Revision rates and reasons for revision for cohorts of defined indications for total elbow arthroplasty.

Diagnosis	Cohorts	Weighted mean follow-up (months)	Number of arthroplasties (n)		Infections (n, % of revisions)	loosening (n, % of	Periprosthetic fracture (n, % of revisions)
Rheumatoid	35	129	2795	302	50	196	14
arthritis				11	17	65	4.6
Trauma	12	109	369	13	6	3	4
				3.5	46	23	31
Post-traumatic	6	149	158	5	2	2	1
osteoarthritis				3.2	40	40	20
Non-union	3	61	29	2	1	0	0
				6.9	50	-	-
Primary	2	115	40	6	1	3	0
osteoarthritis				15	17	50	-
Haemophilia	2	107	15	4	2	2	0
				27	50	50	-

Discussion

In this article the modes of failure of total elbow arthroplasty were studied by performing a systematic review of literature, published after a previous systematic review[7]. The revision percentage of total elbow arthroplasty for rheumatoid arthritis is significantly higher than for trauma and post-traumatic osteoarthritis. Aseptic loosening was seen less in linked implants, yet infections and periprosthetic fractures did not differ between design groups.

Even though steps have been undertaken to improve outcomes after total elbow arthroplasty, a comparable percentage in revision rates was observed when compared

to the review of Little et al. This might be due publication on predominantly the same implant models as in the review of Little et al. Contrary to the review of Little et al, we have primarily searched for implant failure modes. From our data, aseptic loosening remains the main reason for revision, followed by infections and periprosthetic fractures. Concerning complications after total elbow arthroplasty, a comparable literature search was performed by one of the authors[76].

Literature on revisions of more 'modern' implants, such as the Latitude elbow arthroplasty, was included in the undistinguished group as this particular models can be used both linked as unlinked.

In the linked arthroplasty group, both the high rate of polyethylene wear and low dislocation rate might be contributed to the inherent stability of linked designs, where repetitive strain is seen on the bushings or coupling mechanism. The unlinked arthroplasty group relies on capsuloligamentous stability, which explains the higher dislocation rate compared to the linked group. Aseptic loosening is more substantial in the unlinked designs; we believe this is due to multiaxial forces in the elbow exerted at the implant-cement and cement-bone interfaces. The forces on the ulnar and humeral implant differ in different angles of flexion of the elbow[77]. The larger polyethylene bearings of unlinked designs might pose a larger site of microabrasions leading to more aseptic loosening. Unfortunately, the site of loosening remained unmentioned in the original articles.

In case-series all revisions are mentioned, in contrast to (national) implant registers, which rely on correct input from all surgeons and information might be lost during reporting. Of all articles included, seven were level 3 studies and 62 were level 4 case-series. The retrospective nature of most studies might have led to information loss during follow-up.

Periprosthetic fractures are interestingly the third most-encountered mode of failure and pose a difficult patient group for revision. Bone stock in both the ulna and humerus is limited and when combined with a fracture, revision surgery is a challenge. Because of heterogeneity of reportings, no numbers on ulnar or humeral factures nor clear numbers on reasons for periprosthetic fractures can be given, yet they seem to occur most often after a fall and with already present radiologically confirmed loosening. When taken the ageing population into account, falls are a non-implant specific reason for revisions and a potential threat to the patient.

The revision rates for rheumatoid arthritis seem higher than for (post-traumatic) osteoarthritis, which can be explained by pathophysiology, as rheumatoid arthritis tends to affect the capsuloligamentous structures too and has a progressive nature. The (post-traumatic) osteoarthritis has more influence on the articulation itself and is not progressive once the articulation is resected and the prosthesis has been implanted.

Concerning our statistical analysis, implant registry reports have been omitted as they did not provide completeness of data. These large registry reports did provide more than half of the elbow arthroplasties included and thus might have proved a registration bias.

For future improvement of outcomes in total elbow arthroplasty, the problem of aseptic loosening could be addressed by using cementless fixation or inventing a highly stable cement fixation method. Failure due to malposition could be prevented using fluoroscopy of three-dimensional per-operative guidance, as suboptimal implantation of TEA has a negative influence on prosthesis survival[46]. Dislocation is a specific problem in unlinked arthroplasties, which might be addressed by alteration of the implant to provide more intrinsic restraint and improvements in ligamentous repair during surgery.

Infection has been addressed using antibiotic-containing cement and general aseptic measures as local actions. The elbow has a relatively low amount of surrounding tissues which could act as an infection-barrier; therefore most infections are caused by skin bacteria such as Staphylococcus Aureus and Staphylococcus Epidermidis. As a general action to lower infection rates, a whole-body infection focus analysis as used in transplantational medicine might reduce the risk of hematogenous infections, as well as decolonization of Staphylococcus Aureus-carrying patients[78]. Concentration of the relatively low numbers of patients requiring total elbow arthroplasty to specialty centers might improve the outcomes and post-operative complication rates[79].

Conclusion

In the current systematic review of recent literature, a similar revision rate is observed as in a previous systematic review thirteen years ago. In this review we searched for modes of failure, which has not been done before. Aseptic loosening and infection remain the foremost reasons for revision. Linked arthroplasties tend to have more revisions due to polyethylene wear, where unlinked designs have more revisions due to instability and dislocations. Periprosthetic fractures are a third most frequent reason for revision. Elbow arthroplasty for rheumatoid arthritis has higher revision rates than post-traumatic osteoarthritis and in trauma

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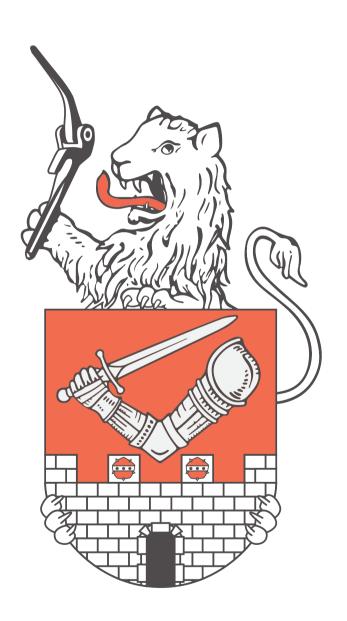
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Chapter five

The Influence of Short-term Complications on the Outcomes of Total Elbow Arthroplasty

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Abstract

Background

The reported complication rate after Total Elbow Arthroplasty is high, and objective outcomes are not always predictive of satisfaction. This study aims to investigate the effect of a short-term complication on patient satisfaction and patient-reported outcome measures (PROM).

Methods

We retrospectively included 126 patients that received a primary total elbow arthroplasty at our hospital between 2008 and 2018 and compared outcomes between patients with a complication and patients without complications occurring within one year using t-tests or Mann Whitney U tests. P-values were corrected using the Benjamini-Hochberg procedure.

Results

In total, 26 patients developed a complication (21%). At one-year follow-up there were no significant differences between the groups. At three-year follow-up, patients with a complication had a lower median satisfaction score (8 versus 10; p=0.0288) and Oxford Elbow Score (27 versus 43; p=0.0048). At the five-year follow-up, there were no differences between the groups. However, the number of patients that completed the five-year follow-up is low (42 patients).

Discussion

Complications occurred in 21% of patients undergoing total elbow arthroplasty and lead to a decrease in satisfaction and Oxford Elbow Score after three years.

Introduction

Total elbow arthroplasty (TEA) is a relatively uncommon procedure, and the results are not comparable to those in hip and knee arthroplasty. 16,24 Clinical outcomes of arthroplasty are traditionally assessed using objective outcomes, such as implant survival, reoperation rate, or length of stay. However, these outcome measures are not always predictive of patient satisfaction. 4,10 Non-surgical peri-operative factors such as empathy, management of expectations, and pain relief are factors that influence postoperative satisfaction the most 4,11,14

In comparison to hip and knee arthroplasties, the reported complication rate after TEA is relatively high, ranging between 11 and 38%.^{9,19,22} The most common complications after TEA are (early) loosening, infection, ulnar nerve symptoms, peri-prosthetic fractures, and triceps insufficiency.²² Besides the effect on the parameters mentioned above, it is rational to expect that such a complication heavily impacts the patient's satisfaction and reported elbow functionality. To quantify the outcomes of TEA from a patient's point of view, patient-reported outcome measures (PROMs) can be used in the form of questionnaires, performance scores, quality of life, pain or patient satisfaction measured on visual or numerical scales. ^{2,5,20,23} There is a sparsity in the current literature regarding the influence of a complication on the patient-reported outcomes or satisfaction after TEA. This study aims to investigate the effect of a short-term complication on patient satisfaction and PROMs.

Materials and Methods

All patients who underwent total elbow arthroplasty at our hospital between 2008 and 2018 were identified. Exclusion criteria were revision surgeries of the implant with primary arthroplasty performed at an outside hospital, lack of completed follow-up visits or questionnaires, and a follow-up of less than 1-year. Implant types other than Coonrad-Morrey (Zimmer, Biomet, USA) were excluded to increase the internal validity of the study. This resulted in a cohort of 126 patients. Patients were included in the complication group if a complication occurred within one year after primary surgery. In case of revision surgery in which at least one component of the implant is replaced, the patient was censored at the time of revision. In case of bilateral elbow arthroplasty, only the implant that was placed first was included to minimise the chance of bias due to previous experiences. Demographic data, surgical data, arc of motion, and complications, including nerve symptoms, triceps insufficiency, infection, and loosening or fractures were extracted from the electronic patient files. Complications were registered in the electronic patient files as defined in the guideline of the Dutch Orthopedic Society including all adverse events that require a change of policy or cause transient or permanent impairment to the patient.¹³

PROM data were extracted from our digital follow-up system onlinePROMS (Interactive Studios, Rosmalen, the Netherlands).²⁰ If patients had no access to the internet or were not able to fill in the questionnaires online, the questionnaires were performed handwritten on paper and later added to the onlinePROMS system by the researchers. The collected outcome scores include the numerical rating scale (NRS) for satisfaction ranging from o (completely unsatisfied) to 10 (completely satisfied); the EuroQol Five Dimensions Questionnaire (EQ5D) combining all five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) into a continuous score ranging from o (the worst outcome) to 1 (the best possible outcome); the Oxford Elbow Score (OES) in which o is the worst and 48 the best outcome; visual analogue scales (VAS) for pain in rest and pain during activities ranging from o (no pain) to 100 (the worst possible pain); and a VAS for perceived health status with o being the worst perceived health status and 100 the best.

The patients were divided into two groups for the primary analysis: patients with a complication occurring within one year after primary surgery and patients without complications in the first year. First, the patient characteristics between the groups were compared using independent t-tests for continuous data in case of a normal distribution or Mann Whitney U tests for skewed data, Fisher's exact tests were used for categorical data, followed by post-hoc t-tests per category in case of significance. For comparison between the complication and non-complication groups with regard to outcome scores and arc of motion, independent t-tests were used for normally distributed data, and skewed data were analysed using Mann Whitney U tests. The Benjamini-Hochberg procedure was applied to both sets of analyses to correct for false positives. A corrected p < 0.05 was regarded as statistically significant. The data were analysed using STATA software, version 14 (StataCorp, College Station, Texas, USA) and R software (R Foundation for Statistical Computing, Vienna, Austria).

After approval of the Institutional Review Board, 126 patients that received a TEA between 2008 and 2018 were included in this study. The mean age at the time of surgery was 70 years (standard deviation (SD): 7.6), and the majority of the patients were female (83%). A posterior approach was used leaving the triceps intact in 40 patients (32%), and dissecting the triceps in 85 patients (67%), olecranon osteotomy was used in 4 patients (1%). The demographic data are described in Table 1. At the time of the study, 126 patients (100%) had reached the 1-year follow-up period, 94 patients (75%) the 3-year follow-up period, and 55 patients (44%) the 5-year follow-up and were invited for their respective follow-up visits. The response rate was 100 per cent for the pre-operative objective outcomes and PROMs, and 92 per cent (116 patients), 89 per cent (84 patients), and 76 per cent (42 patients) respectively for the 1-, 3- and 5-year postoperative follow-up. All patients completed at least one of the follow-up periods. At the time of the study, twelve patients (9%) were deceased, two patients (2%) declined further follow-up visits, and the remaining patients did not respond. Two patients were censored because a component

was replaced in revision surgery. The median completed follow-up period was three years (range: 1 - 5 years). The data completeness at the specified follow-up moments was 65 per cent for the pre-operative outcomes, and 63, 69, and 73 per cent respectively for the 1-, 3-, and 5-year follow-up. (Table 1)

Results

In total, 26 patients developed a surgery-related complication (21%). Complications consisted of ulnar nerve symptoms, radial nerve dysfunction, fissure fracture, hematoma, marked triceps weakness, infection, and sepsis. One patient with ulnar nerve symptoms required surgical decompression. In two patients a deep infection occurred, in the first patient the infection occurred four months postoperatively and was treated with a single irrigation and debridement and intravenous vancomycin, the second patient with a deep infection, occurring 11 months post operatively, required irrigation and debridement three times and was treated with intravenous amoxicillin and clavulanic acid. The remaining complications were treated conservatively. Two patients underwent a revision four years after primary surgery: a broken bushing was replaced in both cases, the results following replacement were censored. No other complications occurred after one year. (Table 1)

Table 1. Demographics

Completed follow-up period in years, median (IQR)	3 (1-5)
Age in years, mean (SD)	69.6 (7.6)
Female sex, n (%)	108 (84)
Right side, n (%)	58 (45)
Diabetes, n (%)	11 (9)
Smoking, n (%)	17 (13)
Complication, n (%)	27 (21)
Superficial wound infection	2 (2)
Deep infection	3 (2)
Radial nerve dysfunction	2 (2)
Transient ulnar nerve symptoms	13 (10)
Sensory	12 (9)
Motor	2 (2)
Requiring decompression of ulnar nerve	1 (1)
Permanent ulnar nerve damage	2 (2)
Fissure ulna	3 (2)
Hematoma	1 (1)
Triceps weakness	1 (1)
Sepsis	1 (1)

IQR: Interquartile range, SD: Standard deviation

After correction using the Benjamini-Hochberg procedure, we found a significant difference in the indications for TEA between the complication and non-complication group (p = 0.044). Post-hoc analysis of the indications for TEA showed more patients with osteoarthritis in the complication group (19% versus 3%, p = 0.011) and one patient with osseous metastasis of a primary tumour in the complication group versus zero (7% versus 0%, p = 0.045). However, both indications are rare (eight and two patients, respectively). Other patient characteristics were comparable between the two groups, and there were no significant differences in pre-operative PROMs between the groups. (Table 2)

Table 2. Comparison of cohorts

Complication	Yes (n=27)	No (n=102)	Test statistic	P-Value
Patient characteristics				
Age, mean (SD)	68 (8.7)	70 (7.2)	1.319	0.190*
Female sex, n (%)	21 (78)	87 (85)		0.382
Right elbow, n (%)	15 (56)	43 (42)		0.277
ASA, n (%)				0.924
1	1 (4)	3 (3)		
2	15 (56)	56 (59)		
3	11 (41)	36 (38)		
BMI, median (IQR)	26 (24-30)	27 (23-30)	-0.214	0.831'
Diabetes, n (%)	1 (4)	10 (10)		0.457
Rheumatoid arthritis, n (%)	9 (33)	30 (30)		0.814
Anticoagulant use, n (%)	2 (7)	17 (17)		0.360
Smoking, n (%)	6 (22)	11 (11)		0.196
Indication, n (%)				0.005
Rheumatoid arthritis	6 (22)	29 (28)		0.630"
Post-Traumatic	12 (44)	57 (56)		0.386"
Osteoarthritis	5 (19)	3 (3)		0.010"
Fracture	2 (7)	12 (12)		0.733"
Metastasis	2 (7)	0 (0)		0.043"
Previous surgery, n (%)	16 (60)	56 (55)		0.828
Completed follow-up period in years, median (IQR)	3 (3-5)	3 (1-5)	-1.438	0.150'
Pre-operative measurements				
Health status, median (IQR)	69 (42-71)	67 (55-75)	0.414	0.679'

The Influence of Short-term Complications on the Outcomes of Total Elbow Arthroplasty.

Table 2. Comparison of cohorts (continued)

Complication	Yes (n=27)	No (n=102)	Test statistic	P-Value
Pain in rest, median (IQR)	53 (38-72)	45 (21-68)	1.104	0.270'
Pain during activities, median (IQR)	82 (73-91)	89 (79-93)	-1.304	0.192'
MEPS, mean (SD)	52 (4.1)	56 (2.6)	0.774	0.444*
OES, median (IQR)	29 (13-60)	16 (7-60)	1.818	0.069'
EQ5D, median (IQR)	0.25 (0.19-0.73)	0.69 (0.31-0.81)	1.236	0.217'
Degrees of flexion-extension, median (IQR)	90 (75-110)	90 (60-105)	0.680	0.497'
Degrees of pronation-supination, median (IQR)	130 (115-150)	140 (120-150)	-0.692	0.489'
Treatment characteristics				
Approach, n (%)				<0.0001
Triceps on	2 (7)	41 (40)		0.001"
Triceps off	24 (89)	61 (60)		0.005"
Olecranon osteotomy	1 (4)	0 (0)		0.209"
Ulnar nerve release	25 (93)	94 (92)		1.000
Postoperative casting, n (%)	23 (85)	44 (43)		<0.0001

ASA: American Society of Anesthesiologists physical status classification, BMI: Body mass index, EQ5D: EuroQol five dimentions, IQR: Interquartile range MEPS: Mayo Ebow Performance Score OES: Oxford Elbow Score, SD: Standard deviation

At the one-year follow-up, there were no significant differences in the outcomes between the groups.

At the three-year follow-up, the NRS for satisfaction was worse in patients with a complication, with a median of 8 (IQR: 7-9) compared to 10 (IQR: 9-10) in patients without a complication (p = 0.0288). The OES was also worse in patients with a complication, with a median of 27 (IQR: 20-37) compared 43 (IQR: 35-47) to for patients without a complication (p = 0.0048).

At the five-year follow-up, there were no significant differences observed in the outcomes between the groups. (Table 3)

^{*}T-test, 'Mann Whitney U test, "Post-hoc using Fisher's exact est, other: Fisher's exact test

Table 3. Outcome

Outcome, median (IQR)	Complication	No complication	Z-value	P-Value
1 Year	n=23	n=93		
Satisfaction	10 (9-10)	10 (9-10)	-0.309	0.757
Health status	64 (50-77)	79 (66-85)	1.972	0.0486
Pain in rest	4 (0-17)	5 (0-15)	-0.031	0.980
Pain during activities	24 (2-52)	17 (4-40)	-0.655	0.512
MEPS	78 (60-100)	85 (70-100)	1.096	0.273
OES	30 (24-39)	38 (28-46)	1.896	0.058
EQ5D	0.69 (0.69-0.81)	0.81 (0.69-0.90)	1.118	0.264
Flexion-extension	118 (95-123)	120 (110-130)	1.891	0.059
Pronation-supination	140 (120-160)	140 (130-150)	0.305	0.761
3 Year	n=23	n=61		
Satisfaction	8 (7-9)	10 (9-10)	3.037	0.0024
Health status	61 (30-80)	80 (57-85)	2.249	0.0245
Pain in rest	17 (2-40)	5 (1-25)	-1.261	0.207
Pain during activities	33 (9-70)	16 (5-40)	-1.910	0.056
MEPS	98 (85-100)	100 (85-100)	0.246	0.810
OES	27 (20-37)	43 (35-47)	3.748	0.0002
EQ5D	0.78 (0.69-0.84)	0.82 (0.81-1)	2.436	0.0148
Flexion-extension	123 (105-140)	120 (105-130)	-0.700	0.48
Pronation-supination	125 (100-140)	140 (130-160)	2.160	0.0308
5 Year	n=10	n=32		
Satisfaction	10 (10-10)	9.5 (8-10)	-1.576	0.115
Health status	67 (50-80)	70 (60-79)	0.274	0.784
Pain in rest	20 (0-35)	7 (2-33)	0.384	0.701
Pain during activities	20 (0-70)	34 (4-54)	0.281	0.779
MEPS	85 (78-93)	100 (85-100)	1.021	0.308
OES	32 (27-43)	36 (30-43)	0.835	0.404
EQ5D	0.80 (0.69-0.84)	0.81 (0.78-0.86)	0.695	0.487
Flexion-extension	120 (105-130)	120 (110-126)	-0.028	0.978
Pronation-supination	140 (100-160)	140 (120-140)	-0.564	0.573

EQ5D: EuroQol Five Dimensions, MEPS: Mayo Ebow Performance Score, OES: Oxford Elbow Score, IQR: Interquartile range

Discussion

To our knowledge, this is the first study assessing the influence of a complication on the outcomes of TEA. This study shows a short-term complication rate of 21% after TEA, with ulnar nerve symptoms being the most common complication. The patients with a complication had worse outcomes compared to patients without a complication after three years reporting lower satisfaction and OES scores. The difference in OES scores exceed the minimal clinically important difference (OES > 8).7 At the 1-year and 5-year follow-up, there were no significant differences in outcomes.

Our results reflect the impact of complications on the patient's experience after TEA. Notably, in none of the follow-up periods, there was a difference between the groups in pain scores during rest or activity, which is usually an important predictor of patient satisfaction after total joint arthroplasty.^{3,18} This shows that PROMs are required to assess more complex aspects of daily life, other than pain, that are compromised due to a complication.¹ Similarly, we found no difference between the groups in arc of motion. Our results demonstrate that, even when pain scores and arc of motion remain unaffected, a complication may impact the patient's satisfaction and elbow function.

Our results demonstrate an impact of complications at the 3-year follow-up, despite the majority of the complications occurring immediately after surgery (radial and ulnar nerve symptoms, ulnar fissure fracture and marked triceps weakness; 85%), and all complications occurring within 1 year. Interestingly, the 1-year follow-up outcomes showed no significant difference. The reason for this discrepancy is unclear. A logical explanation would be a larger variance in outcomes after one year; a previous study in hip arthroplasty described differences in short-term follow-up between groups of 'fast starters', 'slow starters', and 'late dippers' which gradually level out after a longer followup. 6 However, in our cohort, the means of the interquartile ranges of each outcome, taken as a percentage of the maximum score, show no substantial difference in spread between the 1-year and 3-year follow-up (23% and 25%), suggesting that there is not a wider spread of outcomes after one year. Another explanation could be that the perceived burden of a complication increases over time, and patients initially disregard their symptoms, whereas, if the symptoms persist, patients experience more nuisance. It is possible that functional limitations occur in an early stage, but that there is a delay in the patient's experience. Furthermore, complications that are conventionally labelled as 'minor' or 'transient', such as ulnar nerve symptoms, may appear resolved, but still impact the patient's daily activities and experience. However, larger studies are required to confirm this effect, and consultation with a neurologist would be required to objectify ulnar nerve symptoms. At 5-year follow-up, we found no differences between the groups. This could be explained by the fact that most complications are surgery-related and occur early in the postoperative process, suggesting that after five years the complications have been resolved and the outcome scores of both groups approximate each other. However,

the number of patients included in the 5-year follow-up is low, it is possible that with a larger cohort significant differences may be found. Furthermore, long-term complications such as implant loosening or material failure may severely impact the satisfaction and PROM scores. In our cohort, two patients required partial implant replacement and were censored after 4 years.

The complication rate in the current study (21%) is congruent with reported complication rates in previous studies; Welsink et al. published complication rates from 70 studies ranging between 11 and 38%.²² Transient ulnar nerve symptoms were the most common complication in our cohort, occurring in 16 patients (59% of all complications). Despite the ulnar nerve being released during surgery in the majority of our cohort (94%), thirteen patients had transient ulnar symptoms, of which 11 were sensory, one was motor, and one was both. One patient had an ulnar nerve palsy that was resolved by ulnar nerve decompression, and two patients had permanent ulnar nerve damage. Intraoperative ulnar nerve release was not correlated with complications (p = 1.000). However, despite ulnar nerve symptoms often being classified as 'minor' and 'self-limiting' complications by clinicians, their impact on the satisfaction and health status should not be underestimated. Similarly, a previous study assessing PROMs after elbow contracture release found ulnar neuropathy to be a predictor of worse Disability of the Arm, Shoulder and Hand (DASH) scores and less postoperative improvement in DASH scores.+ Semicircular casting was also correlated with complications (p < 0.001). The pressure of soft tissue swelling and hematoma formation may attribute to postoperative compression of the ulnar nerve, ultimately leading to nerve palsy. It is possible that refraining from semi-circular casting can decrease ulnar nerve-related complications. Furthermore, the surgical approach dissecting the triceps was correlated with complications (p < 0.001). The triceps-on approach does not require splitting or manipulation of the triceps muscle and is, therefore, less prone to postoperative bleeding.^{12,17} However, after surgery with the triceps-on approach, patients are not treated with postoperative casting. Therefore, these findings may be confounded. In previous literature, no differences between the approaches in complication rates are described, but larger studies are required to determine the independent effects of casting and surgical approach.^{19,21}

The majority of complications were surgery-related and occurred early in the postoperative process; nerve palsy, fissure fractures and marked triceps weakness account for 85% of complications. The remaining 15% of complications are infectious sequelae, of which deep infections (two patients) tend to be the worst for both patients and clinicians. However, our cohort is too small to analyse the specific impact of this challenging complication.

The results of this study must be interpreted in light of its limitations. Firstly, due to the rare occurrence of TEA, the cohort size is small. Consequently, we were unable to perform a regression model to determine the independent effects of explanatory variables.

However, the study was conducted at a large centre specialised in TEA and includes one of the largest cohorts available nationally. Second, in collecting data retrospectively, this study relies on the accuracy and completeness of the electronic medical charts and online PROM system. Despite the improvement in follow-up rates due to the implementation of the online PROM system, 20 not all patients respond to the online questionnaires, potentially leading to an overrepresentation of the most satisfied or dissatisfied patients. This is inherent to the study design. Third, the number of patients that completed the 5-year follow-up questionnaires is relatively low, leading to an underestimation of the differences between the groups. However, the medians are comparable between the groups, and the statistical results show no trend towards significance. Furthermore, the majority of the results are concentrated around the positive end of their respective spectrum, demonstrating satisfactory outcomes in both groups. Fourth, the majority of the complications occurred immediately after surgery. Consequently, we did not perform a sub-analysis of the time until a complication occurred. Last, we included patients with Coonrad-Morray implants exclusively, while increasing the internal validity of the study, the results may not be directly applicable to other implant designs.

Conclusions

Complications occur in 21% of patients undergoing total elbow arthroplasty. A short-term complication may lead to a decrease in patient satisfaction and OES scores at 3-year follow-up compared to patients without a complication. Larger prospective cohort studies are required to confirm long-term results. Complications comprise a severe burden on the patient and the healthcare system, and more research is required to further prevent complications after total elbow arthroplasty.

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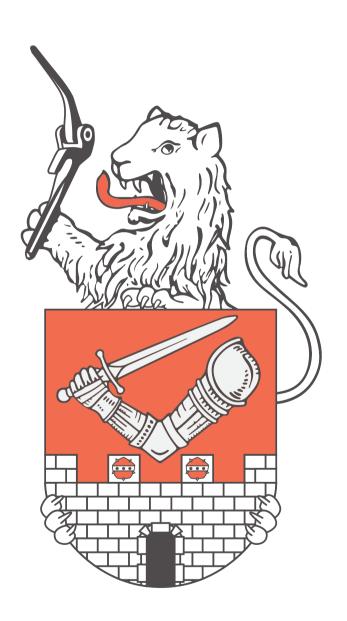
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Part three





Chapter six

How well do orthopedic surgeons recognize different models of total elbow arthroplasties on plain radiographs with the use of a diagnostic flowchart?

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Abstract

Object

Recognition of total elbow arthroplasties (TEAs) on plain radiographs is difficult due to a multitude of different types and models. Especially if surgery reports and documentation are not available, lost or when the primary surgery was performed in another hospital the prosthesis type may be undeterminable. Therefore we investigated in this platform study if a flowchart aids in recognition of thirteen different total elbow arthroplasty models on plain radiographs.

Methods

An online questionnaire on the Shoulder and Elbow Platform was developed. Plain radiographs of thirteen TEA models were shown with and without the help of an especially developed flowchart describing distinguishing features.

Results

Ten orthopedic surgeons specialized in upper extremity surgery completed the study. Recognition rates of the thirteen total elbow arthroplasty models ranged between 20 and 100 percent without the flowchart. Using the flowchart recognition varied between 40 and 90 percent. The recognition rates with the flowchart were not significantly higher. Inter-observer reliability did not increase on a significant level.

Conclusions

Correct recognition of total elbow arthroplasty models with plain radiographs remains imperfect with our developed flowchart. The flowchart increased correct recognition rates and inter-observer reliability.

How well do orthopedic surgeons recognize different models of total elbow arthroplasties?

Introduction

Recognition of total elbow arthroplasties (TEAs) on plain radiographs is difficult due to a multitude of different types and models. Especially if surgery reports and documentation are not available, lost or when the primary surgery was performed in another hospital prosthesis type may be undeterminable. Since the 1970s many different models and brands of TEAs have been used (1,2). Commonly the hinge mechanism is used to classify TEAs in two basic design forms: linked and unlinked prostheses. Besides linkage type, fixation methods in the bone differ as well. The prosthesis can be fixated by screws, cement or with an osseo-integrative coating (2).

The differences in the hinge design and linkage type are important for pre-operative planning of revision surgery. Special equipment, such as model-specific screwdrivers for decoupling or broaches for removal of a cement mantle, need more preparation and scheduled time for revision surgery.

We assumed that recognition might be aided by a flowchart that uses the main distinguishing characteristics of each prosthesis. In literature we identified one study that describes model-specific characteristics of total elbow arthroplasties (3). In other studies, total elbow arthroplasties are only described by their function of replacing the elbow joint (4–7). This information only helps the surgeon by giving an overview of arthroplasty models.

This study compares accuracy and inter-observer agreement of orthopedic surgeons specialized in upper limb arthroplasty to recognize prosthesis models with and without a flowchart. Our primary hypothesis is that there is no difference in recognition of arthroplasty models with and without a flowchart. Our secondary hypothesis is that the flowchart makes no difference in inter-observer reliability.

Methods

Study Design and Setting

An online questionnaire on the Shoulder and Elbow Platform was developed at the Amphia Hospital, Breda, the Netherlands. Plain radiographs of thirteen TEA models were shown [Figure 1]. The questionnaire consisted of anterior-posterior and lateral radiographs of each model. The participants had to choose from a list of all included models. After choosing a model name from the list and confirmation of the choice, no feedback was provided and the next model was shown.

Participants

Sixty-five independent orthopedic surgeons were invited from different countries who had participated before on the Shoulder and Elbow Platform and who are specialized

in upper limb surgery. On behalf of the senior authors, the Platform website sent an e-mail providing an internet link to the questionnaire. A reminder e-mail was sent to initial non-responders.

Study description

We developed a flowchart focused on distinctive features of each design [Figure 2]. The first session was performed without this flowchart. The same set of radiographs was presented in the same order. After the first session, a link to the flowchart appeared highlighted in the announcement of the second session. Then the same set of total elbow arthroplasty models was presented in a different order than before. A new link to the flowchart accompanied every new question in case of closure of the flowchart.

Statistical analysis

Inter-observer reliability of the use of the flowchart was tested with Fleiss' kappa test for multiple observers. Frequently used interpretations of kappa values are used (8). Percentages of correct recognition per arthroplasty model and per surgeon were calculated for both sessions by dividing the number of correct answers by all possible answers. Significance was set at a p-value of less than 0.05. Differences were analyzed with McNemar's test for paired dichotomous data. The outcomes were scored by recognition of coupling mechanism (linked and unlinked) and by model type if applicable, as for instance the Kudo prosthesis has been produced in several versions.

Results

Ten orthopedic surgeons specialized in upper extremity surgery completed the study. Seven worked in the Netherlands, two in Belgium and one in France. Percentages of correctly recognized total elbow arthroplasty models, including p-values of statistical difference for the use of the flowchart [Table 1].

Recognition of the Coonrad Morrey prosthesis scored a lower value with the use of the flowchart, compared to all other models who demonstrated an equal or higher recognition rate. However, any model had a significant change in recognition.

Seven out of ten surgeons performed better with the flowchart, two performed the same and one performed worse. Accuracy per surgeon is shown [Table 2], as well as significance. Surgeon no. 5 performed significantly better with the flowchart than without.

Inter-observer reliability increased in twelve of thirteen arthroplasty models. As demonstrated [Table 3], five of thirteen models demonstrated substantial to almost perfect inter-observer reliability with use of the flowchart compared to two of thirteen without the flowchart.

Analysis of incorrect answers revealed six percent (8/130) of possible choices in the wrong category of linkage model without the flowchart. With flowchart, this percentage decreased to three percent (4/130). The correct possible choices of any Kudo prosthesis (Kudo 4 of Kudo 5) increased from 65 percent to 85 percent using the flowchart. Souter Strathclyde prosthesis (Souter Strathclyde primary or revision prosthesis) recognition

How well do orthopedic surgeons recognize different models of total elbow arthroplasties?

Table 1. Recognition rates per total elbow arthroplasty model with and without the flowchart. The p-values are shown in the right column.

increased from 85 percent to 95 percent.

Total elbow arthroplasty model	Correct – no flowchart (%)	Correct – with flowchart (%)	Difference (%)	Significance (p-value)
Coonrad Morrey	100	80	-20	0.50
Discovery	50	90	+40	0.38
GSB-III	30	40	+10	1.00
Instrumented Bone Preserving	60	80	+20	0.50
Kudo 4	20	40	+20	0.63
Kudo 5	40	40	=	1.00
Latitude	90	90	=	1.00
Nexel	30	50	+20	0.63
Norway Elbow	50	70	+20	0.63
Sheer	30	40	+10	1.00
Solar	30	60	+30	0.38
Souter Strathclyde	80	90	+10	1.00
Souter Strathclyde - revision	80	90	+10	1.00

Discussion

Using the flowchart correct model recognition improved in seven of ten orthopedic surgeons, however significant for one surgeon. We found no significant difference in correct recognition per arthroplasty model with and without the flowchart, and therefore we have to accept our primary hypothesis.

As a secondary hypothesis, we tested the inter-observer reliability. Inter-observer reliability increased for all TEA models using the flowchart. However, the increase was not significant, whereby the secondary hypothesis has to be accepted. Nevertheless, recognition of linkage type appears acceptable on plain radiographs.

Since different total elbow arthroplasties have been used, correct model recognition is important to plan revision surgery and to anticipate on model-specific pitfalls or implant linkage instruments. Correct recognition of model type is therefore paramount. This is the first study to determine reliability of recognition of total elbow arthroplasty models on plain radiographs. In literature, only one article emphasizes on distinguishing characteristics of different models of total elbow arthroplasty (3). Therefore, unfortunately, no comparisons can be made to other studies.

For clinical practice, a flowchart offers a simple tool for aid in recognition. The contemporary practice at our institution is consulting a colleague, which requires face-to-face or telephone contact, exchange of patient identification numbers and viewing the radiographs. This process might be time consuming. On the contrary, a flowchart is always available and repeatable and a colleague can still be consulted as well.

This study should be interpreted in light of its limitations. Firstly, a relative small group of observers completed the study. The number of orthopedic surgeons specialized in elbow arthroplasty is relatively low compared to, for example, hip and knee surgeons. This together with non-responders lead to a fairly small number of observers. Secondly, we did not perform intra-observer reliability since inter-observer agreement is clinically more relevant as the surgery requirements are ordered once per surgery.

On plain radiographs three-dimensional structures can be depicted inaccurately because of angulation and relative magnification of the radiation beam. Flexion contractures of the elbow can distort the two-dimensional view of the radiographs. A computerized three-dimensional shape-recognition programme might aid in distorted images. Correct recognition of orthopedic implants remains a challenge, as assessors have to be aware of the appearance of contemporary and historic implant models (5).

Table 2. Overall recognition rates per surgeon, for with and without the flowchart. The p-values are shown in the right column.

Orthopedic surgeon	Correct – no flowchart (n)	Correct – with flowchart (n)	Difference (%)	Significance (p-value)
1	11	11	=	1.00
2	4	7	+30	0.25
3	7	12	+50	0.06
4	2	6	+40	1.00
5	5	12	+70	0.02
6	11	12	+10	1.00
7	9	9	=	1.00
8	4	7	+30	0.25
9	4	5	+10	1.00
10	9	6	-30	0.45

How well do orthopedic surgeons recognize different models of total elbow arthroplasties?

Table 3. Inter-observer agreement per total elbow arthroplasty model. Shown values are Fleiss' kappa values (κ-values). Interpretation of κ values: <0, less than chance. 0-0.20, slight. 0.21-0.40, fair. 0.41-0.60, moderate. 0.61-0.80, substantial. 0.81-0.99, almost perfect. 1, perfect.

Total elbow arthroplasty model	Inter-observer agreement – no flowchart	Inter-observer agreement – with flowchart
Coonrad Morrey	0.62	0.67
Discovery	0.33	0.65
GSB-III	0.00	0.09
Instrumented Bone Preserving	0.31	0.53
Kudo 4	0.04	0.30
Kudo 5	0.18	0.17
Latitude	0.70	0.78
Nexel	0.07	0.23
Norway Elbow	0.14	0.35
Sheer	0.07	0.24
Solar	0.09	0.25
Souter Strathclyde	0.59	0.88
Souter Strathclyde - revision	0.40	0.78

Conclusions

Correct recognition of total elbow arthroplasty models with plain radiographs remains imperfect with our developed flowchart. In general, however not significant, the flowchart increased correct recognition rates and inter-observer reliability. Therefore, we do encourage use of the flowchart to aid in determining unknown total elbow arthroplasty models

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Figure 1. The radiographs used in the questionnaire with their specific design features.

Total elbow arthroplasty model	Radiopgraphs – anterior-posterior and lateral views	Specific features
Coonrad Morrey		Linked prosthesisAnterior flangeCylindrical linkage
Discovery		Linked prosthesisAnterior flangeDiabolo-shaped linkage
GSB-III	San	 Linked prosthesis No anterior flange Tapered humeral and ulnar stems

Figure 1. The radiographs used in the questionnaire with their specific design features. *(continued)*

Total elbow Radiopgraphs – anterior-posterior and lateral views Specific features arthroplasty model Unlinked prosthesis • Humeral Instrumented component Bone Preserving not completely circular on lateral view Unlinked prosthesis • Humeral component Kudo 4 completely circular, with posterior step-off on lateral view Unlinked prosthesis Humeral component Kudo 5 completely circular, with flat posterior side on lateral view

Figure 1. The radiographs used in the questionnaire with their specific design features. *(continued)*

Total elbow arthroplasty model	Radiopgraphs – anterior-posterior and lateral views	Specific features
Latitude	4	 Variable linkage prosthesis, linked type depicted. Anterior flange Capitellar resurfacing Possibility of radial head arthroplasty
Nexel	POSTOP	 Linked prosthesis Anterior flange Cylindrical linkage Rounded shape of humeral component on AP view
Norway Elbow		 Linked prosthesis No anterior flange Tapered stem on lateral view

Figure 1. The radiographs used in the questionnaire with their specific design features. *(continued)*

Total elbow arthroplasty model	Radiopgraphs – anterior-posterior and lateral view	s Specific features
Sheer		 Linked prosthesis No anterior flange Ulnar component has step-off
Solar		 Linked prosthesis No anterior flange Tapered humeral stem on AP view
Souter Strathclyde		 Unlinked prosthesis O-shape in humeral component Polyethylene ulnar component possible
Souter Strathclyde - revision	R	 Unlinked prosthesis O-shape in humeral component Long humeral stem Metal ulnar component with polyethylene inlay

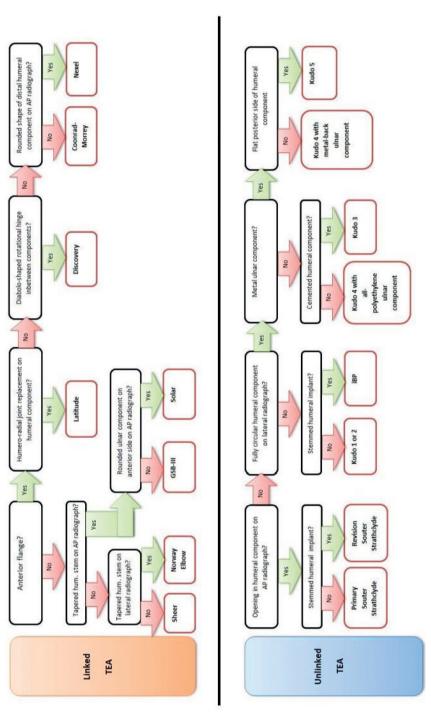
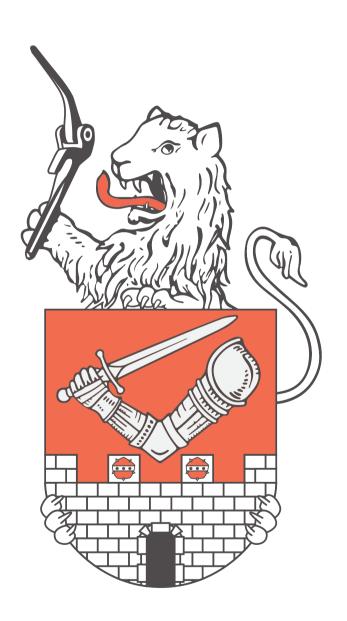


Figure 2. Flowchart to aid in recognition of total elbow arthroplasties, describing distinguishing features. By answering the questions the correct model is found.



Chapter seven

Pre-operative templating in total elbow arthroplasty: not useful

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Abstract

Purpose

Total Elbow Arthroplasty (TEA) is a definitive surgical procedure for treating rheumatoid arthritis and (posttraumatic) osteoarthritis of the elbow and is also useful in comminuted elbow fractures. Pre-operative digital templating may theoretically improve the surgical implantation of TEA, but reliability and predictive values of templating are unknown. The aim of this study was to determine the intra- and inter-observer reliability and the validity of pre-operative digital templating for TEA.

Materials and Methods

All pre-operative plain anterior-posterior and lateral calibrated elbow radiographs from patients who underwent TEA in our center from 2008 to June 2014 were reviewed. Two independent assessors templated implant sizes using digital overlays twice. Intra- and inter-observer reliability were evaluated with Cohen's kappa. Two experienced elbow surgeons reviewed post-operative radiographs for evaluation. The predictive value of templating was the percentage of the correctly templated sizes, with the optimal implant size as the reference standard.

Results

Twenty-one cases were included. Intra-observer reliability was substantial to almost perfect (κ = 0.61 and κ =0.90) for humeral implants, moderate to substantial (κ = 0.54 and κ =0.73) for ulnar implants. Inter-observer reliability was substantial (κ =0.67) for humeral implants and moderate (κ =0.60) for ulnar implants. The predictive value was 53% for both implants.

Conclusions

Pre-operative digital templating for total elbow arthroplasty is a reliable method to plan implant sizes. However, the predictive value is low.

Introduction

In comparison to hip, knee and shoulder arthroplasty, total elbow arthroplasty (TEA) is a relatively new procedure, having a 'modern' start in the 1970s[1]. During TEA surgery the capitulum, trochlea and possibly the radial head are resected and replaced by the prosthesis, leading to the replacement of the diseased cartilage. Today, TEA is used in post-traumatic and non-traumatic osteoarthritis, fractures, rheumatoid arthritis and metastases, yielding relatively good results, with a 10-year survival rate of approximately 80%[2-5]. The use of TEA has more than doubled in the past 15 years in the US and therefore further research on optimal TEA-surgery is required[6].

TEA prostheses can be divided in three main groups: non-constrained (resurfacing), semi-constrained hinge and constrained hinge models[7]. Nevertheless, TEA revision rates for all groups remain high compared to hip and knee arthroplasty due to factors such as fractures, wear and loosening[3, 8, 9]. Malpositioning of the components of TEA is related to a short survival of the implant[10]. Undersizing of the implant might facilitate malpositioning, since the ulnar and humeral medullary canals offer more space to misalign the components.

At our center we use the semi-constrained Coonrad-Morrey (Zimmer®, Warsaw, IN, USA) prosthesis, which is available in several widths and stem lengths. In the literature, a longer humeral stem length has been correlated to a lower revision rate in the short term, but makes no significant difference on the long term[8]. To our knowledge, no studies on the influence of the component width have been performed, but it seems reasonable to assume that it is desirable to prevent undersizing of the component in order to establish an optimal cement mantle and optimal positioning. Pre-operative templating might therefore contribute to better outcomes by establishing the optimal component sizes before surgery[11]. However, a reliable and valid templating method is essential to achieve this goal.

Therefore, we conducted a study on the intra- and inter-observer reliability of digital templating in TEA. To assess the validity of templating, we compared sizes of the templates to the actual sizes implanted.

Materials and methods

We reviewed all plain anterior-posterior (AP) and lateral diagnostic radiographs taken at our center, from a database of patients who received a primary Coonrad-Morrey TEA. Radiographs were included in our study if there were both pre-operative and post-operative radiographs in both directions, with a calibration device of 30.0mm depicted on all pre-operative radiographs. When both the humerus and ulna could not be radiographed together due to an elbow contracture, the radiology assistant made

additional radiographs. On the lateral radiographs, partial summation from the radius onto the ulna was inevitable.



Figure 1. Lateral radiograph with a digital template.



Figure 2. AP radiograph with a digital template.

All included pre-operative radiographs were assessed twice by two independent orthopedic trainees. The measuring sessions had at least a two-week interval to avoid recognition and the radiographs were sorted in a different, random order before each

session. Templating was done with AGFA-Orthopaedic Tools, Version 2.10 (Mortsel, Belgium). Using this software, radiographs were first calibrated using the calibration device and then the most suitable implant size was chosen. In the AGFA-Orthopaedic Tool the template appears as an over-lay that can be rotated 360°, and different sizes can be changed accordingly (Figures 1 and 2).

Appropriate sizing was defined as replacing the center of rotation (defined as the center of the humeral capitulum[12]) to a pre-morbid state, with a stem width that fills the medullary canal, but does not require resection of the cortex. In cases in which the center of rotation could not be replaced, proper fit in the medullary canal determined the appropriate implant size. In the case of discrepancy of the implant size on AP and lateral radiographs, the smaller size was chosen to ensure as little as possible cortex resection.

The Coonrad Morrey humeral component is available in three different stem lengths. In this study only the shortest four-inch humeral components were used for templating, since the size of the hinge mechanism is equal for all lengths. We preferably use the shortest stem to minimize bone stock loss. Standard use of longer 6-inch stems has not proven to lead to a higher implant survival rate[8].

Intra-observer reliability was assessed by unweighted Kappa analysis, comparing the first session with the second per observer. Inter-observer reliability was assessed by comparing the observers' results per implant. Accuracy of the implant size prediction was calculated as the percentage of well-predicted sizes. Used implant sizes were extracted from the patients' surgery records.

To perform a check on the implants used, two experienced orthopaedic surgeons, specialized in elbow surgery, assessed all post-operative radiographs to form an expert-based opinion on the implant sizes, as well as ascertaining possible improvements. All post-operative radiographs were independently reviewed. The expert-opinion of both TEA components consisted of three options: too small, fitting, or too large. In case of disagreement the surgeons had to form a consensus. With this data, a second analysis of templated sizes was performed, to assess the predictive value of templating for 'preferred' sizes.

Results

Eighty-five cases received a Coonrad-Morrey prosthesis as a primary TEA between October 2011 to July 2014. Of these, twenty-one cases met the inclusion criteria. Most cases were excluded from the study because not all radiographs had a calibration device depicted. Surgery of the included cases was performed on twenty female patients (one bilateral), with a median age of 66 years (range from 51 to 86 years). The pre-operative diagnosis was posttraumatic osteoarthritis in thirteen cases (62%), rheumatoid arthritis

in five cases (24%), a pathological fracture due to metastasis in two cases (10%) and osteoarthritis in one case (5%).

Templating was possible in 78 of the 84 assessments (93%), corresponding to 39 templates of humeral implants and 39 templates of ulnar implants. In six cases a software error occurred and templating was not possible because radiographs could not be imported into the templating system on multiple attempts.

The intra-observer reliability for the two observers were κ =0.90 and κ =0.61 for the humeral component and κ =0.54 and κ =0.73 for the ulnar component. Inter-observer reliability was κ =0.67 for the humeral component and κ =0.60 for the ulnar component.

The predictive value of templating with the implanted sizes as a control group, was 53% for both the humeral and ulnar components (41/78 correct). Templating predicted a larger implant than the one used in 46% of the cases.

Table 1. Interpretation of k-values.

к-value	Interpretation of agreement		
<0	Less than chance		
0-0.20	Slight		
0.21-0.40	Fair		
0.41-0.60	Moderate		
0.61-0.80	Substantial		
0.81-0.99	Almost perfect		
1	Perfect		

Expert opinion evaluation showed appropriate sizing in 86% (18 out of 21) of the cases and possible undersizing in 14% (3 out of 21). The predictive value, with the expert opinion as a control group, was 59% for the humeral component (46/78 correct) and 54% for the ulnar component (42/78 correct).

Table 2. Results of intra- and inter-observer reliability and the predictive value of digital templating.

	Intra-observer reliability 1 st session (K)	Intra-observer reliability 2 nd session (K)	Inter-observer reliability (κ)	Predicitive value (%)
Humeral component	0.61	0.90	0.67	53
Ulnar component	0.54	0.73	0.60	53

Discussion

The purpose of this study was to evaluate the intra- and inter-observer reliability and validity of digital pre-operative templating in total elbow arthroplasty. Table 1 shows a frequently used scale to interpret κ -values. The κ -values of this study showed a substantial to almost perfect intra-observer reliability for the humeral component and a moderate to substantial intra-observer reliability for the ulnar component. The inter-observer reliability was moderate to substantial. Exact values of the templating results are shown in table 2. Thus, the templating software allows repeatable results, yet individual variability may lead to inter-observer disagreement.

However, the predictive value of templating was only 53%. Expert opinion evaluation showed a possible undersizing in 14% of cases but using that opinion as the reference standard did not substantially change the predictive value. However, of the possible undersized components, 46% were predicted larger-than-used by templating. In these cases, the surgeon could be alerted for discrepancies between templated and actual implant sizes.

We consider the high intra-observer reliability to be the result of systematic templating. This makes the digital templating software a reliable tool to make a pre-operative prediction on implant size. Surprisingly, the templated sizes did not correlate well to either the expert-opinioned or implanted sizes. Considering the intra-observer reliability, the probable cause of error is not within the templating software itself. Analysis of incorrect templates showed that templating in many cases does not match with the implanted size, especially in cases of pathological fractures and rheumatoid arthritis. This might be related to joint deformity and non-perpendicular radiographs.

One similar study has been performed earlier[13]. In that study plain radiographs and manual templates were used to propose implant sizes pre-operatively. A fair to substantial intra-observer reliability was seen for the aspects we measured in our study[13]. When compared with the study of Pappas et al, we calculated a similar k-value for the intra-observer reliability of templating. However, we found lower predictive values for implant size, even though we had a digital templating system using a calibration device on the plain radiographs to reduce measuring error.

Nevertheless, we identified two issues that may have resulted in the low predictive value of pre-operative templating. Firstly, measuring errors might have occurred because of a relative enlargement of the calibration device if the device was not exactly next to the patients' elbow.

Secondly, the x-ray device should make a perpendicular angle to the elbow joint. However, it is not always possible to depict both the ulna and the humerus perpendicular on the

anterior-posterior radiographs due to concurrent flexion contractures. Therefore, the radiographic protocol might be improved by taking two separate AP radiographs instead of one

Furthermore, templating performed by plain radiographs relies on the assumption that two-way views form an acceptable depiction of three-dimensional anatomy, which might not be the case in deformities. In addition, it might be debatable whether the value of pre-operative planning needs to be linked to a more biomechanical or reconstructive aim, i.e. optimizing the re-establishment of the native center of rotation of the elbow. Accurate sizing would still be a prerequisite, but the end goal would be to inform the surgeon in advance on the ideal placement of the components (depth and rotation) and the bony adjustments that are needed to achieve this goal.

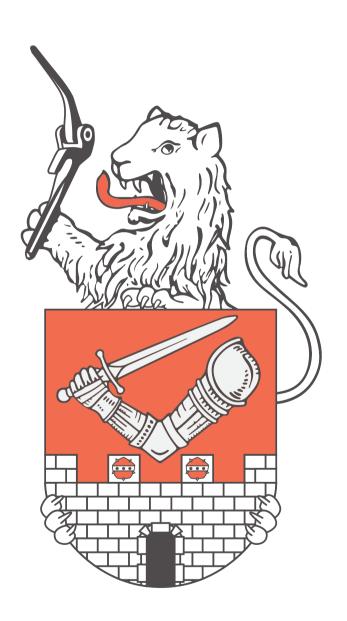
Since we assume relatively inexperienced orthopedic surgeons have most benefits from pre-operative templating as it might guide them during surgery, orthopedic trainees performed the templating in this study. As the intra-observer reliability was high, and templating instructions were clear, we do not assume their relative low experience with TEA is a compromising factor in this study.

Future research should therefore focus on perpendicular radiographs and on threedimensional pre-operative planning, for example, using CT-based software or threedimensionally printed models as a practice.

In short, pre-operative digital templating for the Coonrad-Morrey total elbow arthroplasty has a high intra-observer reliability. However, there is a substantial difference between planned and used implant size. Therefore, according to the findings of our study, pre-operative templating using plain elbow radiographs does not add benefits in pre-operative decision making.

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Chapter eight

Comparison of isometric triceps brachii force measurement in different elbow positions.

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Abstract

Purpose

Objective and reliable force measurement is necessary to monitor the rehabilitation after triceps brachii pathology, injuries and posterior approach based surgery. It is unclear at which amount of extension the triceps is best tested and if comparison to the uninjured sided is reliable. This study aims to identify the most reliable elbow position at which elbow extension force is measured using a dynamometer. Furthermore, it aims to compare extension strength of the dominant arm with that of the non-dominant arm.

Methods

Isometric elbow extension force of the dominant and non-dominant arms of healthy subjects was measured. The measurements were taken in three sequences per arm in 0, 30, 60, 90 and 120 degrees of flexion. A subgroup repeated the measurements to analyze test-retest reliability using intraclass correlation.

Results

We included a total of 176 volunteers. The ANOVA repeated measures tests for withinsubject effect showed the lowest variation coefficient at 30 degrees of flexion.

Extension forces showed a mean difference of 3.2 to 6.9 Newton in advantage of the dominant arm, resulting in ratios from 1.05 to 1.09.

Learning curve analysis showed that during the first session in dominant and non-dominant arms less forces were exerted.

Conclusion

The most reliable isometric triceps brachii muscle strength measurement was at 30 degrees of flexion of the elbow.

Considering the learning curve, a first try-out session for both arms is indicated. Then a second measurement suffices as no further learning curve is observed.

Comparison of isometric triceps brachii force measurement in different elbow positions.

Introduction

As the elbow provides flexion, extension and rotation of the forearm, several muscle groups are involved. Contraction of the triceps brachii muscle and, when almost in full extension, the anconeus muscle, leads to elbow extension. In case of insufficiency if the triceps brachii tendon rupture, active extension of the forearm is not possible resulting in impairment of the upper limb (1).

Traumatic rupture of the triceps tendon is not frequently encountered and is often missed in the emergency department (2-4). It is unclear in which amount of flexion the triceps is tested, nor is clear if comparison to the uninjured site is reliable.

Insufficiency of the triceps can also be seen after posterior approach based surgery as reconstruction of a ruptured triceps, after fixation of fractures of the proximal ulna or after exposure for distal humeral fractures or total elbow arthroplasty (5–8). For surgical repair of a ruptured triceps tendon, several methods have been described for fixation (9–11). Complete ruptures are commonly treated by surgical repair, whilst partial ruptures can be treated conservatively by splinting (4,11,12).

During follow-up after triceps rupture or other pathology, detailed, objective and repeatable information on muscle force is essential. To monitor rehabilitation and guide return to activity, extension force can be measured during follow-up. The five-point Medical Research Council muscle strength scale can be used but lacks detail as it describes muscle force against subjectively described criteria as 'slight', 'moderate' and 'strong resistance' (13). More objective elbow extension force testing is needed. Moreover it is not clear of comparison to the uninjured side is reliable.

Simple muscle force testing can be a solution to objectify muscle strength. Muscle strength testing may consist of dynamic isokinetic testing or static isometric testing. Isokinetic testing usually involves a large apparatus, whilst isometric testing can be performed with a portable, small dynamometer and also has an acceptable test-retest reliability for elbow flexion and extension (14). However, multiple sources of error are likely to be introduced by the procedure or the examiner (14). Standardized positioning of the patient is of importance, as during movement of a joint the contracting muscle shortens and leverage forces change. Moreover, the triceps brachii exerts different forces at different angles of the elbow (15).

Therefore, this study investigates the reliability of elbow extension force in healthy volunteers using a dynamometer in different angles of elbow extension. Reliability is defined by a low coefficient of variation and a high test-retest reliability. In addition, we explored if the uninjured side can be used reliably to assess the recovery after posterior approach based surgery, with the uninjured arm as reference.

Materials and methods

Subjects

176 healthy volunteers, above 18 years of age without any pathology of the elbow, were enrolled.

The volunteers were recruited from the orthopedic staff (nurses, secretaries, staff) and interested visitors of the outpatient clinic. Exclusion criteria were current or previous elbow surgery or elbow complaints and inability to follow instructions and filling in questionnaires. The Institutional Review Board of our hospital waived approval for the study. All subjects provided informed consent before participation in the study.

Experimental setup

All measurements were performed using the MicroFet 2 dynamometer (Hoggan Health Industries, Salt Lake City, US). The dynamometer was programmed to measure the forces in Newton (N). The session consisted of sequences of tasks in which extension was performed in full extension (o degrees of elbow flexion) and in 30, 60, 90 and 120 degrees of elbow flexion. The sequence always started at the smallest degree of flexion of the non-dominant arm and the angle was increased incrementally. Subsequently, the dominant arm was tested in all previously mentioned angles. We performed three of these sequences per arm during one session.

The examiner sat at a table in front of the volunteer. The volunteer placed the elbow on a plateau of the same height as the top part of the dynamometer to prevent leverage over a ramp under the forearm. For standardized angles of flexion of the elbow, wedges of 30, 60 and 90 degrees were sequentially placed under the upper arm as illustrated in Figure 1. With the thumb pointing upwards, the pronators and supinators of the forearm could not exert extra pressure on the dynamometer. The dynamometer was positioned in line with the plateau one centimeter proximal to the styloid process of the ulna, to prevent forearm muscles and the wrist to interfere with the force produced by the triceps brachii. To measure the extension force in 120 degrees of flexion, the volunteer had to flex the elbow to 120 degrees and push against the dynamometer held by the examiner. This was done in a standing position for both the volunteer and the examiner, or in a sitting position of both. The examiner had to withstand the extension force to maintain elbow flexion of 120 degrees, so no actual extension of the elbow was made and isometric force was measured.

Comparison of isometric triceps brachii force measurement in different elbow positions.

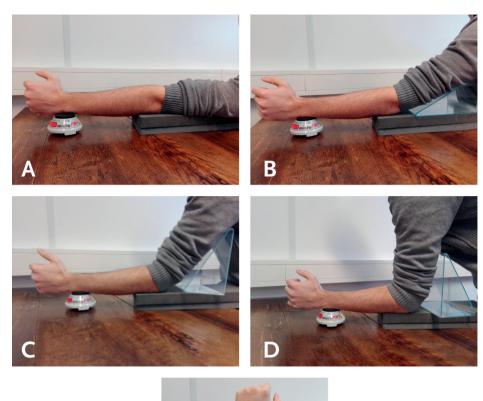




Figure 1. Set-up for testing of different flexion angles using the wedge. The upper arm is put on the wedge, with the elbow on a plateau of the same height as the dynamometer. A: o degrees of flexion. B: 30 degrees of flexion. C: 60 degrees of flexion. D: 90 degrees of flexion. E: 120 degrees of flexion.

To evaluate repeatability of the tasks, a random subgroup of twenty volunteers performed a second session with a minimum interval of one week. The same examiner performed the measurements using the same protocol as during the first session. The volunteers were blinded to previous measured values.

Data- and statistical analysis

Data were collected and analyzed using SPSS version 23 (IBM, Armonk, Ney York, USA). The variation-coefficient was calculated for both dominant and non-dominant arms to analyze which degree of flexion was most accurate. The variation-coefficient is calculated by dividing the standard deviation by the mean, which results in a ratio that describes the dispersion in measured values. Since previous research showed a 'try out' measurement was useful in measuring hip flexors because of a learning curve, the first step in the analyses was to determine whether we would use all three measurements or only the second and/or third measurement (16). Therefore, a potential learning curve was examined using a repeated measures ANOVA test for all measurements per arm in each elbow flexion angle. A significant difference implies a difference between sessions and could reveal a learning curve.

Test-retest reliability was measured with two-way random intraclass correlation coefficients (ICC) for the subgroup of volunteers who completed a second session. For each arm and every flexion angle an ICC was calculated. To determine ratios between dominant and non-dominant arms, a ratio was calculated by dividing the mean extension force of the sequences of the dominant arm by the mean extension forces of the non-dominant arm in each position. Paired t-tests were used to test the differences between dominant and non-dominant arms. A P-value of less than 0.05 was considered as significant, and when five or more tests were performed on the same subject a significance level of P<0.01 was used.

Results

We included 176 volunteers, 88 women and 88 men. Mean age was 44.1 years with a standard deviation (SD) of 18.8 years (mean age of men 50.4 years, range 19-93 years, mean age of women 37.7 year, range 18-87 years). Of all participants, 86% had the right arm as dominant side (men 86% right dominance, women 86% right dominance).

Assessment of the learning curve revealed a significant difference in the repeated measurement ANOVA for almost all tasks (Table 1). Post-hoc analysis showed that during the first sequence in non-dominant arms significantly fewer forces were exerted on the dynamometer, for all degrees of flexion, compared to the second and third sequence. For the dominant arm, this effect was observed in 0, 30 and 60 degrees of flexion (Table 1). Because of this learning curve, only the second and third trial of each task were used in the subsequent analyses.

The variation coefficients across all subjects ranged from 0.31 to 0.39 across the different elbow angles (Table 1). The measurement in 30 degrees of flexion had the lowest values with 0.31 for the non-dominant side and 0.32 for the dominant side. Measurements in 0 and 120 degrees of flexion had the highest values.

Comparison of isometric triceps brachii force measurement in different elbow positions.

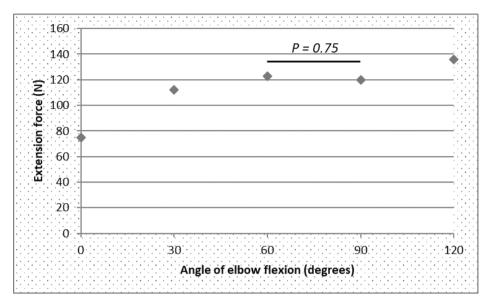


Figure 2. Repeated measurements ANOVA for all tested angles.

Significant differences between all positions (P < 0.001), except for the difference between 60 and 90 degrees of flexion (P = 0.75).

Test-retest reliability was calculated for twenty volunteers who repeated all tasks in a second session. The intraclass correlation coefficients ranged from 0.86 to 0.96 in non-dominant arms and from 0.89 to 0.97 in dominant arms (Table 1). The measurements in 30 degrees of flexion had the highest ICC.

 Table 1. For every elbow flexion angle, the results of the learning curve assessment using repeated measurements ANOVA, variation coefficients, intraclass
 correlation coefficient, absolute difference in Newton and ratio between dominant and non-dominant side is given.

Degrees of elbow flexion	Degrees Learning curve (repeated of elbow measurements ANOVA)	repeated ANOVA)	Variation coefficients	ients	Intraclass correlation coefficients (absolute agreement)	ation	Absolute difference dominant - non-dominant (N)	Ratio (>1 favors dominant side)
	Non-dominant	Dominant	Non-dominant	Dominant	Non-dominant Dominant Non-dominant Dominant	Dominant		
0	***(1 st lower)	***(1 st lower)	0.39	0.37	96.0	68.0	1.5*	1.02
30	***(1 st lower)	***(1st lower)	0.31	0.32	0.92	0.97	2.8*	1.02
9	***(1st lower)	$%(3^{rd} \text{ higher, } P=0.048)$	0.34	0.34	0.87	0.94	2.0%	1.02
90	** (1st lower)	NS (P=0.21)	0.35	0.33	0.89	06.0	1.8*	1.01
120	**** (1st<2nd<3rd)	NS (P=0.41)	0.38	0.37	96.0	06.0	9.7*	1.06

^{***}P<0.001 **P<0.005

Comparison of isometric triceps brachii force measurement in different elbow positions.

For all elbow angles, extension forces were higher (ranging from 3.2N to 6.9N) for the dominant arm compared to the non-dominant arm. These differences were significant for all measurements except in 90 degrees of flexion. The ratio produced by this difference indicates the dominant side has a positive ratio of 1.01 to 1.06, compared to the non-dominant side during all elbow extension tests (Table 1). The influence of elbow flexion on triceps brachii force is depicted in Figure 2. Repeated measurements ANOVA showed significant differences between all positions (P < 0.001), except for the difference between 60 and 90 degrees of flexion (P = 0.75).

Discussion

This study shows that isometric triceps brachii force of healthy volunteers can be most accurately and consistently measured using a handheld dynamometer in 30 degrees of elbow flexion. This position has the lowest coefficients of variation and highest intraclass correlation coefficients. The dominant arm provides 2% more extension force in this position than the non-dominant arm.

In the literature, the extension force of the triceps brachii is usually tested in 90 degrees of elbow flexion (14,17–22). However, we found this position less reliable than 30 degrees of elbow flexion.

The measurements in 30, 60 and 90 degrees of flexion can be performed in a sitting position, which is most comfortable. In accordance with previous research by Pinter et al., the flexion angles of 60 and 90 degrees exhibit more force than 30 degrees of flexion (20). Contradictory, in our study most force was exerted in 120 degrees of flexion. However, overall it was shown that triceps force measurement in 30 degrees of elbow flexion is more reliable than the commonly used 90 degrees of flexion. The test-retest variation coefficients were excellent in all positions(23). In case of contracture of the elbow of more than 30 degrees, we advise to use an angle of 60 degrees of flexion as it has second-best variation and intraclass correlation coefficients.

In line with the study of Askew et al. we observed a ratio that favored the dominant arm in extension force (18). We calculated a positive ratio of 1.01 to 1.06, depending on the amount of elbow flexion. In the same elbow flexion as in the study of Askew et al. (90 degrees), our ratio was 1.01 compared to their ratio of 1.04. This ratio is helpful in unilateral conditions, i.e. traumatic triceps brachii ruptures or triceps brachii-affecting surgery, as the 'full recovery force' may be calculated from the contralateral arm, bearing in mind the dominant arm is stronger than the non-dominant arm.

In cadaveric studies the tensile strength resistance of repaired triceps brachii tendon appeared to be 17% to 60% of normal triceps brachii tendon, varying on the surgical approach (24,25). Augmented repair using autologous flexor carpi radialis or hamstring

tendons significantly increases tensile strength after triceps tendon repair, yet provides more patient morbidity (22). Mode of failure exists of loss of grip from the proximal sutures (22,24,25). In practice however, the testing of the triceps brachii will be performed in an outpatient setting several weeks after surgery, allowing the healing process to improve tensile strength resistance. We regard triceps brachii force testing safe when performed at least 6 weeks after surgery.

There are some limitations to our study. First, a multitude of muscle contractions might lead to fatigue and thus to erroneously lower measured force values. Our testing method requires five muscle contractions per arm per session. In literature, no signs of fatigue were seen with electric myographic activity monitoring up to five muscle contractions of the triceps brachii (21). Therefore, we do not consider fatigue as a compromising factor in our study protocol. Secondly, we observed a learning curve during the data analysis. The first measurement was in almost all flexion angles significantly lower than the subsequent measurements. This effect was seen in isometric testing of hip flexors too (26). Our data analysis thus exclude all first measurements to correct for this learning curve. A 'try out measurement' for both arms could have minimized this phenomenon.

Furthermore, the 120-degree test was not possible with a wedge on the table. Some volunteers tried to push with their entire body and it was hard to instruct the subjects not to do this. Previous research already demonstrated that when measuring isometric force against an observer, the observer's strength affects the values; stronger observers score higher force values (19). This might have influenced the measurements in 120 degrees of flexion most, as the volunteer pushes against the observer who keeps the dynamometer in place. Variation in the amount of abduction of the upper arm to place it on the ramp does not interfere with the accuracy of the measurements (20). When used clinically in patients with elbow disorders, not all patients will be able to extend the elbow to full extension. During the measurement in full elbow extension the anconeus muscle may act as an elbow extensor because the line between origin and insertion lies posterior to the center of rotation of the elbow, up to 15% of the elbow extension force (27,28).

Concluding, the most reliable isometric triceps brachii muscle force measurement position using a dynamometer was at 30 degrees of flexion of the elbow. Test-retest reliability was excellent for both dominant and non-dominant arms. A learning curve of one measurement was observed. Therefore, isometric force testing of the triceps brachii muscle is advised in 30 degrees of flexion of the elbow after one try-out session to diminish a learning curve effect. To assess full recovery, the ratio to the contralateral side of 1.02 can be used as a reference.

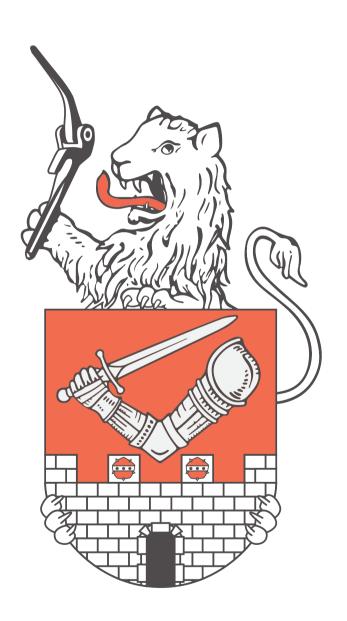
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Comparison of isometric triceps brachii force measurement in different elbow positions.



Chapter nine

Early mobilization and functional discharge affecting length of stay after total elbow arthroplasty

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Abstract

Purpose of the study

Decline in length of stay is of growing interest for patients, doctors and health insurances. The aim of our study was to assess the safety and length of stay after omission of casting, start of early mobilization and implementation of functional discharge criteria after total elbow arthroplasty (TEA).

Material and methods

We retrospectively reviewed all patients' records who received a Coonrad-Morrey TEA in the period from January 1st, 2011 to December 31st, 2018. From these records, indications, demographic information and complications were derived. Length of stay was calculated from the hospital administration. Patients were divided in three groups to evaluate the two changes in post-operative care.

Results

In total 125 patients receiving 126 Coonrad Morrey TEAs were included with a mean length of stay of 5.5 days (range 2-23) for the entire group. Omitting a post-operative cast led to decline in length of stay from 6.2 to 5.4 days (p < 0.001). Introduction of functional discharge criteria in August 2017 declined mean length of stay to 3.8 days (p < 0.001). The surgical technique (triceps-on versus triceps-off) was not a confounder (p = 0.20). Range of motion after one year was not significantly different between groups.

Discussion

The length of stay declined after omission of a cast, and declined further after introducing functional discharge criteria. Since no higher complication rates were observed, the shortening of length of stay appears to be safe. This is in line with other fast-track programs, i.e. hip and knee arthroplasty. The surgical technique used were not a confounder for the shortened length of stay, which further adds to the safety of the functional discharge criteria.

Conclusion

Omitting a cast and splint as regular post-operative treatment reduced the length of stay significantly without leading to more complications. Introduction of functional discharge criteria lowered the length of stay further without more complications.

Early mobilization and functional discharge affecting length of stay after total elbow arthroplasty

Introduction

The introduction of fast-track total hip and knee arthroplasty has increased patient satisfaction and reduced length of stay at the hospital.^{9,12} A shorter hospital stay is therefore valuable for patients, as well as healthcare insurances. In multiple hospitals, the introduction of 'functional discharge criteria' after hip and knee arthroplasty were successful with a reduction in hospital stay without an increase of complications.^{9,12}

In analogy of total hip and knee surgery, we implemented 'functional discharge criteria' for total elbow arthroplasty (TEA) patients. These criteria are adequate mobility to resume the activities of daily living, sufficient pain control for physiotherapy exercises and a wound that addresses no further specialized care. The goal was to reduce hospital stay, without an increase of complications with comparable functional outcomes. Previous studies have shown that TEA can be performed safely in an outpatient procedure and even in an outpatient setting for selected patients. However, the patients who were included in those analyses had proven to be able to be discharged the same day and all other patients were not included in the analyses.

Therefore, the aim of our study is to perform an analysis of our own practice since 2011, which has undergone these two major changes in peri-operative care. To avoid the aforementioned risk of inclusion bias, all patients receiving a primary TEA will have to be included. First, a comparison will be performed for the influence of a cast after surgery. Second, the implementation of the functional discharge criteria will be analyzed.

We hypothesized that an arm without a cast will facilitate activities in daily life more easily and will reduce the length of stay in the hospital. To secure safety of early mobilization without a cast, we compared wound leakage and other complications with the hypothesis that wound leakage and other complications are not affected by early mobility after surgery. With implementation of the functional discharge criteria, we expect no difference in post-operative complications, yet we expect length of stay to decline further.

Materials and Methods

Patients

We reviewed patients' records who received a primary Coonrad-Morrey (Zimmer®, Warsaw, USA) TEA in the period from January 1st, 2011 to December 31st, 2018. All primary Coonrad-Morrey TEAs were included in this retrospective analysis. This was defined as all patients who did not have any (hemi)arthroplasty in the affected elbow and received a Coonrad Morrey TEA. From the patient records, demographic information, indications and complications were collected.

Study design

Length of stay was calculated from the patients' records and double-checked with the hospitals' administration in case no medical annotation was written in the patient file on the day of discharge. Day of surgery was defined as day o as patients are not hospitalized the day before surgery.

Three cohorts were made; first the index cohort, which consists of all patients that received an arthroplasty before January 1st, 2016 as we then changed our institutional policy to omit casting post-operatively. The semicircular casts in 60-90 degrees of elbow flexion, applied directly after the wound was closed, were used up to December 2015 with the hypothesis wound healing in the first days after surgery would be promoted on. The cast was applied for three days, and once removed the rehabilitation process with the physiotherapist could be started. For the patients with a triceps-flap approach, passive motion was promoted for 6 weeks, and for patients with a triceps-on approach active motion was promoted directly after surgery. All patients in this cohort received a night splint for 6 weeks.

Second, a cohort of patients without functional discharge criteria was labeled as 'empirical discharge'. This group consists of all patients receiving an arthroplasty between January 1st, 2016 and August 1st, 2017. During the empirical discharge period, patients were informed orally and with a booklet that their hospitalization would last for 5 to 7 days, depending on the aspect of the wound. Since a cast was omitted, absorbable gauzes with cotton wool and a pressure bandage that permitted limited elbow movements were used for three days, and changed when needed. A night splint for 6 weeks was provided to avoid undesirable or extreme movements. With the pressure bandage, limited range of movement was promoted with the physiotherapist; passive range of motion exercises for triceps-on approaches.

Third, a cohort with functional discharge criteria was defined with all patients who received a primary total elbow arthroplasty since August 2017. From this time, all patients were discharged after fulfilling the functional discharge criteria, which were defined as adequate mobility to resume activities of daily living, sufficient pain control for physiotherapy exercises and a wound that addresses no further specialized care. During the pre-operative counselling at the outpatient clinic, patients were informed orally and with a booklet about the functional discharge criteria. Patients still were not discharged as long as the wound had leakage and thus required specialized wound care with absorbable dressings, or showed signs of infection. These patients received a bulky dressing of pressure bandage for three days, what could be removed by the patients themselves after discharge took place before three days. Rehabilitation consisted of passive exercises for triceps-flap approaches and active exercises for triceps-on approaches.

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For all patients, physiotherapy was provided on all days of the week during hospitalization. The hospital's physiotherapist provided a protocolled handover to the patients' own physiotherapists, and consisted of range of movement training and for the triceps-flap patients, strength improvement starting after 6 weeks. Follow-up was performed on the outpatient clinic after 2 weeks, 3 months and 1, 3, 5, 7 and 10 years in all cohorts. On all follow-up visits complications were asked to patients and clinical examination was performed. Because of the retrospective design of this study, Institutional Review Board approval was waived.

Statistical analyses

Length of stay between cohorts is compared using the Mann-Whitney U test as the Shapiro Wilk test showed a non-normal distribution of data. Complications, such as wound leakage, were compared using the Chi-square test. To assess the influence of the weekday on length of stay, the Chi-square test was used. The risk factors and possible confounders for length of stay and wound leakage were tested using ANOVA. Statistical significance was set at the level of p < 0.05.

Results

In total, 125 consecutive patients received 126 primary elbow arthroplasties performed using the Coonrad Morrey TEA between January 1st, 2011 and December 31st, 2018. One patient received bilateral arthroplasties in two separate procedures, which counted as two separate arthroplasties throughout this study. Mean duration of follow-up was 45 months. The index cohort consisted of 70 patients, the cohort with empirical discharge consisted of 31 patients and the functional discharge criteria cohort of 25 patients. Demographic and surgical data are shown in Table 1. Indications were predominantly secondary osteoarthritis following trauma, followed by elbow joint destruction because of rheumatoid arthritis. Rheumatoid arthritis as a comorbidity was present in 31% of total cases. One olecranon osteotomy was performed in a trauma case with an olecranon fracture that was used as an access portal. More than half of the patients (60%) had undergone previous surgery on the affected elbow. Most frequent reported previous surgeries were open reduction and internal fixation of a radial head, humeral and/or ulnar fracture, in 41% of patients.

 Table 1.
 Demographic and surgical data of the whole cohort of primary total elbow arthroplasties. Percentages are given between parentheses.

Mean age [SD]	[9.2]	~	43 (34)
Gender	18 male, 108 female	4	0
Indication		Rheumatoid arthritis	39 (31)
Primary osteoarthritis	8 (6)	Diabetes	(2) 6
Secondary osteoarthritis	71 (56)	Smoking	17 (14)
Rheumatoid arthritis	33 (26)	Therapeutic anticoagulant use	13 (10)
Fracture	12 (9)	Length of stay in days [SD]	5.5 [2.6]
Metastasis	2 (2)	Complications	
Surgical approach		No complications	92 (73)
Triceps-on	43 (34)	Transient ulnaropathy	16 (13)
Triceps-flap	82 (65)	Blistering of skin	12 (10)
Olecranon osteotomy	1 (1)	Deep prosthetic infection	5 (4)
Previous surgery (% of total group)	75 (60)	Fissure ulna	2 (2)
Arthroscopy	5 (4)	Permanent ulnaropathy	2 (2)
Arthrotomy	(6) 11	Transient radiopathy	1 (1)
Fracture	51 (41)	Superficial wound infection	3 (2)
Ulnar nerve release	2 (2)	Pneumonia	2 (2)
Luxation	1 (1)	30-day mortality	2 (2)
Comorbidities		Triceps weakness	(۱) ر
ASA classification		Hematoma evacuation	1 (1)
1	4 (3)	Hematoma, bandage	1 (1)
2	79 (63)		

ASA: American society of Anaesthesiologists. SD: standard deviation

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Comparing the index cohort with the non-casting cohort revealed that the length of stay was significantly reduced from a mean of 6.2 to 5.4 days (p < 0.001). The number of complications was comparable between our casting and non-casting groups (p = 0.29). When focusing on wound leakage requiring specialized wound care, no clinical nor statistical difference was seen (Table 2).

The introduction of functional discharge criteria led to a decline in length of stay from 5.4 to 3.8 days (p < 0.001). As shown in Table 3, the demographic and medical factors were not different between the cohorts. In the functional discharge criteria group, one patient visited the outpatient clinic before the regular appointment after two weeks because of wound leakage on day 8; no signs of infection were present, and an expectant policy was provided.

Weekday of surgery did not influence the length of stay on the whole cohort (p = 0.87), nor on the non-cast group (p = 0.31) nor on the functional discharge group (p = 0.82). The surgical technique used was not a significant confounder on length of stay (p = 0.20), even though since 2014 the triceps-on technique is used more often (Tables 2 and 3).

Complications occurred in 25% of cases; most were transient ulnaropathies (14% of total cases) and blistering of the skin (10% of total cases). From the eighteen ulnaropathies, two have proven permanent sensory and motoric malfunction. Blistering of the skin was present in 10% of patients with a cast, in 6% of patients without a cast and in 12% of patients with the functional discharge criteria (p = 0.76) and blistering showed not to be related to diabetes (p = 0.31), rheumatoid arthritis (p = 0.83) nor smoking (p = 0.57) in this study.

In five cases a deep infection occurred. In one of those patients, it occurred after a bushing exchange because of failure of the hinge mechanism. Two patients developed an aspiration pneumonia, which accounted for both fatalities; one patient was resuscitated without success, and one patient died because of sepsis and multi-organ failure after aspiration pneumonia.

Persistent wound leakage on day 4, 5, 6 and 7 post-operatively was noted in respectively 17, 10, 7 and 4 patients. From these patients with persistent wound leakage, one patient developed a deep prosthetic infection requiring lavage and antibiotic treatment. From the eight patients with a superficial or deep infection, two patients had persistent wound leakage on day 4.

After one year, range of motion arcs of the casting group was 114 degrees for flexion and extension (N = 52, SD 20 degrees), for the non-casting group 113 degrees (N = 22, SD 12 degrees) and for the functional discharge criteria group 119 degrees (N = 4, SD 18 degrees). The flexion-extension range of motion did not differ (p = 0.87). Pronation and

supination arcs of the casting group was 114 degrees for flexion and extension (N = 52, SD 24 degrees), for the non-casting group 129 degrees (N = 20, SD 29 degrees) and for the functional discharge criteria group 155 degrees (N = 4, SD 18 degrees). The pronation-supination range of motion did not differ (p = 0.12).

Table 2. Comparison of the groups of patients with and without a cast after surgery.

	Index cohort (n = 70)	No cast (n = 31)	p-value
Mean age [SD]	69 [7.8]	70 [6.6]	0.560
Gender	10 male, 60 female	6 male, 25 female	0.662
Indication			0.628
Primary osteoarthritis	7	1	
Secondary osteoarthritis	37	19	
Rheumatoid arthritis	19	8	
Fracture	5	3	
Metastasis	2	-	
Surgical approach			<0.001
Triceps-on	8	27	
Triceps-flap	61	73	
Olecranon osteotomy	1	1	
Previous surgery			0.088
Arthroscopy	2	4	
Arthrotomy	10	-	
Fracture	17	7	
Ulnar nerve release	1	2	
Luxation	1	-	
External fixation	2	-	
Radial head surgery	6	5	
Comorbidities			
ASA classification			0.288
1	2	3	
2	49	67	
3	19	31	
4	0	-	
Rheumatoid arthritis	23	10	0.572
Diabetes	5	2	0.633
Smoking	13	4	0.348
Therapeutic anticoagulant use	5	5	0.151

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Table 2. Comparison of the groups of patients with and without a cast after surgery. *(continued)*

	Index cohort (n = 70)	No cast (n = 31)	p-value
Length of stay in days [SD]	6.2 [2.0]	5.4 [3.4]	<0.001
Wound leakage (days)			
4	8	5	0.529
5	6	1	0.433
6	3	Ο	0.551
7	1	1	0.521
Complications			0.292
Transient ulnaropathy	12	2	
Permanent ulnaropathy	2	-	
Transient radiopathy	1	-	
Superficial wound infection	2	-	
Deep prosthetic infection	1	2	
Fissure ulna	2	-	
Hematoma evacuation	1	-	
Triceps weakness	1	-	
Pneumonia	-	2	
30-day mortality	-	2	

ASA: American society of Anaesthesiologists. SD: standard deviation

Table 3. Comparison of the groups with empirical discharge after 5 to 7 days and the group with functional discharge criteria.

	No cast (n = 31)	Functional discharge (n = 25)	p-value
Mean age [SD]	70 [6.6]	71 [8.3]	0.541
Gender	6 male, 25 female	2 male, 23 female	0.276
Indication			0.736
Primary osteoarthritis	1	-	
Secondary osteoarthritis	19	15	
Rheumatoid arthritis	8	6	
Fracture	3	4	
Metastasis	-	-	
Surgical approach			0.529
Triceps-on	27	16	
Triceps-flap	73	9	
Olecranon osteotomy	1	-	
Previous surgery			0.339
Arthroscopy	4	-	
Arthrotomy	-	-	
Fracture	7	9	
Ulnar nerve release	2	1	
Luxation	-	-	
External fixation	-	-	
Radial head surgery	5	3	
Comorbidities			
ASA classification			0.535
1	3	1	
2	67	12	
3	31	12	
4	-	-	
Rheumatoid arthritis	10	6	0.353
Diabetes	2	2	0.608
Smoking	4	-	0.086
Therapeutic anticoagulant use	5	3	0.482
Length of stay in days [SD]	6.0 [2.5]	3.8 [2.3]	<0.001

Early mobilization and functional discharge affecting length of stay after total elbow arthroplasty

Table 3. Comparison of the groups with empirical discharge after 5 to 7 days and the group with functional discharge criteria. *(continued)*

	No cast (n = 31)	Functional discharge (n = 25)	p-value
Wound leakage (days)			
4	5	4	0.645
5	1	3	0.239
6	0	4	0.037
7	1	2	0.431
Complications			0.436
Transient ulnaropathy	2	2	
Permanent ulnaropathy	-	-	
Transient radiopathy	-	-	
Superficial wound infection	-	1	
Deep prosthetic infection	2	2	
Fissure ulna	-	-	
Hematoma evacuation	-	-	
Triceps weakness	-	-	
Pneumonia	2	-	
30-day mortality	2	-	

ASA: American society of Anaesthesiologists. SD: standard deviation

Discussion

The aim of this study was to evaluate two changes in our post-operative regimen after TEA. First, the complication rate without a cast after surgery, most notably wound leakage, does not differ without a cast. Second, a reduction of length of stay after implementation of functional discharge criteria led to a reduction of almost three full days. Therefore, we can conclude that omitting a cast after primary TEA is safe, and implementing functional discharge criteria provide a safe method to reduce length of stay after primary TEA further.

The elbow casts were used in the past to prevent wound leakage in the first few days after surgery. From January 2016 on, patients did not receive a cast post-operatively, unless the type of surgery required a cast (i.e. after revision surgery or periprosthetic fractures). The decision to change to a drape instead of a cast implied the possibility to start more early with physiotherapy and rehabilitation. Early physiotherapy has been proven to be beneficial in hip and knee arthroplasty, especially in the early phase after surgery. Besides, before patients are ready for discharge, a basic level of independency in activities

of daily living has to be present in our opinion. As casting after surgery provided no benefits in neither diminishing persistent wound leakage nor other complications, we opt there is no room for regular casting after TEA using the Coonrad-Morrey prosthesis in our hospital. We believe that faster return home leads to less hospitalization, more self-independence and less intervention on patient's habits, which will be experienced as positive by the patients in analogy to total hip and total knee replacement patients.^{6,12}

Implementing functional criteria instead of regular admission days leads to further decline in hospitalization. In our experience, this seems to be valuable for both patients, who return home earlier, and to the hospital, as the inpatient beds can be used for other patients. Discharge when meeting functional discharge criteria to optimizes patients' expectations, what may result in higher satisfaction scores. 12

The complication rate of a shorter hospital stay is not higher than after a longer hospital admission and no more adverse events such as wound problems or blistering of the skin were seen, what implies that a shorter length of stay is not harmful. In addition, when the whole cohort is divided into three subgroups the length of stay declines significantly from 6.2 to 5.4 to 3.8 days, respectively. In our opinion, this way of determining readiness for discharge gives more autonomy to the patient, which may lead to better understanding of the recovery. Strength of this study is the organization-wide implementation of the functional discharge; we made no distinction between patients and set no inclusion criteria. This approach makes the implementation of these criteria usable in other clinics as well, without increased risks.

In our center we have seen cases with elaborate blistering of the skin, presumably because of the soft tissue swelling after surgery and possibly as a reaction to non-stretching wound dressings used. However, after changing to a more skin-friendly absorbing adhesive plaster in 2016, no decline in skin blistering is observed. Of note is that patients with blistering were not more at risk for wound infections or deep prosthetic infections. We did not find an association between smoking, rheumatoid arthritis, diabetes or indication on wound complications, in contrast to other studies, presumably due to a relatively small sample size effect. 6.8,11,15 As the indications for TEA have shifted more towards secondary osteoarthritis instead of rheumatoid arthritis, and the triceps-on approach has been in use more recently, an indication bias might have occurred that lowered the effect of rheumatoid arthritis on wound leakage in the more recent years.

In a study on fast-track hip and knee arthroplasty, the weekday of surgery had an influence on length of stay with Friday and Thursday having a longer hospitalization, probably because of reduced staff during weekends and the tendency to discharge patients the coming Monday.⁴ Controversially, our study does not support these data, what further strengthens our idea of patient-discharge when possible.

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As the surgical technique has shifted more towards the triceps-on technique since 2014, functional rehabilitation is possible as the triceps tendon or muscle has not been detached.³ Therefore, no restrictions on elbow extension force are necessary and more elaborate physiotherapy is possible. Of interest is that the surgical technique (triceps-on versus triceps-off) has not shown to be a confounder for length of stay, which further adds to the fast-track principle of earlier mobilization without a cast, pre-operative information and functional discharge criteria. However, the exposure during surgery with a triceps-on approach is limited compared to a triceps-flap approach. Therefore, we advise to use the approach preferred by the surgeon based on previous experience, with an own preference to the triceps-on approach.

Limitation of our study is the retrospective design, yet a randomized controlled trial seems unfeasible considering the results of this study. However, our fast-track protocol provides benefits for both patients and professionals without negative consequences. The comparison of the two institutional alterations makes interpretation of results more complicated; nevertheless, length of stay is an easy to measure, hard outcome, and the complications are dichotomous outcomes. With the use of the three subgroups the impact of the individual changes is emphasized and therefore measurable.

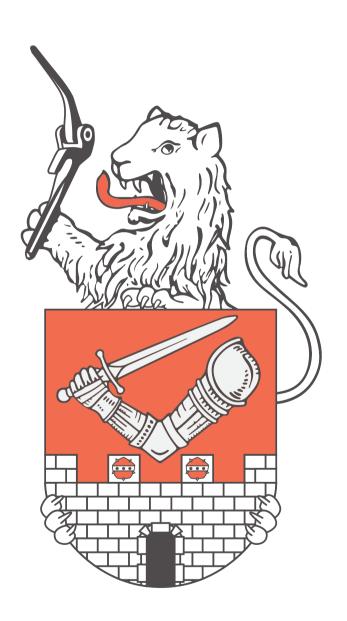
Conclusion

In our cohort of 126 TEAs, omitting a cast as regular post-operative treatment reduced the length of stay significantly without leading to more complications. Introduction of functional discharge criteria lowered the length of stay further to 3.6 days without more complications. Therefore, functional discharge criteria with pre-operative information and early post-operative physiotherapy in unselected patients is possible without negative effects.

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Chapter ten

Recommendations for follow-up after total elbow arthroplasty based on objective and subjective outcomes in a high-volume non-design center.

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Abstract

Introduction

In recent years the incidence of total elbow arthroplasty (TEA) has increased. While long-term functional- and patient reported outcomes are relatively good, complication rates as high as 16% and a revision rate up to 14% in Coonrad-Morrey prosthesis were found in recent systematic reviews, which are significantly higher than joint arthroplasties like the knee and hip. This, despite ongoing innovations in and modification of total elbow arthroplasties. A large number of series reporting outcomes after TEA originate from institutions that are design centres or are involved otherwise in the development of these implants. This, in turn can lead to several kinds of bias including publication bias, and may not be representative for other non-designer institutions.

The aim of the current study is to assess both objective and subjective functional outcomes as well as patient reported outcomes after total elbow arthroplasty using the Coonrad-Morrey prosthesis in a non-design centre. The second aim is to evaluate the value of the patient reported outcomes in relation to objective functional outcomes and complications such as loosening, stiffness or ulnar nerve dysfunction.

Methods

A consecutive series of 142 (144 TEA) patients receiving a Coonrad-Morrey total elbow arthroplasty were included in a retrospective cohort study. Revision surgery and other arthroplasties such as radial head, distal humerus or radiocapitellar prothesis were excluded. Patient follow up was performed using an online follow up system, a standardized physical and radiographic evaluation. The assessments took place before surgery, and 1,3,5,7, and 10 years post surgery.

Evaluation consisted of range of motion of the elbow, standard radiographs in AP and lateral view, the Mayo Elbow Performance Score (MEPS), the Health related quality of life (EQ5D), the Oxford Elbow Score (OES) and a patient reported outcome measure.

Results

144 Total elbow arthroplasties (TEA), (119 females, 19 males, two bilateral in women) were included. The mean age at time of surgery was 69 years (range, 47 – 86 years). Ulnary nerve dysfunction was seen in 16 patients (11,1%) of which 14 were transient and 2 were permanent. A superficial wound infection occurred in 2 patients (1,4%) post-surgery and 4 patients (2,8%) suffered from a deep prosthetic infection. 8 Patients (5,6%) showed progressive radiolucency on radiographs. A total of 4 revisions were performed (2,8%).

All objective and subjective outcomes had improved one year after surgery compared to the preoperative situation. The range of motion improved with pronation-supination 131° to 139° / flexion-extension 90° to 115°. The EQ5D improved form 0.50 to 0.77, the

OES from 17.69 to 35.02 and the MEPS from 44 to 83. Longer follow up did not show a significant increase or decrease of all outcomes.

No relationship was found between radiolucency at any time during follow-up and ROM, pain, OES, MEPS or EQ5D. Transient ulnaropathy post-surgery was associated with lower outcomes of the OES at one and three years post-surgery.

The pre-operative range of motion was a significant predictor with a medium effect size for post-operative range of motion. Compared to men, women showed significant better subjective and objective outcomes. Surgery for rheumatoid arthritis, fractures and late posttraumatic deformities showed better results compared to surgery for tumour metastasis and osteoarthritis..

Conclusions

We conclude that our objective mid-term results are comparable to previously reported outcomes after TEA. Furthermore the current study found no relationship between radiolucency and ROM, pain or outcomes on the OES, MEPS and EQ5D questionaires during follow-up. It did find that transient ulnaropathy is associated with lower outcomes of the OES on both one and three years after surgery. Female gender and a better preoperative range of motion are predictors for post-operative range of motion and preoperative pain is a predictor for post-operative pain. These factors should be discussed pre-operatively with patients during shared decision making.

Introduction

In recent years the incidence of total elbow arthroplasty (TEA) has increased (1). While long-term functional outcomes and patient satisfaction are good, complication rates up to 16% and revision rates up to 14% in Coonrad-Morrey prosthesis were found in recent systematic reviews (2-4). These numbers are significantly higher compared to knee or hip arthroplasty. Observational registry studies are best for analyzing revision rates and general trends, yet single center studies can be designed to identify relevant variables related to more successful patient selection or clinical outcome that are currently not implemented in registries. Examples are the influence of preoperative range of motion on postoperative range of motion, or identification of variables correlated to early postoperative radiolucency. The largest cohort studies are often published by the designer centers, which have the most elaborate experience and longest follow-up (5, 6).

While large cohorts are needed to evaluate outcomes, the appearance of bias, most notably publication bias, cannot be ignored. (7). Therefore, the primary aim of the current study is to make recommendations about follow-up based on both objective and subjective outcomes after total elbow arthroplasty using the Coonrad-Morrey prosthesis in a non-design center. The secondary aim is to find predictors for these outcomes to aid in shared decision-making.

The primary outcomes are functional range of motion, the Mayo Elbow Performance Index (MEPI), the Oxford Elbow Score (OES) and the quality of life (EQ-5D-3L). Secondary outcomes are revision rates, complications, satisfaction scores and pain scores in rest and during activity and possible predictors for mid-, to long-term outcomes. Our hypothesis states that both functional and radiological follow-up are necessary and that the functional outcomes after TEA are comparable to previous studies. Furthermore we hypothesize that revision rates and complications may differ from design centers.

Patients and Methods

We performed a retrospective study of patients who underwent primary total elbow arthroplasty at our hospital between May 2008 and April 2019. All patients who received a Coonrad-Morrey (Zimmer, Warsaw, IN, USA) prosthesis were included. Data collection was performed before surgery and at 1, 2, 3, 5, 7 and 10 years after surgery during the visits at the outpatient clinic, with paper questionnaires or with a digital follow-up system. During the visits at the outpatient clinic patients were asked about adverse events. The objective follow up consisted of functional outcomes of the elbow including range of motion (flexion, extension, pronation and supination). Patient Reported Outcome Measures (PROMs) consisted of pain in rest and pain during activity using a visual analogue scale and multiple questionnaires. Three questionnaires were included. The Mayo Elbow Performance Score (MEPS), which consists of questions regarding elbow

function, pain and stability. It is an accurate and reliable test in patients with elbow dysfunction(8). Patients can score up to 100 points with a higher score representing a better outcome. The Oxford Elbow Score (OES), which consists of 12 questions regarding elbow pain, function and psycho-social effects. It is validated in Dutch and is scored from 0 to 48 with a higher score representing a better outcome(9). And the Health related quality of life (EQ-5D-3L) which measures quality of life. It consists of questions regarding mobility, pain, self-care, usual-activities, anxiety and general health. The answers result in a score between 0 and 1 with a higher score representing better quality of life.

Collection of data on post-operative complications and demographic data was done using the patient files. Institutional review board approval was not necessary for this study, yet the advisory board of our institution gave approval.

Data were analyzed using SPSS 25 (IBM corp.). The pre-operative outcomes will be compared to one year post-operatively and then to the further follow-up moments to analyze whether further improvement will be seen. Paired T-tests are used for the assessment if assumptions for normality are met. If these assumptions are not met, then the Wilcoxon's signed ranked test will be used instead. A p-value of < 0.05 is considered statistically significant.

Independent samples T-tests were performed to check whether post-operative transient ulnaropathy and radiolucency during follow-up were associated with worse mid-, to long-term outcomes of the MEPS, OES and EQ5D compared to patients without these findings. T-tests were also performed on patients with radiolucency on x-ray during follow-up to assess whether these patients experienced more pain during follow-up or had worse ROM compared to patients without signs of loosening.

ROM (flexion-extension and pronation-supination), and pain in rest and activity were checked for correlation with the corresponding outcomes of the EQ-5D-3L at all follow up moments. Assumptions of linearity and normality were checked. When assumptions were met correlations were checked using Pearson's r and if assumptions were not met Spearman's r was used. The proportion of shared variance was calculated using r^2 .

For each of the outcome measures we fit a linear mixed model to find predictors. The models are fit with diagnosis, previous surgery, sex, age and the baseline value of the respective outcome as fixed effects. No random effects are added to the model. We use a step-down approach to fit the model where all fixed effects were initially incorporated in the model. Missing data were assumed to be missing at random. Variable outcomes were transformed to standardized scores. Dichotomous variables can be interpreted as Cohen's d (< 0.3 = small, 0.3-0.8 = medium, > 0.8 = large). Continuous variables can be interpreted as r (< 0.1 = small, 0.1-0.5 = medium, > 0.5 = large) (10).

Results

Patients

A total of 144 total elbow arthroplasties were performed in 142 patients. Of these patients 119 were female and 23 were male. Two women received bilateral total elbow arthroplasties. The mean age at time of surgery was 69 years (range, 47 - 86 years). All operations were performed by one of two surgeons (DE or BT). Since 2014, the triceps-on technique was used more often, as the triceps-flap approach was used mostly before. The most common indications were late posttraumatic osteoarthritis (N = 77), rheumatoid arthritis (N = 38) and fractures (N = 16). Other indications were primary osteoarthritis, metastases and ulnohumeral arthritis. Further demographic details are described in Table 1. The mean follow-up period was 57 months (range, 0-120 months).

Of the 144 surgeries, 109 had an uncomplicated in-hospital stay. Ulnary nerve dysfunction was seen in 16 patients (11,1%) of which 14 were transient and 2 were permanent. A superficial wound infection occurred in 2 patients (1,4%) post-surgery and 4 patients (2,8%) suffered from a deep prosthetic infection. Further complications are described in table 2. 8 Patients (5,6%) showed progressive radiolucency as a sign of loosening on radiographs with a mean follow up of 48 months, a minimum of 11 months and a maximum of 93. Humeral loosening was seen in 5 cases, ulnar loosening in 1 and in 2 cases loosening was seen in both components. A total of 4 revisions were performed (2,8%).

Objective outcomes

For all range of motion test, after the first year no further improvement or decline occurred. On average, the pre-operative flexion and extension range of motion was 90° (SE = 3°) and one year after receiving a total elbow arthroplasty this was 115° (SE = 2°). This difference of 25° (95% CI: 19°-30°) was significant (p < 0.001). For pronation and supination, post-operative range of motion was 131° and increased to 139° one year after surgery. This difference was also found to be significant (95% CI [2°-14°], p = 0.007).

For post-operative flexion-extension ROM the pre-operative ROM was a significant predictor with a medium effect size (r = 0.498). Tumor metastasis showed significantly worse outcomes compared to all other diagnoses with a large effect size. For post-operative pronation-supination ROM the pre-operative ROM was a significant predictor with a medium effect size as well (r = 0.388). Moreover, women showed significant better outcomes with a large effect size compared to men (d = 0.511, p = 0.017).

Table 1. Patient characteristics and indications. SD: standard deviation. ASA: American Society of Anaesthesiologists.

of Allacstifesiologists.		
Patients (n)	142	
Prosthesis (n)	144	
Age in years (mean, SD)	69 ± 7.64	
Gender (n)		
Female	121	
Male	21	
Surgery side (n, %)		
Right	65	(45,1)
Left	79	(54,9)
Dominant		(46,1)
Indications (n, %)		
Rheumatoid Arthritis	38	(26,4)
Late posttraumatic	77	(53,5)
Acute fracture	16	(11,1)
Primary osteoarthritis	8	(5,6)
Tumour metastasis	2	(1,4)
Ulnohumeral osteoarthrosis	1	(0,7)
ASA class (n, %)		
1	4	(2,8)
2	72	(50)
3	43	(29,9)
Missing	25	(17,4)
Smoking (n, %)	17	(11,8)
Rheumatoid arthritis (n, %)	43	(29,9)
Diabetes (n, %)	12	(8,3)
Therapeutic anticoagulants (n, %)	22	(15,3)

Subjective outcomes

The course of the subjective outcomes over time is shown in Figure 1 to 3. After the first year, none of the subjective outcomes changed significantly. Quality of life, measured with the EQ-5D, improved significantly from a mean of 0.50 before surgery to 0.77 one year after surgery (95% CI [0.15, 0.38], p < 0.001) and showed a large-sized effect (d = 0.89). No predictors were found.

Mean pre-surgery pain scores in rest improved significantly from 48 to 14,7 one year after surgery (95% CI [-41.93, -24.53], p < 0.001), and presented a large effect size, d = 1.81.

Female sex was identified as a predictor for lower pain scores with a medium effect size (d=-0,406, p=0.036). Pain in activity showed similar results with pre-surgery scores improving significantly from 75,71 to 27,12 one year after surgery (95% CI [-57.37-39.82], p<0.001), and also presented a large effect size, d=3.30. Pre-surgery pain score in activity was identified as predictor with a small effect size (d=0.165, p=0.034)

Table 2. Revisions and	complications, 30-	day mortality was	counted from discharge.

Revisions (n, %)	4	(2,8)
Complications (n, %)		
Transient ulnaropathy	14	(9,7)
Permanent ulnaropathy	2	(1,4)
Transient radiopathy	2	(1,4)
Superficial wound infection	2	(1,4)
Deep prosthetic infection	4	(2,8)
Fissure ulna	3	(2,1)
Hematoma evacuation	1	(0,7)
Triceps weakness	1	(0,7)
30-day mortality	2	(1,4)

The OES increased from a mean of 18 to a mean of 35 one year after surgery (95% CI [13.5, 21.1], p < 0.001), and represented a large-sized effect, d = 1.61. Diagnosis was identified as a predictor; tumor metastasis and primary osteoarthritis had worse outcomes than rheumatoid arthritis and late posttraumatic osteoarthritis, which showed significantly better outcomes with a large effect size (p = 0.002 and p = 0.03, respectively). The MEPI improved from a mean of 44 to a mean of 83 after one year after surgery (95% CI [30.44, 46.31], p < 0.001). No predictors were identified in further analyses.

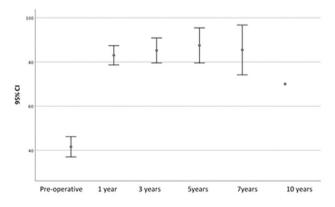


Figure 1. Course of the MEPI over time, starting with the situation before surgery. Given as mean values with 95% confidence intervals.

Of the patients who reported their satisfaction 74.1% said to be fully satisfied with their prosthesis 1 year after surgery, 14.8% were mostly satisfied, 7.4% were somehow satisfied and 3.7% reported to be neutral.

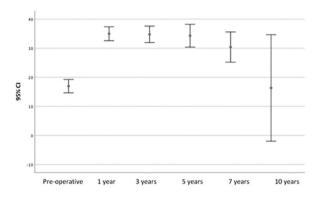


Figure 2. Course of the OES over time, starting with the situation before surgery. Given as mean values with 95% confidence intervals.

Three years after surgery 47.8% reported full satisfaction, 25% of patients were mostly satisfied, 16% somewhat satisfied and 8.3% reported neutral satisfaction. Being unsatisfied about the prosthesis was reported in 4.2% of cases.

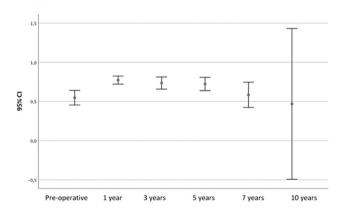


Figure 3. Course of the EQ5D over time, starting with the situation before surgery. Given as mean values with 95% confidence intervals

No significant differences were found between patients who developed radiolucency at any time during follow-up and patients without radiolucency in ROM, pain, OES, MEPS or EQ5D at all follow-up moments. Patients with post-operative transient ulnaropathy showed no significant difference in outcome in both the EQ5D and MEPS one-year post surgery (p = 0.66 and p = 0.21 respectively) compared to patients without any

complications. They did however show significantly lower scores in the OES at both one and three years post-surgery. At one-year follow-up patients with transient ulnaropathy scored a mean of 28 compared to a mean of 36 for patients without complications. This difference is significant (p = 0.02) and represents a large effect size (r = 0.82). At 3 years follow-up patients with transient ulnaropathy scored a mean of 29 compared to 38 for patients without complications. This difference was significant (p = 0.01) and represented a large effect size (r = 0.74). Longer follow up showed no significant differences.

No significant correlation between ROM in both flexion-extension and pronation-supination and their corresponding EQ5D outcomes was found (P-values ranging between 0,14 and 0,42). A significant correlation between pain in rest at one year and the EQ5D was found (p = 0,01, $r^2 = -0,11$). At three years both pain in rest and during activity had a significant correlation with it's respective EQ5D (p = 0,045, $r^2 = -0,07$ and p = 0,03, $r^2 = -0,09$ respectively). All other follow-up moments found no significant correlation.

Discussion

The results of the current study show that both the objective and subjective outcomes after TEA improved significantly, yet after the first year no significant changes occurred. However, the current study also found that the percentage of patients who were fully satisfied with their prosthesis dropped between year one and three. The outcomes were correlated to the indication and gender.

Even though the positive outcomes were to be expected after surgery, we observed an above-average improvement of ROM in our cohort compared to the results of a recent systematic review. The current study found an average flexion-extension arc of 115° while the weighted mean of 17 articles in the systematic review showed an average flexion-extension arc of 96°. The results of the pronation-supination arc were nearly equal, being 139° in the current study and 138° in the systematic review. The difference could be due to different indications, demographics and rehabilitation schemes (4). It is interesting to see that females had a larger pronation-supination ROM, while the flexion-extension ROM was not influenced by gender.

Our mean MEPI after 5 years was 88 which is comparable to a recent systematic review which found a mean of 86 after 4,4 years. (4). Another cohort of a European non-design center, comparable to ours, had a similar improvement of ROM and MEPI after a mean of 5 years after surgery (11). The complication rates and revision rates in this study are comparable to recent literature (2-4). For both the EQ-5D and the MEPI, no predictors were observed, yet for the OES diagnosis was of influence. Another interesting outcome regarding the OES is the significantly lower outcomes both one and three years post-surgery in patients who experienced transient ulnaropathy after surgery. This suggests that this complication has effects that outlast the ulnaropathy itself.

The diagnoses of primary osteoarthritis and metastasis are relatively rare, and have a different pathophysiology than rheumatoid arthritis and post-traumatic osteoarthritis. We believe the longstanding and generalized pathology as rheumatoid arthritis and post-traumatic osteoarthritis influence the psychological part of the subjective outcomes. However, the impact of psychological or mood factors, as i.e. for total knee arthroplasty, have not been described in TEA populations so far (12). Nevertheless, as the factors of gender and indication correlate with the outcomes, these factors should be addressed during the pre-operative counseling.

In addition to the MEPI, we included pain scores, quality of life, satisfaction of the procedure, and the OES, to investigate more detailed than the MEPI what the impact of TEA is to the patients' daily life. As stated previously we observed an increase of satisfaction and possibilities to perform activities of daily life as expected in the first year after surgery. As stated above, we found a significant decrease in patient satisfaction between year one and three. This marks the importance of expectation management and informing patients about expected long-term outcomes. Moreover, radiolucency was seen after a mean time of four years. Therefore, these factors justify a minimum follow-up of three to five years. This follow-up should include a radiological examination, as patients who develop loosening do not show significantly different functional or subjective outcomes during follow-up as a sign of loosening.

Considering that the overall subjective and objective outcomes did not change significantly after one year of follow-up, we believe that patient achieve the most of rehabilitation in this first year. Therefore, in our opinion, intensive rehabilitation is necessary to maximize the benefits of TEA. At our institution, the post-operative instructions have changed in such way that desired direct mobilization is possible and supported by physiotherapists. The subjective outcomes can help to aid in signaling patients who develop unintended adverse events and should be monitored to minimize harmful effects.

In this study, several factors are associated with outcomes; however, the outcome scores such as the MEPI and pain scores are interconnected as pain is a factor in both outcomes. Therefore, it is not possible to state causality and mere associations are reported, even though this is the best option for this kind of research. It seems logical that good objective scores, for example range of motion reflect in better satisfaction. However, the PROMs can score the subjective outcomes more consistently (13, 14).

As this study is retrospective, we cannot rule out any form of bias. Considering not all patients have a ten-year follow up yet, our dataset is missing some data. Clearly, a complete dataset is desired and several problems have to be surmounted (15). To maximize the rates of follow-up data, we introduced a digital system to collect PROMs data, which has shown to aid in completeness (16). A prospective clinical study with patient consent after a formal inclusion could be able to monitor the patients more

completely as they would feel responsible for answering a research question, for example during the rehabilitation process in the first year.

Conclusion

Following TEA, a significant improvement after one year for all subjective and objective scores were observed. During the rest of the follow-up, no significant change in these outcomes was observed. Complications and revision rates found in the current study are comparable to previous studies.

A minimum follow-up period of five years is recommended as mean satisfaction lowered after three years, and radiological signs of loosening were seen after more than five years. The follow-up should contain several objective and subjective components in combination with radiologic examination. Gender and indication for TEA had a correlation with several outcome measures, and should be accounted for during pre-operative counseling. Special attention also has to be given to the possible occurrence of transient ulnaropathy after surgery, as the current study has shown that it's negative effects can last as long as three years.

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Discussion

The first part of this thesis describes the historical pathway of the development of total elbow arthroplasties. This trajectory could be compared with the evolution of a new car model by a large car manufacturer, whose endpoint is to improve quality by improving the work processes and implementing changes^{1,2}. This vision, or way of working, can be divided into four distinct categories/ stages that can be projected on this thesis as well.

It starts with a 'philosophy'. When the philosophy of the team is to deliver best possible care, a common purpose and therefore commitment is etched into the members' minds. Second is that 'processes and results' should be ordered in such way a reproducible result is delivered constantly, allowing for prevention of problems instead of coping with them after they occur. Therefore, it is paramount to register problems and complications instead of ignoring them. Third is 'training the people' who are involved in the process. This can be an educational program, guideline or simply providing information to those who need. The fourth part is to 'continuously solve problems and implement solutions' to put the previous three steps in use and to provide systematical improvement. Similar to the automotive industry, in medicine, and in arthroplasty in particular, we continuously strive to deliver the best possible care an best product by improving processes, educating people, and investigating and solving problems, ultimately adding up to the fulfillment of our philosophy and deliver the best possible care.

However, orthopedic surgeons work with a broad selection of patients who all react differently; this is a major difference to car mechanics, who work with reproducible and predictable car parts. This predictability is grasped in the p-value, used by researchers. The p-value was introduced by Karl Pearson in 1900 and further elaborated by Ronald Fischer, to describe the 'probability of obtaining the same effect again'3.

The willingness to obtain the best effect, at all times, to all patients, makes the art of medicine. In this discussion, the focus is set on potential improvements and their impact on daily care in total elbow arthroplasty.

The historical and surgical proceedings of total elbow prostheses

In **Part one**, the historical and surgical practice is reviewed, to understand the development of the current care of total elbow arthroplasty. From the philosophy of creating the perfect elbow prosthesis, lessons are learned as described in **Chapter one**. For instance, fixed-hinged designs are not used in contemporary orthopedics because results of these designs were mediocre. **Chapter two** describes the more recent surgical approaches used in the Netherlands. A difference is observed between large- and low-volume hospitals; this could reflect a difference in expertise or institutional preference.

The unique aspects of the collected data are the surgical approach and previous surgeries. Unfortunately, no subjective or objective outcomes can be observed from the Dutch Arthroplasty Register yet, as the elbow arthroplasties were added to the Register only

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recently, in 2014. This would be a next step forward in elbow arthroplasty data collection. The preferred outcome measure is debatable. Because literacy could be suboptimal, the Oxford Elbow Scale is potentially difficult to complete⁴. The Mayo Elbow Performance Score needs an assessor for the range of motion and stability, which makes data input difficult and requires a physical visit to the hospital. Therefore, a single question that correlates to the Oxford Elbow Scale would be an easy and simple solution to the current lack of patient-reported outcomes in registries⁵. This could be collected using an online data collection system, which has shown to have good compliance⁶.

With regard to different surgical approaches, **Chapter three** shows one of the possible approaches to perform an arthroplasty. Ideally, soft tissue dissection is minimal to optimize recovery by avoiding destruction of important structures; in this specific approach, the medial epicondyle is detached and refixated for stable anchoring of the medial collateral ligament to the prosthesis.

The learning point of this part is that, in analogy to car manufacturers, the process of creating 'the best' total elbow arthroplasty started with a philosophy, continued with improvement of processes and materials¹. Today, we know that historical constrained designs have worse results, although this could be biased by the use of inferior materials in the 1950's and 1960's. The more recent semi-constrained prosthesis yields better results, yet the 'sloppy hinge' is susceptible for wear of the polyethylene bushing with forthcoming problems^{7–10}. In the search for solutions, biomechanical, patient and surgical factors are of interest¹¹. One solution is the development of a convertible arthroplasty, so the surgeon can decide whether a linked, semi-constrained or unlinked, non-constrained situation is created, depending on the ligamentous integrity¹².

Overall, the perfect elbow arthroplasty would be an implant engineered in such way, it prevents occurrence of material related complications because engineering and technology kept it ahead of complications¹³. It should allow sufficient flexion and extension, have a firm integration into the humerus and ulna with multiple implant sizes, be unsusceptible for material wear and have easy-to-use surgical equipment to avoid surgical complications.

CLINICAL IMPLICATIONS

- Trauma and posttraumatic deformities are an emerging indication for total elbow arthroplasty, while rheumatoid arthritis is becoming less common. The results of total elbow arthroplasty are in general good, however patients are still plagued with a substantial number of complications.
- Understanding the design rationale of the prosthesis used is mandatory. Results from the past have shown the (dis)advantages of several fixation, linkage and material options. Fully constrained total elbow arthroplasty models have a higher complication rate and should only be used with caution.
- Surgical approaches in the Netherlands differ between higher- and lower-volume hospitals. In literature, performing less than 10 total elbow arthroplasties by a single surgeon per year has shown to have inferior results.
- Patient characteristics and surgeon familiarity/experience should lead to the 'best' surgical approach and care. Particular caution should be present for high-demand patients, as well as frail and uncooperative patients.
- If the surgeon decides for a triceps flap or triceps reflecting approach, meticulous reconstruction of the triceps is required.
- In the Netherlands, most often a semiconstrained, 'sloppy hinged' prosthesis is used. An unlinked prosthesis can be used for specific indications.
- The 'perfect' total elbow arthroplasty does not yet exist, but every implant has its own specific options.

Complications and failures

In **Chapter four,** the failure mechanisms that can be improved are addressed. **Chapter five** focusses on the perceived impact of such complications. Prevention of 'serious' complications such as prosthetic infections and early loosening are of importance, yet 'mild' and frequently encountered complications as (transient) ulnar nerve dysfunction have shown to have a highly negative impact on satisfaction and patient-reported outcomes¹⁴.

To obtain the best results, complications should be prevented. Infections could be related to surgical technique, patient characteristics or operation room circumstances. Aseptic loosening could be related to cementing technique, type of implant fixation or used materials. The high incidence of periprosthetic fractures, however, is a result of falls in the relatively old and frail population. Even though frailty is not a common subject in orthopedic practice, it is a relevant point that should be addressed by clinicians; not only

do falls lead to periprosthetic elbow fractures, they are also a possible cause of other serious complications and morbidity¹⁵.

Concerning ulnar nerve dysfunction, multiple options could prevent this complication. The nerve should be identified and protected during surgery to avoid direct trauma. After arthroplasty is performed, the anatomy may have changed because of another center of rotation or resection of the epicondyles; therefore, possible ulnar nerve entrapment should be meticulously checked from the arcade of Struthers all the way down into the fascia of the flexor carpi ulnaris. Even though anterior transposition is correlated with more complications than decompression alone in ulnar nerve entrapment cases, it should be considered in total elbow arthroplasty patients as well¹⁶. no literature is available about routine transposition of the ulnar nerve or decompression only. It is imaginable that an additional ulnar nerve transposition can be beneficial when the posterior medial capsule cannot be closed and the nerve would be in contact with the prosthesis. In cases were the condition of the former cubital tunnel is destroyed a transposition can be considered as well. The medial septum and edges of the medial epicondyle should be checked and optimized if transposition is not considered. In thin patients, submuscular transposition is preferred as they do not have sufficient subcutaneous tissue to protect the nerve¹⁶.

CLINICAL IMPLICATIONS

- Aseptic loosening, periprosthetic fractures and infections are the most common modes-of-failure, and should therefore be discussed pre-operatively with the patients.
- Ulnar nerve dysfunction is a common and usually self-limiting complication. However, the impact on the patient is substantial.
- During surgery, the ulnar nerve has to be carefully handled and checked for interference with the hinge of the prosthesis and impingement against sharp edges of the cubital tunnel. When necessary or in doubt, an anterior nerve transposition should be performed.

Improvements of current care

As the previously described car manufacturer's vision on improvement states, continuous problem-solving and implementing changes are mandatory. One way of working associated with this process, is 'lean working'. According to the lean working model, unnecessary tasks should be avoided and efficiency should be promoted.

Chapter six shows a flowchart that helps to determine an unknown prosthesis on plain radiographs easy using specific prosthetic features^{17,18}. This could aid in the planning of revision surgery or when dealing with an unknown, out-of-use prosthesis.

The prosthesis used most in the Amphia Hospital has only three width-sizes. Preoperative templating is an option to plan the implant size but costs time, requires specific radiographs, and eventually did not contribute to the per-operative decision making. In addition, its predictive value of prosthesis size was low. Therefore, **Chapter seven** advocates the cessation of pre-operative templating for this prosthesis type in standard cases. However, developments in imaging and printing could aid in optimizing the preoperative workup of TEA. Three-dimensional, digital planning could potentially be beneficial in post-traumatic cases¹⁹. Another option is printing the affected bones as sawbone models, and perform sample surgery on that model.

When the outcomes of changes in processes are assessed, previous studies use objective and subjective outcome measures, such as range of motion and validated questionnaires. **Chapter eight** focusses on the most reliable position of measuring extension force, which can monitor the differences in extension force during recovery and on the long term. Presumably, when the triceps muscle is left intact, less dysfunction or triceps-related complications will occur, even though they are rare and therefore potentially overlooked or not assessed 14,20.

In **Chapter nine** the use of functional discharge criteria and early movement after total elbow arthroplasty is evaluated. When a cast is applied after surgery, the elbow cannot be used and therefore patients have more morbidity because of a completely dysfunctional arm. Three decades ago, a cast was used to prevent wound complications²¹. In these years, indications, patients and the community have undergone extensive changes and in our study no influence on wound complications was observed. Moreover, no literature is available about above-the-elbow casts and falls in the elderly (elbow arthroplasty) population, but it is imaginable that above-the-elbow casts can lead to falls with forthcoming injuries. The study showed that routine postoperative casting is not beneficial in prevention of complications such as wound problems. Moreover, no differences in infection rates or other adverse events were seen. Furthermore, in the light of **Chapter five**, the cast can lead to ulnar nerve compression when applied tightly or when swelling occurs, leading to ulnar nerve symptoms.

Chapter ten focusses on the need of follow-up. As no clear duration of follow-up after total elbow arthroplasty has been described in the literature, duration and frequency can be debatable. For instance, asymptomatic aseptic loosening can be detected with radiographs, before a periprosthetic fracture occurs when the bone stock reached a critical point. When this fracture would occur, the revision options are more difficult compared to a situation where this loosening was detected earlier during follow-up. As described in this chapter, patient-reported outcomes do not 'detect' aseptic loosening and therefore the follow-up should consist of radiographs as well.

CLINICAL IMPLICATIONS

- Before performing (partial) implant revisions, detailed information about the implant is mandatory. A flowchart can aid in recognition.
- The value of pre-operative templating in total elbow arthroplasty with the Coonrad-Morrey arthroplasty is very low in standard cases.
- Post-operative casting does not aid in preventing wound complications such as leakage or superficial wound infections.
- Functional discharge criteria reduce length of stay without more complications.
- 30 Degrees of flexion is most reliable for triceps strength testing and should be evaluated during follow-up to detect triceps failure.
- Follow-up after total elbow arthroplasty should be at least five years, with patient reported outcomes and radiographs. Loosening is not detectable with patient reported outcomes only.

Future perspectives

The main improvements that can be made to achieve the same success as total hip arthroplasty – the surgery of the century²² – are found within three aspects: indication, operation and rehabilitation.

Concerning the indication, world-wide shifts have been observed from mostly rheumatoid arthritis to mostly post-traumatic osteoarthritis and acute injuries^{23,24}. Because of the disadvantages of total elbow arthroplasties, i.e. lifestyle restrictions and potential revisions, the indication to perform an arthroplasty has to be thoroughly considered. Fortunately, this is the case in modern-day medicine with shared-decision making as the gold standard^{25–27}. As the patients need to make a thorough decision, it helps them to make the future their own²⁸.

Possible improvements consist of better patient-education to prepare the patients for the post-operative period and to level expectations. This could be done using informative group sessions where patients are educated about their problem and interventions, with booklets, infographics or digital apps. The unique point of apps is that they are interactive and prone to changes. Therefore, when patients are capable of working with a smartphone or tablet, these apps would provide an up-to-date platform for information and supervision. Perhaps the extra information and supervision would aid in the feeling of mutual commitment and lead to better outcomes, both subjective as objective.

Also another options than total elbow arthroplasty should be considered in young patients. Because of all the described risks of elbow arthroplasty, postponing the moment of arthroplasty could be beneficial on the long term. Arthroscopy, with debridement and removal of loose bodies, could be a stopover for some time, and assessment of the cartilage could lead to an hemiarthroplasty first when indicated^{29–31}.

The operation also entails a field that has potential for improvement; different surgical techniques, prosthetic designs and experience. Even though one should 'never change a winning team', improvements are neccessary³². A volume of more than 10 elbow arthroplasties per surgeon are related to less complications and better outcomes, what could be realized with more referrals to specialised centers³³. Over the decades, less loosening, infections and better functional outcomes are seen, yet these problems still have a higher incidence than in hip or knee arthroplasty. When a good solution to a problem such as aseptic loosening would arise, such as other cement or prosthetic coating, it should be implemented. Nevertheless, these solutions have to be implemented in a safe way without leading to unwanted harm, as has occurred more often in orthopaedics³⁴.

As described in this thesis, pre-operative planning had no potential benefit in standard cases. Nevertheless, planning still can be useful when deformities or extreme body sizes are present. A more elaborate method would be 3D-planning, which has benefits over 2D-planning as the humerus, ulna and radius are three-dimensional structures moving around each other. Even though it would entail more work for the surgeon, it could provide more insight into the anatomy and therefore aid during surgery¹⁹. A pitfall is the posterior ulnar dorsal angle (PUDA)^{35,36}. A futuristic aid to conquer the problem of this angle could be the use of three-dimensional patient-specific jigs that aid during surgery, as used in for example knee arthroplasty. Implant alignment in the flexion-extension plane could be optimized using these jigs. However, the implant size options are limited, with sometimes a quite large difference between two sizes as for instance with the Coonrad-Morrey implant. Moreover, to place the jigs on the ulna, a large are would be needed to dissect, with more soft tissue damage.

Perhaps the least noticeable trajectory of any hospital-based doctor is the phase of the rehabilitation. After discharge from the hospital, the patients go home and start rehabilitating, usually supervised by a physiotherapist. Afterwards, the patients only visit the outpatient clinic for follow-up appointments.

Therefore, for future improvements in total elbow arthroplasty care, more emphasis should be put on the rehabilitation. With the use of extra information, i.e. a digital app, the hospital could assist patients and physiotherapists during the (p)rehabilitation process, in analogy to upper gastro-intestinal surgery and thoracic surgery^{37,38}. Better prehabilitation and information could help in improving the patients' status before surgery; the better-

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in, better-out principle³⁹. Prehabilitation would entail optimizing the shoulder, elbow and wrist functions. After surgery, the patients hopefully will benefit from a better preoperative muscular function.

Presumably, when large cohorts of patients will be followed thoroughly with national register data with patient-reported outcomes, a wealth of information regarding total elbow arthroplasties will be available on the mentioned aspects of indication, operation, and rehabilitation. This means that stronger conclusions on all these aspects can be drawn with forthcoming next improvements in patient care.

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This thesis focused on the historical developments of total elbow arthroplasty, an analysis on modes of failure and complications, and finally on improvements for future care to optimize outcomes.

Chapter one discussed the course elbow prostheses have taken in the twentieth century. Several differences were described regarding fixation and general design. Earlier clinical studies showed that a 'loose hinge' design offered better results than a 'fixed hinge'. A linked prosthesis does not require intact ligamentous structures, and therefore offers more stability in ongoing pathophysiology such as rheumatoid arthritis. A multitude of fixation methods has been tried and tested, of which currently the cemented, uncemented, and osteo-integrative coating are used most often^{2–9}.

Chapter two discussed the different surgical approaches used in the Netherlands using data from the Dutch Arthroplasty Register. This study showed the approach mentioned in chapter three is only one of many methods to implant a total elbow arthroplasty, and that approaches in higher- and lower-volume hospitals differ.

In **Chapter three** a surgical approach using an osteotomy of the medial epicondyle was described step-by-step, with an instructional video. This specific prosthesis is available with several options for linkage type and the possibility to perform a radial head arthroplasty as well. Therefore, this instructional publication may help surgeons in their treatment strategies and per-operative decisions. In **Chapter four** modes of failure of total elbow prostheses were discussed in a systematic review. This adds to an ongoing search for improvements of contemporary total elbow arthroplasties. The outcomes showed that loosening still is the most common mode of failure, yet periprosthetic fractures and infections play a major role as well.

In **Chapter five**, the influence of complications on patient-reported outcomes was investigated. Ulnar nerve dysfunction was associated with high morbidity. However, because the symptoms are usually transient, its influence on the patient reported outcomes is often underestimated by medical professionals. This, combined with the high incidence and its impact on patient-reported outcomes, make the transient ulnaropathy a substantial problem after total elbow arthroplasty¹⁰.

Chapter six evaluated the effectiveness of a flowchart diagram with model-specific features. A general increase in recognition rates was seen, yet it was not significant statistically. In regular use, this flowchart may aid in ease of recognition of total elbow arthroplasty models. The specific features of the different prostheses can be clearly distinguished on plain radiographs, which makes it a low-cost diagnostic tool when information is missing^{11,12}.

Chapter seven discussed the need of pre-operative templating. The results showed that planning is not necessary in regular cases when using a prosthesis which has only three sizes, yet could provide surgeon guidance during surgery when a large difference between the planned and actual surgery is observed.

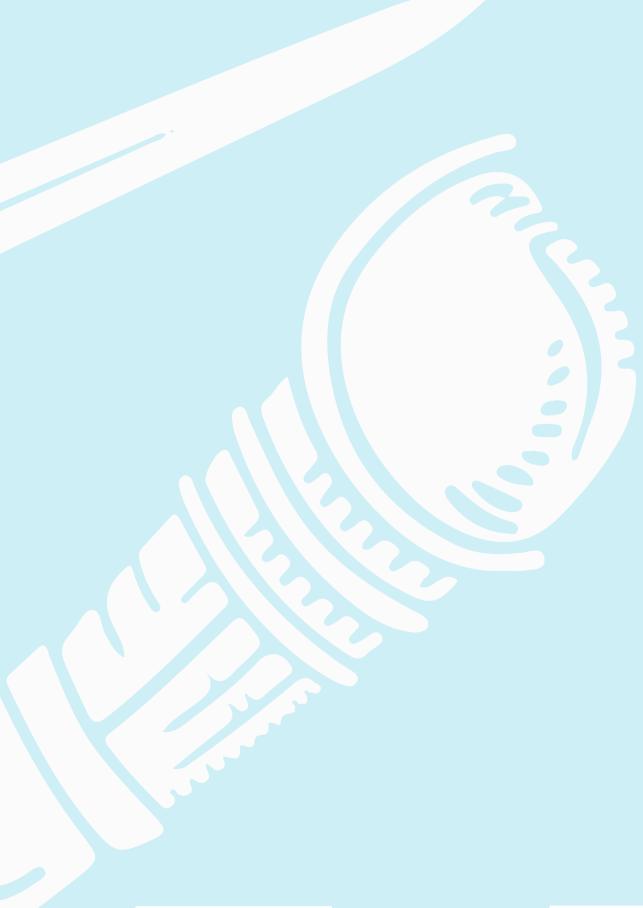
In **Chapter eight** the most reliable position of triceps brachii force testing was described. Even though the triceps consists of three separate heads whose function differs, this apparatus provided a testing method of triceps function that is fast and easy applicable in clinical settings¹³.

In **Chapter nine**, the introduction of functional discharge criteria was assessed. The hospital stay was significantly shortened without safety concerns. Cessation of a post-operative cast was not associated with more wound problems, and reduced the hospital stay. Discharge when possible instead of a fixed time of hospitalization was safe.

In **Chapter ten**, the overall subjective and objective outcomes were described in the cohort of total elbow arthroplasties performed in the Amphia Hospital. This is the largest cohort of the Netherlands, and one of the larger cohorts in Europe. Subjective and objective outcomes improved after surgery, and remained stable after several years. Nevertheless, periodical evaluation remained necessary in detecting loosening of the prosthetic components.

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Nederlandstalige samenvatting

Dit proefschrift richt zich op drie aspecten rondom de totale elleboogprothese: de historische context en ontwikkeling vanaf de eerste tot de huidige designs, een analyse van de meest voorkomende problemen door patiënt-ontevredenheid, complicaties en falen, en tot slot de toekomstige verbeterpunten in de zorg rondom totale elleboogsprothesen.

Hoofstuk één beschrijft de evolutie van visie over de optimale design rationale van de totale elleboogsprothesen in de twintigste eeuw. Er zijn diverse pogingen gedaan om de uitkomsten te verbeteren, waarbij het aanpassen van het scharnier belangrijke veranderingen heeft ondergaan. Zo toonde onderzoek aan dat een scharnier met enige speling in varus- en valgusrichting tot betere resultaten leidde dan een scharnier, dat nauwelijks speling toestaat tussen de twee componenten¹. Daarnaast geldt ook dat gekoppelde prothesedesigns niet afhankelijk zijn van de gewrichtsbanden of kapsel voor het behoud van de gewrichtsverhouding (dus het voorkomen van het gedeeltelijk of geheel uit de kom gaan), waardoor deze beter geschikt zijn bij patiënten met aandoeningen aan die structuren, zoals reumatoide arthritis. Wat betreft de fixatie van de prothese in het mergkanaal zijn meerdere methoden onderzocht, waarvan heden de gecementeerde, ongecementeerde en osteo-integratieve coatings het meest worden gebruikt²-9.

Hoofdstuk twee gaat in op de verschillende chirurgische benaderingen die gebruikt worden in Nederland en vergelijkt de resultaten met behulp van de Landelijke Registratie Orthopedische Implantaten (LROI). Hieruit blijkt dat hoog- en laag-volume ziekenhuizen verschillen qua toegepaste benadering, waarbij de eerste groep vaker gebruik maakt van een tricepspees-sparende techniek.

In **Hoofdstuk drie** wordt een frequent gebruikte benadering stap voor stap toegelicht in tekst en beeld. De prothese die wordt gebruikt in dit hoofdstuk kan op verschillende manieren worden gebruikt; met of zonder koppeling en met of zonder radiuskopcomponent. De tips en trucs in dit hoofdstuk kunnen helpen bij beslissingen tijdens de ingreep.

Hoofdstuk vier analyseert de manier van falen van totale elleboogsprothesen in een beschrijving van recente literatuur. Hieruit blijkt dat loslating, infecties en breuken rondom de prothese nog steeds de meest voorkomende redenen voor falen zijn.

In **Hoofdstuk vijf** wordt de invloed van een complicatie op de uitkomst beschreven. Met name tijdelijke uitval van de nervus ulnaris wordt als de meest ingrijpende complicatie ervaren door de patiënten. Dit leidt verrassend genoeg tot een blijvende verminderde patiënt-tevredenheid, ook na het volledig terugkeren van de zenuwfunctie. De combinatie van ervaren ernst en veelvuldig voorkomen zorgt er dus voor dat dit een van de belangrijkste complicaties is.

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Hoofdstuk zes gaat in op de toegevoegde waarde van een stroomschema om het exacte model van een totale elleboogsprothese te herkennen, wat bij een heroperatie voor bijvoorbeeld loslating van een prothesecomponent belangrijk is, gezien er vele protheses in omloop zijn geweest en nog steeds zijn. Hieruit blijkt dat het stroomschema effectief is om op nauwkeurige wijze het exacte model te identificeren. Hierdoor is een simpele manier ontwikkeld om ontbrekende informatie te verkrijgen op basis van een röntgenfoto^{11,12}.

Het nut van pre-operatieve planning wordt besproken in **Hoofdstuk zeven**. Hieruit blijkt dat planning van de maat niet zinvol is in reguliere gevallen. Het voordeel zou wel kunnen zijn dat grote discrepanties tussen planning en maatbepaling tijdens de ingreep gesignaleerd worden en dat diverse andere factoren gestandaardiseerd vooraf gevisualiseerd worden, waarmee mogelijk complicaties zoals fracturen en faux routes kunnen worden verminderd.

Hoofdstuk acht beschrijft de meest betrouwbare manier van het vervolgen van de tricpeskracht na de ingreep. Het apparaat en de opstelling zijn simpel en gemakkelijk in gebruik¹³. Deze werkwijze zorgt voor een gestandaardiseerde en betrouwbare meting die gebruikt kan worden om het resultaat met betrekking tot een van de kwetsbare structuren bij elleboogchirurgie, de tricepspees, objectief te beoordelen en vervolgen.

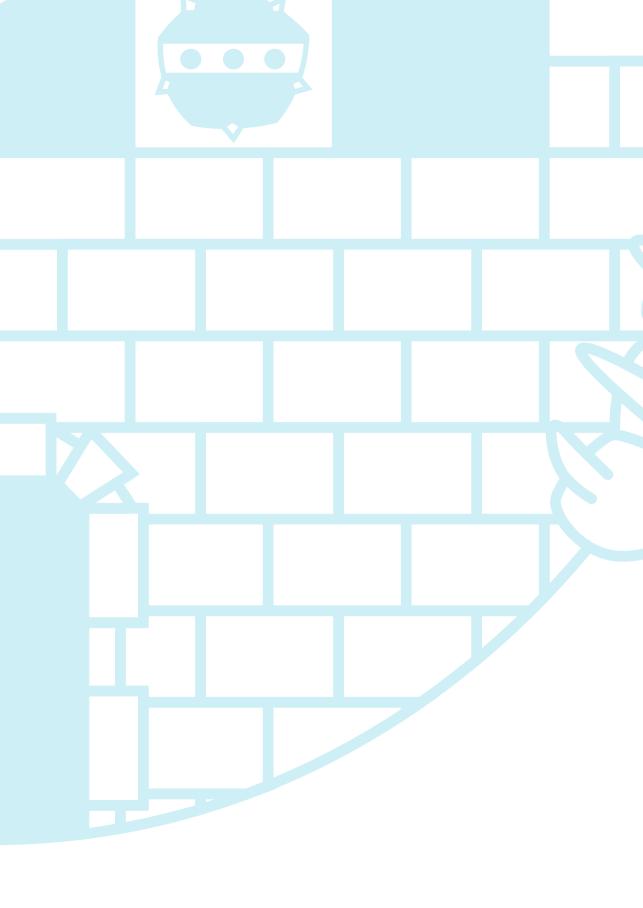
In **Hoofdstuk negen** wordt beschreven hoe het afschaffen van gips na de ingreep en het invoeren van functionele ontslagcriteria heeft geleid tot een aanzienlijk kortere opnameduur. Daarnaast is er geen verschil in complicaties, waardoor snel ontslag met een functionele nabehandeling veilig zijn gebleken. Dit is van evident belang om op kosteneffectieve wijze hoge kwaliteit van zorg te kunnen blijven leveren.

Hoofdstuk tien beschrijft wat de uitkomsten zijn van de totale elleboogsprothesen die geplaatst zijn in het Amphia Ziekenhuis. Dit is een van de grootste cohorten van Europa en laat zien dat de subjectieve en objectieve uitkomsten verbeteren na de operatie en jarenlang stabiel blijven. Anderzijds wordt ook het nut van periodieke evaluatie met een röntgenfoto duidelijk, gezien loslating niet wordt opgemerkt door andere uitkomstmaten.

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Appendix

About the author

Ante Prkić was born in Gouda on April 26th, 1991. He was raised in Schoonhoven, a town in Het Groene Hart, where he still likes to cycle, run and inline-skate when possible. After he graduated with honors in 2009 at CSG Willem de Zwijger, he started to study Medicine at FrasmusMC in Rotterdam

Next to his studies, he started to work in a student team at the transplantation and vascular surgery ward, where he was pointed at the needs of research by one of the staff members



Already during the bachelor, his interest in orthopedics was taken. Before attending the clinical rotations, he went for an internship at the orthopedic department of the Charles University in the beautiful city of Prague. During this internship, his interest in orthopedics was confirmed. Therefore, most freely selectable internships were at the orthopedic department at the 'gezellige' Amphia Hospital in Breda.

Once graduated in 2016, he started to work at the ErasmusMC and later on at the Amphia Hospital. There, he experienced the orthopedic problems and patients, which further confirmed his choice for orthopedics. His orthopedic training started in 2018, at the Albert Schweitzer Hospital with general surgery. At this moment, his further training is taking part at the Amsterdam UMC area, from Breda to Amsterdam and Alkmaar.

Dankwoord

Ongetwijfeld zijn er een hoop mensen die bijgedragen hebben aan de totstandkoming van dit proefschrift, die hieronder niet expliciet genoemd worden. Al diegenen ben ik van harte dankbaar! Hieronder een aantal personen die ik speciaal wil uitlichten.

Hooggeleerde vrouwe, mw. Prof. dr. D. Eygendaal, beste Denise. Elke zin die begint met 'wat zou het toch mooi zijn als...' is bij jou niet alleen een aansporing, maar ook een moment om te reflecteren. En om te dromen. In de jaren dat ik met dit werk ben bezig geweest, en als assistent in het gezellige Bredase, heb ik die zin vaak gehoord. En uiteindelijk, wat is het toch mooi dat dit nu eindelijk klaar is!

Beste Bertram, jouw doortastendheid en daardoor het gevoel dat je altijd een stap verder bent, is motiverend. Soms was het echter ook wat demotiverend, omdat jouw opmerkingen vaak een soort spiegel bleken waar je daarna weer tijden bezig was om die opmerkingen te verwerken in tekst en gedachtegang. Maar altijd, zeer welkome en structurele feedback. Dank!

Christiaan, in het begin dat ik jou leerde kennen en ook af en toe zag lopen in De Boei, was ik ervan overtuigd dat je ook co-assistent moest zijn. Wie anders zou er ook in dat gebouw leven? Maar je down-to-earth pragmatische aanpak, en het 'gewoon zijn' is iets dat jou zo speciaal maakt als mens, leraar en co-promotor.

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Ruud Selles, ooit, jaren geleden, kruisten onze wegen bij de minor Plastische- en reconstructieve chirurgie. Toen had ik al de indruk, dat lesgeven, bijsturen en onderzoek goede eigenschappen van je waren. Later kwam de titel professor, wat die punten beaamt!

Gino Kerkhoffs, leider en aanvoerder van het Amsterdam UMC-team. Werk en privé, onderlinge cohesie en doortastendheid. Dat zijn enkele steekwoorden die jou omschrijven zoals ik je heb leren kennen. Opleider in hart en nieren, dank voor de opmerkingen die vaak met een knipoog (of twee tegelijkertijd) gegeven worden.

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Mam, dank je wel voor de steun in al die jaren dat ik hiermee bezig ben geweest. Ook al zeg je vaak dat je er niet veel van snapt, vind je het wel fijn als ik weer eens ergens ben geweest om de onderzoeken ergens uit te leggen. Niet alleen aan tafel of in de tuin, maar zeker ook in het buitenland.

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Ante Prkic

Description	Organizer	EC
Required		
Comprehensive Review Course (2016)	FORTE	2.00
Scientific writing (2017)	Text and Training	2.00
Oral presentation (2017)	FORTE	1.00
Comprehensive Review Course (2017)	EFORT	1.00
Poster presentation (2017)	SECEC - ESSSE	0.50
Poster presentation (2017)	SECEC - ESSSE	0.50
Poster presentation (2017)	Amphia Hospital	0.50
Poster presentation (2017)	Amphia Hospital	0.50
Poster presentation (2017)	Amphia Hospital	0.50
Imperial Trauma Conference (2017)	Imperial College London	3.00
Good Clinical Practice (2018)	EMWO	1.00
Oral presentation (2018)	EFORT	1.00
Poster presentation (2018)	EFORT	0.50
Perioperatief traject bij ouderen (2018)	Albert Schweitzer Hospital	1.00
Coach de Co (2018)	DOO AUMC	1.00
Imperial Trauma 2018 (2018)	Imperial College London	1.00
Evidence Based Surgery (2018)	Albert Schweitzer Hospital	1.00
Kennis van Zorgkosten (2018)	Albert Schweitzer Hospital	1.00
Coaching PhD students - Jetske Viveen (2018)		3.00
Poster presentation (2019)	EFORT	0.50
Poster presentation (2019)	EFORT	0.50
SECEC - ESSSE Elbow symposium (2019)	SECEC – ESSSE	0.50
SECEC - ESSSE Closed Meeting (2019)	SECEC – ESSSE	1.00
Oral presentation (2019)	SECEC - ESSSE	1.00
Oral presentation (2019)	NOV	1.00
Oral presentation (2019)	SECEC	1.00
Poster presentation (2019)	SECEC	0.50
AO trauma Complex Elbow Fractures (2020)	AO trauma	1.00
Poster presentation (2020)	EFORT	0.50
Poster presentation (2020)	EFORT	0.50

Description	Organizer	EC
Poster presentation (2020)	EFORT	0.50
Teach the Residents (2020)	Amphia Hospital	1.00
SECEC - ESSSE digital conference (2020)	SECEC - ESSSE	2.00
Poster presentation (2020)	SECEC - ESSSE	0.50
Oral presentation (2021)	SECEC - ESSSE	1.00
Coaching PhD students - Arno Macken (2022)		3.00
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Discipline Overstijgend Onderwijs - Management en Organisatie (2022)	DOO AUMC	1.00
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