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Risk factors for reoperation after total wrist arthroplasty

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RISK FACTORS FOR REOPERATION AFTER TOTAL WRIST ARTHROPLASTY

by

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ABSTRACT

Background: Total wrist arthroplasty (TWA) is a surgical option for treatment of end-stage wrist arthritis and other debilitating wrist conditions. Despite improvements in the TWA implant and procedure, there are still many complications after an initial TWA. The most common complications include infection, hardware loosening, and tendon rupture. These complications are indications for an unplanned reoperation after an initial TWA.

Objective: The purpose of this retrospective study was to determine the rate of reoperation and implant removal after TWA. We tested the null hypotheses that there are no demographic or surgery-related factors associated with an unplanned reoperation or implant revision after a TWA. We also studied the secondary question whether there were radiographic features that predicted reoperation or implant revision after a TWA.

Methods: We used Current Procedural Terminology (CPT) codes to identify all 29 consecutive TWAs performed at two academic medical centers between 2002 and 2015. We manually reviewed medical records to collect demographic (age, sex), patient- or disease-related (tobacco use, indication of rheumatoid arthritis, prior wrist surgery) and surgery-related (implant type) factors. Reoperation was defined as any unplanned wrist surgery related to the TWA. We used a Fisher's exact test to

compare the proportions of categorical variables and a Mann-Whitney-U test to compare the average age among wrists that did and did not undergo reoperation and implant removal, and calculated P-values.

Results: The rate of reoperation was 48% (14 of 29 TWAs performed); of which 34% (10 of 29) underwent implant removal. The most common indication for reoperation was component loosening, which occurred in 5 wrists. Five patients had wrist surgery prior to their TWA, of whom 4 eventually had their implant removed ($p = 0.036$). No other factors were associated with reoperation or implant removal.

Conclusions: We found that reoperation and implant removal after TWA are common. Despite improvements, approximately 1 in 3 wrists are likely to undergo revision surgery. Prior wrist surgery was the only risk factor statistically associated with implant removal after TWA. Patients should be counseled of the high rate of reoperation and implant removal before electing to undergo TWA when considering all treatment options for end-stage wrist arthritis.

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LIST OF ABBREVIATIONS

ASSH..American Society for Surgery of the Hand

CMC ....Carpometacarpal

CPT ....Current Procedural Terminology

CTS...Carpal Tunnel Syndrome

DIP ....Distal Interphalangeal

DRUJ..Distal Radio-Ulnar Joint

IQR...Interquartile Range

MCP ....Metacarpophalangeal

NAR.. Norwegian Arthroplasty Register

NSAIDs .... Nonsteroidal Anti-inflammatory Drugs

OA.. Osteoarthritis

PIP... Proximal Interphalangeal

PRC ....Proximal Row Carpectomy

RA.. Rheumatoid Arthritis

RL ....Radius and Lunate

RSL...Radius, Scaphoid and Lunate

SD ....Standard Deviation

SL... Scapholunate

SLAC... Scapholunate Advanced Collapse

SLIL...Scapholunate Interosseous Ligament

INTRODUCTION

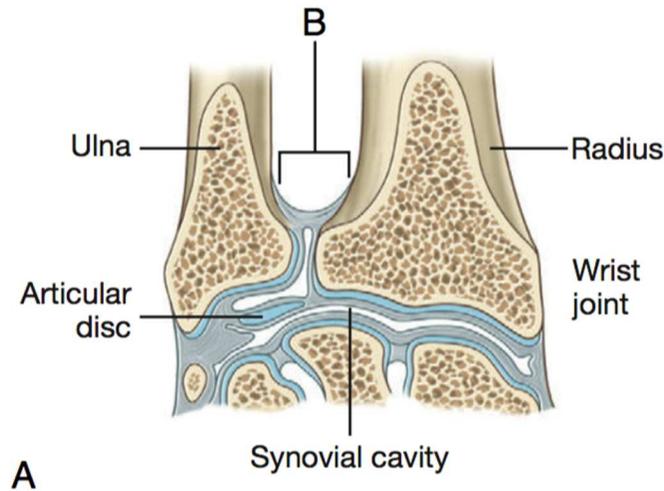### *Normal Hand and Wrist Anatomy*

The normal hand anatomy consists of the digits and metacarpals, which articulate with the wrist (carpus). The bones of the fingers are the phalanges. The four fingers have three phalanges (proximal, middle, and distal), whereas the thumb has two phalanges (proximal and distal). The joints between the bones of the phalanges form interphalangeal joints. The phalanges articulate with the metacarpal bones to form metacarpophalangeal joints, which are condylar joints, a type of synovial joint. Figure 1 from the American Society for Surgery of the Hand (ASSH) shows the anatomy of the hand and the joints formed between the phalanges and metacarpals. The normal movements for the second through fifth digits are flexion, extension, abduction, adduction, and circumduction (Drake, Vogl, & Mitchell, 2012). In addition to flexion, extension, abduction, adduction, and circumduction, the saddle joint formed between the thumb metacarpal (metacarpal I) and the carpal bone (trapezium) is a unique joint to provide rotation at the thumb (first digit), which allows for pinch and grip strength (Drake et al., 2012).

MIDDLE JOINTS
Distal Interphalangeal
Proximal Interphalangeal
Metacarpophalangeal
Carpometacarpal

RING JOINTS
Distal Interphalangeal
Proximal Interphalangeal
Metacarpophalangeal
Carpometacarpal

INDEX JOINTS
Distal Interphalangeal
Proximal Interphalangeal
Metacarpophalangeal
Carpometacarpal

SMALL JOINTS
Distal Interphalangeal
Proximal Interphalangeal
Metacarpophalangeal
Carpometacarpal

THUMB JOINTS
Interphalangeal
Metacarpophalangeal
Basal Carpometacarpal

Scaphotrapeziotrapezoidal
(STT) Joint

ASSH

Radius   Ulna

Figure 1: Hand and Wrist Anatomy. This figure shows the hand anatomy and joints made up of the phalanges, metacarpals, and carpal bones (adapted from ASSH, 2017b).
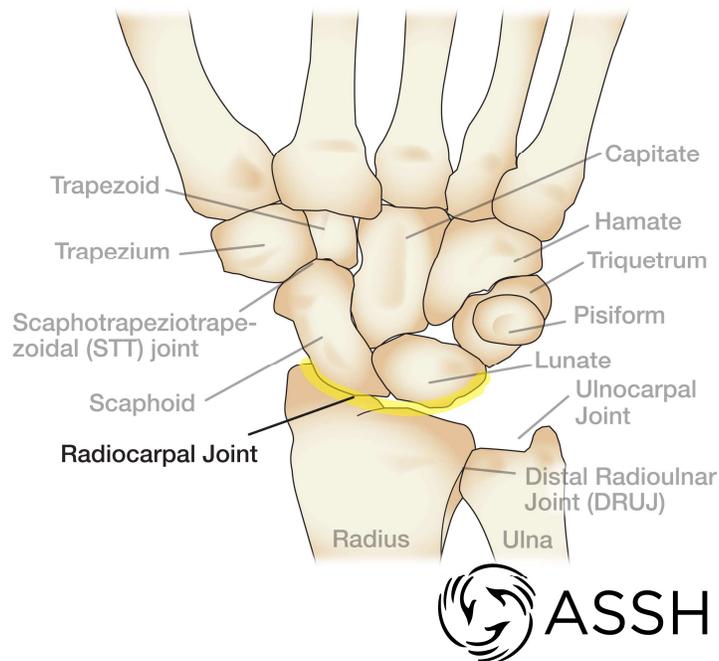
Normal Wrist Joint Anatomy

The normal wrist joint anatomy consists of eight small carpal bones, articular cartilage, ligaments and tendons, which allow for the carpal bones to articulate with the bones in the forearm, the radius and ulna (ASSH, 2017f). The distal radius and distal ulna, along with the carpal bones, form the wrist. The articular cartilage covering the bones acts as a padding and serves to absorb some of the shock across the joint and prevent pain across the joints if the bones were to rub against each other (ASSH, 2017b). The wrist joint is a type of synovial joint. A synovial joint consists of a joint capsule made up of a synovial membrane to lubricate the joint, and a fibrous membrane to hold the joint together (ASSH, 2017b; Drake et al., 2012). Figure 2 (Drake et al., 2012) shows the synovial joint of the wrist. The joint anatomy allows people to rotate and bend their wrist without experiencing any pain when completing everyday tasks.
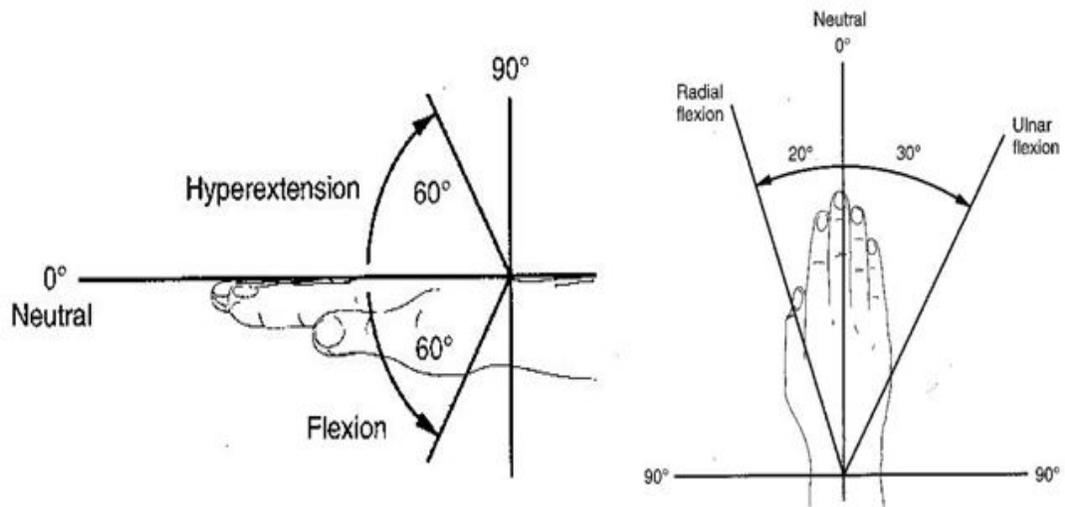
Figure 2: Synovial Joint of the Wrist. This figure shows the synovial joint between the distal radius and ulna and the proximal carpal row (A). The distal radius and ulna form another type of synovial joint, which allows for rotation at the wrist (B) (adapted from Drake et al., 2012).

The eight carpal bones of the wrist are divided into the proximal and distal row. The proximal carpal row consists of the scaphoid, lunate, triquetrum and pisiform, which directly articulate with the distal radius and ulna. The distal row consists of the trapezium, trapezoid, capitate, and hamate, which connects with the metacarpals in the hand. Figure 3 from the American Society for Surgery of the Hand (ASSH) shows the carpal bones of the wrist. We rely on a normal wrist anatomy to preserve function for activities of daily life. The ligaments provide stability to the wrist and rotational range of motion occurs through the distal radius and ulna joint (McBeath & Osterman, 2012; Trieb, 2008). The palmar radiocarpal, palmar ulnocarpal, dorsal radiocarpal, and radial and ulnar collateral ligaments provide

reinforcement and stability to the wrist during range of motion movements (Drake et al., 2012). Normally, the wrist provides the following range of motion: 60 degrees of extension, 60 degrees of flexion, 30 degrees of ulnar deviation, and 20 degrees of radial deviation, which is necessary for most standard tasks (Sheth, 2017) (Figure 4). However, in the setting of pain, disease, or injury, these numbers decrease, which can severely compromise normal everyday function. Some of the most common reasons for disruption of the normal wrist anatomy include traumatic injury or rheumatoid arthritis.

Figure 3: Anatomy of the Wrist Joint. This figure shows the wrist joint where the carpal bones articulate with the distal radius and ulna (adapted from ASSH, 2017f)

Figure 4: Normal Wrist Range of Motion. The left panel shows the normal range of motion for the wrist in flexion and extension. The right panel shows the normal radial (thumb side) and ulnar (little finger side) deviation of the wrist (adapted from Sheth, 2017).

Diseases of the Wrist Joint

Rheumatoid Arthritis (RA), a type of inflammatory arthritis, is an autoimmune disease in which the body's cellular immune system attacks the joints, more specifically, the articular cartilage, ligaments, and bone. RA initially attacks the soft tissues and as it progresses it attacks the cartilage and bone (Moore, 2017). RA typically affects the finger joints and the wrist joints of both hands (ASSH, 2017d). The chronic inflammation erodes the joint over time and causes deformity to the ligaments and tendons, ultimately compromising normal range of motion (ASSH, 2017d; Kumar, Abbas, & Aster, 2013). Patients with RA typically have morning

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stiffness in the affected joint for longer than one hour, swelling, and develop nodules over the joints (Moore, 2017). The joints most often affected are the proximal interphalangeal (PIP) and metacarpophalangeal (MCP) joints on both hands. The joints usually show the typical signs of infection, including swelling, redness, warmth, and pain (Grassi, De Angelis, Lamanna, & Cervini, 1998; Kumar et al., 2013).

  The criteria to diagnose RA include swelling, stiff joints, laboratory testing, and radiographic imaging. Typically, RA affects the wrist joint in 50% of people at 2 years after onset of disease and increases to >90% of people after 10 years. It usually appears in both wrists (Trieb, 2008). There are several RA classification systems utilized by physicians to determine the severity of the disease, which help guide physicians toward the best treatment course. Common referenced classification systems are the Larsen's Classification and Simmen's Classification system (Table 1 and Table 2, respectively) (Ilan & Rettig, 2003).

Table 1: Larsen's Classification for Rheumatoid Arthritis. The table below describes the radiographic classification system for RA of the wrist (Ilan & Rettig, 2003).

0	No changes
1	Soft tissue swelling, demineralization
2	Marginal erosions, initial deviation
3	Articular erosions, joint line narrowing, mild instability
4a	Midcarpal ankylosis, major radiocarpal instability
4b	Radiocarpal ankylosis, stable
5a	Destruction of carpus, radiocarpal dislocation
5b	Destruction of carpus, complete ankylosis

Table 2: Simmen's Classification for Rheumatoid Arthritis. The table below represents a common classification system for progression of RA in the wrist (Ilan & Rettig, 2003).

Type I (ankylosis)	Spontaneous tendency to fuse, stable pattern
Type II (arthrosis)	Articular loss progresses at equilibrium with arthrosis, stable
Type III (disintegration)	Progressive destruction, loss of alignment, unstable

Disruption to the normal wrist anatomy leads to instability and prevents normal function of the hands. The wrist degeneration occurs when the cartilage starts to degrade and the ligaments loosen. Due to the instability of the ligaments, the proximal carpal row can dislocate and collapse, leading to subluxation and instability of the entire wrist (McBeath & Osterman, 2012). Figure 5 shows a

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comparison of radiographs demonstrating a normal wrist and a wrist affected with RA. When looking at radiographs of patients with RA, physicians see the disruption to the outline of the normal carpal bone anatomy and the relationship between each of the carpal bones is compromised, due to the narrowing of the joint space (Moore, 2017). This debilitating disease affects quality of life and patients usually seek care to try to relieve chronic pain and retain function of their wrists to continue everyday tasks.

Figure 5: Radiographic Comparison of the Wrist. This figure shows the wrist with rheumatoid arthritis (left) compared to a normal wrist (right).
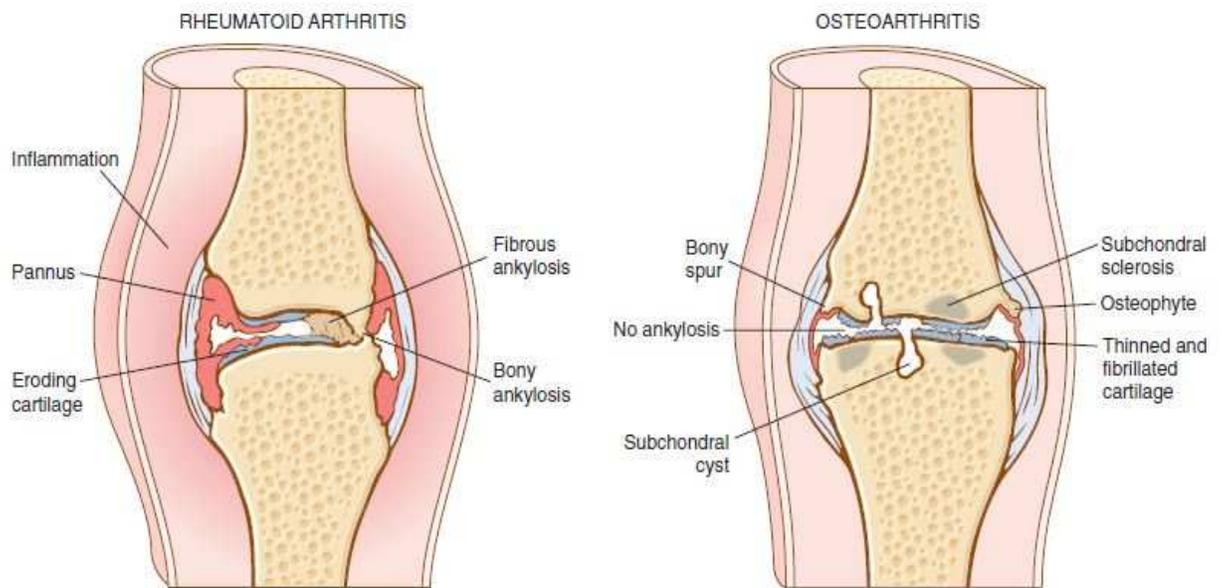
In contrast to RA, osteoarthritis (OA) is a non-inflammatory type of arthritis that can affect the fingers, hand, and/or wrist joints. OA occurs when the articular cartilage starts to degenerate due to mechanical stress and aging (Kumar et al., 2013). When the articular cartilage starts to deteriorate, patients lose the extra

support on their bones to absorb some of the shock and force on the joints, which can be painful when trying to use the affected joint. OA can occur due to an injury, which is considered post-traumatic arthritis, or secondary arthritis. In post-traumatic arthritis, the articular cartilage or bone is damaged due to physical injury and the result is the joint becomes arthritic. As opposed to RA, the joints most often affected by OA are the distal interphalangeal (DIP) and first carpometacarpal (CMC) (Kumar et al., 2013). OA in the hands are more common in females compared to males (Drake et al., 2012). Diagnosis of OA relies on complaints of stiffness, pain, and radiographic imaging (ASSH, 2017c). On radiographic imaging, physicians can detect OA by the presence of osteophytes, which occurs in response to OA when the bone attempts to remodel itself (McKean, 2017).

Initial conservative treatment options for hand OA include nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, or splinting. Operative treatment options include fusing the phalangeal joint (McKean, 2017). For CMC (thumb) arthritis, conservative treatment includes the above options, as well as thumb muscle strengthening exercises with a hand therapist (Abbasi, 2017; ASSH, 2017c). Some patients will seek therapeutic care for their arthritis and recently turmeric has been utilized for treatment of arthritis. It is thought that the anti-inflammatory properties in turmeric could help prevent degradation of articular cartilage without having side effects (Henrotin, Priem, & Mobasheri, 2013). When conservative treatment options fail to relieve pain, patients may seek operative treatment for OA, such as joint fusion, which connects the bones of the joint

together, or for thumb OA, removing the carpal bone (trapezium) and replacing it with a tendon to act as a cushion (Abbasi, 2017; ASSH, 2017e). In most instances, patients choose operative treatment in order to address the chronic pain associated with OA.

Figure 6 shows the difference between RA and OA. RA occurs when the immune system attacks the joint space and OA is a natural thinning of the cartilage (Kumar et al., 2013).

Figure 6: Rheumatoid Arthritis versus Osteoarthritis. This figure shows the features of rheumatoid arthritis (left) compared to osteoarthritis (OA) (adapted from Robbins Basic Pathology, 9th Ed.).

Post-traumatic arthritis usually occurs after an injury to the scaphoid bone, which is important for wrist movements (Laulan, Marteau, & Bacle, 2015). Injury to the scaphoid or other carpal bones in the proximal row can proceed to disrupt the

wrist joint. For instance, after a scaphoid fracture, there is a chance that the bone does not heal properly and can result in a scaphoid nonunion. An injury to the scaphoid can lead to a scaphoid non-union advanced collapse (SNAC) wrist. After a tear or other injury to the intrinsic ligament between the scaphoid and lunate – scapholunate (SL) ligament, the wrist can progress to a scapholunate advanced collapse (SLAC) wrist (Orthobullets Team, 2017; Vitale, 2017). Both of these conditions tend to be associated with post-traumatic OA in the wrist (Laulan et al., 2015). In both situations, surgical intervention may be the only treatment option to preserve wrist function.

Treatment Options for Wrist Joint Conditions

Although there is no cure for RA or OA, there are several treatment options, which aim to slow the progression of the disease and provide pain relief. Initial conservative treatment for RA consists of anti-inflammatory medication and anti-rheumatoid medication (McBeath & Osterman, 2012). With the advancement of these medications, some patients do well with conservative treatment alone. However, as the disease progresses or if conservative treatment alone does not provide relief, orthopedic surgical intervention may be necessary. In treating injuries or diseases at the wrist joint, hand surgeons try to resolve pain while preserving wrist joint function. However, in some instances, the only option is to sacrifice wrist function and motion to address painful arthritis. Joint preserving treatments include a synovectomy to remove inflamed synovium around the joint or

a tenosynovectomy to remove inflamed tissue around the tendon (Weisman &

Rinaldi, 2016). Other options include removing the proximal carpal bones that

articulate with the distal radius and distal ulna to provide some pain relief, which is

known as a Proximal Row Carpectomy (PRC). After an injury to the SL interosseous

ligament (SLIL), surgeons attempt to reconstruct the ligament in order to provide

stability to the wrist. When the distal radio-ulnar joint (DRUJ) is affected, the distal

ulnar head can be removed to allow for wrist movement without pain, which is

known as the Darrach procedure (Trieb, 2008). Additionally, partial wrist fusions

could help relieve pain at the wrist before undergoing complete wrist replacement

or fusion (Ilan & Rettig, 2003). Limited fusions involve connecting some of the

carpal bones, such as fusing the radius and lunate (RL), distal radius to the scaphoid

and lunate (RSL), or the scaphoid, trapezium and trapezoid (STT) (Gaspar, Kane, &

Shin, 2015). Physicians can elect to perform partial joint replacement as another

treatment option. A partial joint replacement, hemiarthroplasty, replaces either the

proximal carpal row or the distal radius (Gaspar et al., 2016). If these initial options

fail to provide relief or in patients with late-stage RA, there are few other surgical

treatment options available. Other surgical interventions include total joint

replacement or total joint fusion to relieve pain.

Wrist Joint Replacement

Total wrist arthrodesis (fusion) is a surgical option for relieving pain, but at

the expense of normal wrist function. After a wrist fusion, patients can no longer

bend at the wrist joint. With this in mind, physicians consider their patients' lifestyle

before considering a fusion as a treatment option. Typically, patients that undergo

wrist fusion are younger (Melamed, Marascalchi, Hinds, Rizzo, & Capo, 2016). With

the improvement in treatment options to preserve the wrist joint, the TWA has

become an option for patients to relieve pain, while maintaining mobility. As this

has become the better option, indications for the procedure have widened (Ogunro,

Ahmed, & Tan, 2013). In 2008, Weiss et al. determined that 179 TWAs were billed to

Medicare in the United States (Weiss AP, Kamal RN, 2013). Patients that undergo

TWA are usually older and have RA with low-demanding lifestyles, which do not

require a lot of stress on the hand and wrist, for instance, someone who is not a

laborer or does not play a sport or instrument (Melamed et al., 2016). Implant

designs have continued to improve over the years as this treatment option has

become favorable to physicians and patients. Previous implant designs include a

silicone implant, which resulted in frequent cases of silicone synovitis (Kennedy &

Huang, 2016b). The earlier generations of implant designs required cementing to

hold the implants in place (Halim & Weiss, 2017). The newest generation of implant

designs no longer use cement and instead are porous to allow for osseous

integration. In all implant designs, contraindications include patients with active

infection or poor bone quality, which could result in implant failure (Kennedy &

Huang, 2016b).

　　　The TWA procedure involves removing the abnormal bone and joint and

replacing it with a wrist implant (ASSH, 2017a). Figure 7 shows an example of a

wrist with a common TWA implant, Universal 2 Total Wrist Implant System (Integra

LifeSciences, Plainsboro, NJ), compared with a radiographic image of a wrist after

undergoing treatment for a total wrist fusion. In the left example in Figure 7, the

proximal part of the prosthesis is fixed in the distal radius and the distal part is

fixated with screws to the distal carpal row and metacarpal of the index finger with

the proximal carpal row resected. In most RA cases, a Darrach procedure is

performed prior to inserting the implant (Weiss AP, Kamal RN, 2013). In the right

example in Figure 7, the procedure for a wrist fusion involves fixing a single plate

over the distal radius straight to the third metacarpal, over the lunate and capitate.

However, there are many complications related to a TWA, which can lead to

reoperation or implant removal. These complications include implant loosening,

dislocation, infection, and tendon rupture (Boeckstyns et al., 2013). In some cases,

carpal tunnel syndrome (CTS) can occur due to compression on the median nerve

that travels under the carpal bones, which results in loss of sensation in the thumb,

index, middle, and ring fingers (Gaspar et al., 2016; Zyluk, 2013).

Figure 7: Total Wrist Arthroplasty Compared to Wrist Arthrodesis. This figure shows a radiographic image of the wrist after undergoing a TWA using a Universal 2 implant (left) compared to a wrist after a wrist arthrodesis (right).

SPECIFIC AIMS

Although TWA attempts to preserve mobility in comparison to total wrist arthrodesis, complications can occur that result in reoperation. Although current indications for a TWA include many debilitating wrist joint conditions, there should be careful consideration when choosing to perform this procedure on any patient because of the risk of complications. These complications include implant loosening, implant dislocation, infection, tendon ruptures, and carpal tunnel syndrome (CTS) (Boeckstyns et al., 2013). Previous research has shown that there is a relatively high rate of reoperation after a TWA procedure, but few studies have shown specific risk factors that lead to these complications (Gaspar et al., 2016).

Retrospective database studies allow for comparison of various treatment outcomes after relatively rare procedures, which cannot be easily be studied by randomized clinical trials. Database studies allow for researchers to capture relatively rare events and compare complications after procedures (Grauer & Leopold, 2015). In a previous study performed by Gaspar et al., they described complications after distal radius hemiarthroplasty, carpal hemiarthroplasty, and TWA performed by 1 or 2 attending surgeons (Gaspar et al., 2016). The goal of this retrospective study was to determine the rate of reoperation and implant removal after a primary TWA. This study attempted to identify potential risk factors for unplanned reoperation and implant removal after TWA. We tested the primary null hypothesis that there are no demographic- and surgical-related factors associated with reoperation or implant revision after TWA. We also studied the secondary null

hypothesis that there are no identifying radiographic features that predict

reoperation or implant revision. Our study allows for comparison of treatment

outcomes after TWA performed by various attending surgeons at two academic

medical centers and one affiliated community hospital in one metropolitan location.

METHODS

After obtaining Institutional Review Board (IRB) approval, we used Current Procedural Terminology (CPT) codes to identify subjects that underwent a TWA between January 2002 and December 2015. We used the following CPT codes 25332, 25441, 25442, 25443, 25444, 25445, 25446 for "wrist arthroplasty" or "arthroplasty with prosthetic replacement, distal radius," "arthroplasty with prosthetic replacement, distal ulna," "arthroplasty with prosthetic replacement, scaphoid," "arthroplasty with prosthetic replacement, lunate," "arthroplasty with prosthetic replacement, trapezium," "arthroplasty with prosthetic replacement, distal radius and partial or entire carpus," respectively. In order to identify subjects that underwent a removal of a wrist prosthesis or revision, we used CPT codes 25250, 25251, 25449 for "removal of wrist prosthesis; separate procedure," "removal of wrist prosthesis; complicated, included total wrist," and "revision of arthroplasty, including removal or implant, wrist joint." We included subjects at two tertiary academic medical centers and one community hospital in one metropolitan area. We excluded subjects that were under the age of 18 at the time of procedure and subjects that had an initial TWA procedure performed at another institution.

We identified 30 primary TWAs performed on 26 patients by 5 attending surgeons. After manually reviewing medical records, we excluded one patient because the primary indication for a TWA was due to giant cell tumor in the distal radius, which would lead to multiple operations not indicative of implant failure

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that could be relatable to the general population that undergoes an operation for TWA. Our final study cohort consisted of 29 primary TWAs performed on 25 patients. Four patients had bilateral TWA, 15 had right-sided TWA, and 14 had left-sided TWA. In order to identify potential risk factors related to reoperation, we manually reviewed medical records. Our search included demographic-related factors, including age at the time of surgery, sex, race, as well as patient- or disease-related factors, such as tobacco use, diabetes, indication for surgery, prior wrist surgery, hand dominance, and surgical-related risk factors, such as the type of implant.

Reoperation was defined as any unplanned wrist surgery related to the TWA, as opposed to a staged surgery where another surgery is planned in addition to the TWA. For instance, a TWA may be implanted but a pin is placed at the index surgery to treat a different condition. The removal of the pin would be a planned surgery. Implant removal was defined as any surgery that involved the removal or replacement of the implant after the initial TWA. The surgeon and patient determined the decision for reoperation or implant removal.

Pre-operative radiographs were obtained to evaluate the severity of subluxation and wrist deformity in 24 wrists. Pre-operative radiographs were not available for 5 of the 29 wrists. In order to determine if there were radiographic features that predicted reoperation, we developed a score to determine if pre-operative wrist deformity was significantly associated with reoperation and/or implant removal. The subluxation score range was from 1 to 4, where 1 = no

abnormal carpal relationship; 2 = abnormal carpal relationship; 3 = subluxation

with abnormal carpal relationship; and 4 = complete subluxation. Figure 8 shows

examples of radiographs at each subluxation score. One trained investigator and one

physician reviewed all pre-operative radiographs for any carpal abnormality and/or

subluxation and then reviewed them with an experienced orthopedic hand surgeon.

Figure 8: Subluxation Scores. This figure shoes the radiographic progression of the subluxation scores, where 1 contains no abnormal carpal relationship; 2 contains an abnormal carpal relationship; 3 has subluxation with an abnormal carpal relationship; 4 has complete subluxation.

Statistical Analyses

We calculated the reoperation rate and implant removal rate as a percentage of the total number of TWAs performed. Descriptive statistics were used to report the rate and time between the initial TWA and reoperation and between initial TWA and implant removal. In order to determine the most accurate representation of the variables, we first checked for normal distribution by histograms, Q-Q plots, and the Shapiro-Wilk test. When the variable is normally distributed, a histogram has a bell-shaped curve, which implies that most of the cases are near the mean. A Q-Q plot is another graphical representation of distribution of data. When the points are along the diagonal line, it means that the variable is likely to be normally distributed. A Shapiro-Wilk test is a numerical test for normality. A *P*-value of <0.05 means that there is a 1 in 20 chance that this test is normally distributed. If the *P*-value is >0.05, the mean is not an accurate representation of the variable and therefore the data is skewed. When the data is skewed, the median is a better representation of the variable.

Categorical variables were reported as frequencies and percentages and continuous variables were reported as median and interquartile range (IQR) after assessment for normal distribution by histograms and the Shapiro-Wilk test. When analyzing the radiographic subluxation scores, due to the low number of available pre-operative radiographs (n=24) we combined the scores to create two groups: no subluxation (scores 1 and 2) or subluxation (scores 3 and 4). We used a Fisher's exact test to compare the distribution of categorical explanatory variables among

wrists that did and did not undergo reoperation or implant removal. We used a Mann-Whitney-U test to compare continuous explanatory variables among wrists that did and did not undergo reoperation or implant removal, and calculated P-values. P-values of <0.05 were considered statistically significant. Due to the low overall number of TWAs and reoperations, we were not able to perform multivariable logistic regression analyses.

We used a Kaplan-Meier survival curve to display the time for implant survival. As each subject has an implant removed, the number of implants surviving decreases over time until the last event. In our case, the last event was at the final follow-up.

All statistical analyses were performed using the Data Analysis and Statistical Software Stata 13 (StataCorp LP, College Station, TX, USA).

RESULTS

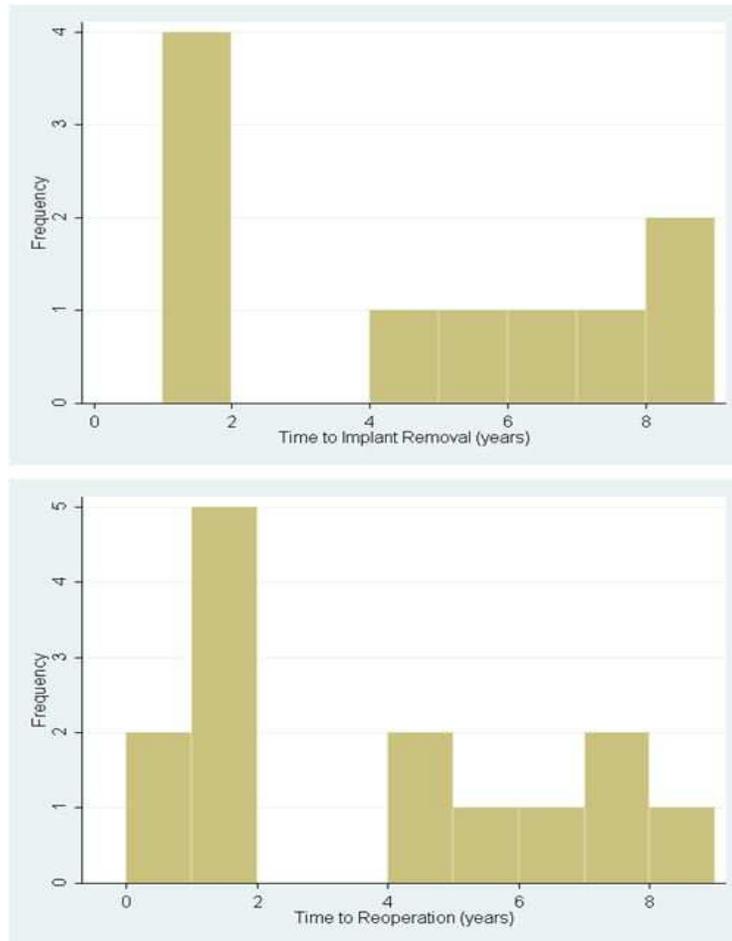### *Description of Patient Characteristics*

The median age of the patients at the time of the initial TWA procedure was 54 years (IQR, 46-58 years). Female patients represented 83% of the total TWAs performed. There were 24 wrists that had pre-operative radiographs available for evaluation. There was no abnormal carpal dislocation in 3 wrists (12.5%), an abnormal carpal relationship in 9 (37.5%), subluxation with an abnormal carpal bone relationship in 8 wrists (33.3%), and complete subluxation in 4 wrists (16.7%). Rheumatoid arthritis was the primary indication for 86% of all TWA procedures (25 out of 29 wrists). Other indications were: osteoarthritis for 1 wrist (3.45%), post-traumatic arthritis for 1 (3.45%), inflammatory arthritis for 1 (3.45%), and Kienbock disease was the primary indication for 1 (3.45%) wrist. The Universal 2 Total Wrist Implant Systems device was used in 27 wrists (93.1%) and the DePuy Biaxial (DePuy Orthopaedics, Inc., Warsaw, IN) was used in 2 wrists (6.90%). Five patients had wrist surgery prior to their TWA (17.2%). The average final follow-up time was 5 years (Standard Deviation [SD], 3.97; range: 0-13 years), 6 patients had a final follow-up of less than 1 year.

Reoperation and Implant Removal

The rate of reoperation was 48% (14 of 29 TWAs performed); of which 34% (10 of 29) underwent a reoperation for implant removal. 2 wrists (6.9%) had at

least 1 reoperation before implant removal for wrist contracture (n=1) and progressive deformity (n=1). Of the 14 wrists that underwent reoperation, 5 wrists had component loosening, 4 had a tendon rupture, and 3 had an infection (Table 1). 1 patient had an additional operation after implant removal for symptomatic hardware after conversion to an arthrodesis. Five patients had wrist surgery prior to their TWA, of whom 4 eventually had their implant removed.

After testing for normality by histogram and Shapiro-Wilk test, we found that the data was normally distributed for both time to reoperation (P-value = 0.110) and time to implant removal (P-value = 0.895) (Figure 9). The average time to the first reoperation was 3 years (SD: 3; range: 0-9 years). The average time to implant removal was 4 years (SD: 3.2; range: 1-9 years).

Figure 9: Histogram to Test for Normality. The figure above represents the histogram to test for normally-distributed data for the average time to implant removal (top) and average time to reoperation (bottom). Normal distribution was confirmed by using the Shapiro-Wilk test.

Table 3: **Overview of Reoperations and Implant Removals.** This table reports the patient characteristics of all included TWA manually reviewed. The age reported for each unique patient is the age at the time of primary TWA.

Patient	Sex	Age	Side	Indication	Prior surgery (number)	Type of prior surgery	Reoperation (number to implant removal)	Indication for Reoperation	Implant removal	Time to implant removal (months)
1	M	65	Left	RA	No		Yes (1)	Infection	Yes	58
2*	F	39	Left	RA	Yes (1)	Distal Ulna Resection	Yes (1)	Loosening	Yes	89
		40	Right	RA	No		Yes (1)	Loosening	Yes	72
3	M	53	Left	Kienbock's disease	Yes (2)	Scaphocapitate Limited Fusion; PRC	No			
4	F	40	Left	RA	No		Yes (0)	Infection; CTS		
5	F	63	Left	RA	No		No			
6*	F	45	Right	RA	No		No			
		46	Left	RA	No		No			
7	F	58	Right	RA	No		Yes (1)	Infection; loosening	Yes	61
8	M	35	Left	Inflammatory arthritis	No		No			
9	F	58	Left	RA	No		No			
10	F	58	Right	RA	No		Yes (1)	Dislocated total wrist, CTS	Yes	119
11	F	61	Right	RA	No		Yes (0)	Flexor tendon rupture; infection		
12	F	58	Left	RA	No		No			
13	F	46	Right	RA	No		No			
14*	M	50	Right	RA	No		Yes (0)	Flexor tendon rupture; loosening		
		52	Left	RA	No		No			
*= Patient had bilateral TWA										

Table 1 continued: Overview of Reoperations and Implant Removals. This table reports the patient characteristics of all included TWA manually reviewed. The age reported for each unique patient is the age at the time of primary TWA.

Patient	Sex	Age	Side	Indication	Prior surgery (number)	Type of prior surgery	Reoperation (number to implant removal)	Indication for Reoperation	Implant removal	Time to implant removal (months)
15*	F	71	Right	RA	No		No			
		71	Left	RA	No		No			
16	F	55	Right	RA	No		Yes (1)	Flexor tendon rupture; loosening	Yes	16
17	F	56	Right	RA	No		No			
18	F	58	Right	RA	Yes (1)	RL Fusion, Distal Ulna Resection	Yes (1)	Infection	Yes	22
19	F	50	Left	RA	Yes (1)	Synovectomy, Darrach procedure	Yes (2)	Progressive deformity	Yes	104
20	F	56	Right	RA	No		No			
21	F	77	Right	OA	No		Yes (2)	Wrist contracture	Yes	13
22		37	Right	Posttraumatic arthritis	Yes (3)	Failed SL Ligament Repair with Scaphoid Lunate Fixation; Modified Brunelli; PRC	Yes (1)	Pain	Yes	12
23		76	Left	RA	No		No			
24	F	35	Left	RA	No		Yes (0)	Extensor tendon rupture		
25	F	57	Right	RA	No		No			
*= Patient had bilateral TWA										

Bivariate Analyses

In bivariate analyses, we found that prior wrist surgery was significantly associated with implant removal (P = 0.036). There were no other risk factors significantly associated with reoperation or implant removal. Table 2 demonstrates the results of our bivariate statistical analyses. Dominant side was not reported for 1 wrist (n=28). Not all wrists had available pre-operative radiographs for analysis of subluxation score (n=24). Analysis for subluxation score was initially performed for each score (1, 2, 3, 4). However, due to the low number of available pre-operative radiographs, subluxation scores were changed into a dichotomous variable and bivariate analysis was performed again. Subjects with a pre-operative subluxation score of 1 or 2 were combined and redefined as "no subluxation" and patients with a subluxation score of 3 or 4 were combined and redefined as "subluxation." We did not find a statistically significant associated with subluxation and reoperation or implant removal after performing each test.
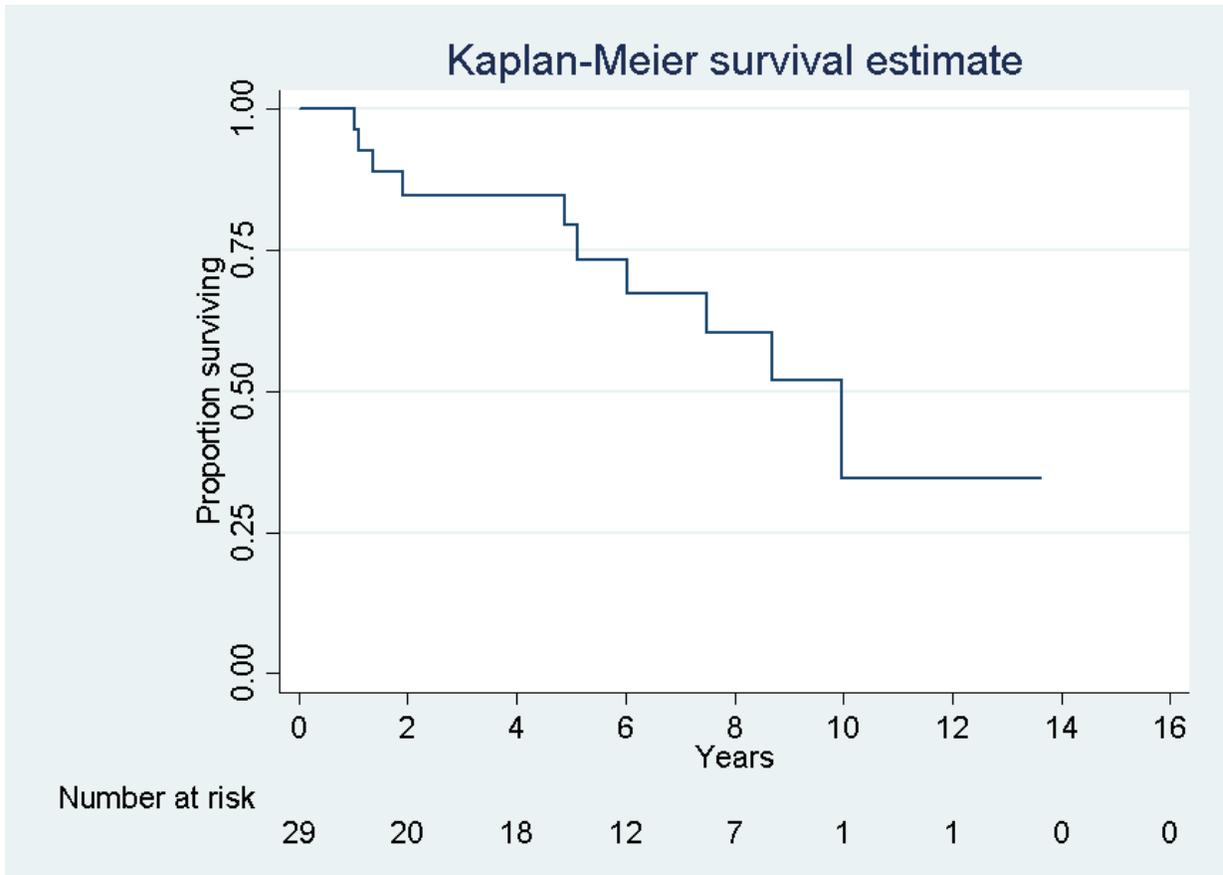
Table 4: Bivariate Analysis. Each continuous explanatory variable is presented as median and interquartile range (IQR). Bold face values indicate statistical significance of P < 0.05. Each bivariate explanatory variable is presented as frequency and percentage.

	Reoperation			Implant removal		
	Yes	No		Yes	No	
	n=14	n=15		n=10	n=19	
	(48%)	(52%)		(34%)	(66%)	
	Median (IQR)	**Median (IQR)**	*P-*value	**Median (IQR)**	**Median (IQR)**	*P-*value
Age	53 (40-58)	56 (46-63)	0.42	57 (40-58)	56 (46-61)	0.96
	n (%)	**n (%)**		**n (%)**	**n (%)**	
Sex			>0.99			0.63
Male	2 (14)	3 (20)		1 (10)	4 (21)	
Female	12 (86)	12 (80)		9 (90)	15 (79)	
Smoking status			0.69			0.28
Yes	2 (50)	2 (50)		1 (25)	3 (75)	
No	8 (57)	6 (43)		7 (50)	7 (50)	
Former	4 (36)	7 (64)		2 (18)	9 (82)	
Dominant side[a]			0.15			0.11
Yes	9 (69)	6 (40)		7 (78)	8 (42)	
No	4 (31)	9 (60)		2 (22)	11 (58)	
Rheumatoid arthritis			>0.99			>0.99
Yes	12 (86)	12 (80)		8 (80)	16 (84)	
No	2 (14)	3 (20)		2 (20)	3 (16)	
Race						
Caucasian	12 (86)	13 (87)	>0.99	9 (90)	16 (84)	>0.99
Not Caucasian	2 (14)	2 (13)		1 (10)	3 (16)	
Prior surgery			0.17			**0.036**
Yes	4 (29)	1 (6.7)		4 (40)	1 (5.3)	
No	10 (71)	14 (93)		6 (60)	18 (95)	
Subluxation[b]			>0.99			>0.99
Yes	5 (45)	7 (54)		4 (50)	8 (50)	
No	6 (55)	6 (46)		4 (50)	8 (50)	
[a]n=28; [b]n=24						

Kaplan-Meier Curve

Our Kaplan-Meier survival curve (Figure 10) demonstrated that at 5 years, of all patients, there was a 76% implant retention rate, and at 10 years, there was about a 30% implant retention rate.

Figure 10: Kaplan-Meier Survival Curve. Kaplan-Meier survival estimate curve for implant removal after TWA.

DISCUSSION

This study examined a large database to identify all of the TWAs performed at two tertiary academic medical centers in one metropolitan area. The aims of this study were to report the reoperation rate after TWA at our institution and to determine risk factors associated with reoperation or implant removal after TWA. We found that the rate of reoperation was 48%, of which 34% (n=10) underwent implant removal. The most common indication for reoperation was component loosening, which occurred in 5 wrists. The only risk factor statistically associated with implant removal was prior wrist surgery. Five patients had a prior wrist surgery, of which four had an implant removal. The prior surgeries performed on the four patients made the wrist weak on the ulnar side. This implies that the distal ulna may be an important component to a successful TWA. It has been demonstrated that poor bone stock is one of the contraindications to a primary TWA, which could be one of the reasons for this finding (Kennedy & Huang, 2016b). However, in the operative journey before a primary TWA, distal ulna resection is a good option to attempt to preserve wrist function while relieving chronic pain.

Besides a prior wrist surgery, we found no other factors statistically associated with an unplanned reoperation or implant removal. At the 5-year follow up, we found a 76% implant survival rate, which then decreased over time. The data from this database study, coupled with manual chart review, allows clinicians to

identify potential risk factors associated with revision surgery after TWA in order to improve clinical care for future patients.

Our reported high failure rate is consistent with previous studies. Ward et al. reported a 50% revision rate and a 75% implant survival rate at 5 years in a prospective study of the Universal wrist prosthesis (KMI, Carlsbad, California) in 24 wrist arthroplasties. They found that the most common reason for revision was due to implant loosening (Ward, Kuhl, & Adams, 2011). Another study performed using the Norwegian Arthroplasty Register (NAR), found a 78% five-year survival rate and 71% ten-year survival rate and the implant revision rate was 21% in 189 primary wrist replacements. They also found that females had a higher revision rate compared to males (Krukhaug, Lie, Havelin, Furnes, & Hove, 2011). However, a prospective study by Sagerfors et al. found a 5-year implant survival rate of >80% for all implant types studied, which could be attributed to the large sample size of 206 primary TWAs. The purpose of their study was to report patient reported outcomes and compare implant types (Sagerfors, Gupta, Brus, & Pettersson, 2015b). In the United States, TWA is still a relatively uncommon procedure so perhaps the surgeons participating in the study are more experienced and therefore more comfortable in performing TWA, which could explain their high survival rate. In a retrospective study looking at potential risk factors associated with complications following partial and total wrist arthroplasty in 105 wrist surgeries, Gaspar et al. found that prior surgery was associated with higher complication and revision rates (Gaspar et al., 2016). Because of the high number of Universal 2 implants, our study

could not draw specific conclusions regarding implant type compared to other studies. We did not find pre-operative features to be statistically associated with either reoperation or implant removal, which could be due to the low sample size available for analysis.

Due to the retrospective nature of this study, we did not look specifically at surgical technique or post-operative management. Surgical technique and post-operative care was determined by the attending physician. Our data represents the typical experience at the orthopedic practices included in our database, which may not be representative across all practices in the United States. Our data reflects variations in surgeon treatment preferences. Individual surgeon values could influence recommendations for TWA. For instance, the surgeons' treatment preferences may rely on several factors, such as patient characteristics and familiarity with surgical procedure and implant. Because this is a relatively rare procedure, many surgeons may not offer TWA as a treatment option if they do not have a lot of experience with a TWA implant or due to the low success rate. Additionally, because it is an uncommon procedure, it is not a standard for many fellowship-training programs (Melamed et al. 2016). Our data reflects what occurs when surgeons elect to perform a TWA without having implant device conflicts of interest or being strong advocates for TWA.

In addition to considering the risks of revision surgery, patients and physicians should consider the costs associated with both TWA and total joint fusion procedures. In a study performed by Caveliere and Chung, 2010, they found that the

total cost of a TWA was approximately $18,478 compared to $6,607 for a total wrist fusion, but after considering quality-adjusted life-years, TWA was adjusted to $2,328 more costly compared to total wrist fusion. The costs associated with TWA continue to increase dramatically when factoring in the costs of revision surgeries as well (Cavaliere & Chung, 2010).

Lately, there has been an increasing trend in orthopedics toward a shared decision-making model, where both physicians and patients are active members in deciding on the treatment plan. Shared decision-making allows for patients to consider their personal preferences when there are multiple treatments and there is not a clear consensus on the best option (Charles, Gafni, & Whelan, 1999). TWA is a treatment option that would benefit from the shared decision-making model so that patients also consider the risks and benefits of the various treatment options. It is important that patients and physicians consider our data and data from other studies when considering the surgical treatment options for RA, OA, or other traumatic injuries that result in wrist debilitation.

Limitations

There are several limitations to our study because of the retrospective nature of this study. This study represents the experience from two tertiary academic medical centers and one community hospital affiliated with one of the academic medical centers, therefore, our data may not be representative of all hospitals and the average physician and patient population. Additionally, we identified patients

using CPT codes, which are subject to coding errors; therefore we could have missed TWAs that were not included in our study cohort. In order to account for this limitation, we manually reviewed medical records. Because a majority of the implants used were the Universal 2 implant, we could not look specifically at implant-type and its association with reoperation or implant removal. Additionally, we are unable to comment on the surgical techniques and its affect on the rate of reoperation and implant removal.

Six patients did not return after 1 year, so we cannot draw conclusions on their post-operative course because there was no information in the medical record. We did not include patients that had their primary TWA performed at an outside institution and their revision operation performed at one of the academic medical centers included in our study. Patients could have followed-up at another institution, moved, or died, and therefore the revision rate and implant removal rate may be higher than we reported. We considered the final follow-up visit as the last visit related to the patients' TWA procedure at one of the three institutions included. Due to the retrospective nature of this study, we do not have any data on patient-reported outcomes after a primary TWA because this data was not available in the medical record system. In addition, due to the low number of TWAs included in our study cohort, we could not perform a multivariable logistic regression analysis. Therefore, we were not able to assess whether the association between an implant removal and prior surgery to the affected wrist was confounded by other potential risk factors.

Implications

This study and previous studies have demonstrated the treatment course after a primary TWA. It is important that surgeons inform their patients of this long journey associated with a TWA. With improvements in non-operative treatments for RA, patients are able to delay surgical intervention and opt for conservative treatments (Melamed et al., 2016). However, with the population living longer, patients can outlive the TWA implants and the treatment options for a patient after a TWA are limited. Recently, decision aids have been incorporated into orthopedic clinics in order to help patients become active participants in their clinical care and decide on the treatment best suited for them (Jayadev, Khan, Coulter, Beard, & Price, 2012). Surgeons and patients could both benefit from implementing decision aids for patients considering TWA. If patients understand the realistic expectations, perhaps their decision on whether or not to undergo a TWA would change. In a study performed by Aterburn et al. 2012, they looked at the effects decision aids have on surgery rates for total hip and total knee replacements and found that the intervention group that received a decision aid was less likely to undergo operative treatment for a total joint replacement compared to the control group (Arterburn et al., 2012). Therefore, the implementation of a decision aid for treatment options for advanced RA, OA, or debilitating wrist joint diseases, could help patients make an informed decision on the best course of treatment. Future studies should look at the effect of reviewing a decision aid prior to treatment of RA or OA on patient satisfaction and patient outcomes.

CONCLUSIONS

In conclusion, patients should be counseled that reoperation and implant removal after a primary TWA are common. Surgeons should consider their patient's characteristics, in particular a prior wrist surgery, in the decision-making process when electing to perform a TWA. Together, surgeons and patients should consider the reoperation rate and implant removal rate when making a shared decision about whether TWA is worth the risks associated with the long journey after a TWA, which could ultimately end in a total wrist fusion. Effective shared decision-making is important when considering a TWA given that approximately 1 in 3 TWAs will need at least one revision surgery.

LIST OF JOURNAL ABBREVIATIONS

ASSH   American Society for Surgery of the Hand

J Am Acad Orthop Surg   Journal of the American Academy of Orthopaedic

                              Surgeons

J Bone Jt. Surg Am   Journal of Bone Joint Surgery America

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