Title

Total Elbow Arthroplasty: A Prospective Clinical Outcome Study of Discovery Elbow System with a 4-Year Mean Follow-Up

Running Title

Clinical Outcome of the Discovery Elbow

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Disclaimer: Professor Frostick received royalties and consultant payments from Biomet Inc.

Ethical Approval: Sefton Research Ethics Committee - REC Number: 08/H1001/109

Trust Study Number: 3735

Total Elbow Arthroplasty: A Prospective Clinical Outcome Study of Discovery Elbow System with a 4-Year Mean Follow-Up

Abstract

Background: Total elbow arthroplasty (TEA) is increasingly used for the treatment of advanced elbow conditions to reduce pain and improve function. However, TEA is still associated with a higher complication rate compared to the total hip and knee arthroplasty despite advances in the design and surgical techniques. This prospective clinical study reports the outcome of the Discovery Elbow System (Biomet Inc., Warsaw IN, USA) system which has been in clinical use in the UK since 2003.

Methods: The study included a total of 100 Discovery elbows (April 2003 to January 2010) with a minimum 2-year follow-up including 75 primary and 25 revisions (60 % females and 40% males; mean age, 62 years). Outcome was assessed by means of Liverpool Elbow Score, pain experience, patient satisfaction, range of movement, and radiographic imaging.

Results: Mean follow-up was 48.5 months (range: 24-108 months). Liverpool Elbow Score improved from 3.79 to 6.36 (P<.001). Pain-free patients were substantially increased form 7% preoperatively to 64% at the final follow-up. Patient satisfaction rate was over 90%. The arc of flexion-extension and pronation-supination increased from 72º to 93º and from 86º to 111º, respectively (P<.001). Major post-operative complications included deep infection (2%), progressive aseptic loosening requiring revision (primary, 5%; revision 12%), persistent ulnar neuropathy (3%), and periprosthetic fracture (primary, 6.8%; revision, 8%).

Conclusion: Discovery elbow resulted in improved function, reduced pain, and high patient satisfaction. Long-term results are required for assessing the survivorship of this system.

Keywords: Total Elbow Arthroplasty; Discovery Elbow; Clinical Outcome; Elbow Prostheses.

Level of Evidence: Level III

BACKGROUND

Total elbow arthroplasty (TEA) has increasingly become a popular reconstructive procedure due to improved surgical techniques, advanced implant designs, and enhanced clinical outcomes.[39] The modern era of TEA began in the late 1970s when the prosthetic design evolved following several key developments: the use of high-density polyethylene as a bearing surface to metal, the use of methyl methacrylate bone cement, and the implementation of biomechanical science to reproduce normal joint kinematics.[7] Modern TEA implants are designed as linked or unlinked. Linked implants are coupled together through a hinge allowing for some degrees of laxity in the medial, lateral, and rotational planes consistent with normal elbow kinematics. A "sloppy hinge," design is associated with a reduced the rate of aseptic loosening and instability of the articulation.[32] Unlinked implants are not mechanically coupled and mostly rely on matching shapes of the bearing surfaces, adequate bone stock, and, the integrity of capsular and ligamentous structures.[5,7] Unlinked designs have been associated with higher rate of instability as their stability mainly depends on their geometry and surrounding soft tissues (ligaments and bone stock) rather than the intrinsic constraint of the articulation.[5]

The use of unlinked prostheses may be preferred when there is less bone or articular destruction and in younger patients who may need later revision surgery. From the other hand, the increased stability of the linked implants has expanded their use in conditions with increased bone destruction and ligamentous incompetency such as advanced stages of rheumatoid arthritis, posttraumatic and degenerative osteoarthritis, and complex distal humerus and intra-articular fractures (particularly in elderly patients).[5,7,21]

Despite considerable developments in the prosthetic design, TEA has been associated with a high rate of complications, ranging from 20% to 45%, compared to other main total joint (hip

and knee) replacements[14,25,37] potentially because of the difficulty of surgical procedure in a complex joint with minimal soft tissue support.[10] Gschwend et al,[14] reviewed the literature and reported an overall complication rate of up to 43% including aseptic loosening, infections, ulnar nerve complications, instability, disassembly, dislocation, subluxation, intraoperative fractures, fractures of the prosthesis, implant loosening, periprosthetic fracture, triceps insufficiency, and ectopic bone formation. In another review, Little et al,[25] reported a complication rate of 14%-80% including deep infection and septic loosening (up to 10%), ulnar neuropathy with permanent dysfunction (up to 10%), hinge failure (up to 6%), and polyethylene bushing wear (14% to 47%) for various semiconstrained prostheses.

The Discovery Elbow System (Biomet Inc, Warsaw, IN, USA), was developed with the intention of addressing some of above issues associated with previous linked designs by means of decreasing polyethylene bushing wear, reinforcing anatomic stem design, restoring natural elbow joint biomechanics, and producing a hinge that could be easily revised.[16] The Discovery elbow has been in clinical use in the UK since 2003. The structural specifications and design rationale of the system have been described in full details by Hastings and Theng[18] and Hastings.[16]

This study aimed to 1) report functional and radiological outcome of the Discovery elbow in a large series of primary and revision TEAs with various elbow pathologies; and 2) compare the clinical outcome and complications with published literature on other prostheses.

PATIENTS AND METHODS

One hundred Discovery elbows with a minimum 2-year follow-up were included in the study. All TEAs were performed in a single centre by the same surgeon (April 2003 to January 2010). The technical properties of the prosthetic system and surgical technique have been described in full details by Hastings et al.[16]

The mean age of patients (females, 60 %; males, 40%) was 62 years (range: 22-86), weight 71.8kg (±18.3), and height 166 (±12.5). The mean follow-up period was 48.5 months (range: 24-108 months). Inclusion criteria were advanced arthritis unresponsive to non-operative management, acute distal humerus fracture and revision for loosening of other elbow prostheses in skeletally mature patients (>18 years old). Exclusion criteria included systematic metabolic diseases affecting the bone formation and active infection. The main underlying pathologies (diagnoses) are outlined in Table1. Primary and revision TEA comprised 75% and 25% of the cases, respectively. Study received approval from a local research ethics committee and all patients gave informed consent prior to the surgery.

FOLLOW UP ASSESSMENT

Functional Outcome

Main clinical information and data including underlying pathology (primary diagnosis), type of TEA (primary, revision), follow-up period, pain experience, patient satisfaction, range of movement (flexion/extension of the elbow and pronation/supination of the forearm), and complications were collected using a purpose-designed elbow arthroplasty proforma. A validated elbow score, Liverpool Elbow Score (LES), was also used for functional assessment.[33,38] The patient-rated section of the LES has good correlation to MEPS and has been suggested as an outcome measure for evaluating results of TEA.[4] The AO handbook for Musculoskeletal Outcomes Measures and Instruments rated this score as a superior quality

outcome assessment tool compared to the Mayo Elbow Performance Score (MEPS).[36] A score of 0 and 10 indicate worst and best outcome, respectively.

Radiographic assessment

Where available, the anterioposterior and lateral views of pre- and postoperative plain x-rays (Figure.1) were reviewed for humeral and ulnar stem alignment in sagittal and coronal planes, aseptic loosening, periprosthetic fracture, dislocation, and hypertropic ossification. Imaging assessment pattern followed the principles explained in a recent comprehensive radiographic review of TEA.[29] For assessing the component alignment, angles between the axis of the shaft of humerus and the stem of the humeral component and between the axis of the shaft of ulna bone and the stem of the ulnar component were measured in the early post-operative x-rays.[12] A malalignment of $>10^{o}$ was considered as significant.[11,12,37] Periprosthetic fracture was evaluated based on Mayo Classification System (Figure.2).[28]

Data Analysis

Continuous and descriptive data are reported as mean and standard deviation (Mean $\pm$ SD) and 95% confidence interval. Categorical data are described using proportion and percentage. Paired Student *t* test or ANOVA were used to compare the preoperative LES and ROM with those at the final follow-up for the entire patient group and according to underlying pathology (primary diagnosis) and type of TER (primary, revision), as appropriate. The level of significance was set at 5 % ($p < 0.05$). SPSS package (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) was used for data analysis.

RESULTS

Functional Outcome Results

Preoperatively, 61% and 21% of patients experienced severe and moderate pain, respectively which was then reduced to 11% and 14% post-operatively. The percentage of pain-free patients was substantially increased form 7% preoperatively to 64% at the final post-operative follow-up. In terms of patient satisfaction, 63%, 8%, and 23% of patients were classified as 'Very Satisfied', 'Somewhat Satisfied', and 'Satisfied', respectively. Only 6% remained unsatisfied with the outcome mainly involving revision cases.

The mean preoperative and final follow-up LES were 3.79 (±1.71) and 6.36 (±1.85), respectively which highlighted a significant improvement ($p< 0.001$). Similar improvements were observed for all main pathology groups (inflammatory and non-inflammatory arthritis, and Fracture), however, LES improvement was significantly higher in the primary (6.41±17) compared to revision TEA (5.78±14) ($p<0.05$). Table 2 summarises the results of ROM for flexion and extension of the elbow and pronation and supination of the forearm for entire patient group and according to the main diagnoses. Except elbow extension (extension lag) all movements including flexion-extension and pronation-supination arc were significantly improved. ROM improvements in revision TEA were comparable with those of primary TEA.

Radiographic Assessment Results

Imaging was available for 88 TEAs (88%) (primary, 70; revision, 18). Table3 presents the degree of alignment of humeral and ulnar components (stems) in both sagittal and coronal planes. Around 90% of the evaluated TEAs presented with a good alignment (<5º) for both components in both planes. A significant malalignment (>10º) was seen in one primary TEA elbow; however it was not associated with early loosening.

The overall incidence of periprosthetic fracture was 14.8% (primary, 6.8%; revision, 8%) involving humeral condyles and olecranon in 9.1% and 5.7% of elbows, respectively. All fractures were classified as Mayo Type 1 and managed conservatively. Hypertropic ossification occurred in 6.8% of TEAs (primary, 5.7%; revision, 1.1%).

In the primary group, areas of non-progressive lucency were noted around the bone-cement interface of 10 TEAs without any further progression. Marked osteolysis around the humeral component observed in two cases but the prosthesis remained stable with no need for revision. Four TEAs developed significant osteolysis and required revision of either humeral component (n=3) or both humeral and ulnar components (n=1). In the revision group, non-progressive lucency was noted in seven TEAs. Marked osteolysis occurred in one elbow (humeral component); however, prosthesis remained stable with no need for revision. Three revision cases developed progressive loosening of both humeral and ulnar components; two underwent 2nd revision and one is awaiting revision.

Complications

In addition to the complications reported in the radiographic assessment results (malalignment, periprosthetic fracture, aseptic loosening, and hypertrophic ossification), deep infection occurred in 2 cases (both required a 2-stage revision), persistent ulnar neuropathy in 3 cases (managed with nerve decompression and transposition), and prosthetic failure (dissociation of the condyle and screws from main components) in 1 case (revised).

DISCUSSION

Despite recent developments in the design of elbow prostheses, advances in surgical techniques, and marked improvements in pain and function, TEA is still associated with high complication and revision rates compared to hip and knee arthroplasty.[7,38,40] This high complication rate is partly related to the anatomical characteristics of the elbow such as insufficient bone stock for implantation and lack of strong supporting soft tissue.[3,23]

Elbow prostheses have been used for decades in linked (e.g. Coonrad-Morrey, GSB III, Triaxial, Discovery System) and unlinked (e.g. Kudo, Souter-Strathclyde, IBP) or both linked and unlinked (e.g. Acclaim) modes. The Discovery elbow is a linked prosthesis with a design that mimics the anatomical characteristics and kinematics of the elbow joint. The present study reports the clinical outcome of TEA with this system over a 4-year mean follow-up and compares the results with other reports. However, direct comparison of clinical outcomes amongst different TEA implants is a challenging task because of heterogeneity in reporting methods of function, pain experience, patient satisfaction, and radiographic assessment.

Pain relief is one of the prime benefits following any joint arthroplasty. In the present study, around 64% of cases had no pain at the final follow-up. The majority of the studies on TEA have used percentage of patients with no pain or mild pain as measure of success of the procedure. By that standard, 78% of our cases had either no pain or only mild pain at final follow-up. The percentage of patients with no pain or mild pain after undergoing Acclaim,[6] Souter-Strathclyde,[31] GSB III[14,22,34] and Coonrad-Morrey[25,35] have been reported as 64%, 67%, 50–92% and 60-100%, respectively. Overall the patient satisfaction rate for our series was 94% with 63% of patients reporting maximal satisfaction (Very Satisfied). A study of different linked prostheses (11 elbows) reported a 73% satisfaction rate.[40] In a study of 51 elbows using the Coonrad-Morrey prosthesis, Hildebrand et al,[19] reported patient satisfaction

of 9.2/10 in inflammatory arthritis and 8.6/10 in posttraumatic arthritis. A recent study of Discovery Elbow replacement patients in 46 elbows reported a patient satisfaction rate of 9.1/10.[17]

Functional capacity was markedly improved in our cohort of patients according to the LES which integrates both patient self-evaluation and clinician's assessments. The majority of TEA studies, however; chose to use MEPS for functional assessment. Considering the strong correlation between LES and MEPS,[4] the marked improvement found for the LES in the present study are in line with those reported for other prostheses.[2,24-26,30] The mean improvement in flexion-extension arc in our TEA series was 21º. Based on systematic reviews of semiconstrained linked and unlinked TEA prostheses, the average improvement in flexion-extension arc ranged between 12º-39º with a weighted improvement of 26°.[25,38] According to individual studies, the mean improvement in flexion-extension arc with Acclaim,[6] Souter-Strathclyde,[31] GSB III,[20,22] and Coonrad-Morrey prostheses[35] were 23º, 15º, 19º-33º and 17º-26º, respectively. A recent study of 46 Discovery elbows reported an improvement of 40º in flexion-extension arc.[17] The mean improvement in pronation-supination arc in our series was 25º. This movement arc has been reported as 21º-28º for Coonrad-Morrey prosthesis[35] and 31º-67º for GSB III prosthesis.[20,22] Hastings et al,[17] reported an increase of 29º in pronation-supination arc with Discovery elbow. It has to be taken into consideration that our reported results combine both primary and revision TEAs.

Deep infection remains the most worrying complication with a rate of around 4% infection reported in longer-term TEA studies.[9,25] The overall incidence of deep infection in our series was 2%. The incidence of deep infection with GSB III TEA has varied between 4%-11%.[14,22,34] Studies on Coonrad-Morrey TEA have reported an infection incidence rate of 6%-8%.[19,25] Hastings et al,[17] recently summarised complications for Coonrad-Morrey, GSB

III, Solar, and Discovery prostheses in 595 TEA patients (561 primary, 34 revision) and cited the average rate of deep infection as 2.9%.

Progressive aseptic loosening requiring revision occurred in 4 primary (5%) and 3 revision (12%) of our series. This complication has been reported in association with other linked prostheses including Coonrad-Morrey (0%-7%),[1,13,15,19,25] GSB III (4%-29%),[8,14,20,34] and Souter-Strathclyde (up to 31%).[15,24,30] Summarising the complication reports from linked devices, Hastings et al,[17] and Kelly et al,[22] have cited the average rate of primary aseptic loosening as 8.9% and 4%-50%, respectively. In a recently published study of 46 Discovery elbow cases, the rate of aseptic loosening was 2.2%.[17]

The overall rate of periprosthetic fracture and cortical perforation was 14.8% (primary, 6.8%; revision, 8%) in the present study. All fractures were classified as Mayo Type 1 and required conservative management. The incidence of periprosthetic fractures with Acclaim,[6] GSB III,[20,34] and Coonrad-Morrey[19] has been reported as 36%, 16%-21%, and 23%, respectively.

Incidence of persistent ulnar neuropathy requiring surgical intervention was 3% in our series. Ulnar neuropathy is seen more commonly in rheumatoid arthritis as close proximity of the nerve to the elbow joint can lead to inflammation of the nerve due to synovitis in the nearby elbow joint and valgus instability can lead to stretching of the ulnar nerve.[27] The incidence rate of ulnar neuropathy with GSB III, Coonrad-Morrey, and Acclaim has been reported as 11%-14%,[8,22] 12%-26%,[1,19] and 8%,[6] respectively. Summarising the complications of TEA in 595 patients, Hastings et al,[17] cited a rate of 4.4% for ulnar neuropathy.

The present study provided comprehensive prospective clinical outcome data on for the Discovery elbow arthroplasty. The study included a large cohort of primary and revision TEAs which reduced the scope of selection bias. Furthermore, clinical and radiographic

assessments were performed by independent assessors other than the principal surgeon thereby decreasing the possibility of information bias. There were, however, some limitations to the study. First, study included both primary and revision TEAs which might have some effect on reported outcome results. In order to address this, significant differences between primary and revision TEAs in outcome measures (e.g. LES) and complications rates are highlighted in the paper. Second, study used LES as a key functional assessment tool. This reduced the scope of comparisons with other studies into some extent as based around half of recent outcome reports used MEPS.[25] Hence, MEPS was added into our functional assessment tools a few years ago and being completed in addition to LES for all prospective TEAs. Third, a 4-year mean follow-up provides a relatively reasonable period for functional outcome report but a longer term follow-up is required for assessing late complications and survivorship of the prosthesis.

CONCLUSION

The results indicate that Discovery elbow is a system viable option for the treatment of advanced inflammatory and non-inflammatory elbow conditions where a TEA is indicated. This was reflected in significant improvements in LES, range of movement, pain experience, and a high patient satisfaction score at a 4-year mean follow-up. The incidence of complications was either comparable or less than that reported for other linked prostheses. We need to wait for the long term results of this prosthesis to assess its survivorship.

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375 **Figure and Table Legends**

376 **Figure1.** Lateral and anteroposterior x-rays of an elbow with osteoarthritis before (a-b) and
377 6-year after total elbow arthroplasty with Discovery Elbow (c-d).

378 **Figure2.** Graphic illustration of the Mayo Clinic classification system used for describing
379 periprosthetic fractures in elbow arthroplasty. It is important to differentiate between different
380 types of fractures as those affecting the hardware stems (types 2 and 3) will potentially
381 require revision. (Reprinted with permission from RadioGraphics.[29]

382 **Table1.** Incidence of diagnoses for primary and revision Total Elbow Arthroplasty (TEA)

383 **Table2.** Comparison of pre- and postoperative elbow and forearm range of motion with
384 Discovery Elbow according to main underlying pathologies in all patients (primary and
385 revision)

386 **Table3.** Prosthesis alignment in primary and revision Total Elbow Arthroplasty (TEA)

Table1. Incidence of diagnoses for primary and revision Total Elbow Arthroplasty (TEA)

Main Diagnoses and sub-diagnoses	Incidence (%) (n = 100 elbows)
Inflammatory Arthritis	
Rheumatoid Arthritis	54
Juvenile Rheumatoid Arthritis	2
Psoriatic Arthritis	2
Non-Inflammatory Arthritis	
Degenerative Osteoarthritis	17
Traumatic Arthritis	14
Haemophilic Arthropathy	3
Nail–patella syndrome	1
Distal Humerus Fracture (acute and non-union)	7
Total TEA	**100**
Revision TEA	
Inflammatory Arthritis	16
Non-Inflammatory Arthritis	7
Fracture	2
Total	**25**

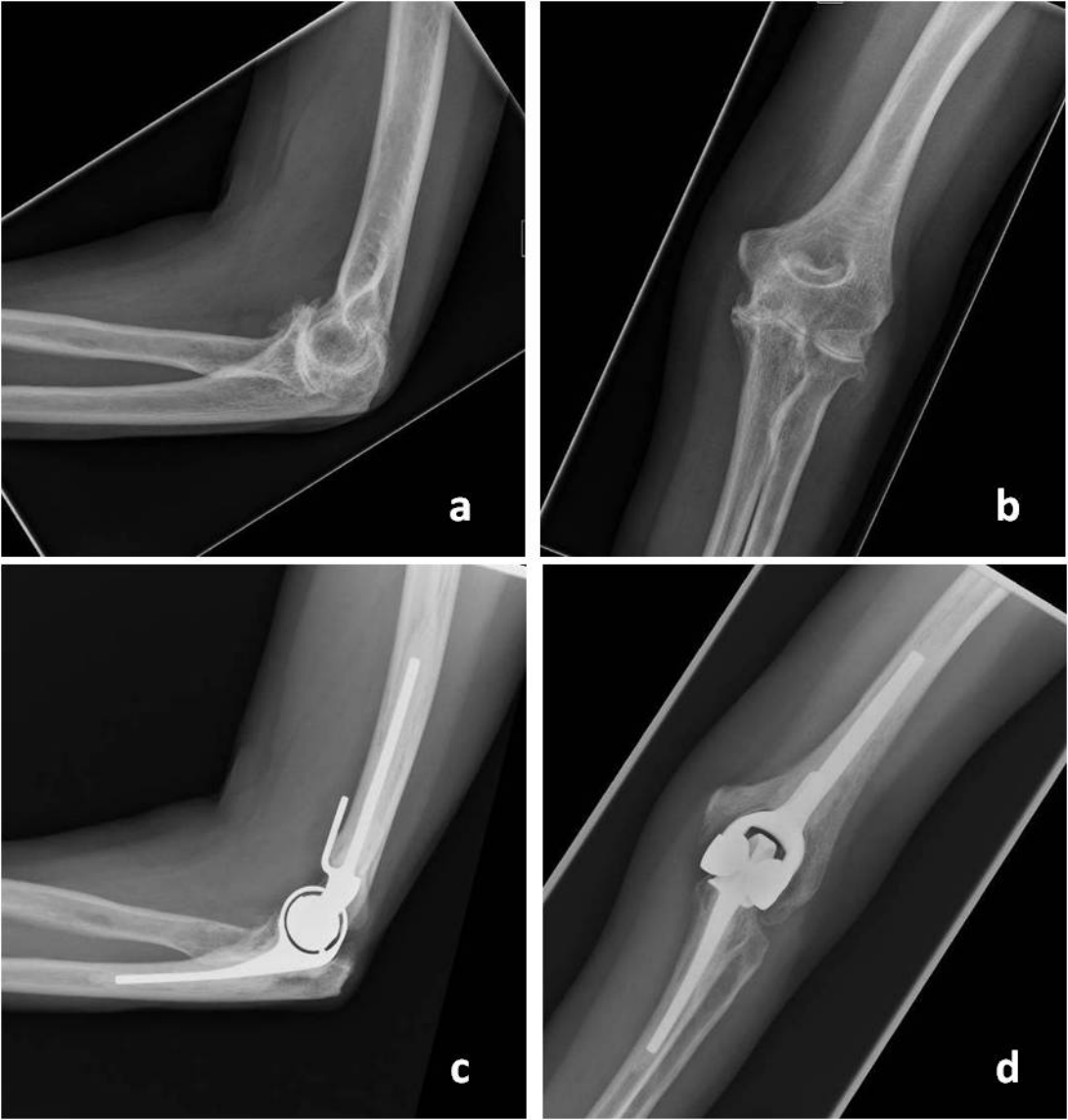
Table2. Comparison of pre- and postoperative elbow and forearm range of motion with Discovery Elbow according to main underlying pathologies in all patients (primary and revision)

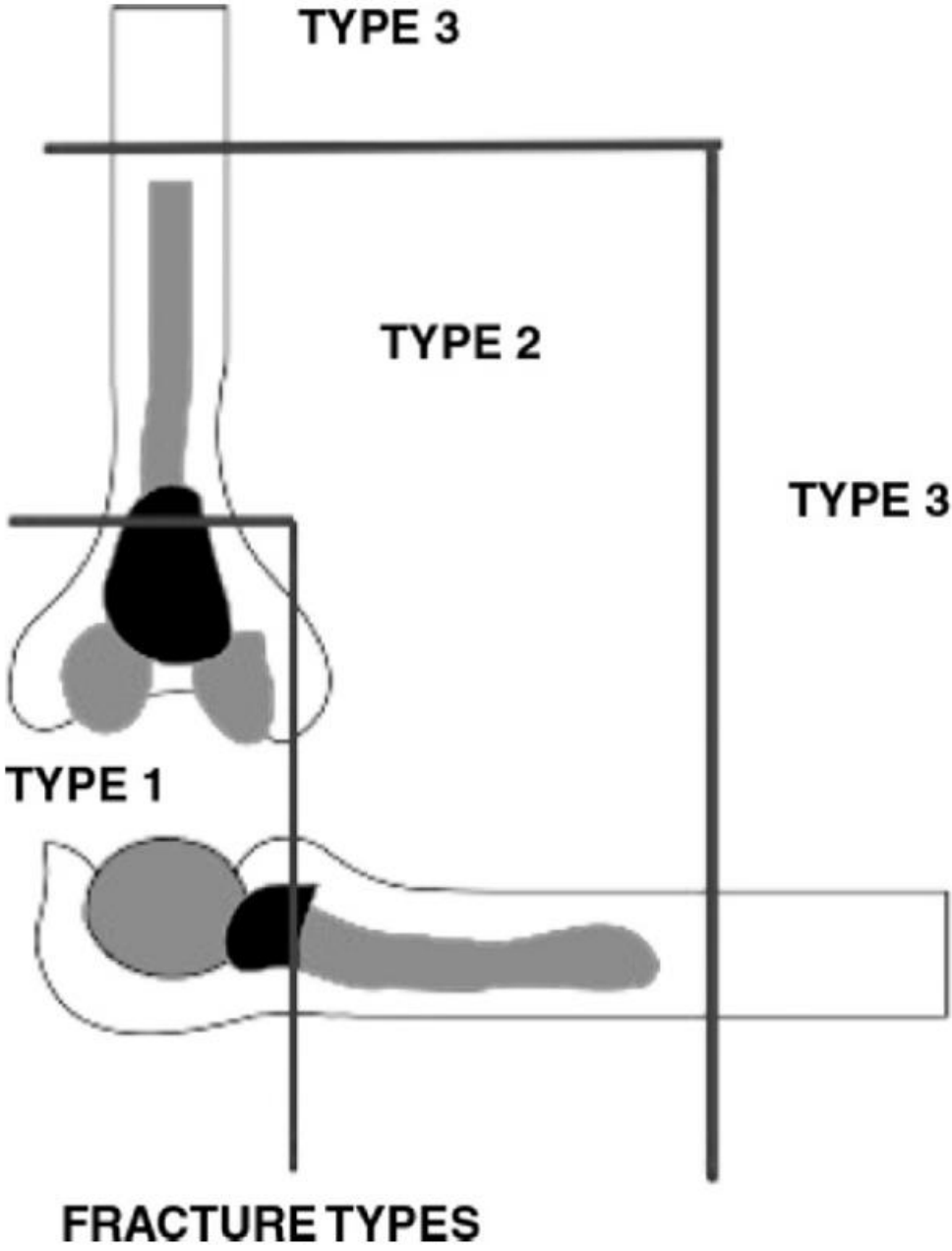
Elbow/Forearm ROM	All Patients		Non-Inflammatory (Osteoarthritis)		Inflammatory (Rheumatoid Arthritis)		Fracture	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
Flexion	100 (24)	118 (17)**	101 (26)	118 (18) *	100 (20)	117 (16)**	92 (38)	115 (28)
Extension lag	28 (14)	25 (14)	28 (11)	25 (12)	28 (16)	26 (16)	23 (15)	18 (17)
FLX-EXT ARC	72 (28)	93 (27)**	73 (30)	93 (26)*	72 (27)	92 (26)**	87 (33)	97 (44)
Pronation	48 (23)	61 (21)**	49 (25)	64 (18)*	46 (23)	59 (22)*	61 (17)	64 (15)
Supination	38 (26)	50 (25)**	42 (26)	55 (21)*	35 (26)	45 (25)*	52 (23)	51 (29)
PRON-SUP ARC	86 (45)	111 (42)**	91 (48)	119 (35)**	81 (44)	104 (42)*	113 (39)	115 (41)

-FLX, Flexion; EXT, Extension; ROM, Range of Motion; Pre-op, Preoperative; Post-op, Postoperative.
-Significant difference at $P \leq .05$ (*) and $P \leq .001$ (**).

Table3. Prosthesis alignment in primary and revision Total Elbow Arthroplasty (TEA)

Degree of Malalignment	Coronal Plane		Sagittal Plane	
	Humerus	**Ulna**	**Humerus**	**Ulna**
PRIMARY TEA				
Less than 5 degrees	61	57	48	63
5-10 degrees	9	13	22	6
More than 10 degrees	0	0	0	1
REVISION TEA				
Less than 5 degrees	16	16	14	17
5-10 degrees	2	2	4	1
More than 10 degrees	0	0	0	0


a
b
c
d



FRACTURE TYPES