RESULTS FROM BI-CONTACT® TOTAL ELBOW ARTHROPLASTY: MULTICENTER STUDY

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ABSTRACT

Objective: To describe the initial experience of four orthopedic clinics from using Bi-Contact® total elbow arthroplasty (TEA), reporting the results and complications of the procedure. Methods: This was a retrospective study, through analysis on the medical records of patients who underwent primary TEA using a prosthesis model developed in conjunction with IOT-HCFMUSP. Forty-six elbows (45 patients) that were operated at four orthopedic clinics between 2000 and 2009 were evaluated. Results: The majority of the patients were female (74%), and the median age was 62.5 years. The diagnoses encountered were trauma sequelae (47.83%), rheumatoid arthritis (32.61%), primary osteoarthrosis (8.7%), acute fractures (6.52%) and heterotopic ossification (2.17%). The median length of follow-up was 2.08 years (0.25-9). The procedure significantly alleviated pain and improved range of motion. It was observed that at least one complication was present in 69.57% of the cases, and the main ones were infection (28.26%), need for revision (28.26%), intraoperative fracture (15.22%) and aseptic loosening (15.22%). Conclusion: Bi-Contact® TEA provided significant alleviation of pain and improvement of range of motion in the present series. The complication rate was high, and the most frequently observed complications were infection, aseptic loosening and intraoperative fracture.

Keywords – Arthroplasty; Elbow/surgery; Elbow/injuries; Retrospective Studies

INTRODUCTION

Total elbow arthroplasty (TEA) is used to treat patients presenting pain and movement limitations resulting from joint degeneration that does not present any improvement through nonsurgical treatment. The main indications are inflammatory arthritis (especially rheumatoid arthritis), sequelae from trauma and primary osteoarthrosis[1].

Several studies have demonstrated that patients undergoing TEA present clinical and functional improvements[2-6]. It is still a little-performed surgical procedure, compared with implantation of knee and hip prostheses in absolute terms, but over the last two decades, its prevalence has been increasing at a proportionately greater pace than have lower-limb arthroplasties[7].

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Within our setting, the high cost of TEA (generally using imported models) limits its use for most patients. For this reason, a new implant model using Brazilian technology has been developed (the Bi-Contact® prosthesis), with the aim of reducing the costs and thus making it easier for Brazilian patients and orthopedists to have access to this surgical option.

The aim of this study was to describe the initial experience of four orthopedic services with Bi-Contact® TEA, reporting the results and complications of the procedure.

MATERIAL AND METHODS

Forty-five patients (46 elbows) who underwent primary TEA procedures using the Bi-Contact® prosthesis were evaluated retrospectively through analyzing their medical files.

This implant model was developed at the Institute of Orthopedics and Traumatology, USP School of Medicine, São Paulo (IOT-FMUSP), in partnership with the orthopedic materials company Impol®. It is a modular prosthesis (humeral component, ulnar component, fixation pins and polyethylene bushings) (Figure 1) of semi-restricted type (allowing 10° of varus-valgus), without blocking extension. The humeral and ulnar components are manufactured using chromium-nickel-molybdenum stainless steel alloy. The polyethylene of the bushing is ultra-high molecular weight polyethylene (UHMWPE). It has two perforated flanges (one anterior and the other, posterior) coated with porous material (medium roughness of 0.033 Ra), with the aim of enabling osseointegration in the distal portion of the humerus and minimizing the loosening rates (Figure 2). It is fixed in the medullary canals by means of cementation, using polymethyl methacrylate in all cases.

This implant has been approved by ANVISA (number 10108770097) and the present study was approved by the Ethics Committee for Research Project Analysis (CAPPesq) of HC-FMUSP. The free and informed consent statement was filled out by all the patients.

The 46 procedures were performed between 2000 and 2009 in four services: IOT-FMUSP [17], Santa Casa de Misericórdia de São Paulo [14], ABC School of Medicine [10] and Federal University of São Paulo [5].

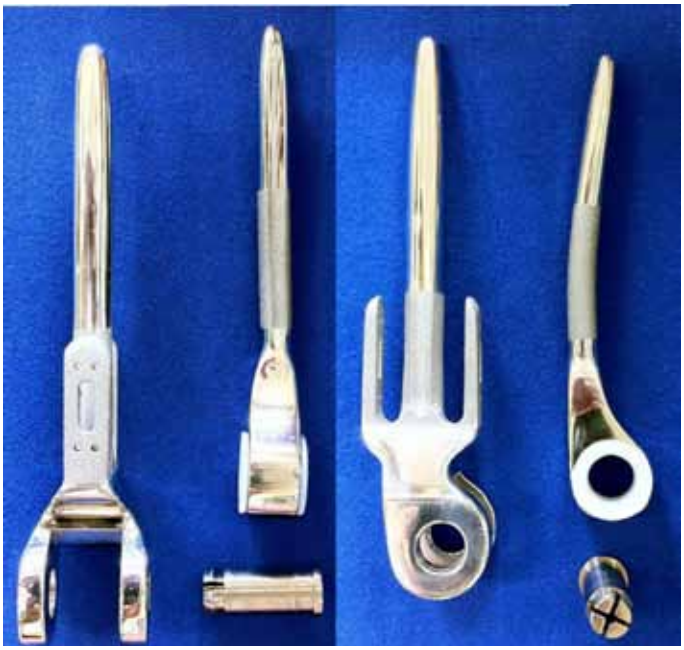

Figure 1 – Components of the prosthesis in frontal and lateral views.

Figure 2 – Flanges (anterior and lateral views), with porous surface and perforations to facilitate osseointegration.

The criteria for indicating the surgical intervention were incapacitating pain without response to conservative treatment and/or functional limitation resulting from diminished range of motion or instability.

Patients operated using other models of implants and patients for whom the Bi-Contact® prosthesis was used in revision procedures on previous arthroplasty were not included in this study. Active infection, insufficient extensor mechanisms and proximal obstruction of the medullary canal due to shoulder arthroplasty using a long nail were also considered to be non-inclusion criteria.

SURGICAL TECHNIQUE

The surgical approach used consisted of the posterior Morrey route[8]. After identification, release and protection of the ulnar nerve, triceps reflection was performed with release done medially to laterally. The periosteum and muscle fascia were preserved laterally. The joint was exposed completely and the bone cuts were made using an oscillating saw with specific guides. The medullary canal of the humerus and ulna were milled and then the test components were inserted. After assessing the range of motion, final adjustments could be made, with additional bone resection or soft-tissue release. The medullary canal was filled with polymethyl methacrylate (with the aid of a syringe), and the definitive components were introduced. The triceps was reinserted using transosseous stitches of non-absorbable thread (Ethibond® no. 5), at the olecranon. The ulnar nerve was transposed anteriorly when deemed necessary. Vacuum drainage was used and maintained for 24 to 48 hours. The patients received second-generation prophylaxis consisting of cephalosporin intravenously for 24 hours. The first dose was applied just after the procedures had been started. During the hospital stay, the limb was kept in compressive bandaging, at around 30° of extension, and at discharge, use of a sling was started.

REHABILITATION

On the first day after the operation, wrist and finger movements were stimulated. The elbow remained immobilized for one week, and then passive movements were started. Active elbow flexion movements were started in the third week. Active extension against resistance was only allowed after six to eight weeks.

Data gathering

A standardized data-gathering form was used to investigate the following variables: age, sex, side affected, preexisting diseases, length of follow-up, pre and postoperative range of motion, pre and postoperative complaints of pain and complications.

Statistical analysis

From the Shapiro-Wilk test, it was found that some variables presented nonparametric data distribution (6 out of 19). Thus, it was decided to treat all the data as nonparametric and to present the median and 25th and 75th percentiles as dispersion measurements. The pre and operative ranges of motion were compared by means of the Wilcoxon test. The chi-square test was used to correlate the diagnosis with the presence or absence of complications. Associations shown by the combined gain in flexion-extension and prono-supination with the diagnosis, the age and length of follow-up and the presence of pain before and after the operation were investigated, respectively, by means of the Kruskal-Wallis, Mann-Whitney and McNemar tests. The significance level used was 5%.

RESULTS

The majority of the patients were female (74%) and the median age was 62.5 years. The right side was operated in 24 patients (52.17%).

The following underlying diseases were diagnosed in these patients: sequelae of trauma (47.83%), rheumatoid arthritis (32.61%), primary osteoarthrosis (8.7%), acute fractures (6.52%) and heterotopic ossification (2.17%). The median length of follow-up was 2.08 years (0.25-9).

The general characteristics of the sample can be seen in Tables 1 and 2.

The pre and postoperative extension, flexion, pronation, supination, combined flexion and extension and combined pronosupination can be seen in Table 3. There were significant gains in all of these measurements ($p < 0.001$).

Table 1 – Epidemiological characteristics: categorical variables.

		n	%
Diagnosis	Sequela from fracture	22	54.35
	Rheumatoid arthritis	15	32.61
	Primary osteoarthrosis	4	8.70
	Acute fracture	3	6.52
	Heterotopic ossification	1	2.17
Institution	USP	17	36.96
	Santa Casa	14	30.43
	ABC	10	21.74
	EPM	5	10.87
Side	Right	24	52.17
	Left	22	47.83
Sex	Female	33	71.74
	Male	13	28.26

Table 2 – Epidemiological characteristics: continuous variables.

	Median	p25	p75
Age	62.5 (33-83)	49	72
Follow-up (years)	2.08 (0.25-9)	1.25	3

Pain was the preoperative complaint of 93.48% of the patients (43/46). After the procedure, 32.61% (15/46) presented complains of pain. The improvement was significant ($p < 0.001$) (Table 4).

It was observed that at least one complication occurred in 69.57% of the cases (32/46). The main complications were: infection (28.26%), need for revision (28.26%), intraoperative fracture (15.22%) (Figure 3), loosening (15.22%) (Figure 4), nerve lesions (8.7%) and breakage of the implant (4.35%) (Figure 5). The data relating to the complications can be seen in Table 5. The causes of revision (13 prostheses) were: infection[7], aseptic loosening[2], breakage of the implant[2], heterotopic ossification[1] and periprosthetic fracture[1]. Among the patients with nerve lesions (4/46), two presented neuropraxia (one of the ulnar nerve and one of the radial nerve). Complete tears occurred in two patients, in the median

Table 3 – Range of motion.

	Before operation			After operation			
Range of motion	Median	p 25	p 75	Median	p 25	p 75	p (Wilcoxon)
Extension	40	30	60	20	15	40	p = 0.0001
Flexion	100	87	120	130	110	113	p = 0.0001
Combined flexion-extension	45	20	85	100	80	115	p < 0.0001
Pronation	40	25	50	70	45	80	p < 0.0001
Supination	52	10	70	80	50	80	p < 0.0001
Combined pronosupination	85	40	110	150	90	160	p < 0.0001

Table 4 – Pain.

Pain	Yes		No	
	n	%	n	%
Before operation	43	93.48	3	6.52
After operation	15	32.61	31	67.39

$p < 0.0001$ (McNemar)

Figure 3 – Pre and postoperative radiography on patient with rheumatoid arthritis. Note fixation of fractures of the medial condyle and ulna that occurred during the operation.

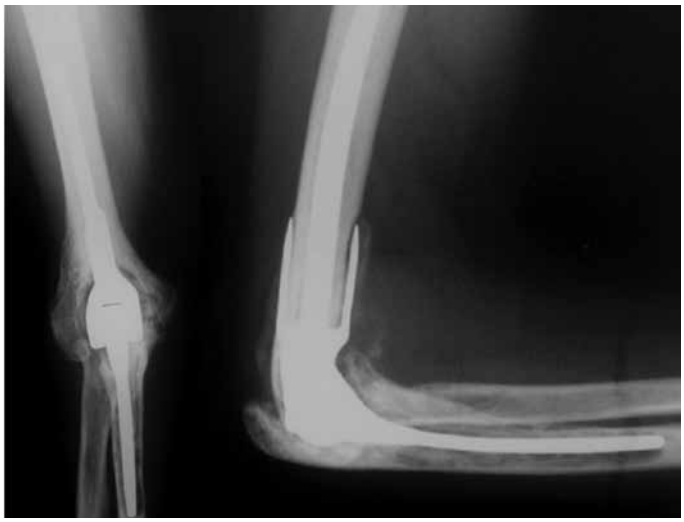

Figure 4 – Loosening of the ulnar component.

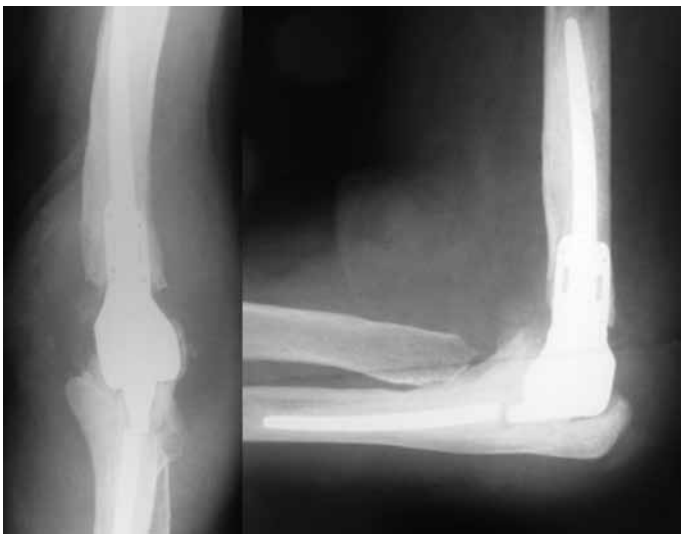

Figure 5 – Fracturing of the implant (ulnar component).

Table 5 – Complication.

Complications	n	%
Infection	13	28.26
Revision	13	28.26
Intraoperative fracture	7	15.22
Aseptic loosening	7	15.22
Nerve lesion	4	8.7
Breakage	2	4.35
At least one complication	32	69.57

nerve and posterior interosseous nerve. These patients subsequently underwent muscle transfers (Green transfer) and nerve grafting using the sural nerve, respectively. The two cases with implant fractures had suffered trauma (falls).

The presence of complications did not show any relationship with age (p = 0.155) or with the diagnosis (p = 0.53). On the other hand, there was a correlation with the length of follow-up (p = 0.0246).

The diagnosis also did not show any relationship with gains in flexion-extension (p = 0.25) or in pronosupination (p = 0.19).

DISCUSSION

The predominance of female patients undergoing TEA in our study (71.74%) is consistent with the literature[2,4,9]. Our study differed from what was presented by Cook *et al*[10], who found that the number of female patients with rheumatoid arthritis undergoing TEA was greater than the number with sequelae of trauma (81.3% versus 65.6%). We found that the numbers in these two subgroups of female patients were similar (77.3% with sequelae of trauma and 75% with rheumatoid arthritis).

The median age of our patients at the time of undergoing the procedure was 62.5 years, which was similar to the mean age presented in other studies (range: 62 to 69)[2,9].

With regard to etiology, several series have evaluated the results among patients with a single diagnosis. Naqui *et al*[5] evaluated the results in a population with primary osteoarthrosis. Other authors have evaluated the results among patients with rheumatoid arthritis[6,11,12]. In mixed series, there has generally been a large predominance of rheumatoid arthritis cases[9], but our series different in this respect (54.35% with sequelae of trauma and 32.61% with rheumatoid arthritis). This can probably be explained by the lower incidence of rheumatoid arthritis in Brazil than in the USA and Europe[13], or by the higher incidence of sequelae of trauma in tertiary-level hospitals.

Regarding range of motion, there was an increase of 55° in flexion-extension and 65° in pronosupination. These results are better than those presented by Kelly *et al*[3] (37° in flexion-extension and 57° in pronosupination), Malone *et al*[4] (26° in flexion-extension and 40° in pronosupination), Naqui *et al*[5] (40° inflexion-extension) and Willems and De Smet[6] (26° in flexion-extension), although the gain in amplitude depends not only on the success of the procedure but also on the initial limitation of the disease. The range of motion did not present any correlation with the diagnosis (p = 0.25 for flexion-extension and p = 0.19 for pronosupination).

Analysis on the improvement in pain in comparison with other studies was made somewhat more difficult because we did not used scales or grades of intensity but only a binary division of presence/absence of pain. Furthermore, some authors' results combined patients without pain with those presenting mild pain. We observed that before the operation, 93.48% of the patients presented pain and only 32.61% presented pain after the operation. Kelly *et al*[3] observed that 44% of their patients had mild or intermittent pain and none had intense pain. Malone *et al*[4] found complaints of occasional pain in 14%, and the remainder were asymptomatic. Schneeberger *et al*[14] presented less encouraging results, in which 70% presented mild pain or no pain, while 30% had moderate or severe pain.

The length of follow-up in our series (median of 2.08 years) is short compared with other studies (mean of 4.5 to 10.6 years)[2-6,9,14].

The complication rate found was greater than what has been reported in the literature. Around 70% (32/46) of the elbows presented at least one complication. Kelly *et al*[3] and Schneeberger *et al*[14] reported overall complication rates of 39% and 43%, respectively. This becomes more worrying when we take into account the shorter follow-up in our study. However, it needs to be highlighted that in our sample, we had a high number of cases of

sequelae from trauma, which might have increased the infection rate. The length of evolution correlated significantly with the presence of complications (p = 0.0246). The presence of complications did not present a correlation with the ages of the patients (p = 0.155) or with the diagnosis (p = 0.53).

In analyzing the different complications, it could be seen that the main factor leading to our high rate was the incidence of postoperative infection. In an epidemiological survey of TEA in the USA, Cook *et al*[10] only reported two cases out of 3,617 arthroplasties. In some smaller series, there were no reports of infection[2,4,5]. The highest rate found was 8%, in the study by Ikävalko *et al*[11], which was a series of 522 elbows in patients with rheumatoid arthritis, with a mean length of follow-up of 10.6 years. While most studies have shown small numbers of this complication, our rate was 28.26% (13/46). In our opinion, this high number of infections did not have any correlation with the type of implant used, but may have been influenced by the socioeconomic profile of the population attended at the services involved, in comparison with developed countries. Other factors may have related to the longer duration of surgery required in the cases of sequelae from trauma, in relation to cases of osteoarthrosis or rheumatoid arthritis.

Although our incidence of aseptic loosening (15.22%) was similar to that of Schneeberger[14] (17%), it was greater than most other studies. Amirfeyz *et al*[2] reported only one in 54 cases. Fevang *et al*[9] presented 36 cases of loosening in 562 arthroplasties (6.4%). Prasad and Dent[12] analyzed two models of TEA and did not observe any cases of loosening among 55 Coonrad-Morrey prostheses with a mean follow-up of 60 months, while among the Souter prostheses (mean follow-up of 108 months) 18% (8/44) presented this finding. We believe that the high rate of loosening among our sample may have been related to mechanical stress caused by the blocking of extension that was present in the first models of the implant, which impeded extension beyond 0°. In the more recent models of our prosthesis, this blocking has been removed, and extension is limited by the tension in the soft tissues, thereby diminishing the mechanical overload on the prosthesis-bone and cement-bone interfaces. There has not been enough follow-up to determine what impact this change may have had.

Neurological lesions have shown varying incidence in the literature. Amirfeyz *et al*[2] reported absence of such complications (0/54), while Kelly *et al*[3] reported that 29% of the cases presented paresthesia (25% ulnar and 4% median). In the biggest survey on TEA that exists, Cook *et al*[10] reported that 4% of the cases had neurological complications. Although the great majority of the neurological lesions consisted of neuropraxia, the need for reoperation has also been described[4,14]. The present series found four cases (8.7%) of neurological abnormalities, of which one was a complete tear of the median nerve (which underwent reexploration and grafting), one was a complete tear of the posterior interosseous nerve (subsequently subjected to Green transfers), one was neuropraxia of the ulnar nerve and one was neuropraxia of the radial nerve. We believe that the greater the severity of the case is, like in sequelae from trauma, the greater the change of occurrences of nerve lesions will be.

The presence of intraoperative fractures has also presented wide variation. Fevang *et al*[9] and Amirfeyz *et al*[2] showed rates less than 2%. In turn, Willems and De Smet[6] reported a fracture rate of 16.6%, which was similar to our findings (15.22%). It needs to be borne in mind that the bone quality in cases with rheumatoid arthritis increases the frequency of this complication.

Revision was performed on 13 of the 46 arthroplasties in our sample (28.26%). This rate was higher than what was reported by Fevang *et al*[9], who found a rate of 10.32% among 562 arthroplasties. However, Schneeberger *et al*[14] presented a revision rate greater than ours (30%). If it is taken into account that out of the 13 revisions, seven were because of infection, we had six cases of revision due to aseptic loosening (13%), which is a closer figure to what has been reported in the literature, albeit with a shorter follow-up.

Breakage of the implant is a rare complication in TEA, and is not mentioned in most of the series cited. Gschwend *et al*[15] reported an incidence rate of 0.5%. We observed two cases of implant breakage among our sample (4.35%).

The main difference between the implant model developed (Bi-Contact® prosthesis) and the model that is currently most widely used (Coonrad-Morrey prosthesis) is in the number and format of the flanges. The idea of the flange is to increase the stability and allow load to be transmitted by means of a route other than the cement-bone interface, thus diminishing the stress shielding and the loosening rate[16]. In the Coonrad-Morrey prosthesis, there is a rigid anterior flange, and this prosthesis is used in conjunction with a block of bone graft. In the Bi-Contact® prosthesis, there are two flanges, one anterior and the other posterior, and these are less rigid (semi-flexible) and are in close contact with the bone, without the need for bone grafting. With the porous coating and the perforations, the aim is to achieve osseointegration between the flanges and the distal humerus. Controlled prospective studies would be necessary in order to show whether one model has any advantage over any other.

The main limitations of this study are that its design was a retrospective case series and that the data were gathered from analyzing the medical records. Moreover, the length of follow-up was relatively short, in comparison with the majority of published series. The most positive points from this study are its sample (the biggest in the Brazilian literature, to the best of our knowledge) and the involvement of four important shoulder and elbow services in Brazil (multicenter study).

CONCLUSION

Bi-Contact® TEA provided a significant improvement in pain and range of motion in the present series. The complication rate was high, and the most frequent complications were infections, aseptic loosening and intraoperative fractures.

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