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Results of 110 IVORY® prostheses for trapeziometacarpal osteoarthritis with a minimum follow-up of 10 years

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Abstract

The IVORY® prosthesis is a total trapeziometacarpal joint prosthesis used for the treatment of symptomatic trapeziometacarpal osteoarthritis. The aim of this prospective study was to evaluate its long-term outcomes with a minimum follow-up of 10 years. From 2004 to 2007, 110 trapeziometacarpal prostheses (95 patients) were implanted. The implant survival curve was constructed using the Kaplan–Meier method. Five patients were lost from follow-up and two died. Six prosthesis (5.5%) were removed after dislocation or fracture of the trapezium. The survival rate of the prosthesis was 95%. After 10 years, the mean visual analogue pain score was 0.24/10 and the key-pinch force was similar to the other hand. Dislocations occurred for eight implants (7.3%). No radiological loosening was noted. In conclusion, the long-term results with the IVORY® prosthesis are very satisfactory in terms of pain relief, function and survival.

Level of evidence: II

Keywords

Clinical outcome, IVORY® prosthesis, survival analysis, 10 years follow-up, trapeziometacarpal arthroplasty

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Introduction

When non-surgical modalities have failed to address symptoms of pain in trapeziometacarpal (TMC) osteoarthritis, surgical treatments aim to achieve restoration of thumb function with a pain-free, stable, and mobile joint and good strength (Comtet and Rumelhart, 2009). Several surgical techniques are available (Vermeulen et al., 2011; Wajon et al., 2015). The current gold standard treatment is trapeziectomy with or without tendon interposition, or suspension arthroplasty because of its efficacy in relieving pain (Gervis, 1949; Vandenberg et al., 2013; Yeoman et al., 2019). However, trapeziectomy is associated with partial weakness of the pinch strength and a loss of thumb length (Ulrich-Vinther et al., 2008).

Total TMC joint replacement, which is now part of the therapeutic arsenal, is being more widely used. It allows a faster return to traditional habits (activity) and, in the long-term perspective, provides good results as far as pain relief, the recovery of mobility and strength are concerned (Gaisne et al., 2009; Vissers et al., 2019). However, joint replacement may lead to complications, such as dislocation and loosening (Kollig et al., 2017; Ledoux, 1997).

The primary aim of this prospective study was to report long-term (minimum follow-up of 10 years) joint survival with the IVORY® implant. Our secondary aim was to evaluate the clinical and functional results of this implant.

Methods

Patients and radiological data

This was a prospective study including a consecutive case series of patients with TMC arthritis treated with an IVORY® implant between May 2004 and November

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2007 in our hand unit. The institutional review board approved the study and informed consent was obtained from every patient. For some patients, both hands were operated on successively, with an interval of at least 6 months between the two operations, in order to allow full recovery.

We used the radiological views described by Kapandji et al. (1980) (antero-posterior and lateral views of the thumb) to assess joint damage according to the Dell classification (Allieu, 2009). The height of the trapezium was calculated according to the Saffar and Goffin index (Goffin and Saffar, 1990).

The criteria for inclusion were the presence of pain at rest or affecting daily living activities, despite at least 3 months of conservative treatment. The indication for surgery was based on clinical features rather than radiological appearances. Patients with scaphotrapeziotrapezoid (STT) osteoarthritis or Stage IV of the Dell classification with insufficient height of the trapezium (<8 mm) were considered not suitable for replacement arthroplasty and were therefore excluded from the study.

In order to assess the possible effect of age, two subsets of patients ('young' and 'elderly'), were arbitrarily defined as those below or above the median age of the cohort. Patients were also asked about their professional activities and split into two groups: intensive use of the hand (manual workers, farmers) and non-intensive use of the hand (tertiary sector employees).

The patients did not undergo operation for any other hand conditions in the same hand within the first 6 months after the TMC arthroplasty.

The prosthesis

The IVORY® implant (Memometal, Stryker European Holdings I, LLC, Amsterdam, Netherlands) was produced from 1994 to 2017. It was made of stainless steel and included an uncemented anatomical stem coat with hydroxyapatite and a cup available in three sizes (9, 10 and 11 mm), also coated with hydroxyapatite that provided maximal secondary stability and bone ingrowth. The cup had a trapezoidal shape, which contributed to its primary stability. It was the first implant to have a separate polyethylene liner, therefore allowing change of the insert without removing the cup if dislocation occurs. Several offset neck sizes (0 = medium, − = short and + = long) could be placed on the metacarpal stem. The neck could be placed for neutral rotation, anteversion or retroversion (0°, + 30°, −30°). The maximal mobility arc of the IVORY® implant was 91°. It was completely flexible, since all of the components were separately interchangeable (Goubau et al., 2009) (Figure 1). After the dual mobility implants became available, use of the IVORY® implant declined and it is no longer available commercially.

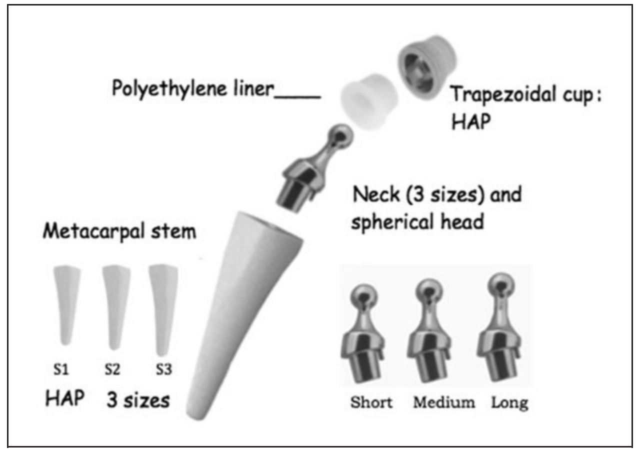

Figure 1. The IVORY® implant.

Surgical technique

A single specialist highly experienced surgeon (AT) of expertise Level 4 (Tang and Giddins, 2016), performed each arthroplasty under regional anaesthesia and with a pneumatic tourniquet. An antero-lateral approach was used, exposing the TMC joint avoiding the branches of the superficial radial nerve. The abductor pollicis longus (APL) was detached with the periosteum. The base of the first metacarpal and osteophytes were resected, and the metacarpal freed from capsular-ligament attachments. The definitive stem was inserted into the metacarpal. The distal articular surface of the trapezium was resected. The definitive cup was inserted after manual drilling of the bone. After reducing the prosthetic joint, its stability and thumb mobility were checked.

The APL tendon was reinserted onto the first metacarpal base with transosseous sutures. The wound was closed with suction drainage. An immediate postoperative radiograph was obtained. After surgery, the wrist and the thumb were not immobilized (no cast nor splint). The dressing was removed after 2 weeks. Normal activities were encouraged as soon as possible. No physiotherapy or specific exercises were recommended.

Follow-up and outcome assessment

Clinical and radiological follow-up was standardized for each patient: one preoperative consultation, then postoperative consultations at 1, 3, 6 and 12 months, and every 2 years thereafter. Postoperative results were compared with the contralateral thumb and with the preoperative data. One investigator, independent of the operating surgeon, performed clinical and radiological assessments in order to avoid the bias.

A visual analogue scale (VAS) was used to assess pain. Range of motion of the TMC joint and thumb opposition were assessed using the Kapandji method (1986), which goes from 0 (thumb against the radial side of the index finger proximal phalanx) to 10 (thumb reaching the palmar crease of the little finger metacarpophalangeal joint). Thumb-index key and tip pinch strength was measured using a pinch gauge (Preston, Clifton, NJ, USA). Grip strength was measured using a Jamar grip dynamometer (Asimov Engineering, Los Angeles, CA, USA). We determined the time after surgery before there was no significant differences between the operated and contralateral hand. For these comparative strength measurements, we only included patients who had unilateral surgery (80 patients). After 10 years of follow-up, daily activities and autonomy were evaluated by the global QuickDASH questionnaire, with a score out of 100. Satisfaction with the long-term outcome was evaluated according to the terms: *disappointed*, *moderately satisfied*, *satisfied* or *very satisfied*.

Radiographic assessment

Follow-up radiographs were used to assess the stability of the implant over time. Dislocations and complications, such as fractures of the trapezium and loosening of the implant, were recorded. After 10 years of follow-up measurements were made to determine: (1) the depth of insertion of the cup, the height, '*surface cup –> base trapezium*' (Figure 2), and the ratio, *Depth after 10 years/postoperative depth*; (2) the depth of insertion of the stem was calculated using the Wachtl and Sennwald definition (1996) (Figure 2), *Length of the stem/Distance 'stem surface –> head of first metacarpal'* and its ratio, *Depth after 10 years/postoperative depth*; and (3) shortening of the thumb was assessed by calculating the ratio (Ledoux, 2017). *Length of first metacarpal + trapezium/Length of second metacarpal + trapezoid.*

Statistics

The prostheses ($n = 110$) were taken as the statistical unit because the operations were assumed to be independent even for the few patients with bilateral surgery. In this case, hands were not operated during the same procedure and the second surgery did not disturb the convalescence of the first one and vice versa.

Descriptive statistics are presented as means and standard deviations (SD), or by medians and range. The binomial test was used to test the compliance of

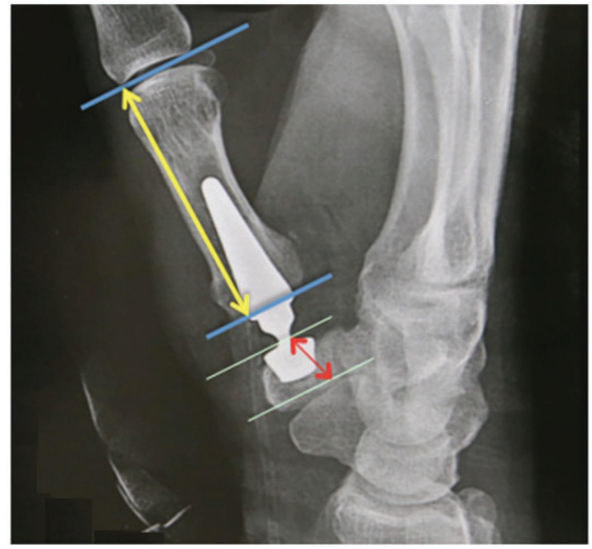

Figure 2. Radiological measurements, in red '*the height surface cup –> base trapezium*', in yellow '*the distance surface stem –> head of first metacarpal'*.

the observed proportion of males and females in patients with an expected natural proportion (H0 hypothesis) of 50% and for dominant/non-dominant hand proportions and for active/non-active hand proportions. The age of males and females were compared with Wilcoxon–Mann–Whitney test. The longitudinal analysis was done by fitting data with a mixed model for repeated measures where hand (operated vs. contralateral) and time were included as fixed effects and subject as a random effect on intercept.

There was an increase of missing values over time. We assumed that patients missed their medical consultations when they had a good mobility without pain. Therefore, missing values were imputed with the predictive mean matching (PMM) method. Since the PMM method draws imputations from the observed data, imputed values have the same gaps as in the observed data, and are always within the range of the observed data (Van Buuren and Groothuis-Oudshoorn, 2011). To reduce the risk of error, the missing data imputation was iterated five times, to generate five datasets that were subjected to analysis of variance. The consequent post-hoc multiple pairwise comparison of means was carried out with the method of Bonferroni. For the pain, the non-parametric test of Friedman was used before the comparison of means with the Conover–Nemeyi test. The implant survival curve was constructed using the Kaplan–Meier method. Failure corresponded to removal of the implant and the conversion to trapeziectomy. The Cox proportional hazard model was used to examine the influence of sex or hand activity on the survival curve.

Results

Patients

One hundred and ten IVORY® implants were inserted in 95 patients, with both hands operated in 15 patients. The minimum follow-up was 120 months. Five patients, who had unilateral procedures, were lost to follow-up. Two patients died, including one bilateral procedure. Most of the patients were female: 82 women (86%) and 13 men (14%). The mean age in our population was 61 years; 59 for women versus 68 for men. The dominant hand was treated for 54 patients (49%) and was not different from the proportion of non-dominant treated hands ($p = 0.92$). The most frequent Dell score for the grade of arthritis was III.

Among the population studied, only 27% (30 hands) were subjected to intense manual activity, while for 73% (80 hands), the use of the hand was considered as non-intensive (retired persons and non-manual professions). Twenty-four patients (22%) had a history of other conditions in the operated hand, which were treated at least 1 year before the TMC surgery including: carpal tunnel syndrome, De Quervain's syndrome, synovial cyst, thumb trauma, other sites of osteoarthritis. Four patients had another procedure associated with the TMC surgery.

Pain

Before the planned surgery, mean pain reached 7.5/10 (median of 8.0) on the VAS score. One month after the surgery, the mean score was 1.1/10; 70 patients (64%) had a score of 1 or less out of 10. For most patients, the pain had disappeared 3 months after the procedure. After 10 years, the mean pain score was 0.24/10 (Table 1). There were no cases of neuropathy affecting the radial nerve.

Mobility and strength

One month after surgery, the number of patients who presented a Kapandji index <9 decreased quickly. The mean key-pinch force of the operated hand was similar to the contralateral hand after 10 years (Tables 1 and 2).

Patient reported outcomes

After 10 years, 88% of patients were satisfied or very satisfied. The most frequent QuickDASH score was 0/100. Overall, the QuickDASH scores did not exceed 14/100. On average, patients returned to work or their usual activities within 3 months. At 12 months, all of the patients had returned to their usual activities.

Postoperative radiological assessment

The base of the cup was parallel to the scaphotrapezial joint space and aligned with the dome of the scaphoid

Table 1. Pain and strength measurements before and after operation.

	Before surgery	After surgery (months)						
		1	3	6	12	36	60	120
Pain								
Mean VAS (scores)	7.5	1.1	0.6	0.2	0.1	0.1	0.1	0.2
VAS >1 (patients)	24	29	16	6	3	3	1	3
Key pinch strength (%)	0	–0.8	28	53	60	55	53	71
Tip pinch strength (%)	0	–27	9.3	3.6	–1.8	–6.8	–17	32
Grip strength (%)	0	–35	–9.3	16	23	23	21	34

(Change in pinch and grip strength is expressed as mean percentage of the preoperative value.)

Table 2. Mean thumb key pinch, tip pinch and grip strengths in operated hand and contralateral hand before surgery and at different time-points after surgery.

	Key pinch strength (kg)				Tip pinch strength (kg)				Grip strength (kg)			
Hands	Preoperative	1 year	5 years	10 years	Preoperative	1 year	5 years	10 years	Preoperative	1 year	5 years	10 years
Operated	3.8	6.0	5.7	6.4	1.9	2.7	2.3	3.5	19	23	23	26
Contralateral	6.0				2.6				25			

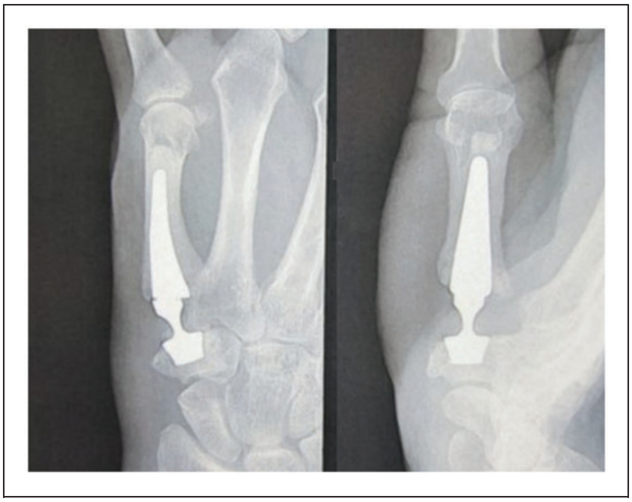

Figure 3. Radiograph at 10 years follow-up.

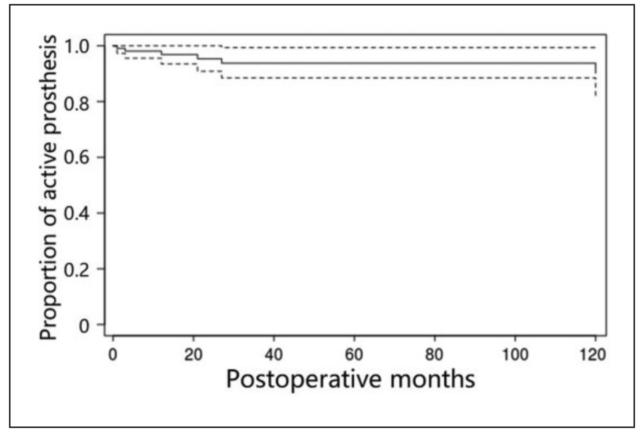

Figure 4. Kaplan–Meier survival curve for the IVORY® implant.

for 91 hands (82%). The cup was placed at the centre of the trapezium for 78 hands (71%). The stem was against the dorsal cortical bone of the metacarpal in 100% of operated hands.

We did not observe any case of loosening (Figure 3). Final follow-up X-ray showed no pathological appearances for 110 hands. In 50% of cases ($n = 55$), the cup had sunk into the trapezium (mean 7% of the height: *surface cup -> base trapezium*). In 20% of cases ($n = 22$), the stem had sunk into the first metacarpal. The depth of stem insertion (Wacht ratio) decreased by a mean of 1.5%. The mean ratio, *length first metacarpal + trapezium/length second metacarpal + trapezoid* was 0.77 before surgery, compared with 0.78 at 10 years. There was no shortening of the thumb. The changes occurred between the first and the sixth months after surgery. After 6 months, the values remained stable until the last radiological analysis at 10 years.

Dislocations

Eight (7.3%) dislocations occurred in our study. In six cases, patients had fallen down stairs or while walking, with a direct trauma to the operated hand. The two other cases used their hand for heavy activity too soon after surgery. Closed reduction was immediately performed without recurrence for three of them. For one patient, salvage surgery had to be performed and the polyethylene (PE) liner was changed. For the remaining four dislocations, PE was too damaged, therefore the implant was removed and a trapeziectomy had to be completed.

Implant survival

The survival rate was 95%. Six implants were removed (Figure 4), including four cases of dislocation, when salvage surgery was not possible, and two cases of traumatic fracture of the trapezium. In these cases, secondary trapeziectomy with suspension system (Tight Rope®, Arthrex, Saint-Didier Au Mont D'Or, France) was performed (revision surgery). In two cases, the metacarpal stem could be removed. All six patients had resolution of pain. The implant survival for men was not different from women ($p = 0.72$). In the six cases of implant removal, patients were younger than 60 years old at the time of the surgery and seemed to have higher levels of activity ($p = 0.03$).

Discussion

This study shows that treating TMC osteoarthritis with an IVORY® implant gives good results after 10-year follow-up. The survival rate is 95%. These results are as good or even better than the short-term outcomes reported by Spaans et al. (2016) and at 5 years (Goubeau and Benis, 2011; Goubau et al., 2013) using the same implant. At 10 years, Vissers et al. (2019) reported 85% of survival rate for 26 IVORY® arthroplasties. We can also compare our results with other modular TMC joint prostheses. Dehl et al. (2017) reported 87% of survival at 10 years for 298 RUBIS® implants; Moutet et al. (2015), reported 91% for 64 ROSELAND® implants at 10 years, and Martin-Ferrero (2014) reported 94% for 69 ARPE® implants at 10 years.

Introduced in 1994, the IVORY® implant was one of the first uncemented, so-called 'press-fit', implants available. The first generation of implants (cemented), which was still available 10 years ago, had been associated with a large number of complications, and the indications were restricted to female patients older than 65 years, who did not engage in intense manual activities (Lisfranc and Tubiana, 1984; Romano and Lisfranc, 2009). It was therefore interesting to study this second generation of implants, even though it is not any longer available. The (statistical) contribution of our study is substantial, regarding the large number of studied hands (110 in total) and also the long-term follow-up (10 years or more)

The indications are wide as profession, sex, age, medical history and radiological score do not play a determinant or decisive role in the onset of complications. In our series, we did not have to treat a coexisting STT joint, which is still a matter of debate. According to us and some other authors, STT osteoarthritis is an indication of trapeziectomy (Gay et al., 2016). Pain relief and the return to activity are fast after joint replacement. Three months after surgery, the mean pain VAS was 0.6/10 and the majority of patients had returned to their usual activities. Jager et al. (2013) showed that postoperative pain relief, mobility and strength were far more satisfactory after prosthetic arthroplasty than after trapeziectomy. Moreover, the length of the thumb remained stable over 10 years, whereas shortening inevitably occurs after a trapeziectomy procedure.

There were eight dislocations (7.2%), which is within the range reported in the literature (Maes et al., 2010) or even lower (Regnard, 2013). In most cases, dislocations occurred during the first year after surgery, following minor trauma. All dislocations could be reduced closed and three remained stable after immobilization. The stability of the IVORY® implant can be improved. Many details of the surgical procedure (positioning the cup, releasing the ligament and capsular attachments from the base of the first metacarpal to avoid stresses, osteophytes resection, applying dressings to allow first web opening without a splint to avoid the cam effect) and careful rehabilitation play a role in reducing the risk of dislocation.

Duerinckx and Caekebeke (2016) have suggested that the cup should be positioned parallel to the proximal articular surface of the trapezium, as we did in this study. There were no cases of loosening in our series. This result was linked to the initial quality of the trapezium (the earlier the surgery is performed, the better the bone quality is), manual burring of the trapezium, careful freeing of the base of the first metacarpal and resection of osteophytes (trapezium horns and anterior beak of the metacarpal). Consequently, all these elements contribute to decrease cup mechanical strains and avoid loosening. The hydroxyapatite coating of the cup and its quadrangular shape also seem to play a major role (Wachtl et al., 1997). We found several cases of sinking of the stem or the cup, but they were not significant (<1 mm) and mostly occurred in the first 6 months following the surgery.

Our study has some limitations. It as a case series from a single surgeon (AT). However, we have a long follow-up of 10 years, and there was no deterioration after this time. Two authors (AT, YM) carried out the radiological assessment. Our results provide reliable substantiation that prosthetic arthroplasty can reliably address symptoms of pain associated with TMC osteoarthritis. More recently, the use of the IVORY® implant has declined as dual mobility implants have become available. The preliminary results suggest that the new implants may reduce the risk of dislocations (Toffoli and Taissier, 2017). In any case, prosthetic arthroplasty delays the use of trapeziectomy, which can still be done if the implant fails. Secondary trapezectomy has been reported to provide equivalent or better results than primary trapeziectomy (Huang et al., 2015).

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