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Original article

Pyrocardan® implant arthroplasty for trapeziometacarpal osteoarthritis with a minimum follow-up of 5 years

Arthroplastie par l'implant Pyrocardan® dans l'arthrose trapézo-métacarpienne avec un recul minimum de 5 ans

E. Gerace, D. Royaux, E. Gaisne, L. Ardouin, P. Bellemère *

Institut de la Main Nantes-Atlantique, Santé Atlantique, Avenue Claude Bernard, 44800 Saint-Herblain, France

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ABSTRACT

Many surgical procedures are available for treating trapeziometacarpal (TMC) osteoarthritis (OA). The aim of this study was to analyze the mid- to long-term outcomes of 103 pyrocarbon interposition arthroplasties in the TMC joint with Pyrocardan® implant performed prospectively in a single center to treat painful early stage OA. There were 96 patients with a median age of 59 years. Twenty-eight percent of patients were manual workers and 39% had a fixed dislocation of the first metacarpal. Fifteen percent of patients were 50 years old or more. After a minimum follow-up of 5 years, there was a marked improvement in the pain level (0.6/10), QuickDASH (9/100) and PRWHE (4/100) scores and strength (key pinch 8 kg, grip strength 27 kg). There were no differences in strength or range of motion compared to the opposite side. Four patients underwent revision surgeries. Two of them were converted to trapeziectomy. The 5-year implant survival rate was 96.2%. Dislocation of the first metacarpal was completely corrected in 80% of cases. Younger patients (≤50 years old) had slightly better outcomes than older ones. Overall satisfaction rate was 96%. Pyrocardan® interposition implant arthroplasty is a reliable alternative to trapeziectomy, total arthroplasty or fusion of the TMC joint especially for young, active patients.

Mots clés :
Pyrocarbone
Implant
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Interposition
Articulation trapézométacarpienne
Rhizarthrose
Arthrose

RÉSUMÉ

Plusieurs types d'intervention chirurgicale peuvent être proposés dans le traitement de l'arthrose trapézo-métacarpienne (TMC). Le but de cette étude prospective é?aittt d'analyser à moyen et long termes les résultats d'une série monocentrique de 103 arthroplasties par interposition de l'implant en pyrocarbone Pyrocardan®. La série comprenait 96 patients d'âge médian 59 ans dont 16% étaient de moins de 50 ans. Les patients ont été revus entre 60 et 120 mois au recul médian de 67 mois. Parmi eux, 28% étaient des travailleurs manuels, et 39% présentaient une subluxation préopératoire permanente de la base du 1er métacarpien. L'amélioration fonctionnelle a été nette sur la douleur, les scores QuickDASH et PRWHE respectivement à 0,6/10, 9/100 et 4/100 ainsi que la force, en moyenne 8 kg pour la pince tripode et 27 kg pour la poigne. Les mobilités et la force étaient symétriques au côté opposé. Il y a eu 4 réinterventions dont 2 pour une conversion en trapézectomie. Le taux de survie était de 96,2%. La subluxation métacarpienne a été corrigée dans 80% des cas. Les patients de 50 ans ou moins ont eu globalement de meilleurs résultats fonctionnels que les autres. Le taux de satisfaction globale des patients était de 96%. L'implant Pyrocardan® est une alternative valable à la trapézectomie, la prothèse totale ou l'arthrodèse TMC, en particulier chez les patients jeunes et actifs.

* Corresponding author.
E-mail address: philippe.bellemere@me.com (P. Bellemère).

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1. Introduction

Trapeziometacarpal (TMC) osteoarthritis (OA) is a common condition that can cause severe pain at the base of the thumb and impair day-to-day life. The treatment often begins with non-operative management. When conservative treatment fails, many surgical techniques have been proposed, though none have demonstrated better long-term outcomes than the others [1]. Trapeziectomy, and its numerous technical variants with or without interposition and ligamentoplasty, is the most popular surgical procedure. It usually provides good pain relief and thumb function recovery [2,3]. However, trapeziectomy has a long recovery time, causes weakness of thumb strength, subsidence, and instability of the first metacarpal and worsening of hyperextension of the metacarpophalangeal (MCP) joint [3–6]. These drawbacks are particularly undesirable for younger and more active patients. TMC arthrodesis is an alternative in these patients but the results are contradictory. Long postoperative immobilization times, high complication rates, especially nonunion (up to 26%), and potential revision surgery cannot be ignored whether K-wires, plate or screws are used [7,8].

Implant arthroplasties preserve the trapezium and the mobility of the TMC joint. Arthroplasty with a total prosthesis has been done for nearly 50 years with numerous models sharing the concept of a "ball and socket" joint with most having metal and polyethylene components. The more recent prostheses seem to yield encouraging short and medium-term clinical outcomes, potentially better than traditional trapeziectomy techniques [9–11]. Concerns remain regarding their longevity, complication and failure rates, and their indication in young and active patients.

Implants made of pyrocarbon have been more recently proposed for hand and wrist arthroplasties [12]. They can be used as a gliding articular surface within an arthritic joint and overcome most of the complications related to a total prosthesis. For the TMC joint, two categories of pyrocarbon implants exist: (1) metacarpal stemmed implants creating a hemi-arthroplasty, and (2) TMC interposition implants. The Pyrocardan® implant (Wright Medical-Tornier SAS™, Bioprofile, Grenoble, France) falls in the latter category and acts as an intra-articular unconstrained interposition, thereby creating a TMC interface [13]. Encouraging short-term results have been reported with this implant [13–18].

The purpose of this study was to report the outcomes of the Pyrocardan® implant at a minimum 5 years of follow-up. The main hypothesis was that the Pyrocardan® implant yields satisfactory outcomes over time, at least comparable to those of trapeziectomy. The second hypothesis was that first metacarpal (M1) subluxation and younger age are not contraindications for Pyrocardan® arthroplasty.

2. Patients and methods

This was a prospective descriptive, continuous study with mid- and long-term follow-up. It evaluated the clinical and radiological results of the Pyrocardan® implant by comparing data measured preoperatively, at 1 year and then after 5 years of follow-up. The study was approved by the local ethics committee.

2.1. Patients

The case series included all consecutive patients with painful TMC OA treated from March 2009 to October 2014, in a single center and after failure of a minimum of 6 months of conservative treatment. Radiographically, patients had Eaton-Littler [19] grade I, II or early grade III OA. Patients with a symptomatic scaphotrapeziotrapezoid (STT) joint, previous operated TMC joint or history of local infection were excluded. In all, 146 patients underwent TMC interposition arthroplasty using the Pyrocardan® implant. They were operated by the same hand surgeon, who is graded level 5 for this procedure according to Tang and Giddins' criteria [20]. All patients signed an informed consent form to participate in the study.

2.2. Pyrocardan® implant

The Pyrocardan® is an intra-articular interfacing free interposition implant of the TMC joint made of pyrocarbon. It is rectangular shaped with two perpendicularly opposing tubular concave faces (Fig. 1). This geometry is intended to replicate the TMC joint's movements as seen on a cadaver model. The implant is 1 mm thick in the center, regardless of its size. There are 7 sizes, between 12 and 18 mm wide. The thickness of the peripheral edges is proportional to the implant size. Its placement requires minimal intra-articular bone resection which preserves the capsule, ligament and muscular insertions [21]. Stabilization ligamentoplasty is therefore not necessary.

2.3. Surgical technique and postoperative care

Patients underwent surgery under regional anesthesia with a tourniquet inflated to 250 mmHg at the base of the arm. All patients had a dorsal approach with a longitudinal skin incision of about 30 mm centered on the TMC joint [13]. The dorsal capsule was incised between the extensor pollicis brevis and the extensor pollicis longus. A rectangular capsuloperiosteal flap was raised from the base of the metacarpal an average of 10 mm distal to the joint, between the insertion of the abductor pollicis longus laterally and a line extending the ulnar edge of the metacarpal medially. The capsuloperiosteal flap remained attached proximally to the trapezium and was folded back to expose the joint line. The intra-articular bone cuts of the metacarpal and the trapezium were performed using a thin oscillating saw. The dorsal and palmar beaks of the metacarpal and the lateral and medial horns of the trapezium were resected, thereby altering the saddle-shape of each surface in order to get the new joint line perpendicular to the thumb column's axis (Fig. 2A and B). A complete joint synovectomy was then performed, preserving the continuity of the capsule. Using an ovoid bur, all irregularities of the bone cuts were removed so that the metacarpal surface was modeled into a slightly spherical convex surface (like the top of a Champagne cork), and the trapezium was modeled into an anteroposterior cylindrical convex surface (Fig. 2C and D). The trial implant was then inserted, and its size and position checked with fluoroscopy. The implant size was selected so that it completely covered the trapezium (Fig. 2E and F). After placement of the final implant, the capsuloperiosteal flap was repositioned and secured firmly without excessive tension at the base of the metacarpal and by three transosseous 3–0 resorbable sutures with a peripheral running suture on its edges. Skin closure was performed with an absorbable 4/0 intradermal suture.

Postoperative care consisted of thumb immobilization using a thermoformed splint worn constantly for 2 weeks. The splint was removed after 2 weeks and worn overnight and occasionally

Fig. 1. Pyrocardan® implant.

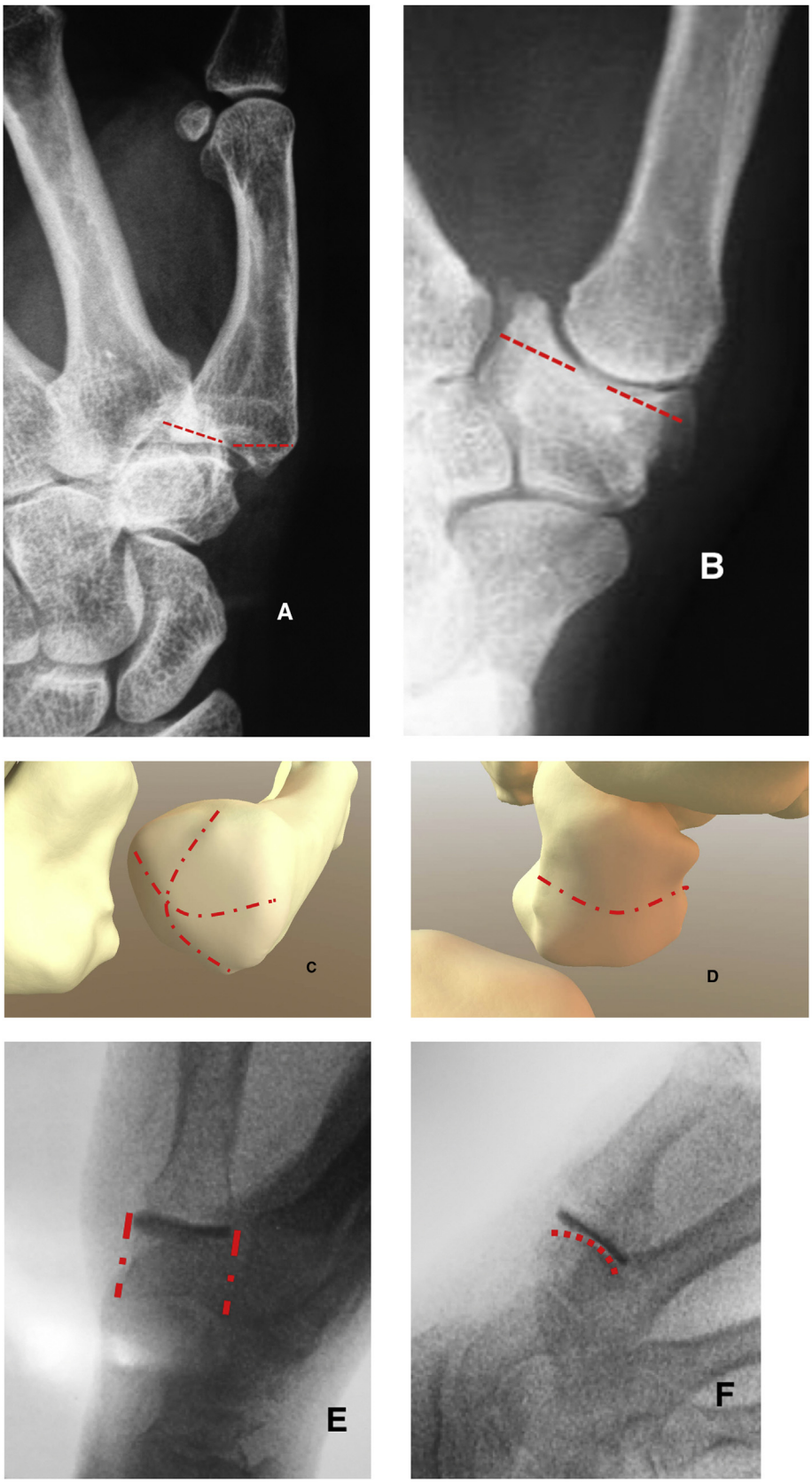

Fig. 2. Surgical technique. Bone cuts on the metacarpal removing the dorsal and palmar peaks (A). Bone cuts on the trapezium removing the lateral and medial horns (B). Surface modeling on the metacarpal to get a slightly biconvex shape like the top of a Champagne cork (C). Surface modeling on the trapezium to make the palmar–dorsal plane convex (D). A-P fluoroscopic view with the final implant in place (E). Lateral fluoroscopic view with the final implant in place (F).

during the day until the 4th week after self-guided rehabilitation. There was no prescribed postoperative physical therapy protocol, and at the end of the 4th week, patients had no restrictions on using their thumb.

2.4. Assessments

Clinical and radiological assessments were done preoperatively by the senior hand surgeon and by an independent examiner postoperatively at 1 year and after a minimum follow-up of 5 years.

2.4.1. Clinical evaluation

Pain was evaluated using the five visual analog scales (VAS) used in the Patient-Rated Wrist/Hand Evaluation (PRWHE) [22]. Each scale ranges from 0, indicating no pain, to 10 indicating the worse pain imaginable. The total score from 0 to 50 was then divided by 5 and reported out of 10.

Strength was measured bilaterally. Grip strength was measured with a hand dynamometer (Jamar®, Sammons Preston™, Bolingbrook, IL, USA), while key-pinch and tip-pinch strength were measured with a hydraulic dynamometer (Baseline Kit1®, AREX™, Palaiseau, France) in kilograms.

Range of motion (ROM) was assessed bilaterally using a goniometer placed on the back of the thumb to measure active flexion and extension of the interphalangeal (IP) and MCP joints in degrees (°).

The angle between M1 and the second metacarpal (M2) was also measured in degrees bilaterally in maximal abduction and antepulsion using a goniometer placed on the back of M1 and M2 on their bone landmarks defining their longitudinal axes.

Thumb opposition was measured with the Kapandji method on a 10-point scale (from 1: unable to do opposition to 10: complete opposition) and thumb retropulsion based on the Kapandji method but measured in millimeters instead of a grade [23].

Function was assessed using two standard questionnaires (PRWHE and QuickDASH) completed by the patients and calculated on a 100-point scale from 0: no disability to 100: complete disability.

Postoperatively, other data were also recorded: implant size, duration of immobilization, need for rehabilitation, duration of postoperative analgesics, duration of work stoppage or time to resume normal activities of daily living, and patient satisfaction on a 4-level scale: 1 – not satisfied, 2 – somewhat satisfied, 3 – satisfied and 4 – very satisfied. We also recorded the number and the type of complications and revision surgeries.

2.4.2. Radiographic evaluation

Preoperatively, anteroposterior (AP) and lateral radiographic views of the TMC joint were used to assess the severity of TMC OA according to the Eaton-Littler classification [19]. Subluxation of the articular surface of the M1 base was evaluated using three grades: grade 1 = reducible subluxation less than or equal to 1/3 of the metacarpal base, grade 2 = irreducible subluxation less than or equal to 1/3, grade 3 = subluxation more than 1/3. The same radiographic views were made immediately postoperatively and after at least 5 years of follow-up to assess current implant position, TMC positioning, possible bone remodeling or subsidence. To determine the degree of bone remodeling or implant subsidence, we used the AP views to calculate a trapezium index (TI) and a metacarpal index (MI) (Fig. 3). To establish the TI, the median height of the trapezium (T) and the median length of the proximal phalanx (P) length were measured. TI was calculated as the ratio T/P. To establish the MI, the median length of M1 (M) and the median length of the proximal phalanx (P) were measured. MI was calculated as the ratio M/P. The evaluation was performed on

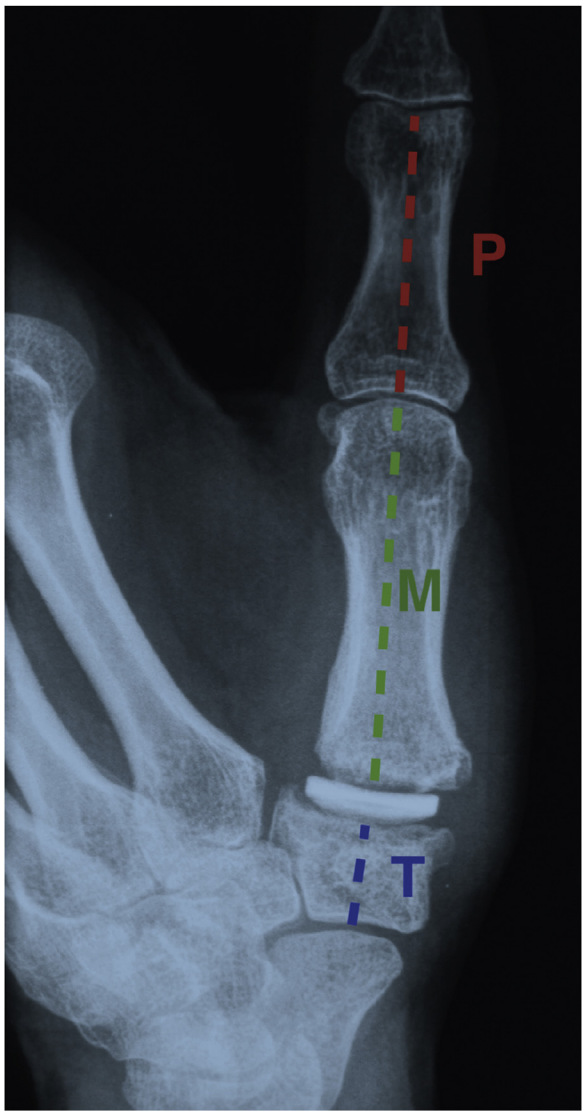

Fig. 3. The trapezium index (*TI*) is calculated by dividing the trapezium height *T* (*blue line*) by the reference proximal phalanx height *P* (*red line*): *T/P = TI*. The metacarpal index (*MI*) is calculated by dividing the first metacarpal height *M* (green line) by *P*: *M/P = MI*.

postoperative radiographs, at the 1-year follow-up and at the 5-year follow-up or later. Measurements were made three times on digital radiographs of the number of pixels using OsiriX® software (Version 6.5, Pixmeo™, Geneva, Switzerland). A difference up to 10% between the three measurements was arbitrarily considered an indication of substantial remodeling or subsidence.

2.5. Statistical analysis

All the data were compiled on a computer spreadsheet (Excel® software, Microsoft™ license). The data were not normally distributed. The qualitative variables were summarized as percentages. Quantitative variables were expressed as median and their dispersion with interquartile range (IQR). A Friedman test was used for repeated measures analysis of variance and a Wilcoxon signed rank test was used to compare two samples, preoperative and at the 1-year and 5-year follow-up. In all analyses, $p < 0.05$ was considered significant. A Pearson correlation test was used to identify correlations between the change in radiographic bone remodeling indices and the clinical data. A

Kaplan–Meier test was used to calculate the implant's survival rate with surgical revision for any reason as the endpoint.

3. Results

3.1. Patients

One hundred forty-six patients were operated for a TMC arthroplasty with Pyrocardan® implant in the same center by the same surgeon between March 2009 and October 2014. Fifty patients could not be included in the study: 30 did not wish to travel for the clinical and radiographic evaluation but still had their implant in place, 19 could not be contacted by any means and were lost to follow-up, and 1 patient died. Thus, the case series included 103 arthroplasties involving 96 patients (7 bilateral cases), of whom 80% were women. Table 1 summarizes the main characteristics of these patients. The median age was 59 years [IQR 8.52] (range 20 to 73 years). Fifteen patients (16%) were 50 years old or younger. The median follow-up was 67 months [IQR 4.24] (range 60 to 120 months). Most of the patients were operated on their dominant side (57%) because of Eaton-stage II TMC OA (78%) (Table 1). Forty-four (46%) patients were actively working: 17 (18%) did sedentary work and 27 (28%) were manual workers, of which 11 (41%) did heavy manual labor. Seventeen patients (18%) were unemployed and 35 (36%) were retired.

The median duration of postoperative analgesia was 7 days [range 0 to 90, IQR 15 days]. The median immobilization period was 2 weeks [range 2–4; IQR 0.9 weeks]. Postoperative physical therapy was needed in 16 cases (16%) for a median of 10 weeks [range 4–20, IQR: 8 weeks].

3.2. Clinical outcomes

The mean VAS score for pain decreased significantly from 7 preoperatively to 1.5 at the 1-year follow-up and 0.6 at the 5-year follow-up (Table 2). The PRWHE and QuickDASH scores improved significantly between the preoperative assessment and the 1-year and 5-year follow-ups. From the preoperative to the final review, the improvement was 54 points and 43 points, respectively (Table 2) while it was 8.5 points and 5 points between 1-year and 5-year follow-up. The median time to return to normal activities of daily living was 12 weeks [range 2–28; IQR 9.5 weeks].

Of the 27 manual workers, 4 retired, 3 shifted to non-manual work and 1 returned to work part-time. The median return to work time for non-heavy manual laborers was 12 weeks [range 2–28; IQR 7.2] and 13.5 weeks for heavy manual laborers [range 4–22; IQR 8.3] (Fig. 4).

Clinical ROM and strength assessments found no significant differences relative to the contralateral side during the 1-year and 5-year follow-ups. At 5 years, the patients' MCP flexion and thumb retropulsion was 125% of the contralateral side. ROM and strength on the operated side are shown in Table 3. No significant improvement or deterioration of the ROM was observed over time.

During the 1-year and 5-year follow-up visits, significant improvements were found in the tip-pinch, key-pinch and grip strengths (Table 3). Their final median values and gains were 7 kg (+2 kg), 8 kg (+3 kg) and 27 kg (+9 kg), respectively.

The clinical results of the patients 50 years or younger are reported in Table 4. Pain, function, and strength were slightly better in this group of patients than in the overall cohort (Fig. 4).

3.3. Radiological outcomes

Preoperatively, 40 cases (39%) had M1 subluxation: 37 cases of grade 2 and 3 cases of grade 3 (Fig. 2). At the last follow-up, 32 were corrected with the Pyrocardan® arthroplasty including the three grade 3 cases. Eight cases remained at the same dislocation stage (grade 2); six were linked to persistence of a slightly oblique joint space, and none had any clinical impact (Fig. 5).

The maximum bone remodeling or subsidence was 14% of the trapezium height and 18% of the M1 height. At the final follow-up visit, the average bone remodeling or subsidence of the trapezium was 2% of its height and 3% of the M1 height. There was no substantial bone remodeling or subsidence between the 1-year and final follow-up. There was no statistical correlation between variations in the clinical and functional results and variations in the radiological indexes (TI and MI) with the follow-up.

No implant instability or migration was found postoperatively and during the follow-up period.

3.4. Complications and revisions

Six cases (6%) underwent one corticosteroid injection during the first postoperative year for localized pain at the M1 dorsal base, which effectively eliminated the pain. One patient developed amyotrophic lateral sclerosis during the follow-up period. He was very satisfied with the outcome of his TMC arthroplasty at the 5-year follow-up visit.

There was a single intraoperative complication: a trapezium fracture occurred during osteotomy of the medial and lateral horns. This was a technical error during the seventh case of the

Table 1
Main characteristics of the study population and their trapeziometacarpal arthritis.

Patients (number)	96
Implant (number)	103
Age (years)	59 [IQR 8.52] range (20; 73)
Women (number, %)	76 (80%)
Right-handed (number, %)	94 (98%)
Dominant side (number, %)	59 (57%)
Manual worker (number, %)	27 (28%)
Follow-up (months)	67 [IQR 4.24] range (60; 120)
Eaton-Littler classification (number, %)	
Stage I	1 (1%)
Stage II	80 (78%)
Stage III	22 (21%)
Stage IV	0 (0%)
First metacarpal subluxation (number, %)	
Grade 1	63 (61%)
Grade 2	37 (36%)
Grade 3	3 (3%)

Median values; [IQR].

Table 2
Median values of pain (VAS) and function (PRWHE and QuickDASH scores) measured preoperatively, at 1 year and after 5 years of follow-up.

	Preoperative	1-year follow-up	5-year follow-up	*p*
Pain on VAS (/10)	7 [5.8–7.8; 1.5]	1.5 [0.8–3.1; 1.2]	0.6 [0–4; 1.6]	<0.0001
PRWHE (/100)	58 [48.5–75.5; 15.2]	12.5 [8–65; 14.2]	4 [0–50; 14.3]	<0.0001
QuickDASH (/100)	52 [38.6–56.8; 15.3]	14 [4.5–20; 14.2]	9 [0.5–15;13.9]	<0.0001

Median values [range; IQR]; significant results if $p < 0.05$; VAS = visual analog scale.

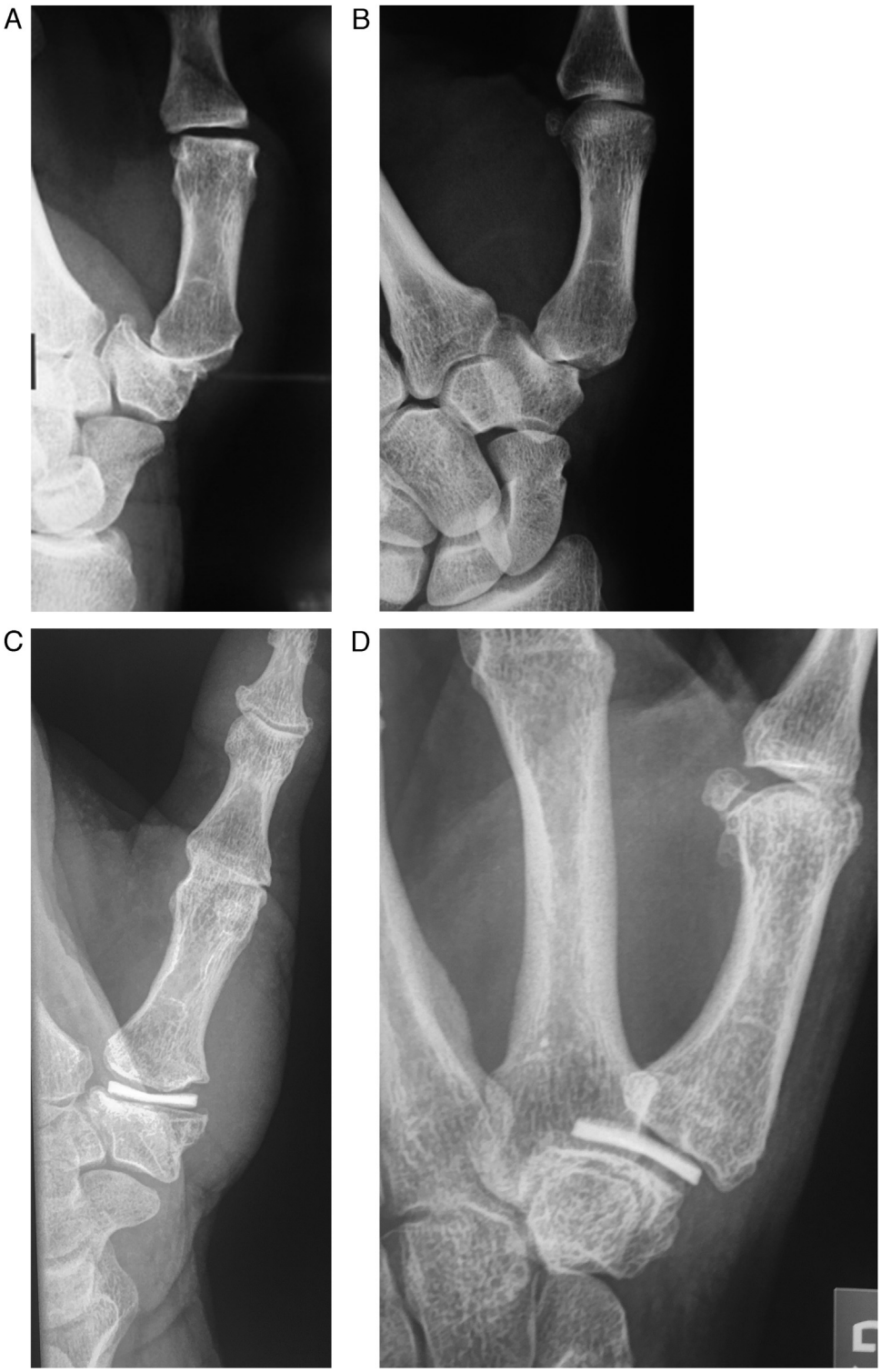

Fig. 4. TMC joint OA with metacarpal subluxation on the left (non-dominant) side in a 47-year-old heavy manual laborer (industrial logistics) treated with a Pyrocardan® implant. Clinical result after 7 years: Kapandji score = 10/10, pain on VAS = 0/10, PRWE = 0/100, QuickDASH = 0/100, Tip pinch = 10 kg, Key pinch = 12.5 kg, Grip strength = 38 kg. Preoperative AP (A) and lateral (B) radiographic views. Postoperative AP (C) and lateral (D) radiographic views after 7 years.

series, when an osteotome was used instead of a power saw. The trapezium healed within a normal timeframe with no impact on the clinical follow-up.

There were four revisions due to persistent or recurring pain. In two cases, the implant was removed and a trapeziectomy done at 19 months and 39 months, respectively. The first one was related to an overstuffed joint and the second one was performed after idiopathic collapse of the trapezium. In another case, an undersized implant was changed for a larger one after 1 year. The fourth patient, a heavy manual laborer, returned because of pain that gradually worsened over 1 year, attributed to repetitive excess pressure (overstuffing) due to his work in a leather shoe manufacturing plant. The surgical revision, 2 years after the initial operation, consisted of trapezium remodeling and changing the

Table 3
Median values of range of motion and strength measured preoperatively, at 1 year and after 5 years of follow-up.

	Preoperative	1-year follow-up	5-year follow-up	*p* Value
M1-M2 abduction (°)	40 [30–60; 11.7]	45 [34–54; 11]	45 [35–45; 10.5]	0.527
M1-M2 antepulsion (°)	45 [35–55; 13.1]	50 [41–54; 12.3]	45 [40–50; 10.4]	0.42
MCP flexion (°)	50 [45–65; 8.3]	50 [40–55; 9.2]	45 [30–45; 8]	0.234
MCP extension (°)	15 [0–30; 6.7]	15 [10–20; 5.4]	5 [0–26; 4.2]	0.311
IP flexion (°)	60 [58–70; 14.9]	65 [50–70; 14.3]	65 [45–70; 12.7]	0.12
IP extension (°)	0 [0–20; 4.3]	10 [0–20; 5.9]	0 [0–20; 4.6]	0.245
Thumb opposition (Kapandji Index)	9 [5–10; 3.8]	10 [8–10; 1.9]	10 [8–10; 1.7]	0.096
Thumb retropulsion (mm)	16 [10–35;7]	22 [15–30; 6.9]	22 [5–25; 7.2]	0.18
Tip-pinch strength (kg)	5 [2–7; 5.4]	6 [3–8; 2.2]	7 [5–9; 3.5]	0.002
Key-pinch strength (kg)	5 [2–8; 2.9]	6 [3–7; 1.6]	8 [4–9; 2.9]	<0.0001
Grip strength (kg)	18 [7–27; 12.2]	22 [13–28; 7.78]	27 [16–42; 9.78]	<0.0001

Median values [range; IQR]; significant results when $p < 0.05$; *NS*: not significant; *M1*: first metacarpal; *M2*: second metacarpal; *MCP*: metacarpophalangeal joint; *IP*: interphalangeal joint.

Table 4
Clinical outcomes in the subgroup of 15 younger patients (≤50 years old).

Pain on VAS (/10)	0.4 [1.5]
Tip-pinch strength (kg)	7.5 [2.4]
Key-pinch strength (kg)	8 [5]
Grip strength (Kg)	30 [11.2]
PRWHE (/100)	5 [15]
QuickDASH (/100)	4.54 [12.2]

Median values [IQR].

implant for a larger one. The patient was able to return to the same job but was not satisfied with the outcome. He contends that he suffered an occupational injury.

The overall 5-year survival rate of the Pyrocardan® arthroplasty was 96.2% (Fig. 6).

3.5. Satisfaction

Overall satisfaction was high for 96% of the patients: 81% were very satisfied and 15% were satisfied. Four patients (4%) were not satisfied: 3 of them had persistent pain at 5 years and 1 implant that was changed for a larger size caused persistent postoperative pain and discomfort.

4. Discussion

Our study is the first one to report the results of the Pyrocardan® implant with such a long follow-up and such a large number of cases. It demonstrates that this interposition arthroplasty used on patients with early stage TMC OA, even with M1 subluxation, was highly effective on pain relief and recovery of function and thumb strength. The satisfaction rate was excellent (96%), with early return to activity even for young and active patients. Functional results continued to improve over the 5-year follow-up period, with no complications found at the final follow-up. Bone tolerance was very good. In our study the Pyrocardan® implant had a 96.2% survival rate after 5 years.

In the literature, mid- or long-term follow-up publications with pyrocarbon implant interpositions for the treatment of TMC OA have shown also good outcomes on smaller case series than ours (Table 5) [14–18,24–29]. Most of the survival rates in these studies were comparable to ours and their revision rates did not exceed 18% [16] (3.8% in our study). Like in our study, progressive improvement during the follow-up period in the pain and function were reported by Logan et al. [18] with the Pyrocardan® implant between 1 and 2 years postoperative. This was also reported in long-term studies by Agout et al. [27] with the PI2® implant and Smeraglia et al. [29] with the Pyrodisk® implant.

Instability of the pyrocarbon interposition spacer after total or partial trapeziectomy is a concern, may be painful and not well tolerated clinically, requiring revision surgery in up to 6.5% of patients [29]. Implant instability may be related to the implant's shape, which is ellipsoidal for the Pi2® and slightly biconvex for the Pyrodisk®. It also may be related to failed stabilization with peripheral ligamentoplasty for the Pi2® and central ligamentoplasty for the Pyrodisk®. These stabilization techniques may have a learning curve as pointed out by Agout et al. [27] and Barrera-Ochoa et al. [26]. Pyrocardan® implant instability did not occur in our case series. This implant, with both surfaces being concave-shaped, is much more stable than biconvex implants thus no ligamentoplasty is needed to stabilize the Pyrocardan®. Moreover, thanks to its 1 mm central thickness, the capsule and periarticular ligaments can be preserved during its implantation. Furthermore, thanks to the bone cuts especially on the trapezium, orthogonal alignment of the arthroplasty with respect to the thumb column axis yields a long-lasting stable Pyrocardan® arthroplasty (Fig. 4). Thus, 80% of our cases with preoperative M1 subluxation were completely reduced postoperatively. However, six out of the eight remaining M1 subluxations were related to a persistent oblique joint line but apparently without clinical consequences (Fig. 5). A meticulous surgical technique for articular bone surface preparation is required for successful Pyrocardan® interposition arthroplasty. This was also pointed out in short-term studies of Pyrocardan® TMC arthroplasty [13–18]. The single intraoperative complication (trapezium fracture) and two cases requiring revision surgery (initial implant was too small) can be attributed to technical errors in the surgical procedure, especially in bone preparation and sizing of the implant. In the past 5 years, we have changed the joint approach to a simpler one (Appendix A. supplementary data: video of the surgical technique). The dorsal capsule is split with a longitudinal median incision in continuity

Fig. 5. TMC joint OA on the dominant side of a 60-year-old retired woman with slight subluxation of the first metacarpal. Persistent subluxation after Pyrocardan® arthroplasty did not progress on AP radiographs during the follow-up period. Final clinical result after 10 years: Kapandji score = 9/10, pain on VAS = 0/10, PRWE = 2/100, QuickDASH = 9/100, Tip pinch = 8 kg, Key pinch = 10 kg, Grip strength = 30 kg. Preoperative X-rays (A). Radiographs after 1 month (B), 20 months (C), 5 years (D) and 10 years (E).

with the periosteum of the base of the metacarpal. For closure, the two dorsal capsuloperiosteal flaps are repositioned and sutured to one another without excessive tension, potentially combined with intraosseous anchorage at the metacarpal base and reinforced with a running suture on the periosteum. This approach provides a better view of the joint and makes bone preparation easier. Furthermore, since we have been using it, there has been no instances of dorsal pain of the M1 base that required subsequent local corticosteroid injection.

Conventional alternatives to the Pyrocardan® implant and other pyrocarbon arthroplasties for TMC OA are trapeziectomy (with or without suspension and ligamentoplasty) and total TMC prosthesis. Their outcomes in the mid- or long-term published in studies during the last decade are summarized in Table 6 for trapeziectomy [3,6,30–36] and in Table 7 for total prosthesis [37–47]. Pain relief provided by trapeziectomy and total prosthesis seems comparable to our results. Strength after trapeziectomy is lower in comparison to total prosthesis and our results, which look better than those of total prosthesis. Strength recovery is an important criterion for patients, especially the younger and more active ones. Persistent thumb weakness may influence the satisfaction rate which seems to be lower after trapeziectomy compared to total prosthesis and Pyrocardan®. Erne et al. [17] compared Pyrocardan® implants with Lundborg's resection arthroplasty and reported significant faster recovery in the Pyrocardan® group than in the resection group (3.7 months compared to 5.9 months). The recent study by Logan et al. [18] comparing Pyrocardan® with LRTI trapeziectomy, also found higher grip strength and faster recovery in the Pyrocardan® group. But these clinical results should be compared carefully as there are no comparative prospective studies of trapeziectomy versus total prosthesis and Pyrocardan® so far. Furthermore, patients on our study may be younger with less advanced OA than those in the trapeziectomy and total prosthesis studies. In fact, the younger

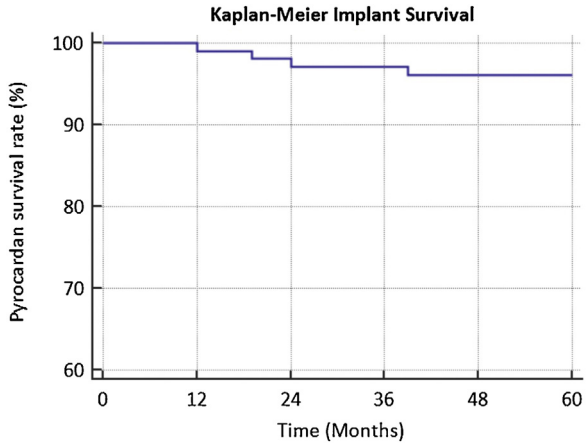

Fig. 6. Kaplan–Meier survival of the Pyrocardan® implant was 96.2%.

patients of our case series had the best results in terms of pain, strength, and function (Table 4).

Total prosthesis has the highest revision rate and the lowest survival rate which worsens with longer follow-up. They are mainly related to a mechanical problem, dislocation, and material (polyethylene and metal) wear, bone fixation problems, or occasionally, metal allergy. These complications are probably facilitated by the non-physiological concept of "ball and socket" joint of total joint arthroplasties. On the contrary, the survival rate of our study was stable during the follow-up period (Fig. 6). No revision was necessary in our patients between 39 months and 96 months (longest follow-up). From our point of view, this is mainly related to the quality of the material and the small size of the implant. Beside its remarkable biomechanical properties, the advantage of a pyrocarbon material is its excellent biocompatibility allowing bone surfaces to glide over and around the implant. Thus, small thin implants such as the Pyrocardan® may be used as an interposition device inside the TMC joint with a minimally invasive procedure preserving the trapezium height. The design of such an interposition implant may allow double-saddle-like motion close to that of a normal TMC joint. The minor bone remodeling observed radiologically in some cases during the first year did not progress over the follow-up period and was not clinically relevant. We think that it reflects an adaptability of the bones facing the implant due to the new biomechanical conditions of the joint. Nevertheless, in case of failure, revision is possible with good local conditions since the soft tissues and the bone stock are preserved. Revision can consist of a new Pyrocardan® arthroplasty, or a standard trapeziectomy, as we did in our study, or by total prosthesis or TM arthrodesis.

Thumb carpometacarpal arthrodesis is a viable solution. It has been traditionally suggested for young and active patients or post-traumatic patients because of the technique's intrinsic stability. A wide range of outcomes have been reported. Non-union is the most reported concern with this procedure although it does not systematically correspond to poor clinical outcomes [7,8]. Arthrodesis

Table 5
Outcomes of pyrocarbon implant arthroplasty of the TMC joint in comparable published studies.

Authors	Year	Implant	*n*	Age (years)	Follow-up (years)	Pain on VAS	Tip or Key pinch (kg)	Grip strength (kg)	Quick-DASH	Satisfaction rate	Survival rate	Complication rate	Revision rate
Present study	2020	Pyrocardan®	103	59	5.5	0.6	7	27	9	96%	96.2%	4.8%	3.8%
Logan et al. [18]	2020	Pyrocardan®	40	58	2.5	1.7	5	30	23	83%	100%	NA	0%
Erne et al. [17]	2017	Pyrocardan®	8	64.3	1.5	1.5	0.73 bar	NA	18.3	7.4/10	100%	NA	12%
Lauwers et al. [16]	2016	Pyrocardan®	28	59	2	NA	NR	NR	NR	75%	NA	NR	18%
Russo et al. [15]	2016	Pyrocardan®	40	58.5	2.5	2.7	4.6	NR	18.7	NR	94.5%	NA	5%
Odella et al. [14]	2014	Pyrocardan®	25	55	1	4	NR	NR	22.4	NR	88%	12%	8%
Bellemère et al. [13]	2011	Pyrocardan®	27	58	1.5	1.3	6.7	NA	10.1	NR	100%	NA	0%
Smeraglia et al. [29]	2020	Pyrodisk®	46	62	9.5	1	4	NR	17.4	93%	93%	NR	6.5%
Oh et al. [28]	2019	Pyrodisk®	20	64	3	5.9	6.6	23.2	55.6	NA	100%	NA	0%
Barrera-Ochoa et al. [26]	2014	Pyrodisk®	19	61	5.3	1.7	5	20	20.2	89%	90%	NA	10.5%
Agout et al. [27]	2016	Pi2®	42	63	10	1.62	5.9	24.2	19.9	97%	100%	10%	0%
Odella et al. [14]	2014	PyroDisk®	34	62	3.5	3.3	NR	NR	19.2	NR	97%	6%	3%
Bengezi and Vo [25]	2014	PyC® spherical	24	56	1.5	1.1	NR	NR	11.8	100%	100%	NA	0%
Ardouin et al. [24]	2011	Pi2®	42	63	5	2.9	5.6	NR	26.4	98%	98%	8.7%	2.4%

NR: not recorded; *NA*: not applicable; *n*: number.

Table 6
Outcomes of trapeziectomy published in the last decade in studies with a minimum of 5 years of follow-up and the present study.

Authors	Year	Technique	*n*	Follow- up (years)	VAS % pain	Tip -Key (kg)	Grip (Kg)	Quick DASH	Satisfaction rate	Survival rate	Complication rate	Revision rate
Yeoman et al. [3]	2018	T	205	8	NR	NR	NR	40	81%	NA	1%	1%
De Maio et al. [36]	2019	TLR	50	8	NR	NA	NR	16	95%	NA	NA	NA
Moneim et al. [35]	2018	PTTI	32	5	0.32	NA	NA	5.06	NA	NA	NA	NA
Rhee and Shin [6]	2018	TTI + TTILR	57	10	23%	4.7	24.1	NR	NA	NA	7%	3.5%
Pomares et al. [34]	2016	TTI	51	13.5	0.6	3.6	25.7	12.8	96%	NA	NA	2%
		TLR	16	11.5	1.6	3.4	22.8	20.7	87%	NA	NA	6%
Vinycomb and Crock [33]	2013	TTILR	15	10	NR	6	NA	NR	87%	NA	NR	NA
Avisar et al. [32]	2013	TTI	15	15	2.1	4.3	25.4	16.8	NR	100%	0	0
Gangopadhyay et al. [31]	2012	T	53	5	0	2.7	20	NR	NR	NA	2.1%	2.6%
		TTI	46	5	1	2.5	18	NR	NR	NA	2.3%	
		TTILR	54	5	0	2.7	20	NR	NR	NA	4.32%	
Ferrière et al. [30]	2010	TTI	18	6.5	1	4.5	20	20	91%	NA	NR	NA
Present study	2020	Pyrocardan®	103	5.5	0.6	7	27	9	96%	96.2%	4.8%	3.8%

NR: not recorded; *NA*: not applicable; *n*: number; *T*: Trapeziectomy; *TTI*: Trapeziectomy + tendon interposition; *TIL*: Trapeziectomy + intercarpal ligamentoplasty; *TLR*: Trapeziectomy + ligament reconstruction; *TTILR*: Trapeziectomy + tendon interposition + ligament reconstruction; *PTTI*: Partial trapeziectomy + tendon interposition.

Table 7
Outcomes of CMC total prosthesis in studies published in the last decade with a minimum of 5 years of follow-up and the present study.

Authors	Year	Implant	*n*	Follow- up (years)	VAS or % pain	Tip-key (kg)	Grip strength (kg)	QuickDASH	Satisfaction rate	Survival rate	Complication rate	Revision rate
Dumartinet-Gibaud et al. [47]	2020	Arpe®	32	10	3	NR	NR	23	97%	NA	NA	NA
Tchurukdichian et al. [46]	2020	Ivory®	102	10	0.2	3.5	26	NA	NR	95%	5%	5%
Gómez -Garrido et al. [45]	2019	Arpe®	151	5	1	5.8	NR	19.55	92%	92.7%	NA	7%
Andrzejewski and Ledoux [44]	2019	Maïa®	113	5	NR	4.8	NR	26.7	92%	92.2%	21.2%	3.9%
Vissers et al. [43]	2019	Ivory®	26	10	1.4	4.4	19.2	29.2	96%	85%	NR	15.4
Cootjans et al. [42]	2017	Arpe®	120	5	0	5.5	25	4.6	NR	96%	11.6%	6.6%
Toffoli and Tessier [41]	2017	Maïa®	80	5	1.2	4.3	19.2	17.5	NR	93%	5.2%	5.2%
Dehl et al. [40]	2017	Rubis II®	115	10	1	59 N	180 N	30	99%	89%	NA	10%
Semere et al. [39]	2015	Roseland®	64	10	91%	44 N	213 N	27.6	100%	91%	25%	9.3%
Martin-Ferrero [38]	2014	Arpe®	65	10	1.1	5.6	NR	20.1	95%	93.9%	8%	4.6%
Maes et al. [37]	2010	Rubis II®	77	7	76.5	NR	NR	NR	100%	93%	NA	7.6%
Present study	2020	Pyrocardan®	103	5.5	0.6	7	27	9	96%	96.2%	4.8%	3.8%

NR: not recorded; *NA*: not applicable; *n*: number; *N*: Newton.

has historically been widely compared with trapeziectomy and it has higher revision and complication rates (5% to 29%) [7,48–52]. Furthermore, postoperative protocols require long term immobilization (4–10 weeks) before starting rehabilitation [48–52].

They are some limitations to our study. First, we did not have postoperative long-term clinical and radiological data for 34% of the initial cohort. Only 14% were completely lost to follow-up (died or unreachable), while the remaining 20% still had their implant but did not wish to come back for a clinical and radiological evaluation because they lived too far from our facility or they felt they were too old or not in enough good health to come back. We preferred not to include these patients in the study as we could not do a clinical or radiological assessment. A telephone evaluation with questionnaires is not realistic. Second, we calculated radiographic indexes to evaluate and quantify bone remodeling. This evaluation was done only on standard AP views and three separate measurements had to be made. A less restrictive and more reliable solution could involve 3D reconstructions using a low radiation imaging device. Lastly, the surgeon who did all the operations is the implant designer thus has a conflict of interest; however postoperative and final evaluations were performed independently by two evaluators with no conflict of interest.

In summary, with a long-term follow-up, Pyrocardan® arthroplasty for TMC OA provides pain relief, good strength, and good thumb function recovery with a high survival rate. Clinical and radiological results do not seem to deteriorate over time. This makes it a reliable alternative to trapeziectomy or total prosthesis especially for young active patients. Subluxation of the M1 base is not a contraindication for this minimally invasive arthroplasty. Longer follow-up and prospective comparative studies are needed to confirm all these findings.

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

Author contributions

EG (first author), DB: reviewed the patients, made the data collections, wrote the manuscript.

PB operated the patients, made the preoperative clinical evaluation and made corrections and rewriting of the original manuscript.

EG and LA: contributed to correct the original manuscript.

Informed consent and patient details

The authors declare that they obtained a written informed consent from the patients and/or volunteers included in the article and that this report does not contain any personal information that could lead to their identification.

Declaration of interest

PB declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: he serves as a consultant for Wright-Medical/Tornier (Montbonnot, France) and receives royalties from this company.

The other authors (EG, DR, EG and LA) have no conflict of interest to declare.

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Appendix A. Supplementary data

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