MAÏA®

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TRAPEZIO-METACARPAL JOINT PROSTHESIS FOR BASAL JOINT ARTHRITIS

100 prosthesis with a 4 years follow-up

According to work of:
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KEY POINTS:

- *Functional strength recovery at 3 weeks (highly superior to trapeziectomy)*
- *Restoration of mobility and thumb column stability and length from 3rd month*
- *Survival rate: 95,6% at 4 years*

Goal: The goal of this study was to evaluate the performance of a Maïa® trapezio-metacarpal joint prosthesis in a single-center, retrospective study with an average follow-up of 48-month.

Methods: From June 2005 to September 2007, 94 patients with 100 prosthesis were included in the study. Of these 100 prosthesis, 89 were analyzed. Seven patients were lost of sight, two patients died and there were two surgical revisions in another institution.

Results: Post-operative pain was 0.8/4.0 based on the Alnot score; 93.6% of patients were satisfied or very satisfied. The average Kapandji opposition score was 9.7/10 and the average DASH score was 9.9/100. Key pinch strength was comparable to the non-operated side. There were two surgical revisions for trapezium loosening. There were two cases of De Quervain's tenosynovitis, two cases of reflex sympathetic dystrophy, one post-traumatic trapezium fracture, and one case of trapezium loosening that was not revised. Implant survival rate at 48 months was 95.6%.

Conclusion: The Maïa® prosthesis provides excellent clinical results and the survival is highly satisfactory. The anatomical design and modularity (angled and anteverted necks) results in good adaptability and stability. The Porocoat/hydroxyapatite coating allows for fast bone integration. Trapezium loosening is the main complication in the medium term.

CONTENT:

INTRODUCTION:

Basal joint arthritis is a common problem in older women.
The trapezio-metacarpal joint is often affected by osteoarthritis because it is highly used during activities of daily living. Patients are starting to ask for a pain-free range of motion in this joint. [1,2]
The trapezio-metacarpal joint has been described as a biconcave saddle joint with two degrees of freedom. [3,4]
Total joint replacement has been a treatment option for 30 years. [5]
The range of available trapezio-metacarpal prosthesis has expanded quickly over the past ten years. [2]
The currently marketed prosthesis differ in the position and number of centers of rotation, type of joint (saddle or ball-and-socket), fixation method and range of motion (De la Caffinière®, Rubis®, Roseland®, Isis®, Ivory®, Guepar®, Arpe®, Elektra®, Cardan de Kapandji) [1,6,7]
The prosthesis that we propose to use has a ball-and-socket joint design (single center of rotation) with semi-retentive cup, which allows for a third degree of freedom.

PATIENTS AND METHODS:

Goals:

The main goal was to evaluate the **performance** and **safety** of the Maïa® trapezio-metacarpal prosthesis as a treatment for basal joint arthritis by estimating its **probability of survival** (surgical revision to change all or part of the implant, no matter the cause) in a series of consecutive patients, which represents use in daily clinical practice.
The secondary goals were to perform a detailed clinical evaluation (post-operative improvement in the Alnot pain score, patient satisfaction, Quick DASH score, Kapandji opposition and retropulsion index, Key-Pinch and Grasp strength, post-operative mobility), carry out a radiological evaluation of loosening, subsidence and ossification, look for undesirable effects that did not require prosthesis revision (nosocomial infection, hematoma, dislocation, fracture, loosening, allergy, radial neuralgia, De Quervain's tenosynovitis) and record deaths.

Study type:

We performed a single-center, single-surgeon, retrospective study on a series of 100 consecutive cases.

Patients:

All patients, independent of age or gender, were included in this study if they received the Maïa® trapezio-metacarpal joint prosthesis between June 2005 and September 2007. Doctor Jacques Teissier was the surgeon.
The operative data collected were the gender, age at surgery, operated side, dominant arm, preoperative Alnot score, activity level, Dell radiological scoring.
The procedure date, reason for the implant choice and undesirable effects were noted as features of the surgical procedure.
Monitoring after the hospital discharge was carried out to look for complications or the need for surgical revision. Standard clinical and radiological evaluations were used: Alnot score, patient satisfaction, Quick Dash score, Kapandji opposition and retropulsion index, Key-Pinch and Grasp strength, post-operative range of motion, evaluation of loosening, subsidence and ossification.
All the subjects were contacted by telephone. Most of the subjects agreed to visit the clinic so that the implant could be reviewed. For subjects who could not travel, data were gathered over the telephone. In such a case, only the need for surgical revision was recorded. Some subjects could not be reached (lost of sight).

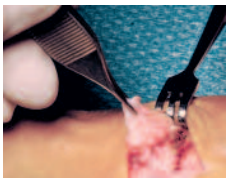
MAÏA® PROSTHESIS:

The Maïa® implant is a non-cemented, trapezium ball-and-socket total joint prosthesis with three degrees of freedom and a single center of rotation.
The metacarpal stem has a triangular cross-section to match the anatomical shape of the medullary cavity of the first metacarpal. The prosthesis has a bi-layer coating: vacuum plasma sprayed T40 titanium with Porocoat / hydroxyapatite, which improves bone integration. Fish-scale macrostructure at the proximal end reduces the risk of the implant subsidence, and helps with bone in-growth in the contact areas. Four sizes are available (7, 8, 9 and 10).
The modular neck is available in 3 models (straight, angled and anteverted left or right) and 3 lengths (medium, long and extra-long). The neck is thin to avoid a cam effect. The head is cast in one piece.
The hemispherical trapezium metal-back cup has an interchangeable polyethylene insert that is available in retentive and non-retentive models. The external diameter can be either 9 or 10 mm; the shape is decagonal. The outer surface of the cup that is in contact with the trapezium has small four fins and a bi-layer coating of vacuum-sprayed titanium and Porocoat / Hydroxyapatite that allows for press-fit fixation without cement. Cup holding forceps are used to manipulate the cup via the two, 1 mm symmetrical holes on the equator of the cup. Although set, the PE insert is removable and can be changed in case of revision.
A 6° morse taper attaches the stem to the neck. The neck is anteverted 30°. The implant provides 120° angular clearance, which is more than the physiological range.

Surgical technique:

• Regional anesthesia with pneumatic tourniquet at the base of the limb.
• Lateral approach with straight incision over the middle of the trapezio-metacarpal joint.

• Sensory branches of the radial nerve are systematically visualized and protected with retractors.



• The EPB is displaced to the outside and the APL to the inside. The APL insertion on the base of the first metacarpal is partially detached with a piece of periosteum.
• Reverse L arthrotomy: A capsular flap is made and turned up dorsally to protect the radial artery.





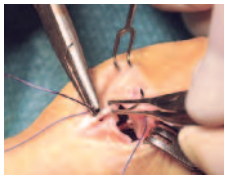

• Synovectomy.

• First step - metacarpal preparation: An oscillating saw is used to cut a 5 mm fragment. The cut is perpendicular to the axis of the first metacarpal and takes out the articular surface, including the cartilage and subchondral bone; any palmar osteophytes are systematically resected and repeated passes are made with bone rasps to determine the size of the final stem.

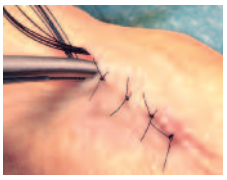
• Second step - trapezium preparation: The trapezium horns are resected with bone forceps. Any osteophytes are systemically trimmed away and repeated passes are made with the reamer, finishing with the manual reamer so as to not burn the bone.


• Implantation of the chosen trapezium implant (semi-retentive) by impaction. Use impactor (straight or angled) to drive in the cup while making sure to maintain 40° of abduction and 40° of anteversion with respect to the axis of the second metacarpal.


• After stem and cup insertion, use trial necks to determine final neck orientation and length. Range of motion and stability are tested.




• Close by returning the capsular flap to its original location; the APL is displaced dorsally and reinserted under tension with the periosteum at the base of the first metacarpal.



• Skin is closed with simple, interrupted, non-resorbable suture, without drain.
• After 48 hours, placement of an orthesis to immobilize the thumb for three weeks.
• The orthesis is removed after 3 weeks then initiation of self-directed rehabilitation.
• Patients are seen again at 2 months.

Radiological assessment:

Standard radiological assessments were performed at follow-up: A/P radiographs of both hands and A/P and lateral Kapandji views of both thumbs.


A/P Kapandji view


Lateral Kapandji view

Statistical analysis:

Qualitative variables were described with percentages, while quantitative variables were described with average, standard deviation, median, minimum and maximum values.
The post-operative change in the PMA score was evaluated with a paired Wilcoxon test.
Any missing data were analyzed with the Kaplan Meier method (with 95% confidence intervals for the probability of survival). The start date was the date the device was implanted and the cut-off date was October 31, 2011. A subject that could not be contacted again was considered as being lost of sight.
All the bilateral tests had a threshold of 5%. The analyses were carried out with Stata 5 software.

RESULTS

All the data available on October 31, 2011 were analyzed.

Description of the included population

In all, 100 Maïa® trapezio-metacarpal prosthesis were implanted in 94 patients (6 patients had bilateral implants) between June 2005 and September 2007. This was a consecutive case series. Features of the patients at inclusion are given in Tables 1 and 2.

Table 1 – Features of the population at inclusion

FEATURE	n (%)
Gender	
Female	92 (97,8)
Operated side	
Right	57 (57,0)
Dominant arm	
Yes	46 (46,0)
Occupation (activity level)	
Heavy manual labor	49 (49,0)
Light manual labor	19 (19,0)
Sedentary	32 (32,0)
Dell classification	
Stage 1	0 (0,0)
Stage 2	0 (0,0)
Stage 3	18 (18,0)
Stage 4	82 (82,0)
STT affected	
0	86 (86,0)
1	11 (11,0)
2	3 (3,0)

Four patients presented with inflammatory arthritis and one patient with diabetes. In terms of treatment history, 35% of patients had joint injections, 26% had a splint and 16% had an injection and a splint.
The trapezium had an average height of 8 mm (minimum 4 mm, maximum 12 mm).

In 5% of cases, the patient also presented with severe osteoarthritis of the metacarpo-phalangeal joint.

Table 2 – Features of the population at inclusion

FEATURE	Avg (SD)	Med (min-max)
Age, years	68,4 (8,2)	68,0 (48-86)
Pre-operative Alnot score	3,2 (1,0)	4,0 (0-4)

Implants

Implant features are given in Table 3.

Table 3 – Implant features

FEATURE	n (%)
Stem size	
7	16 (16,0)
8	38 (38,0)
9	29 (29,0)
10	17 (17,0)
Neck type	
Straight medium	0 (0,0)
Straight long	1 (1,0)
Straight extra-long	2 (2,0)
Angled medium	23 (23,0)
Angled long	67 (67,0)
Angled extra-long	6 (6,0)
Angled - Anterverted right medium	0 (0,0)
Angled - Anteverted right long	1 (1,0)
Angled - Anteverted right extra-long	0 (0,0)
Angled - Anterverted left medium	0 (0,0)
Angled - Anterverted left long	0 (0,0)
Angled - Anterverted left extra-long	0 (0,0)
Cup type	
Size 9 retentive	99 (99,0)
Size 10 retentive	1 (1,0)

Most (96.0%) of the necks used were angled (medium, long, extra-long); only retentive cups were used.

RESULTS OF THE FOLLOW-UP

Data collection

On the 94 patients (100 prosthesis), 83 were seen again at the clinic. Data from others patients were collected by phone.

Probability of implant survival

Of the 100 Maïa® trapezio-metacarpal implants, 11 were not included in the results because of the following reasons:
- 2 patients died (2.0%). The cause of death was unrelated to the device.
- 2 prosthesis were revised in another institution (2.0%)
- 7 patients were lost of sight (7.0%).

The follow-up was on average 45.3 months (+/- 5.5) with a median of 44.2 months (minimum 37, maximum 64).
Implant survival at 48 months was calculated to be 95.6% (95% CI: 82.7 - 98.9) based on the 24 prosthesis available at that time point, as shown in Figure 2.

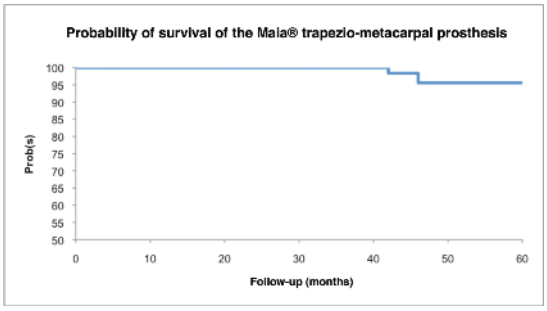


Figure 2 – Probability of survival of the Maïa® trapezio-metacarpal prosthesis.

There were two surgical revisions:
- One revision was done by another surgeon 42 months after the implantation surgery. for trapezium loosening revised by cup with a greater diameter (10 mm).
- One revision was performed 46 months after the initial implantation due to loosening of the trapezium cup in a 48 year old woman who performs heavy manual labor and had isolated rizarthrosis. The revision was carried out as a single intervention that included reconstruction of the trapezium with an iliac cortical-cancellous bone graft and implantation of a size 9 press-fit cup into the graft.

Complications that did not require surgical revision

In the entire series, 9 patients presented with complications that did not require surgical revision:
- The prosthesis dislocated in a 58 year-old patient and was treated with a closed reduction. This patient died one year later after a contralateral proximal femur fracture; no other dislocations were noted.
- Four patients experienced reflex sympathetic dystrophy, which delayed functional recovery by an average of three months.
- A non-displaced trapezium fracture was found in a 67 year-old patient three weeks after the implantation surgery. The fracture was treated conservatively with cast immobilization for two months and then a removable splint for one month.
- Two patients developed De Quervain's tenosynovitis and treated with an injection and immobilization.
- A 77 year-old woman presented with subsidence and loosening of the trapezium cup. The patient refused the proposed revision as she was not symptomatic.

Clinical evaluation

The clinical evaluation was performed on the 83 patients that were seen again at the clinic.
Improvement in the Alnot pain score:

Table 4 – Comparison of the preoperative Alnot score with the score at the last follow-up

FEATURE	Avg (+/-)	p-value
Preoperative Alnot score	3.2 (1.0)	< 0.01†
Postoperative Alnot score	0. (1.0)	
† Paired Wilcoxon Test		

Patient satisfaction:

71.4% of patients were very satisfied, 22.2% were satisfied, 4.8% were somewhat satisfied and 1.6% were not satisfied. The overall satisfaction rate was 93.6%.

Quick DASH score:

The average score at the last follow-up was 9.9/100 (S.D. 10.5, median 6.8/100, minimum 0/100, maximum 47/100).

Kapandji opposition and retropulsion index [8]:

The average opposition index was 9.7/10; the retropulsion index was 2.0/4. The postoperative range of motion was:
- Flexion: 19,0°
- Extension: 40,3°
- Antepulsion: 33,4°
- Retropulsion: 15,6°

Key-Pinch and Grasp strength:

Table 5 – Key Pinch and Grasp strength at the last follow-up

		Operated side	Non-operated side
Male	Key Pinch	9.4 kg	9.3 kg
	Grasp	43 kg	44,2 kg
Female	Key Pinch	5.3 kg	5.5 kg
	Grasp	22.1 kg	23 kg

Radiological examination

The radiological evaluation was performed in the 83 patients that were seen again at the clinic.

Radiolucent lines:

Radiolucent lines around the trapezium were seen in 17.4% of cases and around the metacarpal in 22.2% of cases. These radiolucent lines were asymptomatic.

Ossifications:

Ossifications were deemed small and non-obstructive in 36.5% of cases, medium and slightly obstructive in 23.8% of cases and cumbersome in 3.2% of cases. The latter resulted in moderate stiffness.

Subsidence or movement:

Overall subsidence of the trapezium cup was found in 3.2% of cases. No subsidence of the metacarpal stem occurred. A rocking motion affected the trapezium cup in 4.7% of cases.

DISCUSSION

Treatment of basal joint arthritis with a trapezio-metacarpal total joint replacement is still for some surgeons, a controversial approach.
Surgical alternatives include trapeziectomy, with or without tendon interposition / suspension ligamentoplasty, which is the most typical proposed solution [9,10]. **Pain disappears and strength, motion, stability and length of the first column are restored within three months following a Maïa® prosthesis implantation [11,12].**

The possibility of persistent pain and risk of stiffness in the thumb column exists if the ligamentoplasty is overly tight after the trapeziectomy [13]. The length of the thumb column is significantly reduced, especially in the women who are mostly affected by this disease. The trapezium-scaphoid space was found to be reduced by 27% after a 78 month follow-up [9]. However in the cited trapeziectomy study, the only complications were two cases of reflex sympathetic dystrophy. In contrast, **we found that the Maïa® trapezio-metacarpal prosthesis leads to faster functional recovery, with greater strength than with a trapeziectomy and on-going pain relief after an average follow-up of four years.** The implant survival rate is highly satisfactory and complications are rare (7%). The Maïa® prosthesis is our preferred procedure -- it quickly provides pain relief and stable function over time (average follow-up of four years) and provides the opportunity to perform a trapeziectomy with or without tendon interposition / suspension ligamentoplasty if there are complications with the prosthesis. Few treatment options exist if a patient still has pain after trapeziectomy.

More recently, interposition implants, mostly made of pyrocarbon, with or without partial or complete trapeziectomy, have emerged as a competitive alternative to a total joint prosthesis.

Because of undesirable effects, silastic, polyesther and PLLA implants with full trapeziectomy have lost their credibility [27].

Advantages of a total joint prosthesis:

- Pain disappears
- Motion is recovered
- Strength is restored
- Thumb length is restored
- Classical Z deformity of the thumb is cured

All this occurs in a very short post-operative time frame, about 3 months. In addition, if the prosthesis fails, a trapeziectomy is still possible, and there are other potential solutions if the prosthesis needs to be revised: trapezium reconstruction with bone graft, trapezium prosthesis or dual mobility revision cup, cup implanted in the scaphoid, Foster-type trapezo-metacarpal fusion, etc.

The trapezium is the biggest challenge. Trapezium loosening occurred in 2,2% of the cases in our series. There was a 3.2% rate of overall subsidence of the cup that was asymptomatic, 4.7% stable rocking of the cup and 17% rate of stable trapezium radiolucent lines. In a series with 84 Guepar® prosthesis, 28% of cases had radiolucent lines around the trapezium and 3% had trapezium loosening [6,14]. In a series of 118 Rubis II® prosthesis [15, 16], there were no cases of loosening but stable osteolysis lines were present in the trapezium in 15% of cases. There was trapezium loosening in 15% of cases with a series of 100 Electra prosthesis [17]. Bone integration into the trapezium cup has been greatly improved because of the decagonal shape and the bi-layer coating of titanium / hydroxyapatite that is projected by vacuum plasma spraying. We think that insufficient bone integration can be attributed to poor trapezium bone quality in some cases and limited bone stock in short, dysplastic trapezium bones in other cases.

We think that the lack of loosening and subsidence of the metacarpal stem is related to its anatomical design, scale macrostructure and a prepared bed that includes cortical bone [18, 19,20].

Dislocation is a common complication reported in the published literature. Dislocations occurred in 7% of cases with the Electra® prosthesis and 8% of cases with the Arpe® prosthesis [17,12]. The Rubis II® prosthesis had a 5% dislocation rate [15].

We believe that the very low rate of dislocation in our series (1%) can be attributed to several factors:

- The semi-retentive nature of the polyethylene insert in the trapezium cup [21,22]; this semi-retentive effect of the polyethylene only lasts for a few months because the edge of the polyethylene undergoes progressive matting over six months. Overall, this semi-retentive feature improves primary stability initially without the drawbacks of permanent retention on the fixation into bone. It acts as a protection against early dislocation leaving time for the scar tissue to build.
- The lateral approach used here allows the thenar muscles and anterior ligaments to be preserved, and we made sure to reinsert the APL and repair the capsular flap when closing.
- Emphasis was placed on the centering and proper orientation of the trapezium cup.

Among the complications was a 4% rate of reflex sympathetic dystrophy. We added an arthroscopic release of the median nerve in the carpal tunnel for these patients. We cannot draw any conclusions about the cause-effect relationship of adding a surgical procedure to the prosthesis implantation. In our series, an additional surgical procedure was added to 25 cases of prosthesis implantation (arthroscopic carpal tunnel release, stenosing tenosynovitis of a long finger, aponeurotomy for Dupuytren's disease, interphalangeal fusion of a long finger, etc.).

The trapezium fracture included in this series was a fracture due to trauma that occurred one week after the cast was removed. No trapezium fractures occurred during surgery or in the immediate post-operative period. The design of the trapezium implant with the small tropical fins allows for better anchoring in the trapezium and avoids fractures when impacting the implant into fragile bone.

The survival of Maïa® prosthesis at 4 years was 95.6%, which is excellent. The published rate survival varies: 93% for the Rubis II® prosthesis at 5 years [15] and 85% for the Arpe® prosthesis at 5 years [23, 24]. The de La Caffinière prosthesis had a 68% survival rate after 5 years [25].

The satisfaction rate was also excellent: 93.6% of patients were satisfied or very satisfied. The satisfaction rate was 84.6% with the Roseland® prosthesis [26].

The main limitation of this study was its retrospective nature. However, only a few patients were lost to of sigth, which increases the power of this cohort.

CONCLUSION

The Maïa® prosthesis is a progressive improvement of the Arpe® prosthesis. Along with excellent survival rate at 48 months (95.6%), the prosthesis solved the problem of metacarpal stem subsidence. The Maïa® prosthesis also reduced trapezium complications, expanded the indications and simplified revisions because of the availability of a wide range of necks (straight, angled and anteverted). Clinically, thumb function is restored, pain is relieved and strength and motion are restored. Any Z deformity can be corrected and the thumb column length can be restored.

If the trapezio-metacarpal prosthesis fails, other treatment solutions exist: trapeziectomy, revision prosthesis, trapezio-metacarpal fusion. Based on the results of this series, it seems to us that the Maïa® trapezio-metacarpal prosthesis is the perfect choice for the surgical treatment of basal joint arthritis.

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