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Original article **Pyrocardan[®] implant after failed trapeziectomy** *Intérêt du Pyrocardan[®] après échec de trapézectomie* M. Pouedras^{*}, C. Chaves, E. Gaisne, L. Ardouin, P. Bellemère

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ABSTRACT

The aim of this retrospective study was to analyze the medium-term results of patients treated with a pyrocarbon interposition implant (Pyrocardan[®], Wright MedicalTM) after failed trapeziectomy. Eight female patients with an average age of 63 years were included in this single-center study. The average follow-up was 54 months (28–85 months). The average time elapsed between the trapeziectomy and the revision surgery was 116 months. Trapeziectomy failures were due to a painful scaphometacarpal and/or metacarpotrapezoid impingement. Patients were assessed radiologically and clinically for range of motion, strength (pinch and grip), pain (visual analog scale – VAS) and function (QuickDASH and PRWE scores). We found pain reduction with the mean VAS decreasing from 6.3 preoperatively to 2.5 postoperatively. Function improved with the QuickDASH and PRWE scores going from 52.9 and 49.1 preoperatively to 30.7 and 31.0 at the last follow-up, respectively. Strength and range of motion dislocation or bone reaction around the implant. Revision of failed trapeziectomy with the Pyrocardan[®] implant in cases of severe and painful first metacarpal subsidence is an effective solution that improves pain and function in the medium term.

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RÉSUMÉ

Le but de cette étude était d'analyser rétrospectivement les résultats à moyen terme du traitement des échecs de trapézectomie par interposition libre en pyrocarbone avec l'implant Pyrocardan[®] (Wright MedicalTM). Huit patientes d'âge moyen 63 ans opérées dans le même center ont été incluses. Le recul moyen était de 54 mois (28-85 mois). Le délai moyen entre la trapézectomie et la reprise chirurgicale était de 116 mois. Les échecs de la trapézectomie étaient liés à un conflit douloureux scaphométacarpien et/ou métacarpo-trapézoïdien. Les patientes ont été évaluées cliniquement sur la mobilité et la force (poigne et pince), la douleur (échelle visuelle analogique EVA) et la fonction (scores QuickDASH et PRWE) ainsi que radiologiquement. Il a été constaté une nette amélioration de la douleur avec une EVA moyenne passant de 6,33 en préopératoire à 2,5 en postopératoire, et de la fonction avec les scores Quick DASH et PRWE passant respectivement de 52,9 et 49,1 en préopératoire à 30,7 et 31 au dernier recul. Force et mobilités n'ont pas été modifiées de façon notable. Sept patientes ont été satisfaites ou très satisfaites de leur intervention. Une patiente n'a pas été améliorée par l'intervention. L'analyse radiologique n'a pas montré de luxation ni de réaction osseuse en regard de l'implant. L'implant d'interposition Pyrocardan[®] utilisé dans le cadre du traitement d'échec de trapézectomie pour un collapsus sévère du premier métacarpien avec conflit douloureux semble à moyen terme être une solution efficace améliorant la douleur et la fonction des patients.

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Introduction

Among the different surgical options for treating trapeziometacarpal osteoarthritis, complete trapeziectomy with or without interposition and suspension ligamentoplasty is the standard technique for many surgeons [1]. Indeed, this technique frequently achieves good pain relief and better thumb function that lead to satisfaction rates of 74-94% in the medium and long terms [2-6]. However, some patients may have persistent and disabling pain and functional discomfort that justifies revision surgery in less than 3% of cases [7,8]. Among the causes of failed trapeziectomy, the most frequent is related to collapse of the trapezium compartment resulting in instability and subsidence of the first metacarpal (M1) responsible for metacarposcaphotrapezoid (MST) impingement and pain [9]. The difficulties of performing revision surgery after failed trapeziectomy have been highlighted in the literature [9,10]. Different treatment options have been proposed on small case series with short follow-up: interposition, suspension ligamentoplasty, interposition implant, fusion between M1 and the second metacarpal (M2), arthroplasty and suspension systems between M1 and M2 [7,11–13]. None of these options seems to be more effective than any other in the medium or long term.

Pyrocarbon implants have demonstrated efficacy and safety in the medium and long terms as first-line treatment of thumb osteoarthritis [14–16] or for the treatment of failed total trapeziometacarpal arthroplasty [17]. They can also be proposed for treating MST impingement after failed trapeziectomy [9,18,19] as they are interposed in the impingement zone. The objective of this study was to assess the medium-term results of a Pyrocardan[®] interposition implant after failed trapeziectomy.

Materials and methods

Population

This retrospective, single-center study included patients operated between September 2010 and August 2015 for failed trapeziectomy and with painful MST impingement. Failure was defined as persistent residual pain at the base of the thumb after total trapeziectomy with functional consequences that was resistant to conservative treatment (analgesics, anti-inflammatory drugs, intermittent resting brace or physiotherapy). Pain had to be related to M1 subsidence or to secondary decompensation of scaphotrapezoid osteoarthritis after trapeziectomy. Pain was assessed during the clinical examination by palpation and mobilization of the M1 base. MST impingement was established on radiographs on Kapandji's views when contact of the M1 base with the scaphoid and/or the trapezoid was observed on at least one of the views. In case of doubt, this impingement was confirmed on dynamic views taken while patient was doing a pinch motion. Corticosteroid injections and wrist immobilization were also used to rule out associated pain. An in-depth radiological assessment was required in two cases (CT scan, bone scintigraphy) to determine more precisely the origin of the pain.

The case series included eight middle-aged women with an average age of 63 years (56–66 years). Three dominant hands were operated. All patients were initially treated at our facility for basal thumb osteoarthritis by total trapeziectomy combined with suspension-ligamentoplasty interposition with a Gore-Tex[®] thread [20] in seven cases and with interposition of a PLA (polylactic acid) implant in one case. The average time elapsed between the first procedure and the revision surgery with the Pyrocardan[®] implant was 116 months (18–240 months). Two

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patients had undergone a previous revision surgery consisting of tenosynovectomy and interposition of a flexor carpi radialis (FCR) tendon slip.

Two patients had concomitant clinical symptoms of De Quervain's tendonitis. One patient had concomitant clinical findings of FCR tendonitis. Two patients had painless metacarpophalangeal (MCP) hyperextension of more than 40° without any limitation of active flexion. Three patients also had radiological signs of scaphotrapezoid osteoarthritis.

All patients had given their written consent for revision surgery with an interposition Pyrocardan $^{(\!R\!)}$ implant.

Implant description

The Pyrocardan[®] implant (Wright MedicalTM) was used in this study (Fig. 1). This pyrocarbon implant has a rectangular shape with biconcave and perpendicular surfaces. It has a fixed central thickness of 1 mm while the peripheral edges are proportional to the implant size. It is available in seven different sizes ranging from 12 mm (XXS) to 18 mm (XXL) wide.

Surgery

The implant was placed in the trapeziectomy compartment in seven patients and in the scaphotrapezoid space in one patient. Four different surgeons performed the procedures. One of the surgeons (PB) had a conflict of interest with Wright MedicalTM. The surgical approach was determined based on the previous approach, the requirement of associated procedures and the surgeon's habits. In four cases, the approach was anterior (Gedda-Moberg) and in four cases it was posterolateral. The associated procedures included: (1) anterior MCP capsulodesis with tenodesis of the extensor pollicis brevis to the M1 neck in two patients who had more than 40° thumb MCP hyperextension; (2) tenosynovectomy of the FCR in one patient and (3) tenosynovectomy of the tendons of the first extensor compartment in two patients who had De Quervain's tenosynovitis.

Clinical and radiological assessment

The last follow-up assessment was carried out by an independent evaluator (MP), who worked with a different surgical team. The objective clinical parameters studied were compared on the contralateral side and included:

- Range of motion of the MCP and interphalangeal joints in flexion and extension, measured with a goniometer.
- Retropulsion measured in millimeters with palm flat on the table
- Thumb opposition measured according to Kapandji (0–10) [21].
- Opening of the first web space measured at the maximum angle between the ulnar edge of M1 and the radial edge of M2 in radial abduction and palmar abduction
- Strength evaluated as grip strength with a Jamar[®] dynamometer (Patterson Medical Holdings[™], Bolingbrook, Illinois, USA) and pinch strength with a key test.



Fig. 1. Pyrocardan[®] implant.

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The following subjective data were collected:

- Pain and function assessed by the French versions of the Quick Disability of Arm, Shoulder and Hand (QuickDASH) score [22] and the Patient Rated Wrist Evaluation (PRWE) [23].
- Pain measured using a visual analog scale (VAS).
- Satisfaction defined over five levels (very satisfied, satisfied, moderately satisfied, dissatisfied, very dissatisfied).

Finally, a radiological analysis including standard anteroposterior and lateral radiographs centered on the trapeziometacarpal joint (Kapandji's views [24]) was done to analyze the implant's positioning and to look for signs of bone intolerance at the last follow-up.

The small size of this case series did not allow for any statistical analysis.

Results

The average follow-up between the revision surgery and the last assessment was 54 months (28–85 months). The non-dominant side was treated in five cases out of eight cases. The range of motion and strength results are presented in Table 1. Range of motion was comparable to that of the contralateral side and strength (pinch and grip) was less than that of the contralateral side.

Table 1

Postoperative clinical results of the patients included in this case series.

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The functional results are presented in Table 2. The average VAS went from 6.3 preoperatively to 2.5 postoperatively, i.e. a decrease of 60%. The average QuickDASH and PRWE scores improved by 42% and 37% respectively; they were 52.9 and 49.1 preoperatively and 30.7 and 31.0 at the last follow-up, respectively. Seven patients were very satisfied or satisfied with the surgical procedure. One patient was dissatisfied because she still had notable postoperative pain. This patient was a 56-year-old woman who worked in a restaurant and had high functional expectations. The revision was performed 18 years after the initial trapeziectomy and included FCR tenosynovectomy and Pyrocardan[®] implant. After revision surgery, the patient did not experience any pain reduction (VAS remained at 7) and had substantially identical functional scores pre- and postoperatively (PRWE went from 79 to 75 and QuickDASH from 70 to 63). Range of motion was identical in both hands. Strength was greater on her opposite hand, which was her dominant one (grip strength of 28 kg and pinch strength of 5.5 kg versus 22 and 2.5 kg for the operated hand).

Radiographs showed no signs of implant dislocation or migration at the last follow-up. The implant had good radiological tolerance as no osteolysis was observed around it (Figs. 2 and 3).

There were no complications or revisions at the last follow-up.

Discussion

The goal of trapeziectomy is to reduce pain while maintaining strength and stability of the thumb. This procedure is generally

Patient number	Range of motion	n (CL)	Grip Strength in kg (CL)	Pinch Strength in kg (CL)				
	MCP: E/F	IP: E/F	Retropulsion (mm)	Palmar abduction (M1-M2)	Radial abduction (M1-M2)	Opposition Kapandji		
1	0/30 (10/80)	0/30 (20/30)	30 (12)	40 (50)	40 (50)	10 (10)	22 (30)	3.0 (7)
2	0/40 (0/45)	0/60 (0/60)	20 (25)	50 (50)	40 (50)	10 (10)	14 (14)	2.5 (2.5)
3	30/15 (30/30)	40/85 (10/80)	25 (35)	35 (50)	40 (65)	6(7)	20 (25)	3.0 (4)
4	10/45 (0/55)	35/42 (35/50)	10 (10)	40 (50)	45 (50)	10 (10)	16 (25)	2.5 (2.8)
5	10/60 (0/40)	45/40 (20/40)	20 (20)	45 (45)	45 (45)	10 (10)	20 (25)	2.5 (3.5
6	20/30 (0/30)	80/20 (80/20)	15 (15)	40 (40)	50 (50)	10 (10)	22 (28)	2.5 (5.5)
7	10/50 (0/25)	0/65 (0/65)	15 (8)	50 (50)	45 (45)	9 (9)	19 (22)	3.0 (2)
8	0/30 (0/30)	0/40 (0/60)	20 (20)	40 (50)	50 (50)	8 (8)	18 (20)	3.5 (4.5)
Mean	10/37 (5/42)	25/48 (21/51)	19 (18)	42 (48)	44 (51)	9 (9)	19 (24)	2.8 (4)

CL: contralateral; MCP: metacarpophalangeal; IP: interphalangeal; E: extension; F: Flexion; M1: first metacarpal; M2: second metacarpal.

Table 2

Pain, satisfaction and functional scores.

Patient number	Postop pain on VAS (preop)	Satisfaction	Postop function (preop value) PRWE QuickDASH
1	1 (4)	Very satisfied	17 (35)
			16 (32)
2	3	Satisfied	29.5 (40)
			30 (59)
3	2 (5)	Satisfied	23 (46)
			18 (55)
4	3 (8)	Satisfied	46 (70)
			59 (70)
5	3	Satisfied	23 (43)
			18 (32)
6	7 (7)	Unsatisfied	75 (79)
			63.6 (70)
7	1 (7)	Very satisfied	23 (46)
			18 (59)
8	0(7)	Very satisfied	12 (34)
			22.7 (46)
Mean	VAS=2.5 (6.3)	37.5% very satisfied	PRWE: 31 (49.1)
		50% satisfied	QuickDASH: 30.7 (52.9)
		12.5% unsatisfied	

VAS: Visual Analog Scale; PRWE: Patient Rated Wrist Evaluation; QuickDASH: Quick Disability of Arm Shoulder and Hand.

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Fig. 2. Preoperative anteroposterior (a) and lateral (b) and 5-year postoperative lateral (c) and anteroposterior (d) X-rays of a Pyrocardan[®] implant inserted in the trapezium compartment after failed trapeziectomy.



Fig. 3. Oblique, lateral and anteroposterior X-rays at 7 years of follow-up of a Pyrocardan[®] implant inserted in the scaphotrapezoid joint.

successful and has good results in the medium and long terms [3,4,6] with pain reduction in 85–95% of patients [4–6]. Revision rates are estimated to be less than 3% [7,8]. This procedure is still widely practiced at our healthcare facility, even if several practitioners use a Pyrodisk as an interposition pyrocarbon implant to avoid M1 subsidence.

Pain after trapeziectomy is rare but remains a complex problem that might require multiple procedures [25]. Since the management of these failures is very challenging, clinical and radiological analysis of the base of the thumb must be precise to determine what is causing this pain. Pain can be secondary to M1 instability or to wrist instability with development of scapholunate instability and secondary dorsal intercalated segment instability (DISI) deformity. It can also be due to proximal migration of M1 – although this is often asymptomatic [6,26,27] – or to decompensation of scaphotrapezoid osteoarthritis [28]. Tenosynovitis such as De Quervain's or FCR tendinopathy can occur simultaneously. Corticosteroid injections and wrist immobilization can be used to determine the origin of the pain. An in-depth radiological assessment is required in case of doubt (CT scan, stress-views, etc.). The most popular revision techniques after failed trapeziectomy include scaphometacarpal fusion, suspension-ligamentoplasty of M1 and interposition of synthetic or biological materials [7,10].

Scaphometacarpal fusion is a difficult procedure associated with a high rate of non-union and poor functional results. In 2002, Renfree and Dell reported 7 failures of the scaphometacarpal fusion in a series of 12 patients [11].

Cooney et al. reported a series of 17 cases treated with soft tissue interposition with or without ligamentoplasty after failed trapeziectomy. In 10 cases, the interposition was a biological tissue and in 7 cases, a synthetic material. At 26 months of follow-up, the authors found 76% of good results, with no significant difference between interposition materials. The pain on VAS went from 4.4 to 0.6 and the key pinch and grip strength increased from 2 to 3.4 kg and from 16 to 20 kg respectively [7]. Nevertheless, the choice of interposition by soft tissue is questionable in young patients as their long-term tolerance has been shown to be poor [29–31].

Other treatment options have been proposed, although they have been evaluated mostly in small case series, without long-term

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analysis. In a study published in 2012, the results of the Swanson silicone elastomer implant for revision surgery were analyzed in 10 patients with an average follow-up of 34 months [32]. All patients had scaphometacarpal impingement that was identified as the cause of the pain. The authors found pain reduction as well as better daily activities scores for 9 out of 10 patients and a high satisfaction rate. No complications were reported.

A recent study analyzed the short-term results (average followup of 23 months) of the Mini TightRope[®] as revision treatment after failed trapeziectomy in five patients with scaphometacarpal impingement [13]. The goal of this technique is to suspend M1 and thus remove the pain related to its proximal migration and subsidence. The authors reported a decrease in pain (VAS going from 5.2 to 1.6), an increase in pinch strength (from 0.5 to 3 kg) and an improvement in the Quick DASH score (from 54 to 20).

In 2006, Glard et al. reported moderate to good results in four patients who underwent autologous costochondral grafting. However, the main issue with this surgical technique is its high rates of donor-site morbidity [33]. We believe this is a last resort.

Fusion between M1 and M2 can also be proposed after failed trapeziectomy [8]. In a case series published in 1993, Conolly and Rath described four cases of trapeziectomy failure. In one case, this technique was used because of significant instability of the M1 base and an infectious context which unfortunately had a poor outcome (no functional improvement nor pain reduction) [10].

In our study, we decided to use the Pyrocardan[®] implant as we sought to interpose a small implant in the impingement area. Pvrocarbon has excellent tolerance when used as a first line treatment of basal thumb and wrist osteoarthritis [16,18,34]. In revision cases, it can readdress the causes of post-trapeziectomy pain. This interposition deals with the painful impingement either due to scaphotrapezoid osteoarthritis, or due to a loss of height of the trapezium compartment resulting in scaphometacarpal or metacarpotrapezoid impingement. In addition, the choice of an interposition was done to limit thumb MCP joint hyperextension and therefore reduce loss of strength by preserving the thumb's length. If the scaphometacarpal space allows it, a Pi2 or CMI interposition implant may be used [17,19]. It is not always possible to restore the height of the trapezium compartment due to soft tissue retraction from the initial trapeziectomy. Placing a thicker implant, like the Pi2[®] interposition implant, may result in pain due to excess pressure or instability. As the central thickness of the Pyrocardan[®] implant is 1 mm, it does not have these drawbacks. Surgical revisions by Pi2[®] implant were not included in this study. To us, this material is a good choice in this indication because of its excellent biocompatibility, modulus of elasticity, and density similar to that of cortical bone.

One of the main limitations of our study is its retrospective nature, which did not allow preoperative clinical data to be collected. However, the subjective functional scores were complete. The small size of the case series is another limitation as well as the lack of long-term evaluation. Finally, the associated procedures during revision surgery constitute a bias in the interpretation of the results. Tenosynovectomy was performed in three patients (two De Quervain's tenosynovitis and one FCR tenosynovitis) and correction of the MCP hyperextension in two patients (anterior capsulodesis and tenodesis of the extensor pollicis brevis).

Nevertheless, this implant remains a relevant option for failed trapeziectomy. This study found good clinical results and an improvement in postoperative functional scores in nearly all patients. Seven out of eight patients were satisfied or very satisfied with the outcome. The last patient did not have any pain reduction or improvement in the activities of daily living and can therefore be considered as a failure. Finally, despite the high complication rates reported after revision surgeries (which can reach up to 27% [11]), we do not find any complications in our case series, particularly no lesions of the superficial branch of the radial nerve.

Conclusion

The Pyrocardan[®] interposition implant seems to be an attractive option for the challenging situations of failed trapeziectomy. This interposition implant is used to treat either painful impingement related to the inevitable M1 subsidence or the secondary decompensation of scaphotrapezoid osteoarthritis after trapeziectomy. The medium-term clinical and radiological results are encouraging. This procedure has the advantage of not burning bridges to other surgeries if a second failure occurs. A larger case series with a long-term clinical and radiological analysis is required to confirm these results.

Ethical approval

The authors declare that the work described has been carried out in accordance with the Declaration of Helsinki of the World Medical Association revised in 2013 for experiments involving humans as well as in accordance with the EU Directive 2010/63/EU for animal experiments.

Disclosure of interest

P.B. has conflict of interest with Wright-MedicalTM. M.P., C.C., E.G., L.A., T.L. declare that they have no competing interest.

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