



The pyrosphere prosthesis compared with epping-arthroplasty for Surgical treatment of thumb root arthritis: a clinical cohort study

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ABSTRACT

Objective: Rhizarthrosis indicates osteoarthritis induced degenerative changes of the thumb root. Several surgical interventions have been previously described. Our question is whether the PyroSphere joint replacement shows superior results when compared to other operative techniques such as Epping-Plasty for the treatment of thumb root arthritis. Therefore, the purpose of this study was to compare the efficacy of both interventions. **Methods:** In this clinical cohort study we reviewed our medical database to identify patients who suffered from rhizarthrosis Grade II-III according to Eaton Littler, who were treated operatively between 2002 and 2018. After a mean follow-up of 13 years, 14 cases were evaluated. Evaluation by clinical examination includes range of motion of the thumb, Kapandji score, force measurement of the thumb and hand using JAMAR dynamometer for grip and pinch strength. Pain assessment was done; DASH-Score and DSG questionnaire were also performed. **Results:** 14 hands were included, The PyroSphere joint prosthetics were observed in 7 hands and the Epping-Plasty group included the other 7 hands. In all comparative tests, P values were not statistically significant (all $p > 0.05$). **Conclusion:** This study concludes that PyroSphere prosthetics show no superior results when compared to Epping-arthroplasty for the treatment of thumb root arthritis.

Keywords: Rhizarthrosis, Trapeziometacarpal osteoarthritis, Pyrosphere, Pyrocarbon, Epping arthroplasty, Trapezium

Abbreviations: CMC1: First Carpometacarpal Joint (1st CMC), ROM: Range Of Motion, NSAIDs: Non-Steroidal Anti-Inflammatory Drugs, DSG questionnaire: Daumensattelgelenk (Thumb saddle joint), DASH-score: Disabilities of Arm, Shoulder, and Hand-score, VAS: Visual Analogue Scale, MCP: Metacarpophalangeal, CMC: Carpometacarpal

INTRODUCTION

Rhizarthrosis indicates osteoarthritis induced degenerative changes of the thumb root. Specifically affecting the trapeziometacarpal and, in more severe stages, scaphotrapezial joint [1,2]. The trapeziometacarpal joint, also known as the first Carpometacarpal joint (CMC1), is a saddle-shaped joint with a characteristic concavoconvexity of both articulating surfaces [3-6]. The stability of the CMC1 joint is maintained by many stabilizing and supporting ligaments. These ligaments provide the ability to tolerate high-pressure loads, particularly during pinch and grasp maneuvers [7]. Although the number of ligaments surrounding the CMC1 Joint varies in anatomical literature, most authors state that five of these ligaments are most important for stability. Of these ligaments, the deep anterior oblique ligament, also known as the palmar beak ligament, is considered to be the most important stabilizing ligament [7-11]. Laxity of this ligament in particular, and in addition to the other surrounding ligaments, is involved in the progression of rhizarthrosis [12]. Conservative treatment options for rhizarthrosis include NSAIDs, corticosteroids, and intra-articular hyaluronic acid injections [13]. They're usually used as a temporary measure before surgery, in elderly patients who aren't good candidates for surgery, or in those patients who don't prefer to undergo an operation [14]. Surgical ar-

throdesis was used before advances in arthroplasty took place and it's still in practice today. Nevertheless, it has the disadvantages of functional compromise to reach joint stability and pain relief [15-17]. The least complex form of arthroplasty involves the trapezium excision alone. In 1949, Gervis published the results of total trapeziectomy performed on fifteen patients. It generally showed favorable results with improvement of pain and function except in two patients who had polyarthritis. Although no wires were used for the stabilization of the thumb after trapeziectomy, no obvious deformities were reported [15,16,18,19]. Moreover, partial excision of the trapezium was also performed and described in the literature [20,21]. In 1972, Alfred Swanson described a novel method for rhizarthrosis that involved trapezium resection and silicone implant arthroplasty [22]. This method has significant adverse outcomes including implant instability, implant tear, silicone synovitis, and implant failure [23-25]. One study revealed that on an average follow-up period of 6.5 years, 90% of patients with silicone implants manifested radiologic changes consistent with silicone synovitis [26]. Implants made of degradable polyurethaneurea with biocompatible properties (Artelon) were also introduced. Conversely, they were associated with a significant complication rate and poor preliminary results in the short-term [27-29]. In 1979, de la Caffiniere and Aucouturier introduced arthroplasty with a total prosthesis. This prosthesis uses a ball and socket design and involves the implantation of a cup made of polyethylene in the trapezium, for articulation with cobalt-chromium alloy placed in the first metacarpal shaft [30,31]. The pyrolytic carbon implant has the advantage of being inert and biocompatible. Hence, it has been widely implicated in clinical practice in the last decade [32]. The short-term results of pyrocarbon implants seem promising with positive outcomes in pain relief and range of motion, although the long-term remains unclear [33]. In addition to implants, another main surgical approach is complete trapeziectomy with or without ligament construction. Trapeziectomy without ligament reconstruction commonly involves stabilization by a K-wire. On the other side, tendons of abductor pollicis longus and/or flexor carpi radialis are used for thumb fixation in ligament reconstruction modalities [16]. In Epping arthroplasty, the trapezium is excised and followed by ligament reconstruction using the distal end flexor carpi radialis tendon [34,35]. The question of whether the PyroSphere shows superior results when compared to other operative techniques for the treatment of CMC1 arthritis has not been answered yet. Therefore, the purpose of the present study is to compare the efficacy of PyroSphere prosthesis with that of Epping arthroplasty in the treatment of trapeziometacarpal osteoarthritis.

MATERIALS AND METHODS

In this clinical cohort study we have reviewed the medical database at the Plastic Surgery Department of Aachen University, Germany to identify patients suffered from rhizarthrosis Grade II-III (according to Eaton Littler) who were treated operatively between 2002 and 2018, to evaluate and compare the postoperative outcome of two different surgical techniques, the PyroSphere prostheses and Epping-Plasty [36]. We excluded any patient less than 18 years, doubt inpatient therapy, pregnancy, contraindications for the implantation of pyrospecial prosthesis according to the manufacturer's instructions and FDA approval, patient's participation in interventional studies in the affected hand, contraindications against components of the therapy regimen, previous participation in a similar study, and rhizarthrosis grade IV. We identified and analyzed 21 patients (16 females and 5 males, mean age=66.7 years) who met our criteria. Of these, 6 females underwent a bilateral operation (3 underwent Pyrosphere, 2 underwent Epping-Plasty, 1 underwent both of these techniques). So, a total of 27 hands (11 right hands, 16 left hands), 14 hands treated with PyroSphere, and 13 hands treated with Epping-Plasty (Table 1). Follow-up examinations in the polyclinic after 1 week of wound control and after 3, 6, 12 months for functional evaluation. An e-mail invitation letter has been sent to each patient, and only 11 patients were presented for final clinical examination (8 females and 3 males, mean age=59.45 years). Of these, 3 females underwent a bilateral operation (2 underwent Pyrosphere, 1 underwent Epping-Plasty). So in total, we have 14 hands (7 right (1 male) and 7 left (2 male)). We have made an informed signed consent with each patient. We divided these patients-according to their surgical procedures- into two groups. Group A, we have 5 patients who underwent PyroSphere prostheses (4 females and 1 male, mean age=60.6 years) whereas two of them were treated bilaterally, a total of 7 hands, 3 right and 4 left (1 male). Group B, we have 6 patients who underwent Epping-Plasty (4 females and 2 males, mean age=59.6 years) whereas one of them was treated bilaterally, a total of 7 hands, 4 right (1 male) and 3 left (1 male) (Table 2). Preoperative symptoms were present for a mean of 2.5 years in Group A, while symptoms were present for 7.6 years in Group B. We have asked the patients to complete the DSG questionnaire, before performing the examinations. All patients were examined in terms of 3 months. It took 2 hours to perform the examinations and to fulfill DASH-Score per patient. The examinations were done by the same physician and included the following: Range of Motion of the thumb (Figure 1 and 2), Kapandji score (Figure 3), and force measurement of the thumb and hand using JAMAR dynamometer for grip and pinch strength (Figure 4) (Lafayette Instrument, Model J00105) [6, 37]. Pain assessment was done by Visual Analog Scale (VAS), either with load or

without load. Also, all Patients were asked to complete the DASH-Score (Disabilities of Arm, Shoulder and Hand-questionnaire) (Figure 5) [38].

Table 1 General characteristic of the patients

Total no. of patients	21
Total no. of hands	27
Sex (Female/Male)	16/5
Mean age in years	66.7
Side (Right/Left)	11/16
Procedure (PyroSphere/Epping)	14/13

Table 2 General characteristics of the patients who presented for the final clinical examination (divided according to their surgical procedures) A: PyroSphere prostheses; B: Epping-Plasty

	Group A	Group B
Total no. of patients	5	6
Total no. of hands	7	7
Sex (Female/Male)	4/1	4/2
Mean age in years	60.6	59.6
Side (Right/Left)	3/4	4/3

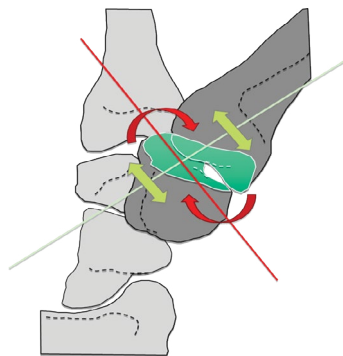


Figure 1 Range of motion of the thumb

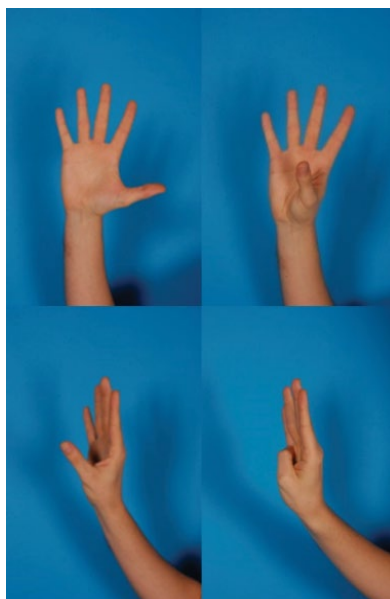


Figure 2 Range of motion of the thumb



Figure 3 Kapandji opposition test

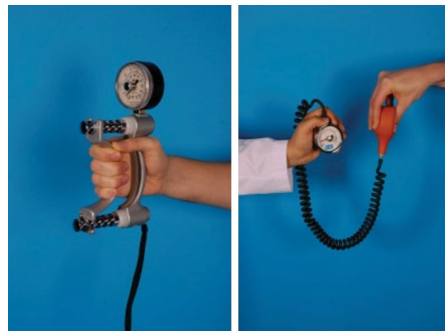


Figure 4 Force measurements of the thumb and hand with JAMAR dynamometer for grip and pinch strength

DISABILITIES OF THE ARM, SHOULDER AND HAND					
Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.					
	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

Figure 5 A part of (Disabilities of Arm, Shoulder and Hand-questionnaire)

Statistical Analysis:

Significance was set at $p < 0.05$. Microsoft Excel, GraphPad Prism were used t-test.

RESULTS

In our study twenty-one, patients were included, identified, and analyzed (17 females, 4 males, mean age=66.7 years) who were treated operatively with rhizarthrosis in the period between 2002 and 2018. Only 11 patients (14 Hands) were presented for final clinical examination. All patients suffered from rhizarthrosis Grade II-III according to Eaton Littler. 7 hands were treated with PyroSphere prostheses and 7 Hands with Epping-Plasty. The PyroSphere Group (Group A) included 7 hands (6 females, 1 male, mean age=68.4 years) and the Epping Plasty Group (Group B) contained 7 hands (5 females, 2 males, mean age=65.4 years). The majority of the patient followed up in a period of five days, 3 months, and 6 months. Most of the patients in both groups were working as a housewife (5 of 7 in group A and 5 of 7 in group B) in Group A, the right hand was affected 3 times, the left hand 4 times and in Group B the right hand was affected 4 times, the left hand 3 times. All patients from both groups are operated on as primary osteoarthritis. Regarding Pain scale (VAS) without load for the PyroSphere Group (Group A), one patient has a score of 1 out of 10, and the rest of the group have a score of 0 out of 10 (0=no pain, 10=Max pain) and for the Epping Plasty Group (Group B) one patient has score 3 out of 10 and rest of group have score 0 out of 10 (p -value=0.539). For the Pain scale (VAS) with load, one patient from Group A who treated by PyoSphere prostheses in both Right and Left hands have a pain scale of 7 out of 10 in his right hand and 10 out of 10 in his left hand and Group B three patient have score 9, 5, 1 out of 10 (p -value =0.893). Fist power pounds (Grip Pounds) were assessed equally for each group, the minimum value detected was 26 lbs and the maximum value was 97 lbs in Group A and the minimum value detected is 32 lbs and the maximum value is 71 lbs in Group B (p -value=0.993) (Figure 6). Key turn power kPa (Pinch Pound) were also assessed in both groups and the minimum value in Group A was 0 and the maximum was 45 and in Group B minimum value was 6 and the maximum value was 31 (p -value=0.893) (Figure 7). Patients were tested using Kapandji opposition test score also, all patients were asked to complete a DASH-Score and the result is summarized in Table 3. In all comparative tests, (DASH-Score p =0.842), (Grip Strength p =0.993) and (Kapandji Opposition test p =0.270) p -value were not statistically significant (all $p > 0.05$).

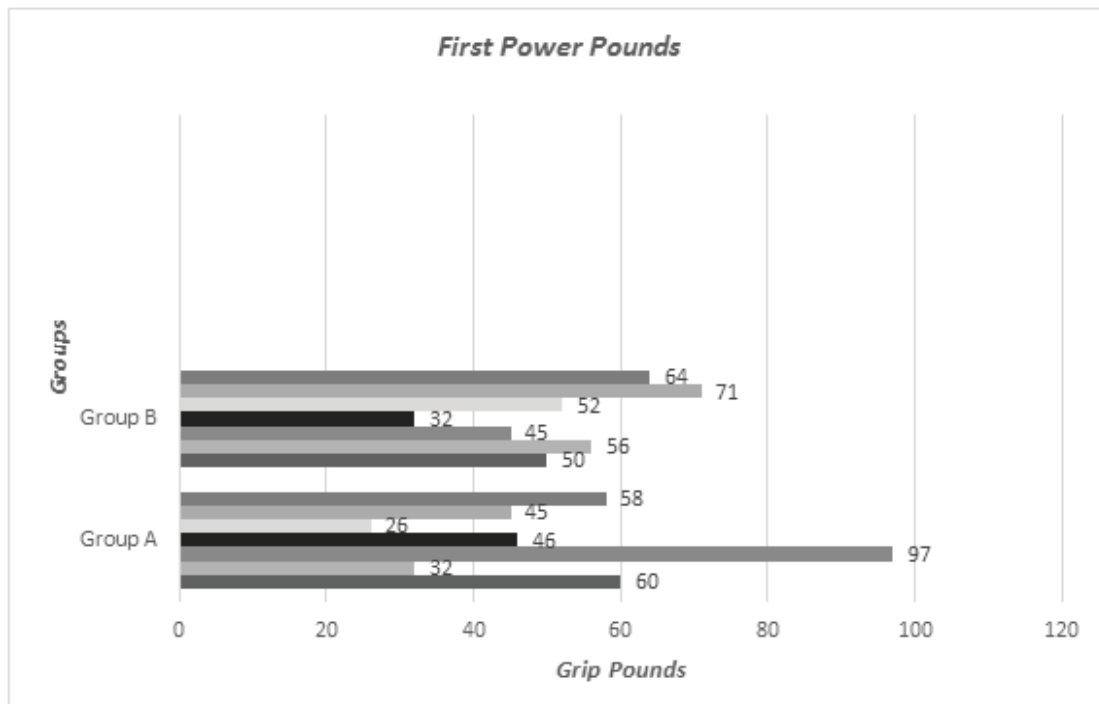


Figure 6 Hand Grip in lbs

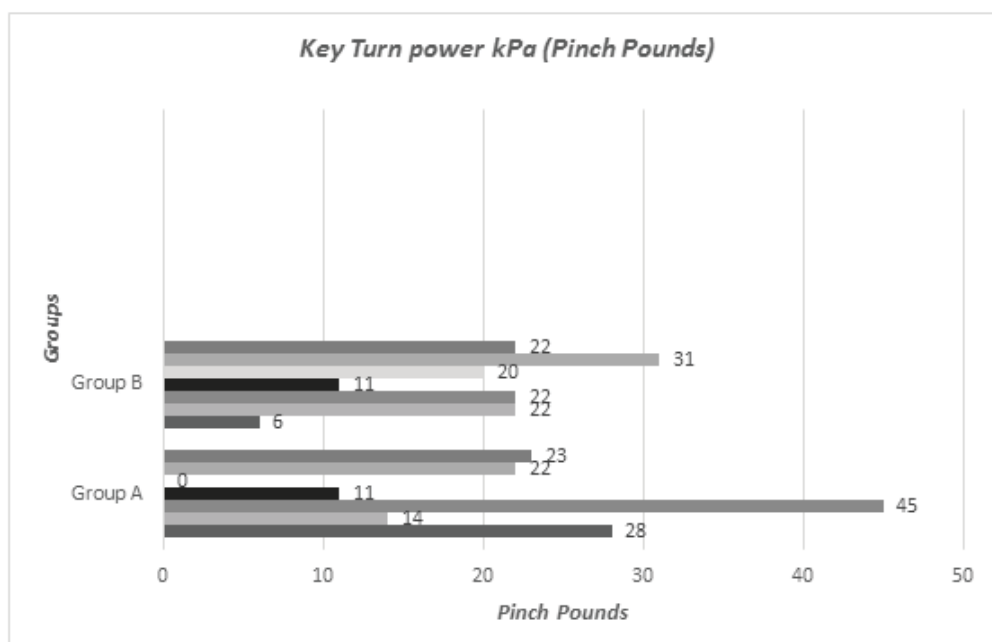


Figure 7 Pinch power in lbs

Table 3 Shows comparison between Group A and B in scoring system

Gender (M/F)	Age (years)	Side (R/L)	Indication	Operation (Pyro vs. Epping)	Pain Scale (VAS) without Load 0=No pain 10=Max. Pain p=0.539	Pain Scale (VAS) with Load 0=No pain 10=Max. Pain p=0.893	Fist power pounds (Grip) Pounds p=0.993	Key turn power kPa (Pinch) Pounds p=0.893	Kapandji Opposition Test Score p=0.270	DASH Questioner Score p=0.842
Group A (Pyro-Carbon-prosthesis)										
F	69	L	Primary	Pyro	0	0	60	28	10	3.3
F	71	R	Primary	Pyro	0	0	32	14	8	6.9
M	53	L	Primary	Pyro	0	0	97	45	10	0
F	49	R	Primary	Pyro	0	7	46	11	8	46.6
F	49	L	Primary	Pyro	1	10	26	0	4	89.7
F	71	L	Primary	Pyro	0	0	45	22	10	1.7
F	61	R	Primary	Pyro	0	0	58	23	9	0.8
Group B (Epping-Arthroplasty)										
M	55	R	Primary	Epping	0	9	50	6	8	67.5
F	58	L	Primary	Epping	0	0	56	22	10	13.3
F	53	R	Primary	Epping	0	1	45	22	10	20.8
M	67	L	Trauma	Epping	0	0	32	11	9	28.3
F	53	L	Primary	Epping	3	5	52	20	10	40
F	64	R	Primary	Epping	0	0	71	31	10	0.8
F	54	R	Primary	Epping	0	0	64	22	9	0.8

DISCUSSION

Several studies were done to review and compare the outcomes of different surgical techniques that are available for

the treatment of Rhizarthrosis [39,40]. Among these techniques, the pyrolytic carbon MCP joint arthroplasty, appears to be of a promising outcome. Pyrolytic carbon implants are available in many designs including the Pyrodisk and PyroSphere. They have the advantage of preserving the collateral ligaments, with a minimal bone resection [33]. The short-term results of pyrocarbon implants have been evaluated by Parker WL and have shown positive outcomes in pain relief and range of motion [33]. High patient satisfaction and excellent pain relief were also reported with the Pyrodisk arthroplasty [41]. However, the pyroSphere implants were reported to have a higher rate of complications [42].

Regarding the pain intensity assessed using the Visual Analogue Scale (VAS) without load and with load, our result found no significant difference between the two groups of patients treated with PyroSphere prosthesis with that of Epping arthroplasty. This is in keeping with that of Claudia Santos, who compared the result of trapeziectomy with or without ligamentoplasty versus total prosthesis and found no significant difference concerning pain, mobility, strength, or activities of daily living [40].

In the view of Evaluation of Pinch grip which is fundamental to many of daily living activities, our result shows no significant difference between the two groups of patients, (p-value =0.893) [43]. This result is also in keeping with that of Claudia Santos [40]. Regarding the maintenance of grip strength, several studies suggest that total arthroplasty of the CMC joint is superior to other surgical procedures [44,45]. However other studies showed insignificant differences [40].

In a previous study, the overall outcome of the modified Epping procedure was found to be encouraging, despite a mean DASH score of 32.39. However, a relatively subjective loss of strength is the main complaint among these patients, whereas instability is less of concern [46].

The DASH score in a thumb-targeted module assessing basal joint-loading in the thumb was 63 points before and 21 points after surgery. In the patients with total joint replacement; total DASH score, 56 and 7 points; thumb module DASH score, 60 and 11 points [47]. Many contradictory results are observed in the literature in comparing the above two techniques. We think it is attributed to the different follow-up periods of patients among these studies.

CONCLUSION AND LIMITATIONS

This study concludes that PyroSphere prosthesis shows no superior results when compared to Epping-arthroplasty for the treatment of thumb root arthritis. However, this study is limited by the small number of patients included. A larger sample comparative study is needed.

DECLARATIONS

Ethics approval and consent to participate:

Ethical approval has been taken and all surgical procedures took place in the Department of Plastic Surgery, Hand Surgery, and Burn Centre at RWTH University Hospital, Aachen, Germany. Each patient signed the consent form. All examinations were carried out in compliance with the Declaration of Helsinki in its current form.

Consent for publication:

Consent to publish was obtained from study participants. They provided written informed consent for their personal or clinical details.

Availability of data and materials:

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions:

AF drafted the manuscript and helped in operations of the patients as well as follows up of previously operated patients and participated in the analysis and interpretation of data. RA and HA conceived the design of the study. AA and SA helped in drafting the manuscript. ZA participated in the operations and follow up previously operated patients as well as revised and edited the manuscript. All authors read and approved the final manuscript.

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Conflict of Interests:

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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