JOURNAL OF PLASTIC SURGERY AND HAND SURGERY
2023, VOL. 57, NOS. 1–6, 230–235
https://doi.org/10.1080/2000656X.2022.2044835

ARTICLE

Long-term follow-up of patients treated with pyrocarbon disc implant for thumb carpometacarpal osteoarthritis: the effect of disc position on outcomes measures

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ABSTRACT

Pyrocarbon disc interposition arthroplasty is an effective treatment for thumb base osteoarthritis. However, as with all implant techniques, the disc can (sub)luxate over time. The relationship between disc position, the experienced pain, and the necessity for revision surgery is not known. This study evaluated the effect of radiographic pyrocarbon disc position on the Michigan Hand Questionnaire (MHQ) outcome measurement. In addition, the correlation between disc position and other factors, including pain intensity, thumb strength, and occupation, was assessed. In this retrospective study, we included 136 patients (161 thumbs) with a mean follow-up of 6.7 years (range 3.3–11). Radiographs were scored on disc position and classified as 'well aligned' (Grade 1) up to 'luxated' (Grade 4). A database used for outcome measures included MHQ scores, pain intensity, satisfaction, thumb strength, range of motion, occupation, and hand dominance. In bivariate analyses, we assessed any association between disc position and outcome measurements. Eighty of the 136 implants (59%) were well-positioned (not displaced), 41% were (slightly) displaced (grade 2–3). No relationship existed between the degree of disc displacement and MHQ scores. Manual labor occupation was the only factor that correlated with more severe disc displacement. We could not detect any association between disc position and other outcome variables including pain intensity, thumb strength, or hand dominance. In conclusion, our study suggests that radiographic disc displacement has little clinical consequences. Future studies must assess if there is a causality between heavy mechanical stress to the CMC1 joint and luxation of the pyrocarbon disc over time.

Level of evidence: IV Therapeutic—Retrospective case series.

ARTICLE HISTORY
Received 6 July 2021
Revised 6 October 2021
Accepted 17 February 2022

KEYWORDS
Carpometacarpal joint; osteoarthritis; thumb; surgical procedures; pyrolytic carbon; hemiarthroplasty; radiography

Introduction

Several surgical techniques, with or without implants, are effective in reducing pain in patients with thumb carpometacarpal osteoarthritis (CMC1 OA), not responding well to non-operative therapy. Likewise, the PyroDisk CMC1 arthroplasty (Integra Life Sciences Corporation©, Plainsboro, NJ, USA) can lead to improved hand function and less pain up to 8 years after surgery [1–5]. Patients have reported high satisfaction rates with a good prevalence of thumb strength and range of motion [6]. In a previous paper from our research group, a survival rate of 91% was found with a minimum of 5-year follow-up [6].

As with any joint implant surgery, one of the main disadvantages is the risk of disc luxation and implant failure over time. The failure rate for the pyrocarbon disc is relatively low (1.0 per 100 procedure years) compared to other CMC1 joint implant arthroplasties as reported in a recent systematic review [7]. Two case series of 19 and 20 patients, respectively, reported disc displacement in 21% (4/19) and 15% (3/20) after a mean follow-up of at least two years [2,3]. Only two of those seven patients with radiographic disc displacement required revision surgery [2,3].

These findings raise the question of whether the position of the disc affects treatment outcomes in patients who underwent pyrocarbon interposition arthroplasty for CMC1 OA. The primary aim of this study was to evaluate the effect of disc position on the patient-reported hand health status measured by the Michigan Hand Questionnaire (MHQ). Secondary, we evaluated if radiological disc position correlated with (1) pain intensity, (2) patient satisfaction, (3) Patient Rated Wrist/Hand Evaluation questionnaire (PRWHE), (4) thumb strength, (5) range of motion, (6) hand dominance, and (7) manual labor occupation.

Materials and methods

Study design and clinical setting

This study concerns a case series and describes retrospectively gathered data. It is part of a multicenter study by van Laarhoven

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Supplemental data for this article can be accessed online at https://doi.org/10.1080/2000656X.2022.2044835

et al. [6] on outcomes after pyrocarbon disc interposition arthroplasty for the treatment of CMC1 OA [6]. The focus of this study is on radiographic outcomes of disc arthroplasty and therefore differs essentially from our previous paper. The local Institutional Review Board approved our study and written informed consent was obtained from all participants. Surgery was performed by one of four surgeons in two different urban centers, who are all hand fellowship-trained and most are certified by the Federation of the European Societies for Surgery of the Hand [8]. Their experience ranges from level 4 to level 5 according to the classification by Jin Bo Tang [9].

Surgical technique

The surgical technique of disc implantation has been described in detail previously [6] . In short, a distal hemitrapeziectomy is performed and the pyrocarbon disc placed. After drilling a tunnel through the base of the first metacarpal and hemitrapezium, the implant is fixated with a tendon strip (of either the flexor carpi radialis or abductor pollicis longus) by looping the tendon through the tunnel in the hemi-trapezium, the central hole in the disc and the metacarpal base tunnel. For proper alignment, the tunnels should be centered to prevent early (sub)luxation. The residual tendon is then folded back and fixed on itself. The position of the implant is checked with radiography. After 4 weeks of immobilization, hand therapy is commenced for 8 weeks thereafter.

Patients

Patients included in this study underwent a pyrocarbon disc interposition arthroplasty between 2006 and 2014. Patients had ongoing symptoms of CMC1 OA despite non-operative care for at least three months and Eaton-Glickel classification II or III on radiographs [10]. Exclusion criteria were the existence of scaphotrapeziotrapezoidal (STT) in addition to CMC1 OA on radiographs (Eaton-Glickel grade IV), a past medical history of inflammatory or rheumatic arthritis, or hyperlaxity syndromes.

Data collection

Between July 2017 and April 2018, 156 patients (188 thumbs) were enrolled in the primary study [6]. Patients were invited at the outpatient clinic to complete several questionnaires about demographic characteristics and PROMs. Radiographs of the operated hand were obtained (thumb PA and thumb lateral views); strength and motion measurements of both hands were performed (see paragraph 'clinical outcome measurements').

In the present study, we focused on the radiographic outcomes of the disc implant. Our primary goal was to evaluate the effect of disc position on MHQ scores. Only thumbs with the disc still *in situ* and with a follow-up duration of at least 3 years were included. For this reason, 27 of the 188 thumbs were excluded from further analysis resulting in 136 eligible patients and 161 thumbs (Figure 1). Reasons for exclusion of these 27 thumbs were: no radiograph obtained at follow-up ($n = 10$), <3 years of follow-up ($n = 1$), or prior removal of the disc ($n = 16$; details are described in the next paragraph).

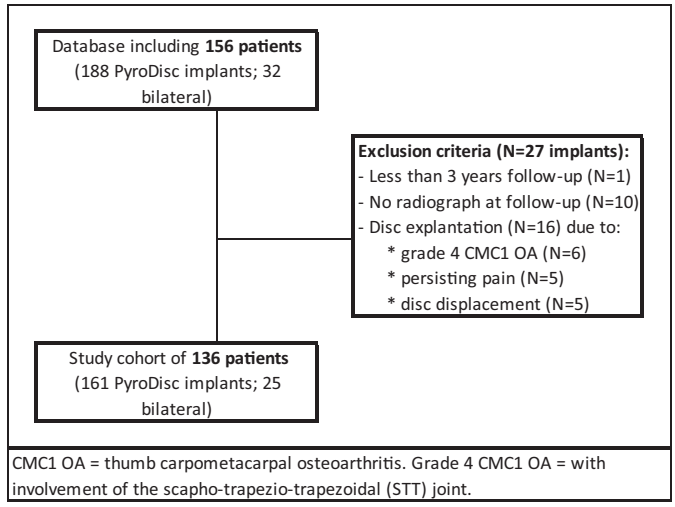

Figure 1. Flow chart.

Prior disc removal

Sixteen patients underwent disc removal before the start of this present study. Patient characteristics and reasons for disc removal are described in Supplementary Appendix 1.

Only patients with a trauma of the operated hand (3/16) had severe disc displacement or luxation on radiographs (Grade 3 or 4) and all underwent re-operation within 2 years of initial surgery (Supplementary Appendix 1). In most patients (13/16) however, the reason for disc removal was not disc dislocation but the progression of CMC1 OA to grade IV OA, including the STT joint (7/16) or persisting unexplainable pain (6/16) (Supplementary Appendix 1). Radiographs of these patients taken at the time of removal showed that most discs (12/13; removed because of STT OA or persisting pain), were well aligned or slightly displaced at the time of removal (Grade 1 or 2). Furthermore, of the patients with the disc still *in situ*, only a small number of patients (3%) developed STT OA without causing pain, as shown in one of our previous studies [6]. Patients with prior disc removal could not be included in this present study because there were no outcome measurements available at the moment of disc removal.

Clinical outcome measurements

The following outcome measures were obtained at follow-up: (1) the MHQ (Dutch Language Version) [11] measures hand health status with scores between 0 and 100, higher scores indicate a better hand health status; (2) the Patient Rated Wrist/Hand Evaluation questionnaire (PRWHE, Dutch Language Version) [12] addresses pain and disability related to the hand and wrist. Scores range from 0 to 100; 50 points are based on reported hand/wrist function and 50 points on pain with higher scores indicating the poorer status for both items. We used the subscale for pain in the PRWHE questionnaire, existing of five dimensions, as an independent variable. This score ranges from 0 to 50 points with 50 points presenting more pain; (3) patient satisfaction was gauged on a 10-point Likert scale with '1' indicating not satisfied at all and '10' excellent satisfaction; (4) operated on dominant hand (yes/no); (5) a history of mechanical stress to the CMC1 joint (yes/no) was based on patient's prior or present self-reported occupation [13,14]. Two authors independently (CvL and JO) classified the patient's occupation as manual labor occupation (e.g. construction worker, carpenter, chef) or not (e.g. office worker,

accountant) [13]. Disagreements were resolved by discussion or consensus involving a third reviewer (BvdH).

Grip strength was assessed with a Jamar dynamometer with the shoulder adducted and in neutral rotation, elbow at 90° flexion, and the forearm and wrist in neutral position (Biometrics® Ltd E-link H500 Hand Kit; Gwent, UK) [15]. Key pinch and tip pinch strength of both hands were measured using a baseline pinch gauge (Biometrics® Ltd E-link H500 Hand Kit; Gwent, UK). Strength measurements were recorded as the average of three attempts. Range of motion measurements included palmar thumb abduction by Pollexograph [14] and thumb opposition using Kapandji scores [16,17].

Radiographic outcome measurements

Radiographs of the operated thumb were obtained at follow-up in lateral and posteroanterior (PA) views. Radiographs taken directly post-operative were compared with radiographs obtained at the follow-up and scored on disc position and bone stock resorption. The radiographic disc position was assessed in relation to the longitudinal axis of the CMC1 joint on PA and lateral views separately—according to a scoring system described by Barrera-Ochoa et al. and previously used in other studies on pyrocarbon disc position [2,3]. The base of the first metacarpal bone was divided into equal quarters and perpendicular lines were drawn parallel to the long axis (Supplementary Appendix 2). Potential ulnar or radial (sub)luxation of the disc was captured on a PA view; on a lateral view, any potential volar or dorsal displacement was assessed. Implant positioning was classified in one of four categories: centered (Grade 1 = no displacement), less than one-fourth displaced (Grade 2 = slight displacement) more than one-fourth but less than one-half displaced (Grade 3 = moderate displacement), or greater than one-half of the first metacarpal base (Grade 4 = severe displacement/luxation). The highest grade of implant displacement—either on PA or lateral view—was used for further analysis.

Intraobserver and interobserver reliability of radiographic scoring for implant position were assessed. For intraobserver reliability, disc position was scored twice on 40 radiographs by a single rater with two weeks in between evaluations. For interobserver reliability, a second reviewer rated a subset of 40 patients on disc position.

Statistical analysis

Continuous variables are reported as the median and interquartile range (IQR) and discrete variables as absolute numbers with percentages. Since only 1 disc was classified as a grade 4 luxation, grade 3 and 4 were merged for further analysis. We excluded one of the bilateral thumbs blinded and at random in all 25 bilateral patients to avoid statistical violence, resulting in 136 thumbs (136 patients) for further analysis. This is based on the principle that statistical independence is violated if left and right-sided measures within one patient are considered to be independent, as stated by Park et al. [18]. Missing values were imputed with the median of the specific measurement at follow-up. Median imputation was used for two missing MHQ questionnaires, six missing pain subscales, eight PRWHE scores, and five satisfaction scores. Based on the non-normally distributed and unpaired characteristics of our data, we used Spearman's rank correlation coefficient to determine any association between disc luxation and continuous variables, including MHQ scores, and Mann–Whitney test for the variables hand dominance and manual labor occupation. Additionally, we dichotomized the variable 'disc displacement' into two groups: not displaced/centered (Grade 1) or displaced/luxated (Grades 2, 3, and 4 merged). We used the Mann-Whitney test to assess any relationships between disc luxation (dichotomized) and other outcome measurements; and Fisher's exact test for the variables hand dominance and occupation. p-Values <0.05 were considered statistically significant.

Power analysis

A *post-hoc* power analysis demonstrated that 84 patients provided 80% statistical power to detect a significant difference, with two-tailed alpha set at 0.05, in MHQ scores with a medium effect size of 0.3. This means we had enough patients to detect a difference in MHQ scores between the different groups of disc positioning with our study size of 136 patients.

Results

Reliability

The intraobserver reliability for scoring disc position on radiographs, determined by weighted kappa, was 0.97 for PA view (standard error [SE] 0.17) and 0.93 (SE 0.17) for lateral view (Supplementary Appendix 3). The interobserver reliability measured by weighted kappa for PA view was 0.91 (SE 0.17) and 0.92 (SE 0.17) for lateral view (Supplementary Appendix 3).

Patient characteristics and radiographic findings

Most of the 136 patients were woman ($N = 92$; 68%) with a median age at operation of 58 years (range 30–82) and a median follow-up time of 6.7 years (range 3.3–11) (Table 1). Thirty-one patients (23%) reported a present or prior manual labor occupation. Median scores of the assessed PROMs, thumb strength, and range of motion are shown in Supplementary Appendix 4. Of the 136 implants, 80 (59%) were well aligned at follow-up and rated as Grade 1 (Table 1; Supplementary Appendix 2). Thirty-eight (28%) discs were slightly displaced (Grade 2), 13% were moderately displaced and 1 disc was luxated (Grade 4) (Table 1; Supplementary Appendix 2). There were no signs of bone stock resorption or osteolysis of the disc implant.

Primary outcome: effect of disc position on MHQ score

In bivariate analysis, we found no relationship between the severity of disc displacement and MHQ scores [Spearman's rank (ρ) = 0.088; $p = 0.31$] (Table 2). Similarly, when treated as a

Table 1. Patient characteristics.

Variables	*N* (%)
Patients	136 (100)
Woman	92 (68)
Age at operation (*y*, (range))	58 (30–82)
Median follow-up (*y*, (range))	6.7 (3.3–11)
Dominant hand operated	57 (43)
Bilateral operated	25 (16)
Manual labor occupation	31 (23)
Radiographic disc position	
Grade 1. Centered/Not displaced	80 (59)
Grade 2. Less than 1/4 displaced	38 (28)
Grade 3. 1/4 to 1/2 displaced	17 (13)
Grade 4. More than 1/2 luxated	1 (0.74)

Discrete variables as number (percentage), unless otherwise specified.

dichotomous variable (centered *vs.* displaced), disc position did not correlate with MHQ scores either [$Z = -0.99$; $p = 0.32$] (Table 3).

Secondary outcomes

Manual labor occupation was the only factor that correlated with more severe disc displacement ($p < 0.001$; Tables 2 and 3). We could not detect any relationship between severity of disc displacement and other outcome variables including patient-reported function by PRWHE scores, pain intensity, patient satisfaction, thumb strength, range of motion, or hand dominance (Tables 2 and 3). Of the 28 patients with a manual occupation, 68% ($n = 21$) had radiographic displacement of the implant (Grade $\geq$2) compared to 33% ($n = 33$) of those with another occupation (Table 3).

Discussion

In an earlier study, pyrocarbon disc interposition arthroplasty for CMC1 OA was shown to improve patient-reported hand function and pain, up to 8 years post-operatively, with a survival rate of 91% [1–4,6]. This present study primarily evaluated the effect of radiographic disc position on MHQ scores. Secondary, we studied if disc position correlated with other factors, including pain intensity, thumb strength, and manual labor occupation.

Table 2. Correlation between disc displacement and outcome measurements (disc position as ordinal variable).

Variables	Disc displacement	*p*-Value
MHQ	0.088	0.31
PRWHE	−0.094	0.28
Pain	−0.044	0.61
Satisfaction	−0.10	0.23
Jamar	0.036	0.68
Key pinch	0.033	0.70
Tip pinch	0.083	0.33
Palmair thumb abduction	−0.12	0.16
Kapandji (0–10)	0.12	0.16
Dominant hand operated	0.60	0.55
Manual labor occupation	−3.3	**<0.001**

Spearman's rank correlation coefficient for all interval variables; Mann–Whitney test for occupation and hand dominance with Z-score. Bold indicates statistically significant difference.

Our results show that patients did not experience more pain, less grip strength, or worse hand function when disc displacement was found on radiographs. This is in line with previous literature, although these studies were underpowered to evaluate the effect of disc position on patient-reported outcome and hand function [1–3]. Other factors than perfect disc alignment seem to be more important in the treatment of CMC1 OA. For example, a positive attitude has been associated with better outcomes after CMC1 surgery [19]. In addition, there is mounting evidence that pain intensity and dissatisfaction with treatment are related to symptoms of depression and less effective coping strategies [20–22]. This underlines that during post-operative follow-up, the main focus should be on patient-reported outcomes measures and adaptive coping strategies instead of radiographic findings.

We doubt the routine utility of radiographs during post-operative follow-up, especially if there is no clinical concern. A study on the hemisphere pyrocarbon implant for CMC1 OA reports low sensitivity (65%) and specificity (63%) of radiography in predicting clinical outcomes [23]. Besides, a study on pyrolytic implants for small hand joints found that the radiographic survival rate is worse than clinical survival [24]. A symmetrical lucency around the pyrocarbon disc of 1 mm can be attributed to the radiolucent coating and a small amount of displacement may be explained by the gliding concept of the disc that allows joint movement. Bone stock resorption is uncommon and was not found in our series, as expected based on findings of a previous study [2].

Our data suggest that (a history of) manual labor occupation is associated with implant displacement over time. To prove causality, future prospective studies are needed. Nevertheless, it is an interesting finding that heavy occupational tasks may be associated with disc displacement over time since this technique is preferred when there is a need to maintain adequate thumb strength and stability, especially in people with demanding occupational tasks. Importantly, the clinical relevance of this potential association however remains questionable because disc displacement seemed to have limited clinical impact.

The disc displacement prevalence of 41% we found is much higher than the 2.2% to 31% prevalence reported in previous studies [1–3,5,25]. This may be explained by the fact that some studies did not use a clear scoring system to assess radiographic disc position [1,4,5]. We used a very strict scoring method in which even a small displacement of the disc was scored as 'displaced'. Another explanation may be the relatively long follow-

Table 3. Correlation between disc displacement and outcome measurements (disc position as dichotomous variable).

	Disc displacement			
Variables	Yes ($N = 56$)	No ($N = 80$)	*Z*	*p*-Value
MHQ	78.0 (64–89)	71.1 (62–89)	−0.99	0.32
PRWHE	15.0 (3.5–40)	20.5 (4.5–48)	0.94	0.35
Pain	10.0 (2.0–18)	11.8 (0.0–26)	0.49	0.62
Satisfaction	9.0 (7.0–10)	10.0 (7.5–10)	1.31	0.19
Jamar	24.0 (16–32)	22.9 (16–34)	−0.38	0.70
Key pinch	4.8 (3.7–5.9)	4.5 (3.2–6.5)	−0.30	0.77
Tip pinch	3.4 (2.7–4.4)	3.3 (2.3–4.3)	−0.90	0.37
Palmair thumb abduction	45 (40–50)	48 (42–56)	1.72	0.086
Kapandji (0–10)	10 (9.0–10)	9.0 (8.5–10)	−1.32	0.19
Dominant hand operated, *n* (%)				
Yes	65 (58)	48 (43)	N/A	0.33
No	14 (70)	6 (30)		
Manual labor occupation, *n* (%)				
Yes	21 (68)	10 (32)	N/A	**0.001**
No	35 (33)	70 (67)		

N/A: not applicable.
Disc position was dichotomized to 'displaced' (Grades 2, 3, 4) or 'centered/not displaced' (Grade 1). Continuous variables shown as median scores (IQR), discrete variables as number (%). Fisher's exact test for occupation and hand dominance; Mann–Whitney test for all other variables. Bold indicates statistically significance.

up of our study (mean of 6.9 years), presenting a more accurate percentage of disc displacement over time. Despite the relatively high percentages of (slightly) displaced discs in our study, the clinical results are good and in correspondence with those of others [2,3,25]. If displacement becomes symptomatic, revision surgery mostly occurs within the first two years after surgery as reported in our and in similar studies [1–3,5].

Our study results must be interpreted in the context of some study limitations. First, preoperative measurements of the different PROMs, thumb strength, and motion were not available. Therefore, we could not assess any differences in outcome measurements over time. However, in the light of our study aim, we believe that it is possible to make a statement about the association between the disc position and the clinical outcomes postoperatively. Second, even a small displacement was judged as 'displaced', which may have led to an overestimation of the number of displaced discs and an underestimation of the possible correlation between outcome and disc position. Third, we were unable to include 16 patients because of disc removal before the start of this study. These patients were not included in the study because of missing outcome data. This may have contributed to a lack of correlation, although it seems unlikely since it concerns a very small amount of our total study cohort. Besides, this study aimed to investigate the clinical outcome related to implant position for those patients with the disc still *in situ*. Fourth, the subgroup of patients with STT OA in our study cohort was too small ($n = 5$) for statistical analysis to detect any relationship with disc position. However, there appears to be no indication for the development of STT OA and implant dislocation. Fifth, we gauged patient's prior and present occupation in a general questionnaire, as performed in previous studies [13], but more specific data on duration of occupational tasks, work postures, or other physical activity was not available. Sixth, this study was conducted in two urban centers in the Netherlands and results may not generalize to other settings.

In conclusion, we could not detect any relationship between the position of pyrocarbon disc on radiographs and a broad variety of clinical outcomes, including patient-reported pain and hand function. Our data suggest that heavy occupational tasks are associated with increased severity of radiographic disc displacement but future studies are needed to study this in better detail and to reveal any causative factors. A variable amount of displacement of the disc occurred in 41% of the patients but this had little clinical consequences. Therefore, follow-up radiographs should not be taken routinely if there are no complaints.

Disclosure statement

All authors (JO, CL, MH, AS, HC, and BH) certify that besides the received research grant they have no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Author contributions

JO: conceptualization, methodology, formal analysis, investigation, writing original draft, and project administrating. CvL: conceptualization, formal analysis, investigation, writing original draft, and project administrating. MvH: conceptualization, methodology, formal analysis, and writing original draft. AS: provision of resources, supervision, visualization, review, and editing. JC: methodology, validation, supervision, review, and editing. BvdH: conceptualization, methodology, investigation, provision of resources, supervision, review, and editing.

Ethical approval

The study was approved by the Medical Ethical Review Board Brabant, the Netherlands, no P1704, NL60003.028.16 at 1 May 2017. This study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki. This study has been carried out in accordance with relevant regulations of the US Health Insurance Portability and Accountability Act (HIPAA). Written informed consent was obtained from all patients before the study.

Funding

The authors received a research grant from Integra Life Sciences. This research grant was used for the execution of the study only and the sponsor was not involved in the collection of the data, analysis of the data, or completion of the manuscript.

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