Research Square

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Interposition Arthroplasty with a Bioabsorbable RegJoint™ Implant Versus Total Joint Replacement with a Touch® Cementless Dual-Mobility Prosthesis in Advanced Trapeziometacarpal Osteoarthritis: A Prospective Comparative Cohort Study with Propensity Score Matching

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Abstract

Background: Osteoarthritis of the thumb carpometacarpal joint (CMC1) is a common cause of pain and impaired hand function, and no surgical technique has proven superior in advanced disease. We compared the early clinical and functional outcomes of interposition arthroplasty with a bioabsorbable RegJoint™ implant and total joint replacement with a Touch® cementless dual-mobility prosthesis.

Methods: In a prospective single-centre comparative cohort study, 100 patients with Eaton–Glickel stage III–IV CMC1 osteoarthritis were allocated by block randomisation between January 2023 and November 2025; 95 completed the 6-month follow-up. Because the preoperative QuickDASH score differed between the groups ($p = 0.0001$), 1:1 propensity score matching was applied, yielding 26 matched pairs. Pain intensity (NRS), range of motion, grip strength and QuickDASH were assessed before surgery and 4 weeks, 8 weeks and 6 months afterwards.

Results: Both groups improved significantly. At 6 months the Touch® group had lower pain intensity (median 0.0 vs. 1.0), greater grip strength (32.0 vs. 19.5 kg), better QuickDASH scores (26.7 vs. 48.4) and a wider range of motion in every plane (all $p < 0.0001$). Grip strength and function already differed at 4 weeks. Complications occurred in 1 of 26 and 2 of 26 patients, respectively.

Conclusions: Total joint replacement provided faster and greater early functional recovery. The non-randomised analysis, the small matched sample and the 6-month follow-up mean that confirmation in registered trials with longer observation is required.

Background

Osteoarthritis of the thumb carpometacarpal joint (CMC1), also referred to as rhizarthrosis, is a common cause of pain and limited hand function, particularly in middle-aged and older individuals and in those who perform repetitive movements that load the thumb. In advanced stages of the disease conservative treatment is ineffective and surgical intervention becomes necessary. Advances in biomaterial technology and small joint arthroplasty have introduced new surgical options, including cementless dual-mobility prostheses and implants made of bioabsorbable materials. Both approaches aim to restore thumb function, reduce pain and improve quality of life [1–3].

The Touch® prosthesis is a cementless, dual-mobility ball-and-socket implant that restores joint mobility while maintaining the biomechanical axis and adequate stabilisation [2]. The RegJoint™ implant, made of a bioabsorbable copolymer, acts as an interposition between the joint surfaces, separating them and allowing the formation of a fibrous pseudo-joint. This technique is considered a minimally invasive alternative to classic resection arthroplasty [3].

The aim of this study was to compare the early clinical and functional outcomes of these two techniques in patients with advanced CMC1 osteoarthritis.

Methods

Study design and setting

This was a prospective, single-centre comparative cohort study carried out between January 2023 and November 2025 at the Department of Orthopaedics and Traumatology, Rydygier Hospital, Brzesko, Poland. Patients were allocated to the two treatment groups in a 1:1 ratio using block randomisation. However, the study was not prospectively registered as a clinical trial, and neither allocation concealment nor blinding of the participants, the surgeon or the assessors was implemented. Moreover, a statistically significant baseline imbalance in QuickDASH score persisted despite randomisation and had to be addressed by propensity score matching. For these reasons the study is reported as a prospective comparative cohort study in accordance with the STROBE statement, and not as a randomised controlled trial. Clinical trial number: not applicable.

Participants

Of 780 consecutive patients referred with pain and/or restricted mobility of the thumb, 162 had radiographic features of CMC1 osteoarthritis and 100 fulfilled the eligibility criteria and were enrolled.

Inclusion criteria were: age 18 years or older; radiographically confirmed CMC1 osteoarthritis of Eaton–Glickel stage III or IV; failure of at least 12 months of structured conservative treatment (analgesics, orthosis, physiotherapy, intra-articular injections); baseline pain intensity of at least 5 points on the NRS; and written informed consent.

Exclusion criteria were: inflammatory or crystal arthropathy; previous surgery of the ipsilateral CMC1 joint; active local or systemic infection; scaphotrapeziotrapezoid osteoarthritis requiring simultaneous treatment; neurological impairment of the operated hand, including carpal tunnel syndrome and paresis; cognitive impairment precluding informed participation; and inability or unwillingness to attend the scheduled follow-up visits.

Allocation to the Touch® group (n = 50) or the RegJoint™ group (n = 50) was performed by block randomisation. Allocation was not concealed, and neither the operating surgeon nor the patients could be blinded, since the two procedures differ substantially.

Interventions

All procedures were performed by a single surgeon with 15 years of experience in hand surgery, under regional anaesthesia and tourniquet control, through a dorsoradial approach.

Total joint replacement was carried out with the Touch® cementless dual-mobility trapeziometacarpal prosthesis (Kerimedical, Geneva, Switzerland), comprising a titanium, hydroxyapatite-coated trapezial

cup, a metacarpal stem and a mobile polyethylene insert. The articular surface of the trapezium and any osteophytes were sparingly resected and the proximal end of the first metacarpal was trimmed using cutting guides. The prepared bone was shaped with dedicated instruments and the final implant size was determined with sizing guides. The capsule of the CMC1 joint was sutured under optimal tension, a 10 mm Redon drain was inserted and a figure-of-eight plaster cast was applied.

Interposition arthroplasty was performed with the RegJoint™ implant (Scaffdex Oy, Tampere, Finland), a bioabsorbable poly-L/D-lactide copolymer scaffold placed between the joint surfaces after partial trapeziectomy. The articular surface of the proximal first metacarpal was conservatively resected and the final implant diameter was selected using sizing gauges. The capsule of the CMC1 joint was sutured under optimal tension, a 10 mm Redon drain was inserted and a figure-of-eight plaster cast was applied in every case.

Postoperatively both groups were immobilised in a thumb spica cast for 7–10 days. Antibiotic prophylaxis and thromboprophylaxis were administered according to institutional protocol.

Rehabilitation protocol

An identical rehabilitation programme was used in both groups. Rehabilitation started on the first postoperative day with oedema control, active mobilisation of the fingers, elevation and isometric exercises. Immobilisation was maintained until suture removal on days 7–10, after which physiotherapy was intensified according to a predetermined programme comprising active and active-assisted mobilisation of the CMC1 joint, scar management, and progressive opposition and abduction exercises from the tenth postoperative day. Progressive strengthening (putty, pinch and grip training) was introduced from week 4 at two thirds of the maximum strength value and from week 8 at the maximum strength value. Sessions were held five times per week for 10 weeks and were supplemented by a home exercise programme. Attendance at the supervised sessions was recorded, but adherence to the home exercise programme was not formally monitored.

Outcome measures

All patients were assessed at four time points: before surgery and at 4 weeks, 8 weeks and 6 months after surgery. Radiographic staging was performed preoperatively according to Eaton and Glickel. Outcomes were recorded by the operating surgeon, always at the same time of day and with the same equipment.

Pain intensity was measured on an 11-point Numeric Rating Scale (NRS; 0 = no pain, 10 = worst imaginable pain). Range of motion of the CMC1 joint — flexion, extension and palmar abduction — was measured in degrees with a goniometer (GIMA, Milan, Italy). The axis was centred over the dorsoradial aspect of the CMC1 joint, just distal to the radial styloid process; the proximal arm was aligned along the lateral midline of the radius, parallel to the shaft of the second metacarpal, and the distal arm along the

dorsolateral midline of the first metacarpal shaft, pointing towards the first metacarpophalangeal joint. The mean of two measurements was recorded. Opposition was assessed with the Kapandji index (0–10 points).

Global grip strength was measured with a SEAHAN hydraulic hand dynamometer (Fabrication Enterprises, White Plains, NY, USA) and expressed in kilograms, with the patient seated, shoulder adducted, elbow flexed to 90° and forearm in neutral rotation; the mean of three trials separated by 60 s of rest was used. Upper limb function was assessed with the QuickDASH questionnaire (Polish validated version), scored from 0 (no disability) to 100 (maximum disability). Complications were recorded prospectively throughout the follow-up period and are reported for the whole operated cohort as well as for the matched cohort.

Sample size

No a priori sample size calculation was performed. The study included all consecutive eligible patients treated during the recruitment period; the resulting sample size and its consequences for statistical power are addressed in the limitations.

Propensity score matching

Of the 100 patients enrolled, five were lost to follow-up: two did not attend the scheduled control visits and three did not have complete medical records (three patients in the Touch® group and two in the RegJoint™ group), leaving 47 and 48 patients respectively with complete data. Despite randomisation, comparison of these two groups showed a statistically significant difference in preoperative QuickDASH score ($p = 0.0001$); no other baseline variable differed significantly (p values from 0.54 to 0.96), so the groups were not directly comparable with respect to baseline function.

To reduce confounding, 1:1 propensity score matching without replacement was applied. Propensity scores were estimated by logistic regression with treatment group as the dependent variable and age, sex, hand dominance, operated side, Eaton–Glickel stage, baseline NRS, baseline QuickDASH, baseline grip strength and baseline range of motion as covariates. Nearest-neighbour matching was performed with a caliper of 0.2 of the standard deviation of the logit of the propensity score. Balance was assessed using standardised differences, with a value below 10% regarded as negligible imbalance. Matching yielded 26 pairs, and all analyses reported below were performed on this matched cohort. The full study algorithm is presented in Fig. 1.

Statistical analysis

The distribution of continuous variables was assessed with the Shapiro–Wilk test. Because the assumption of normality was not met for most variables, all continuous data are presented as median

with interquartile range (IQR) and were analysed with non-parametric tests. Categorical variables are presented as counts and percentages.

Within-group changes between consecutive assessment points (baseline vs. 4 weeks, 4 vs. 8 weeks, 8 weeks vs. 6 months) were analysed with the Wilcoxon signed-rank test. Between-group comparisons at each assessment point were performed with the Mann–Whitney U test; categorical variables were compared with Fisher's exact test. All tests were two-sided and a value of $p < 0.05$ was considered statistically significant. Multiple outcomes were tested at several time points and no formal correction for multiple comparisons was applied; findings with p values between 0.01 and 0.05 are therefore reported as exploratory and interpreted with caution throughout. Analyses were performed with SAS, version 15.4 (SAS Institute Inc., Cary, NC, USA, 2024).

Results

Baseline characteristics

The matched cohort comprised 35 women (67.3%) and 17 men (32.7%). The median age was 57 years in both groups (IQR 52.0–61.0 in the Touch® group and 55.0–59.0 in the RegJoint™ group). Hand dominance and operated side were included among the matching covariates and were therefore balanced between the groups by construction; they are not reported separately. Eaton–Glickel stage IV was present in 33 patients (63.5%) and stage III in 19 (36.5%). After matching, the groups did not differ significantly in any baseline variable; standardised differences were below 10% for all variables except age (11.6%) and extension (11.3%), which showed only marginal residual imbalance (Table 1).

Table 1
Baseline characteristics of both groups after propensity score matching (n = 26 per group).

Variable	Touch® Me (IQR)/n (%)	RegJoint™ Me (IQR)/n (%)	p	Standardised difference (%)
Age (years) §	57.0 (52.0–61.0)	57.0 (55.0–59.0)	0.51	11.6
Sex †			1.00	8.2
men	8 (30.8)	9 (34.6)		
women	18 (69.2)	17 (65.4)		
Eaton–Glickel stage †			1.00	8.0
stage III	10 (38.5)	9 (34.6)		
stage IV	16 (61.5)	17 (65.4)		
Pain intensity, NRS §	7.5 (7.0–8.0)	7.0 (7.0–8.0)	0.80	7.3
Range of motion §				
flexion (°)	8.0 (7.0–9.0)	8.0 (7.0–9.0)	0.98	0.1
extension (°)	22.0 (20.0–22.0)	22.0 (20.0–22.0)	0.92	11.3
palmar abduction (°)	30.5 (29.0–31.0)	30.0 (27.0–31.0)	0.84	2.4
opposition (Kapandji, 0–10)	4.5 (4.0–6.0)	4.5 (4.0–5.0)	0.89	3.3
Grip strength (kg) §	8.0 (6.0–11.0)	7.0 (6.0–11.0)	0.81	8.6
QuickDASH (0–100) §	74.3 (69.1–87.0)	78.2 (73.0–81.7)	0.94	0.8

§ median (interquartile range, IQR); † n (percentage). Me — median. A standardised difference below 10% indicates negligible imbalance. Hand dominance and operated side were included among the matching covariates and are therefore balanced by construction; they are not tabulated separately.

Outcomes in the Touch® group

In the Touch® group, statistically significant improvement was demonstrated for all assessed parameters across all consecutive follow-up intervals. Median pain intensity decreased from 7.5 to 0.0 points, grip strength increased from 8.0 to 32.0 kg and the QuickDASH score improved from 74.3 to 26.7 points over the 6-month period. All within-group comparisons reached statistical significance, although the change in palmar abduction between weeks 4 and 8 was only marginally significant ($p = 0.0254$) and is therefore treated as exploratory. Detailed data are presented in Table 2.

Table 2
Pain intensity, range of motion and functional status at each assessment point in the Touch® group (n = 26).

Parameter	Baseline Me (IQR)	4 weeks Me (IQR)	8 weeks Me (IQR)	6 months Me (IQR)	p baseline vs. 4 w	p 4 vs. 8 w	p 8 w vs. 6 mo
Pain, NRS	7.5 (7.0–8.0)	6.0 (6.0–7.0)	4.0 (4.0–5.0)	0.0 (0.0–0.0)	< 0.0001	< 0.0001	< 0.0001
Flexion (°)	8.0 (7.0–9.0)	10.0 (9.0–12.0)	12.0 (11.0–13.0)	14.0 (14.0–14.0)	< 0.0001	< 0.0001	< 0.0001
Extension (°)	22.0 (20.0–22.0)	22.0 (22.0–24.0)	24.0 (23.0–25.0)	29.0 (29.0–29.0)	0.0002	< 0.0001	< 0.0001
Abduction (°)	30.5 (29.0–31.0)	32.0 (29.0–33.0)	32.5 (29.0–34.0)	38.5 (38.0–39.0)	0.0002	0.0254	< 0.0001
Opposition (0–10)	4.5 (4.0–6.0)	6.0 (5.0–7.0)	7.0 (7.0–8.0)	9.0 (9.0–10.0)	< 0.0001	< 0.0001	< 0.0001
Grip strength (kg)	8.0 (6.0–11.0)	12.0 (9.0–14.0)	17.5 (15.0–23.0)	32.0 (29.0–35.0)	< 0.0001	< 0.0001	< 0.0001
QuickDASH	74.3 (69.1–87.0)	58.1 (50.0–68.2)	40.0 (30.0–45.1)	26.7 (20.0–37.0)	< 0.0001	< 0.0001	< 0.0001

Me — median; IQR — interquartile range. Wilcoxon signed-rank test for consecutive assessment points. No correction for multiple comparisons was applied; p values between 0.01 and 0.05 are regarded as exploratory.

Outcomes in the RegJoint™ group

In the RegJoint™ group improvement followed a slower course. In the first interval (baseline to 4 weeks) all parameters except functional status improved significantly, although the changes in palmar abduction ($p = 0.0156$), opposition ($p = 0.035$) and grip strength ($p = 0.010$) were only marginally significant and are treated as exploratory, while the QuickDASH score did not change ($p = 0.56$). Between weeks 4 and 8, significant improvement was confirmed for pain intensity, flexion, grip strength and functional status, whereas extension ($p = 0.25$), palmar abduction ($p = 1.00$) and opposition ($p = 0.13$) did not change significantly. In the final interval (8 weeks to 6 months) all assessed parameters improved significantly. Median pain intensity decreased from 7.0 to 1.0 points, grip strength increased from 7.0 to 19.5 kg and the QuickDASH score improved from 78.2 to 48.4 points (Table 3).

Table 3
Pain intensity, range of motion and functional status at each assessment point in the RegJoint™ group (n = 26).

Parameter	Baseline Me (IQR)	4 weeks Me (IQR)	8 weeks Me (IQR)	6 months Me (IQR)	p baseline vs. 4 w	p 4 vs. 8 w	p 8 w vs. 6 mo
Pain, NRS	7.0 (7.0–8.0)	6.0 (5.0–7.0)	5.0 (4.0–6.0)	1.0 (1.0–2.0)	0.0004	< 0.0001	< 0.0001
Flexion (°)	8.0 (7.0–9.0)	9.5 (8.0–12.0)	10.5 (9.0–12.0)	13.0 (12.0–14.0)	< 0.0001	0.0024	< 0.0001
Extension (°)	22.0 (20.0–22.0)	22.5 (22.0–25.0)	23.0 (22.0–25.0)	24.5 (24.0–26.0)	< 0.0001	0.25	< 0.0001
Abduction (°)	30.0 (27.0–31.0)	30.5 (30.0–32.0)	30.5 (30.0–32.0)	34.0 (32.0–37.0)	0.0156	1.00	< 0.0001
Opposition (0–10)	4.5 (4.0–5.0)	5.0 (5.0–7.0)	5.5 (5.0–7.0)	8.0 (7.0–8.0)	0.035	0.13	< 0.0001
Grip strength (kg)	7.0 (6.0–11.0)	7.0 (5.0–9.0)	11.0 (9.0–13.0)	19.5 (17.0–23.0)	0.010	< 0.0001	< 0.0001
QuickDASH	78.2 (73.0–81.7)	77.6 (65.2–86.2)	58.4 (50.0–62.0)	48.4 (34.5–56.1)	0.56	< 0.0001	< 0.0001

Me — median; IQR — interquartile range. Wilcoxon signed-rank test for consecutive assessment points. No correction for multiple comparisons was applied; p values between 0.01 and 0.05 are regarded as exploratory.

Between-group comparison of range of motion

Range of motion of the CMC1 joint differed significantly between the groups in favour of the Touch® group for flexion at 8 weeks (12.0° vs. 10.5°; p = 0.015, exploratory) and at 6 months (14.0° vs. 13.0°; p = 0.001), for opposition at 8 weeks (7.0 vs. 5.5 Kapandji points) and at 6 months (9.0 vs. 8.0 points; both p < 0.0001), and for extension (29.0° vs. 24.5°) and palmar abduction (38.5° vs. 34.0°) at 6 months (both p < 0.0001). At 4 weeks none of the range-of-motion parameters differed between the groups. Detailed data are presented in Table 4.

Table 4
Between-group comparison of range of motion of the CMC1 joint at each assessment point (n = 26 per group).

Parameter	Touch® Me (IQR)	RegJoint™ Me (IQR)	p (Mann–Whitney U test)
Flexion, 4 weeks (°)	10.0 (9.0–12.0)	9.5 (8.0–12.0)	0.21
Flexion, 8 weeks (°)	12.0 (11.0–13.0)	10.5 (9.0–12.0)	0.015
Flexion, 6 months (°)	14.0 (14.0–14.0)	13.0 (12.0–14.0)	0.001
Extension, 4 weeks (°)	22.0 (22.0–24.0)	22.5 (22.0–25.0)	0.84
Extension, 8 weeks (°)	24.0 (23.0–25.0)	23.0 (22.0–25.0)	0.13
Extension, 6 months (°)	29.0 (29.0–29.0)	24.5 (24.0–26.0)	< 0.0001
Abduction, 4 weeks (°)	32.0 (29.0–33.0)	30.5 (30.0–32.0)	0.19
Abduction, 8 weeks (°)	32.5 (29.0–34.0)	30.5 (30.0–32.0)	0.09
Abduction, 6 months (°)	38.5 (38.0–39.0)	34.0 (32.0–37.0)	< 0.0001
Opposition, 4 weeks (0–10)	6.0 (5.0–7.0)	5.0 (5.0–7.0)	0.10
Opposition, 8 weeks (0–10)	7.0 (7.0–8.0)	5.5 (5.0–7.0)	< 0.0001
Opposition, 6 months (0–10)	9.0 (9.0–10.0)	8.0 (7.0–8.0)	< 0.0001

Me — median; IQR — interquartile range. Values are absolute measurements at each assessment point, not changes from baseline. No correction for multiple comparisons was applied; the comparison of flexion at 8 weeks (p = 0.015) is regarded as exploratory.

Between-group comparison of pain, grip strength and function

Grip strength and functional status were significantly better in the Touch® group at every assessment point, including as early as 4 weeks after surgery (12.0 vs. 7.0 kg and QuickDASH 58.1 vs. 77.6; both $p < 0.0001$). Pain intensity was comparable in both groups at 4 weeks ($p = 0.12$) and differed from the eighth week onwards (4.0 vs. 5.0 points; $p = 0.028$, exploratory) and at 6 months (0.0 vs. 1.0 points; $p < 0.0001$). The largest between-group differences were observed at 6 months for grip strength (32.0 vs. 19.5 kg) and for QuickDASH (26.7 vs. 48.4 points; both $p < 0.0001$). Detailed data are presented in Table 5.

Table 5
Between-group comparison of pain intensity, grip strength and functional status at each assessment point (n = 26 per group).

Parameter	Touch® Me (IQR)	RegJoint™ Me (IQR)	p (Mann–Whitney U test)
Pain (NRS), 4 weeks	6.0 (6.0–7.0)	6.0 (5.0–7.0)	0.12
Pain (NRS), 8 weeks	4.0 (4.0–5.0)	5.0 (4.0–6.0)	0.028
Pain (NRS), 6 months	0.0 (0.0–0.0)	1.0 (1.0–2.0)	< 0.0001
Grip strength, 4 weeks (kg)	12.0 (9.0–14.0)	7.0 (5.0–9.0)	< 0.0001
Grip strength, 8 weeks (kg)	17.5 (15.0–23.0)	11.0 (9.0–13.0)	< 0.0001
Grip strength, 6 months (kg)	32.0 (29.0–35.0)	19.5 (17.0–23.0)	< 0.0001
QuickDASH, 4 weeks	58.1 (50.0–68.2)	77.6 (65.2–86.2)	< 0.0001
QuickDASH, 8 weeks	40.0 (30.0–45.1)	58.4 (50.0–62.0)	< 0.0001
QuickDASH, 6 months	26.7 (20.0–37.0)	48.4 (34.5–56.1)	< 0.0001

Me — median; IQR — interquartile range. Values are absolute measurements at each assessment point, not changes from baseline. No correction for multiple comparisons was applied; the comparison of pain intensity at 8 weeks (p = 0.028) is regarded as exploratory.

Complications

Within the matched cohort, two complications occurred in the RegJoint™ group (2 of 26 patients, 7.7%): one postoperative wound infection and one extrusion of the implant, the latter requiring revision surgery. One complication occurred in the Touch® group (1 of 26 patients, 3.8%): loosening with dislocation of the trapezial cup, which required revision. In the whole operated cohort the corresponding figures were 2 of 50 (4.0%) and 1 of 50 (2.0%). No other implant-related adverse events were observed during the 6-month follow-up.

Discussion

Surgical procedures currently used in the treatment of rhizarthrosis can be divided into methods applied in the early stages of the disease (Eaton grade I–II), including ligament reconstruction, osteotomy, denervation and arthroscopy, and techniques reserved for advanced stages (Eaton grade III–IV), such as trapeziectomy, arthrodesis, and partial or total arthroplasty [4, 5]. The absence of consensus regarding the optimal surgical treatment of advanced disease remains a key clinical challenge, and no clear superiority of any single technique has been demonstrated so far [6–8].

A persistent problem is the lack of guidelines indicating which intervention is optimal in a given clinical scenario, so that the choice of method is often determined by surgeon preference. In a survey of 823 members of the American Society for Surgery of the Hand, trapeziectomy with ligament reconstruction and tendon interposition (LRTI) remained the most frequently used procedure, chosen by 37.4% of respondents when the whole flexor carpi radialis tendon was used and by a further 18.3% when half the tendon was used, whereas implant arthroplasty was the primary procedure of only 1.7% [5]. Among the international respondents to the same survey, whole-tendon LRTI was far less common than in the United States (13.9% vs. 40.8%), and arthroscopic debridement, arthrodesis and implant arthroplasty together accounted for 12.9% of procedures, compared with 1.4% among US surgeons [5]. Wajon et al. concluded that there is no convincing evidence for the superiority of any single technique in terms of either pain or hand function, while noting that the available studies were of insufficient methodological quality to allow definitive conclusions [9]. A more recent review by Lee et al. comparing joint replacement with LRTI reported superiority of joint replacement in terms of clinical outcomes [10].

Our results are consistent with recent reports on dual-mobility trapeziometacarpal prostheses. Falkner et al. prospectively evaluated 55 Touch® prostheses in 52 patients with a mean follow-up of 25 months and demonstrated significant improvement in pain, strength and function [11]. Dreant and Poumellec reported the functional results of 28 dual-mobility prostheses implanted in 25 patients, with improvement in pain, range of motion and grip and pinch strength [12]. Lussiez et al., in a prospective study of 107 dual-mobility prostheses followed for more than 3 years, confirmed a low dislocation rate together with good functional outcomes [13]. In our series one cup loosening with dislocation requiring revision occurred within the first 6 months, which is consistent with the low but non-zero rate of implant-related complications reported in a recent systematic review of 1421 dual-mobility arthroplasties [14].

In the group treated with the RegJoint™ implant our results are also consistent with the existing literature. Improvement in functional parameters occurred more slowly, but by 6 months it had reached a clinically relevant level. The difference in the dynamics of recovery between the two methods may result from their different mechanisms of action: total joint replacement immediately restores a joint configuration close to physiological, whereas the RegJoint™ implant requires time for a stable fibrous pseudo-joint to form [4]. Kennedy et al., with a minimum follow-up of 2 years, found that the RegJoint™ implant was not associated with more complications than suspension arthroplasty performed without an implant, but conferred no additional functional benefit either [15]; our own 6-month data are consistent with a slower and smaller early gain in this group.

The rehabilitation strategy adopted may also have influenced the results. According to Kanak et al., rehabilitation after CMC1 arthroplasty can begin almost immediately after surgery, with a recommended immobilisation period of approximately 2–3 weeks until suture removal, followed by a programme of strengthening exercises and physical therapy [4]. In the present study rehabilitation was started on the first postoperative day and intensified after immobilisation and suture removal on days 7–10 according to a predetermined programme described in Section 2.4. This is likely to have contributed to the early improvement in grip strength and functional status observed in the Touch® group.

Taken together, our data and the available literature suggest that total joint replacement with a cementless dual-mobility prosthesis may be a particularly favourable option for patients with moderate to high functional demands in whom the speed of functional recovery and grip strength are priorities [4, 11, 16]. It should be emphasised, however, that occupational status and time to return to work were not recorded in this study, so this remains a hypothesis requiring prospective verification. The bioabsorbable RegJoint™ implant may be preferred in patients with lower functional demands, in those concerned about complications associated with total joint replacement, and in those for whom preserving a wide range of revision options is a priority.

Limitations

This study has several limitations. First, although allocation was randomised, the study was not prospectively registered, allocation was not concealed and neither the surgeon nor the patients could be blinded, which may have influenced the subjective outcomes (NRS and QuickDASH) in particular. Second, the groups differed at baseline in functional status, and although propensity score matching was used to improve comparability, matching can only balance measured covariates and reduced the analysed sample from 95 to 52 patients, with a corresponding loss of statistical power for uncommon events such as complications and revisions. Residual imbalance remained for age and extension, with standardised differences slightly above 10%. Third, no a priori sample size calculation was performed, so the study was not powered for the between-group comparisons reported. Fourth, p values were not adjusted for multiple comparisons; given the number of tests performed, the findings with p values between 0.01 and 0.05 — the between-group differences in flexion ($p = 0.015$) and pain intensity ($p = 0.028$) at 8 weeks, the within-group change in palmar abduction between weeks 4 and 8 in the Touch® group, and the within-group changes in palmar abduction, opposition and grip strength during the first four weeks in the RegJoint™ group — should be regarded as exploratory and require confirmation. Fifth, the 6-month follow-up is too short to assess implant survival, late loosening or the need for revision, and no postoperative radiographic assessment was performed. Sixth, adherence to the home exercise programme was not formally monitored, so differences in the amount of unsupervised exercise between patients and between the groups cannot be excluded as a contributor to the observed differences in recovery. Seventh, all procedures were carried out at a single centre by one experienced surgeon, which limits variability in surgical technique but also limits generalisability. Finally, neither occupational status, time to return to work, patient satisfaction nor cost-effectiveness was recorded; these, together with the identification of predictors of a good outcome, are important directions for further research.

Conclusions

Both total joint replacement with the Touch® cementless dual-mobility prosthesis and interposition arthroplasty with the bioabsorbable RegJoint™ implant are effective treatments for advanced trapeziometacarpal osteoarthritis, producing significant reductions in pain and improvements in range of motion, grip strength and hand function within 6 months. In this matched cohort, total joint replacement with the Touch® prosthesis was associated with better clinical outcomes at 6 months, including lower

pain intensity, greater grip strength, better QuickDASH scores and a wider range of motion in all assessed planes. Functional recovery was also faster after total joint replacement: grip strength and hand function already differed significantly between the groups 4 weeks after surgery, whereas differences in range of motion and pain intensity emerged from the eighth week onwards. Both procedures were associated with a low rate of complications at 6 months, although the sample size does not allow reliable comparison of complication rates and the follow-up is too short to assess implant survival.

List of abbreviations

The following abbreviations are used in this manuscript:

Abbreviation	Definition
CMC1	First carpometacarpal (trapeziometacarpal) joint
IQR	Interquartile range
LRTI	Ligament reconstruction and tendon interposition
NRS	Numeric Rating Scale
QuickDASH	Quick Disabilities of the Arm, Shoulder and Hand questionnaire
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Bioethics Committee of the District Medical Chamber in Tarnów, Poland (approval no. 1/0177/2023, 12 January 2023). Written informed consent to participate was obtained from all individual participants included in the study. Clinical trial number: not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests. No author has received funding, consultancy fees, royalties or any other financial or non-financial benefit from KeriMedical, Medartis or Scaffdex, or from any other manufacturer of the implants evaluated in this study.

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Author Contribution

JF and SJ conceived the study, performed the surgical procedures and acquired the clinical data. SJ, FG and RO designed the methodology. FG, RO and AK validated the data. RO performed the formal analysis. JF and KPK provided study resources. SJ and KPK curated the data. JF, SJ and FG drafted the manuscript. RO, KPK and AK reviewed and edited the manuscript. FG and KPK prepared the figures and tables. AK and RO supervised the project, and JF and AK administered it. All authors read and approved the final manuscript.

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work was approved as single-centre comparative cohort study by Bioethics Committee of the District MedicalChamber in Tarnów (approval no. 1/0177/2023 of 12 January 2023) Clinical trial number: not applicable

Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request. The data are not publicly available because they contain information that could compromise the privacy of the participants.

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Figures

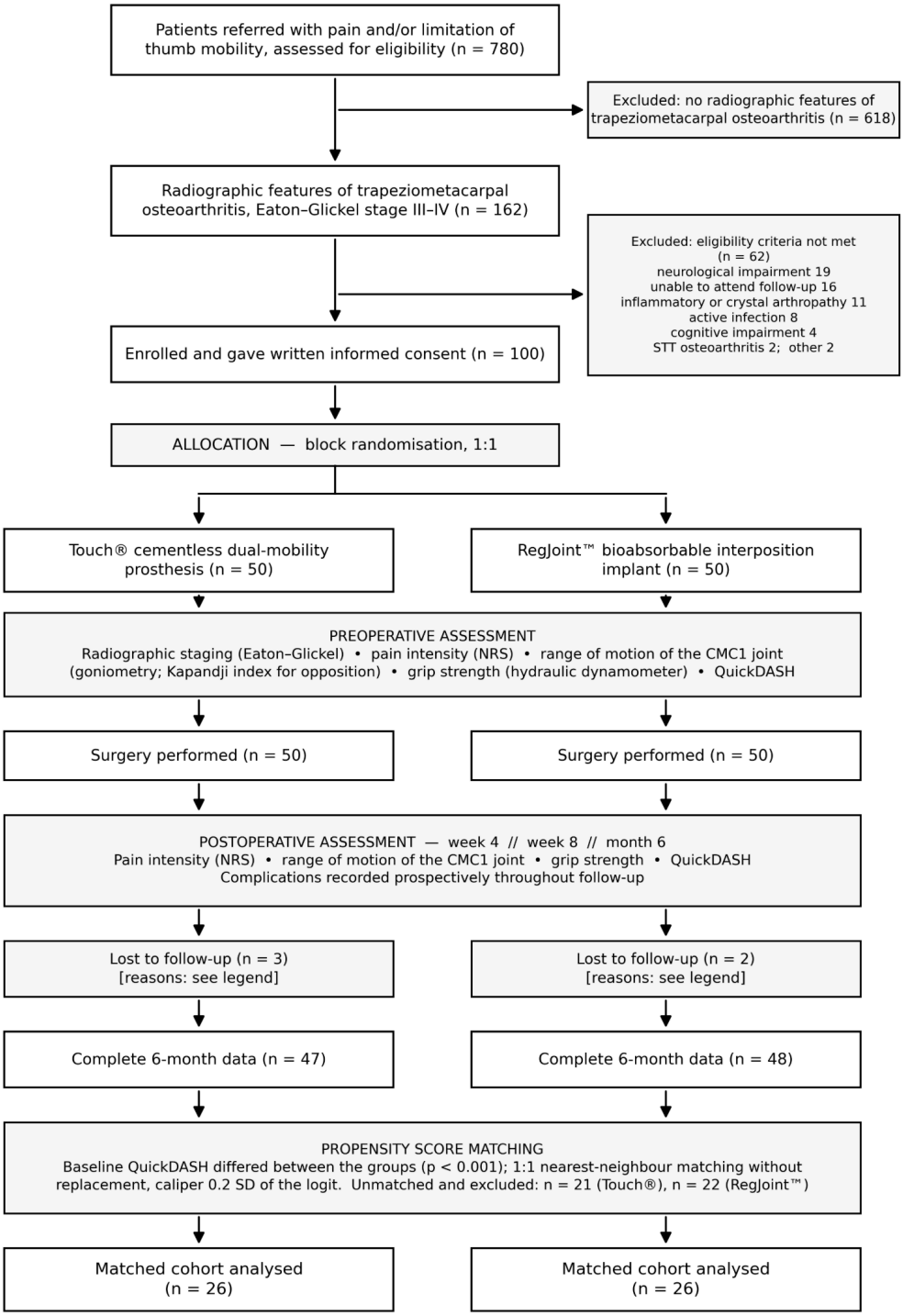


Figure 1

Flow of participants through the study. Five patients were lost to follow-up: two did not attend the scheduled control visits and three did not have complete medical records. CMC1 — thumb carpometacarpal joint; NRS — Numeric Rating Scale; STT — scaphotrapeziotrapezoid.