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Original article

The use of the RegJoint™ implant for base of thumb osteoarthritis: Results with a minimum follow-up of 2 years

Utilisation de l'implant RegJoint™ pour la rhizarthrose : résultats à un minimum de 2 ans de recul

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ABSTRACT

The RegJoint™ (Scaffdex Oy, Finland) implant is a bio-absorbable poly-L/D-lactide implant which acts as a temporary support in resected joint spaces. It can be used in base of thumb surgery as a spacer to prevent first metacarpal subsidence. However, high rates of adverse tissue reactions and bone osteolysis have been reported recently by one group. The objective of this study was to investigate the outcome of patients treated in our institution with this implant. Patients underwent a postoperative clinical and radiological assessment. The QuickDASH questionnaire, Patient Evaluation Measure (PEM) and a visual analogue scale for pain assessment were used. Grip strength, key pinch, pinch strength, thumb palmar and radial abduction and opposition were measured. Trapeziometacarpal height was used to evaluate thumb shortening compared with the preoperative value. Periprosthetic bone-erosion of the trapezium and metacarpal were measured. Subluxation of the joint was evaluated by measuring the step-off between the radial edge of the trapezium and the base of the first metacarpal bone. Twenty-two patients from 2013–2016 were included. There were no postoperative wound complications. There was no significant difference in grip strength, key pinch or pinch between the operated and the contralateral hand. There was no significant difference in the trapeziometacarpal height, trapezial height or the degree of subluxation pre-or post-operatively. Contrary to recent reports, we did not find any adverse soft tissue reactions or significant bone erosion. There was no significant change in hand function. We consider the RegJoint™ a useful adjunct in the management of a select cohort of patients with base of thumb arthritis.

Mots clés :
Rhizarthrose
Arthrose
Pouce
Arthroplastie
Implant
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Poly-L/D-lactide

RÉSUMÉ

L'implant RegJoint™ (Scaffdex Oy, Finlande) est un implant résorbable constitué de poly-L/D-lactide, agissant comme soutien transitoire dans un espace articulaire réséqué. Il peut être utilisé dans la chirurgie de la rhizarthrose comme pièce d'interposition, afin d'empêcher le recul du premier métacarpien. Cependant, un taux élevé de réactions tissulaires adverses et d'ostéolyse a récemment été rapporté par un groupe d'auteurs. L'objectif de cette étude était de rapporter l'évolution des patients ayant bénéficié de la mise en place de cet implant dans notre institution. Les patients ont été évalués cliniquement et radiologiquement en postopératoire. Les questionnaires QuickDASH et Patient Evaluation Measure (PEM), ainsi qu'une échelle visuelle analogique pour évaluer la douleur ont été utilisés. La force de poigne, de pince termino-latérale et termino-terminale ont été mesurées, ainsi que l'abduction radiale et l'opposition du pouce. La hauteur trapézo-métacarpienne a été utilisée pour évaluer le raccourcissement du pouce, par rapport à la valeur préopératoire. L'érosion osseuse péri-prothétique du trapèze et du métacarpien ont été mesurées. La subluxation de l'articulation a été évaluée en mesurant le décalage entre le bord radial du trapèze et la base du premier métacarpien. Vingt-deux

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patients opérés entre 2013 et 2016 ont été inclus. Aucun patient n'a présenté de trouble de cicatrisation. Il n'y avait pas de différence significative en termes de force de poigne, de pince termino-latérale ou de pince termino-terminale entre la main opérée et la main controlatérale. Il n'y avait pas de différence significative entre la hauteur trapézo-métacarpienne, la hauteur trapézienne, ni le degré de subluxation pré- ou post-opératoire. Contrairement aux conclusions de publications récentes, nous n'avons identifié aucune réaction tissulaire adverse ou érosion osseuse significative. La fonction de la main a été conservée. Nous considérons l'implant RegJoint™ comme un dispositif complémentaire, utile dans la gestion d'une cohorte sélectionnée de patients atteints de rhizarthrose.

1. Introduction

Thumb carpometacarpal joint (CMCJ) arthritis is a common and disabling condition which often requires surgery when conservative treatments have failed. Surgical excision of the trapezium with or without surrounding ligament reconstruction and tendon interposition is generally favoured for end stage osteoarthritis (OA) [1,2]. This technique provides excellent pain relief, overall function and strength [3,4] and is considered the 'gold standard' against which newer techniques are compared [5]. However, the complete removal of the trapezium may result in proximal migration of the first metacarpal bone and weakening of key pinch strength [3,4]. Therefore, there is a theoretical benefit in using implants to prevent this proximal migration of the metacarpal.

Multiple implant types have been described including silicone [6], ceramic [7], pyrocarbon [8], gelfoam [9], gore-tex [10] and polypropylene [11]. However, none of these implants have completely satisfactory results [5] and some have caused major complications, such as wear, synovitis and osteolysis [12–14]. The RegJoint™ implant (Scaffdex Oy, Tampere, Finland) is a bio-absorbable poly-L/D-lactide (PLDLA) disc shaped implant designed to function as a temporary porous support in a resected joint space (Fig. 1). The implant facilitates scar tissue in-growth and development of a dense fibrous pseudarthrosis. Its use has been reported previously for reconstruction of the CMCJ [15], metacarpophalangeal (MCP) joints [16] and metatarsophalangeal joints [17] in patients with rheumatoid arthritis (RA).

We typically perform an arthroplasty as a primary procedure for CMCJ arthritis (previously the ARPE prosthesis and more latterly, the Motec implant). However, we use the RegJoint™ implant in those patients who require revision of a failed CMCJ arthroplasty. In this cohort, the original implant is removed and the RegJoint™ is inserted into the space or void left behind to (in theory) allow fibrotic ingress and prevent subluxation of the metacarpal proximally. We also use the implant in those patients who have both CMCJ OA and first MCP joint instability. These patients are not suitable for a CMCJ arthroplasty as the plates used for MCP joint fusion would compete with the arthroplasty for space. Instead, we perform an MCP joint fusion at the same time as a partial trapeziectomy and RegJoint™ insertion. We have used this implant in 22 patients from 2013–2018 and have not observed any adverse complications associated with its use. We were therefore surprised by the findings of Mattila et al. [18,19] who recently published their 1-year and 3-year follow-up. They advocated abandoning the use of the RegJoint™ due to "an unacceptably high rate of adverse tissue reactions and bone osteolysis related to the degradation process of the implant" and even though pain had decreased and strength increased, the authors still advocated the discontinuation of the use of the implant.

The objective of this study was therefore to evaluate the outcome of patients treated in our institution with the RegJoint™ implant using the same methodology as Mattila et al. to determine if our experience mirrored that of theirs.

2. Patients and methods

2.1. Patient population

Patients were retrospectively identified from theatre log books. From January 2013 to July 2016, 25 RegJoint™ procedures for CMCJ OA and 1 procedure for thumb MCPJ OA were performed in 22 patients. Sixteen patients (19 joints) attended for postoperative follow-up. There were 12 women and 4 men with an average age of 69.5 (range 52–80). Six RegJoint™ procedures were performed as primary procedure in combination with a thumb MCPJ fusion. The remaining 13 procedures were revision procedures which consisted of removal of a failed arthroplasty and insertion of a RegJoint™ into the resultant joint space. The average time of follow-up was 36.5 months (range 21–53 months).

All thumbs were staged preoperatively by the Eaton-Glickel classification system [1]: five thumbs were stage 2, 6 were stage 3 and 8 were stage 4. Exclusion criteria included those patients with less than 24 months' follow-up and 1 patient who had a RegJoint™ inserted into an MCP joint.

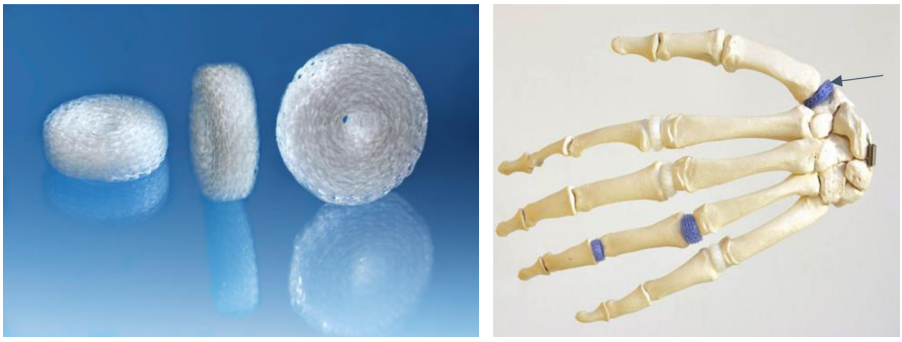

Fig. 1. RegJoint™ with arrow indicating implant in CMC joint.
Reproduced with permission of Scaffdex Oy, Finland).

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All surgeries were performed in a standardised manner by the senior author (GJP).

Institutional ethical approval was granted for this study.

2.2. Clinical assessment

2.2.1. Subjective assessment

Patients were asked to complete the Shortened Disability of the Arm, Shoulder and Hand (QuickDASH) questionnaire [20] and the Patient Evaluation Measure (PEM) [21]. Pain during activity was assessed according to a visual analogue scale ranging from 0–10, with 0 representing 'no pain' and 10 indicating 'worst pain possible'.

The QuickDASH is scored in two components: the disability/symptom section (11 items, scored 1–5) and the optional high performance sport/music or work modules (four items, scored 1–5). A higher score indicates greater disability.

The original PEM consists of a set of 18 questions [22] divided into three sections. The first part consists of five questions assessing the patients' view of the consultation. The second part of the PEM, the Hand Health Questionnaire, has ten questions investigating different attributes of hand health and function. The third part contains three questions which gives a general view on their treatment and of the condition of the hand. Each question from sections two and three are marked from 1–7, 7 being the worst outcome and 1 being the best outcome. The PEM score was then calculated by summing the values for each item in parts two and three and expressing it as a percentage of the maximum possible score. A higher score indicates greater disability. The first part assessing the patient's view of the consultation is excluded.

2.2.2. Objective assessment

Clinical evaluation was performed by an experienced hand physiotherapist. Thumb opposition was evaluated by the Kapandji method [23]. Thumb palmar and radial abduction were measured as the distances between the midpoint of the tip of the fully abducted thumb and the corresponding point on the extended index finger. Grip strength was measured with the Jamar dynamometer (Jamar Dynamometer, North Coast Medical Inc., USA) and pinch and key pinch strength with the Pinch Gauge (B and L Engineering, North Coast Medical Inc., USA) with the mean of 3 measurements recorded. The measurements were compared with the opposite hand. Unfortunately, neither preoperative pain nor objective clinical data were documented in charts for comparison with the follow-up data.

Adverse events, including infection and nerve pain/paresthesia were also recorded.

2.2.3. Radiological assessment

This consisted of anteroposterior, lateral and oblique plain X-rays measuring the same parameters as described by Mattila et al. [19] using Picture Archiving and Communication System (PACS) digital tools. Erosion of the trapezium around the implant was measured as the distance from the proximal joint surface to the base of the erosion cavity. Bone erosion of the metacarpal was measured using the same method (Fig. 2). TMC height (measured distance from the distal end of the thumb metacarpal to the proximal surface of the trapezium) was used to evaluate thumb shortening compared with the preoperative value [24] (Fig. 3). The length of the first metacarpal bone and the height of the remaining trapezium were measured from the uneroded or least eroded surfaces. The height of the interposition space was recorded as the distance between the uneroded or least eroded surfaces (Fig. 3). Subluxation of the joint was evaluated by measuring the amount of radial subluxation of the base of the first metacarpal off the trapezium (A) and the amount of the base of the first metacarpal covering the articulating surface of the trapezium (B), which allowed calculation of the radial subluxation ratio, i.e., (A)/(A + B) [25] (Fig. 4).

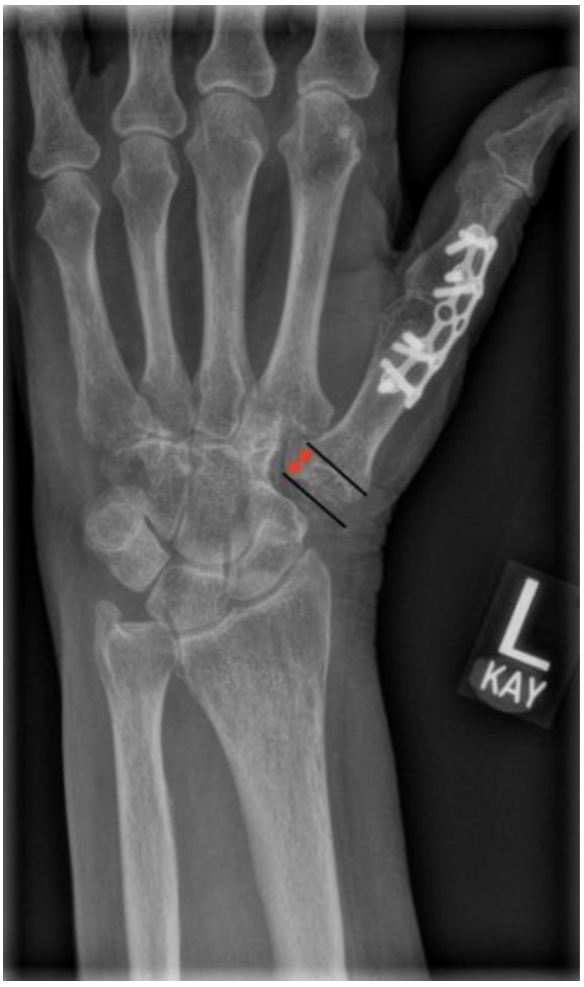

Fig. 2. Calculation of the metacarpal erosion height.

2.3. Surgical technique

The procedure is performed under tourniquet control through a dorsoradial incision after a single administration of IV teicoplanin and gentamicin.

Scar tissue is incised, the joint capsule is opened and the original arthroplasty is exposed and removed. In primary procedures, an oscillating saw is used to remove 3–4 mm from the distal trapezial articular surface. Bone nibblers are used to excise any remaining osteophytes. Trial sizers are used to determine the correct implant size. The RegJoint™ is then inserted into the joint space. The joint capsule and soft tissue are closed in layers with 2/0 Vicryl™ and the skin is closed with 4/0 Vicryl Rapide™. A thumb Spica cast maintains the thumb in an abducted position.

At 2 weeks postoperatively, a removable splint is used and the patient starts active range of motion exercises without loading. After 6 weeks, the thumb is left unprotected and unrestricted activities are allowed.

2.4. Statistical analysis

Data were analysed using GraphPad Prism (Version 8.00 for Macintosh, GraphPad Software, La Jolla California, USA). Data were tested for normal distribution with the Shapiro test. For compari-

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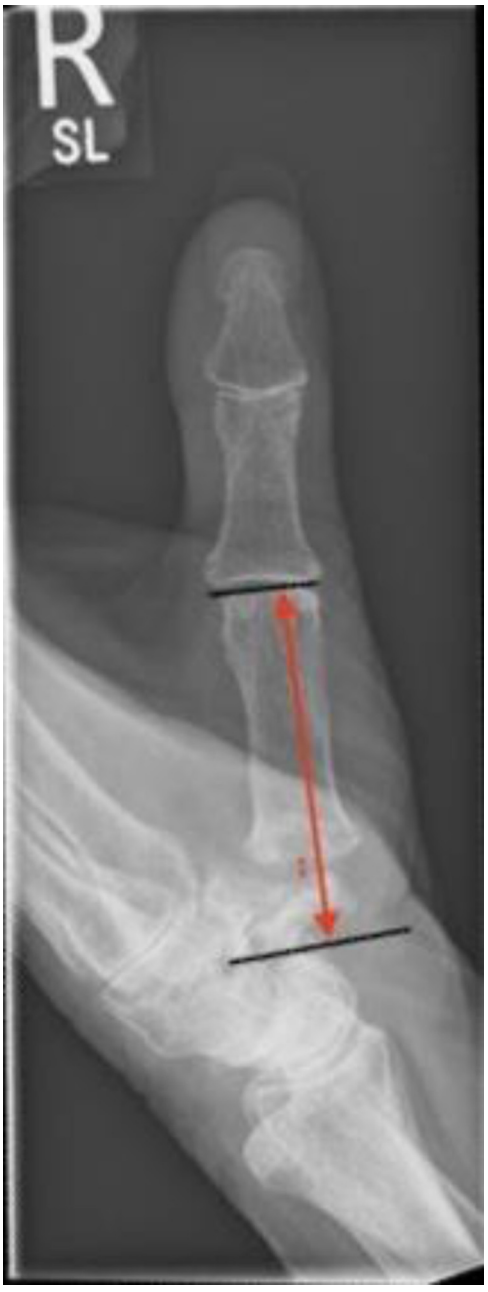

Fig. 3. Calculation of the TMC height and joint interposition height.

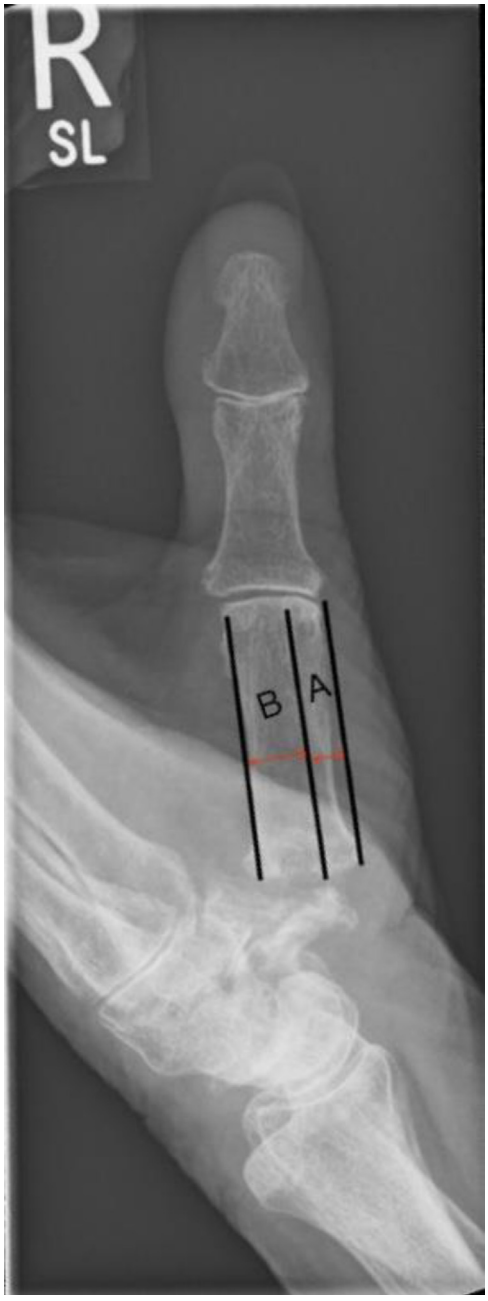

Fig. 4. Calculation of the subluxation ratio: A/(A + B).

son of means we used the student's *t*-test. Nonparametric data were analysed with Wilcoxon signed ranked test. The level of significance was set at $P < 0.05$. Either the Pearson product moment coefficient (r) or the Spearman rank-order correlation coefficient (ρ) was used for correlation analysis depending on the normality of the variables.

3. Results

3.1. Clinical outcomes

There was no significant difference in grip strength, key pinch or pinch between the operated hand and the contralateral hand (Table 1). There was also no significant difference in range of motion (as measured by thumb opposition, radial and palmar abduction) between the operated hand and the contralateral hand. The mean DASH Score was 42.9 (range 6.8–77.2), PEM score 49 (range (19.3–92) and VAS score 2.7 (range 0–8). The scores could not be compared with preoperative score since this information was not available.

Table 1
Clinical outcomes between operated and contralateral hand.

	Operated hand	Contralateral hand
Grip (kg)	11.45 (1–24.5)	12.3 (0–29)
Key (kg)	2.3 (0.5–5.5)	2.4 (0–5.5)
Pinch (kg)	0.9012 (0–3.2)	1.215 (0–3)
Kapandji score/10	8.5 (5–10)	8.8 (5–10)
Palmar abduction (cm, range)	11.35 (9–11.45)	11.68 (3.5–16)
Radial abduction (cm, range)	11.26 (9–15)	11.59 (2–16)

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Table 2
Pre- and post-operative radiological measurements.

	Preoperative (cm)	Postoperative (cm)
TMC height	5.36 (4.6–6.38, 0.45 SD)	5.087 (3.57–6.58, 0.7 SD)
Trapezium height	1.22 (0.7–2, 0.28 SD)	1.08 (0.3–1.6, 0.3 SD)
Metacarpal length	4.36 (3.9–4.9, 0.33 SD)	4.116 (3.6–4.6, 0.3)
Subluxation ratio	0.29 (0–0.78, 0.2 SD)	0.33 (0–0.6, 0.15 SD)
Interposition joint space		0.26 (0–0.55, 0.16 SD)
Bone erosion metacarpal		0.308 (0–1.31, 0.35 SD)
Bone erosion trapezium		0.25 (0–1.6, 0.39 SD)

3.2. Subjective outcomes

There was no correlation between the QuickDASH score and any of the range of motion parameters (palmar and radial abduction or opposition). The QuickDASH score did negatively correlate with grip strength ($r = -0.7$, $P < 0.003$) and key pinch ($r_s = -0.77$, $P < 0.001$). The PEM negatively correlated with grip ($r = -0.76$, $P < 0.001$), key ($r_s = -0.66$, $P < 0.007$) and pinch ($r_s = -0.65$, $P < 0.008$). There was no correlation between the VAS score and range of motion or strength parameters.

3.3. Radiological assessment

There was no significant difference in the trapeziometacarpal height, trapezial height or the degree of subluxation pre- or post-operatively (Table 2). The metacarpal length was significantly less on the postoperative X-rays (4.36 cm preoperative V 4.12 cm postoperative, $P < 0.0013$). There was no correlation between the QuickDASH or VAS score and joint space or subluxation ratio. There was also no correlation between the QuickDASH, PEM or VAS score with the degree of bone erosion of either the trapezium or metacarpal. The PEM score did however correlate with the subluxation ratio ($r = 0.57$, $P < 0.02$).

3.4. Subgroup analysis of primary and revision cases

We found no significant difference between the primary and revision cases with regards to their QuickDASH, PEM or VAS scores. There was also no difference regarding strength or range of motion parameters. Finally, the degree of metacarpal and trapezium erosion, joint space, TMC height and subluxation ratio was similar between the two groups.

3.5. Subgroup analysis based on Eaton stage

We found no correlation between QuickDASH, PEM or VAS scores and the Eaton stage.

4. Discussion

Excision (either partial or total) of the trapezium may result in proximal migration of the first metacarpal bone and weakening of key pinch strength [3,4]. Therefore, there is a theoretical benefit in using implants such as the RegJoint™ to prevent this proximal migration of the metacarpal.

We have used the RegJoint™ implant since 2013 in a select cohort of patients and have not noted significant postoperative complications. We were therefore surprised by the findings of Mattila et al. [18,19]. In their series of 23 patients, 22 demonstrated osteolysis of varying degrees. Seven patients had a clinically manifest foreign-body reaction and three patients required revision surgery. Their results are unexpected as the implant has demonstrated good in vivo biocompatibility and only mild tissue reactions in previous animal and clinical studies [15,26]. Early results of the PLDLA joint scaffold in MCP joints in RA patients showed no significant osteolysis or adverse tissue reactions [27]. A later study by Tiihonen et al. [16] did not demonstrate any bone erosion, osteolysis or adverse tissue reactions after a 2-year follow-up of CMC joint PLDLA implants in RA patients.

We did not observe any of the clinical signs of an adverse tissue reaction (increased pain, stiffness and swelling of the operative area) reported by Mattila et al. [19]. The degree of bone erosion of both the trapezium and metacarpal (2.5 mm and 3.1 mm, respectively) noted in our study is very similar to that recorded by Mattila et al. (trapezial erosion 3 mm, metacarpal erosion 2 mm at 3-year follow-up) [19]. It is notable that the degree of bone erosion in their study did not progress or worsen over a 3-year period. They observed that four of the seven patients who had a foreign-body reaction at the 1-year follow-up who did not undergo revision surgery experienced a decline in their subjective symptoms. In addition, at the final 3-year follow-up (after the implant had completely reabsorbed), the clinical signs of an adverse tissue reaction had completely settled in all four patients and the mean pain level was low with a statistically significant improvement in grip strength.

The manufacturers recently issued a field safety notice [28]. They estimated that there are over 6000 implanted RegJoint™ since 2011 with only 15 implant removals reported to date. After investigation, they concluded that in 4 of the 15 removals, tight insertion of the implant (which may cause the implant to lose its porous quality) may be linked to a foreign-body reaction. They have since amended the instructions for use to emphasise the importance of using the sizer instruments to ensure that the correct implant size is selected and to avoid over distracting the thumb when sizing the gap.

The mean QuickDASH score at final follow-up for all the postoperative patients included in this study was 42. While higher than the Mattila study (13 at 3 years), it is similar to other reported values in the literature. Yeoman et al. reported a QuickDASH score of 40 after simple trapeziectomy [29]. Sadhu et al. reported a QuickDASH score of 47 in ten patients who required a revision ligament reconstruction and tendon interposition after trapeziectomy [30].

Our cohort of patients was considerably older (mean 69.5 years) than the group in the Mattila study (mean 55 years). A recent study investigating normative QuickDASH scores in the general population found that scores increased with age and had a tendency to be higher in women [31]. They found female participants older than 70 years had a mean QuickDASH of 26. Additionally, scores can also be affected by other conditions of the elbow and shoulder.

It is notable that eight patients were classified as Eaton Stage 4. As the RegJoint™ does not address scaphotrapeziotrapezoidal (STT) arthritis, we considered if higher QuickDASH scores may be attributable to untreated STT arthritis. However, we did not find any differences in QuickDASH scores when patients were stratified according to their Eaton stage. We can only postulate as to why older patients who have had previous procedures on the CMC joint (as in our cohort) do not have as good an outcome as younger patients who have a single procedure (as in Mattilas group). This may be due to unrecognised iatrogenic injury to small cutaneous or joint innervating nerves during repeated surgery.

This study has some limitations. Preoperative subjective and clinical data of the patients were not available for comparison with the follow-up data and the sample size of patients was small. Also, our study group characteristics did differ from those of Mattilas cohort – we had older patients who mainly underwent revision or salvage surgery. The patients in Mattilas studies were younger and did not have previous CMC joint surgery before the index

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RegJoint™ insertion. Their patients were also immobilised postoperatively for a longer period than our cohort (4 weeks versus 2 weeks).

5. Conclusion

A guiding principle in medicine is "primum non nocere" or first, do no harm. We did not seek to investigate superiority of the RegJoint™ over other techniques for CMCJ arthritis but to demonstrate that this implant is safe and biologically inert. Our results dispute the contention that the RegJoint™ causes adverse tissue reactions or significant bone osteolysis. Our study also demonstrates that the implant causes no significant change in hand function. We therefore still use the RegJoint™ as a useful adjunct in the management of a select cohort of patients with challenging CMCJ arthritis.

Disclosure of interest

The authors declare that they have no competing interest.

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