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Invited Review

Dubious space for Artelon joint resurfacing for basal thumb (trapeziometacarpal joint) osteoarthritis. A systematic review

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Abstract

Introduction: Trapeziometacarpal arthritis is a common and disabling condition. There is no evidence in the literature of superiority of one surgical procedure over others. Several prosthetic implants have been introduced to preserve joint mobility.

Sourced of data: We searched the on Medline (PubMed), Web of Science and Scopus databases using the combined keywords 'artelon', 'thumb', 'carpometacarpal', 'trapeziometacarpal' and 'rhizoarthrosis'; 11 studies were identified.

Areas of agreement: The use of Artelon implant is not recommended because of its high revision rate and worse outcomes compared to conventional techniques.

Areas of controversy: Inert materials subjected to compressive and shearing forces could produce debris and subsequent inflammatory response. There is debate in the published scientific literature regarding the role of preoperative antibiotic profilaxis and post-surgery inflammatory response.

Growing points: Standard techniques such as trapeziectomy alone or combined with interposition or suspensionplasty offer effective treatment for thumb basal joint arthritis.

Areas timely for developing research: Several prosthetic implants show promising results in terms of pain relief and functional request, but there is a need of long-term randomized controlled trials to demonstrate their equivalence, and eventually superiority, compared to standard techniques.

Key words: artelon, trapeziometacarpal arthritis, rhizoarthrosis

Introduction

Basal joint arthritis of the thumb is a common condition, mostly affecting women older than 45.[1] NSAIDs, splinting or intra-articular injections[2] can be transiently effective for some patients, and, when conservative treatments fail, surgery can offer effective pain relief.

Trapeziectomy alone or combined with interposition or suspensionplasty is a standard technique with good long-term pain relief, though pinch strength maybe be negatively affected.[3–6]

In 2009, a Cochrane systematic review compared the efficacy of different surgical techniques in the treatment of trapeziometacarpal (TMC) osteoarthritis. No procedure was superior to the others, with not enough evidence to provide any recommendation.[7]

The long-term effects in young and high demand patients remain unknown. TMC arthrodesis is effective,[8] but the permanent loss of motion, long-term immobilization and the irreversible nature of the procedure make this option less attractive for the general population. Several prosthetic implants have been introduced to alleviate pain and maintain motion of the TMC joint.

The Artelon CMC Spacer (Artimplant, Vastra Frolunda, Sweden) fulfils this aims. The biomaterial used in this TMC device is a polycaprolactone based polyurethaneurea, which degrades by hydrolysis in ~6 years.[9] The T-shaped device is woven from Artelon fibres which were processed by a wet spinning procedure and it has a dry weight of 0.3 g. The vertical spacer part of the device serves as an interposition in the TMC joint, preventing the metacarpal base to abut onto the trapezium. The horizontal wings augment the dorsal joint capsule, and thus prevent dorsoradial migration of the first metacarpal.[10]

This systematic review aims to ascertain which is the survival rate of the Artelon spacer, its expected outcomes, and whether its use is justified.

Materials and methods

A systematic review of the literature was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We searched the literature using combinations of the keywords 'artelon', 'thumb', 'carpometacarpal', 'trapeziometacarpal', 'rhizoarthrosis', with no limitations regarding year of publication. Medline (Pub Med), Web of Science and Scopus were accessed up to January 23, 2018. There was no limitation of languages. Reviews, biomechanical studies, studies on animals or cadavers, technical notes, letters to the editor, case reports and instructional courses were excluded. Two authors (F.S. and G.B.) independently assessed the abstract of each publication. When it was not possible to include or exclude an article based on the abstract or the abstract was not available, a full-text version of the article was downloaded. In addition, we checked the reference list of each included article to identify additional studies missed at the first electronic search. The two investigators assessed each study according to the Coleman Methodological Score (CMS).[11] This score ranges from 0 to 100, with a score of 100 denoting a perfect study design. Both investigators performed the CMS assessment twice, with a 10 day interval between the two assessments. Then, they discussed the scores when greater than two points difference until consensus was reached. Data on demographic features, operative readings, preoperative assessment, length of follow-up, classification,

fixation method, complication, revision rate, imaging outcomes, objective and subjective outcomes measures were recorded.

Results

One hundred sixty-eight articles were identified after the first search based on the abstracts. Of 16 studies selected, 11[10,12–21] were included in the systematic review after the full texts had been read (Fig. 1). All the studies were published between 2005 and 2015; the total number of implants was 256, 24% (46) were implanted in males and 76% (153) females; gender data were not available in three studies. The age of the patients averaged 57.3 years. Patients from the control groups (abductor pollicis longus (APL) tendon interposition,[10–14] ligament reconstruction and flexor carpi radialis (FCR) interposition[19] and APL suspension and interposition[13]) were excluded from the demographics (Table 1).

All the Coleman scores are given in Table 1. A score >85 is considered excellent, good from 70 to 84, moderate from 50 to 69, and poor when <50. The mean CMS was 53.9 (range 31–78). Two studies were graded as good, four as moderate, and five as poor (Table 1).

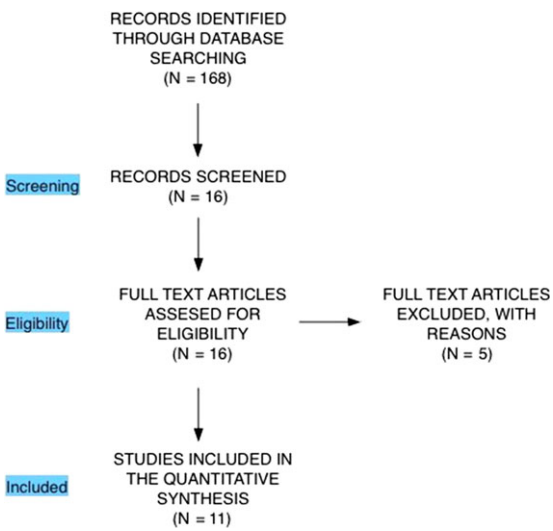

Figure 1 PRISMA diagram.

The mean follow up was 26.1 months (range 8[16] to 49.6[17] months). Three studies did not report follow up.[12,14,15]

The Disability of Arm, Shoulder and Hand score[22] was used in six studies.[13,14,17–19,21] Pinch strength was reported in seven studies.[10,13,14,17–19,21] The range of motion was evaluated in five studies.[10,14,18,19,21] The VAS score was used in four studies.[10,14,17,19] Patients satisfaction was evaluated in four studies.[10,13,14,17] Four studies did not report any outcomes.[12,15,16,20]

All the studies except one[19] used the same immobilization protocol (5 or 6 weeks in a thumb spica cast).

Complications were reported in six studies.[10,15,16,18,20,21]

The total number of revisions was 40 with an overall revision rate of 15%. The revision rate varied from 0%[10,12,18] to 100%.[15]

Histological analysis of the explanted Artelon material was reported in one study,[15] showing a large number of foreign body-type giant cells within the soft tissue and bone closely associated with the implant, with no macroscopic evidence of infection.

Discussion

The quality of the published literature is moderate according to the Coleman Methodological Score (CMS). There are just prospective controlled studies[10,13] and one prospective randomized controlled trial, which was industry-sponsored.[14]

Nilsson *et al.*[10] initial study of Artelon vs. a control group (trapeziectomy + APL suspensionplasty) showed that at 3 years all patients were pain free and showed a better pinch strength compared to the control group; there was no revision. Nilsson *et al.*[14] in a multi-centre study, were not able to confirm the clinical superiority of Artelon spacer on the control group (tendon interposition arthroplasty). Furthermore, there was a revision rate of 8% and a mild to moderate swelling in 32% of the operated hands. Nilsson *et al.*[14] hypothesized that the higher revision rate resulted from the lack of preoperative antibiotics; five of the six patients in whom the spacer was removed did not receive

Table 1 Synopsis of the results of the studies included in the systematic review

Author	Kind of study	Control group	Coleman Methodological Score	Number of implants	Number of revision (revision rate%)
Nilsson[10]	Prospettive case control	APL tendon interposition	85	10	0
Badia[12]	Case series	–	31	13	0
Jorheim[13]	Prospective case control	APL tendon suspension interposition	78	13	2 (15)
Nilsson[14]	Randomized controlled trial	APL tendon interposition	77	72	6 (8)
Robinson[15]	Case series	–	37	3	3 (100)
Clarke[16]	Retrospective case series	–	33	29	4 (13)
Bell[17]	Case series	–	67	49	4 (8)
Park[18]	Retrospective case series	–	60	9	0
Blount[19]	Retrospective case control	Ligament reconstruction and FCR tendon interposition	55	38	12 (31)
Richard[20]	Retrospective case series	–	45	6	4 (66)
Ehrl[21]	Case series	–	45	14	5 (35)

antibiotic, and two of them presented clinical signs of infection but cultures were negative. Blount *et al.*[19] administrated preoperative antibiotics to all the patients, and yet the revision rate was high (37%).

Histological analysis[15] showed large numbers of foreign body-type giant cells within the soft tissues and bone closely associated with the implants. These giant cells contained foreign material. The authors thought it unlikely that the postoperative pain and swelling was caused by infection. There have been two reported cases[23,24] of foreign body reaction. Giuffrida *et al.*[23] hypothesized that, when an inert material is subjected to compressive and shearing loads such as those present at the trapezio-metacarpal joint, it fragments and induces a foreign body reaction.

Badia[12] performed the surgery arthroscopically, and reported promising results, but this is more a technical note than a case series: there author reported no follow up and no description of complication.

Nilsson *et al.*[14] were not able to confirm the promising results of their first series,[10] and all the other studies included in the present systematic review failed to show any superiority of Artelon over trapeziectomy.

The theoretical advantage of a revision surgery compared to trapeziectomy does not justify the use of Artelon. Indeed, it appears that the short-term outcomes of the Artelon TMC implant might at best be similar to those of trapeziectomy, and the cost of the implant is therefore not justified.

A limitation of the present systematic review is the paucity of the number of studies and the absence of a control group in seven studies (Table 1). Despite this, we were able to answer the questions posed when planning the study.

Other prosthetic implants in the literature give more promising results,[25,26] and more studies are needed with longer follow-up.

Arthroscopy is gaining popularity[27] in the treatment of TMC joint arthritis, and its role needs to be properly investigated.

Given the present evidence, the use of the Artelon implant is not recommended: it does not

show superiority over more classical well established treatment modalities, and carries a high incidence of complications. The overall revision rate and the high unpredictability of the middle or long-term performance of the Artelonn TMC implant make it not acceptable for treatment of trapeziometacarpal osteoarthritis.

Conflict of interest statement

The authors have no potential conflicts of interest.

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