ORIGINAL ARTICLE

Is an intervention with a custom-made splint and an educational program useful on pain in patients with trapeziometacarpal joint osteoarthritis in a daily clinical setting?

Susanna MADDALI-BONGI,¹* Angela DEL ROSSO,¹* Felice GALLUCCIO,¹ Fabrizio SIGISMONDI² and Marco MATUCCI-CERINIC¹

¹Division of Medicine, Department of Experimental and Clinical Medicine, University of Florence, and ²Associazione Multidisciplinare Riabilitazione Reumatologica (AMuRR), Florence, Italy

Abstract

Aim: Custom-made splints may be useful in the conservative treatment of osteoarthritis (OA) of trapeziometacarpal (TMC) joint OA. Our aim was to evaluate usefulness of a custom-made splint and educational program in patients with symptomatic TMC joint OA in daily clinical practice.

Methods: Fifty patients with symptomatic TMC joint OA, not treated with surgery, were enrolled in a open prospective study in a clinical day setting and treated with a 'butterfly' custom-made thermoplastic short opponens splint to be worn 16 h/day for 30 days and then when needed, for 12 months. Patients were evaluated at enrolment (T0), at the first month (T1) and at the 12th month (T2) since splint application for pain (main outcome measure) by numeric rating scale 0–10. At T0 and T1, a Jamar dynamometer (kg) was used to assess hand strength, a pinch gauge to evaluate pinch strength (kg) and Dreiser test to assess hand disability (secondary outcome measures).

Results: The comparison between T0 and T1 showed a significant improvement in all the outcome measures (P < 0.0001 for pain, muscle and pinch strength; P = 0.001 for Dreiser test). Moreover, at the end of 12 months follow-up, patients maintained the reduction of pain (T2 *vs*. T1, P = NS) and showed a reduced consumption of analgesics (P < 0.05).

Conclusions: A custom-made thermoplastic short opponens splint for 30 consecutively days for at least 16 h/day, followed by occasional use on pain outbreak is an useful conservative treatment in symptomatic TMC joint OA.

Key words: conservative therapy, osteoarthritis, pain, splint, trapeziometacarpal joint.

BACKGROUND

Osteoarthritis (OA) is the most common chronic joint disorder characterized by loss of articular cartilage with

Correspondence: Dr Angela Del Rosso, Division of Rheumatology, Department of Biomedicine, University of Florence, viale G. Pieraccini 18, 50139 Florence, Italy.

Email: angela.delrosso@fastwebnet.it

*The first two authors contributed equally to the work.

hypertrophic reaction and new bone formation, leading to a reduction of movement and function of the involved joints. OA affects not only the elderly population but also working individuals and it is rapidly becoming a significant burden for health societies.^{1,2}

Pain is the pivotal symptom of OA, beginning within activity and persisting, sometimes for hours after ceasing activity, is worsened by movement and alleviated by rest.

Hand OA is a very common condition,^{3,4} the incidence of which peaks among elderly people, causing

increasing limitations in performing daily and workrelated activities. It is frequently associated with depression and sleep disturbance, additional contributors to disability and impairment of quality of life.^{5,6}

Trapeziometacarpal (TMC) joint OA, leading to squared deformation of the radial base of the thumb and fixed adduction,³ is among the most common causes of severe hand pain and tenderness. Prevalence of TMC joint OA is age-related, reaching 91% in patients older than 80 years of age, and occurs more rapidly in women than in men.⁷ De Quervain tenosynovitis, frequently associated with TMC OA, exacerbates pain and functional limitation.

In 2007, the European League Against Rheumatism (EULAR) published evidence-based recommendations for the management of patients with hand OA,⁸ in which splints and orthoses were considered only to prevent or correct lateral angulations and flexion deformity of TMC OA, although with a low level of evidence. In contrast, local or systemic non-steroidal anti-inflammatory drugs (NSAIDs) or cyclo-oxygenase-2 (COX-2) inhibitors and analgesics were recommended for pain management.⁸

However, after the publication of EULAR recommendations, two controlled clinical trials demonstrated that custom-made neoprene and thermoplastic splints had higher utility than the usual treatments on manual pain, dexterity, strength and function.^{9,10}

Rannou *et al.* in a multicenter randomized trial, compared a custom-made neoprene splint for TMC joint OA to that of usual care. The splint used was a static rigid rest orthosis worn at night, that demonstrated no effect at 1 month but improved pain and disability at 12 months.⁹ Gomes Carreira *et al.* compared the efficacy of a functional thermoplastic splint for TMC OA in two groups of patients. The study group received the splint at baseline and used it during daily activities for 180 days, while the control group used the splint only during the evaluations for the first 90 days and during daily activities for the following 90 days. The first group showed a decrease in pain beginning after 45 days, whereas the control group achieved a reduction of pain only at the end of the study.¹⁰

A more recent review concluded that, despite the great variety in the design of the splints, these tools are useful in reducing hand pain.¹¹ In daily clinical practice, splints could be useful to treat OA of the TMC joint if included in a multidisciplinary management, as advised for hip and knee OA patients.^{12,13} Our experience confirms the need for a multidisciplinary team in the global care of rheumatic patients and, in particular,

stresses a direct collaboration between rheumatologists and physiotherapists skilled in rheumatic diseases, as well as hand and occupational therapists, whose approaches act synergically.¹⁴

The purpose of our study is to evaluate, in a daily clinical practice setting, the usefulness of a custommade thermoplastic short opponens splint, complemented by an educational program, in pain reduction (primary outcome measure) and in improving manual strength and functionality in patients with symptomatic TMC OA.

PATIENTS AND METHODS

Patients and study design

Fifty consecutive Caucasian patients with TMC joint OA were enrolled from the outpatient clinic of our institution in a prospective open study lasting 12 months, from March 2011 to March 2012.

All patients, adequately informed about the study details, agreed by written informed consent. The study was approved by the local Ethics Committee and conducted according to the principles of the World Medical Association's Declaration of Helsinki.

Inclusion criteria were adult patients (no gender or age limit) with symptomatic TMC joint OA in stages I–III confirmed by hand X-ray.¹⁵ Exclusion criteria were previous surgery or infiltrative treatment of the TMC joint, presence of inflammatory arthritis, neuropathies and De Quervain tenosynovitis.

Patients were divided into manual and non manual workers according to the following definition. Manual workers meant workers with an occupation involving manual training, skill and physical strength more than intellectual skills (crafting, manufacturing, mining, construction, mechanical, maintenance, technical installation). Non-manual workers meant workers whose occupations implied intellectual training and skill more than manual skill (office workers, managers, salaried professionals, sales personnel, teachers, retired people).

Patients were fitted with a custom-made 'butterfly' short opponens splint of thermoplastic material to be worn 16 h/day (during waking hours, not at night) for 30 days (treatment period) and were evaluated at enrolment (T0), at the first month (T1) and at the 12th month (T2) since splint application.

Treatment protocol

Educational program

All the patients participated in an educational program, conducted by a physiotherapist (FS) and a rheumatologist

(ADR), consisting of two sessions of 2 h each, including: information on OA and its consequences; treatment options; how to deal with OA; and education about ergonomic principles to prevent TMC overuse. Patients were divided into two groups for convenience of class size (see Appendix I).

Splint

All the patients were fitted with a functional custommade short opponens splint (or butterfly splint) in 1.6 mm thermoplastic perforated material (Poliflex Aquaplast[®], Patterson Medical Holdings Inc. Bolingbrook, IL, USA) (Fig. 1) blocking the first metacarpophalangeal joints (MCP) for stabilizing the TMC in order to reduce pain in residual thumb functions. The



Figure 1 Butterfly splint used for trapeziometacarpal joint osteoarthritis; (a) view from palmar side; (b) view from radial side; (c) view from dorsal side.

splint, made by a physiotherapist skilled in hand rehabilitation and in splint modeling (FS), was modeled in order to maintain unrestricted range of motion at the wrist and interphalangeal joints and to allow working and daily activities.

After staging TMC joint damage by radiographs,¹⁵ the thumb is positioned unloading the more involved TMC areas, placing them in diastasis.

At stages I and II, the forearm is placed in an intermediate position between pronation and supination: TMC in adduction 20°, antero-position 40°, extension 20°; MCP in flexion 20–30°; interphalangeals 30° flexion, free.

At stage III, the position is similar to stages I–II, with a higher compression on the MCP base on the palmar side in order to avoid a further joint dislocation.

Apart from the higher compression on the MCP base on the palmar side of stage III, the positions of forearm, wrist, TMC, MCP and interphalangeals were similar in all patients in stages I–III.

The butterfly splint is shown in Figure 1: a, view from the palmar side, b, view from the radial side and c, view from the dorsal side.

During the treatment period (first 30 days) the splint was worn at least 16 h daily, and in the follow up, only if pain was present. In subjects with bilateral TMC OA, it was applied to both hands. The use of NSAIDs, COX-2 or analgesics during the treatment period was forbidden in order to prevent study biases.

Assessment

Patients were assessed at study entry (T0), at the end of the treatment period (30 days, T1) and after 1 year of follow-up (T2).

At T0 and at T1, hand strength was tested with a Jamar dynamometer (kg) and pinch strength was assessed by a pinch gauge (kg). Both tests were performed with patients seated with the elbow at 90° of flexion and the wrist in the neutral position between pronation and supination.

At T0 and T1, patients were also evaluated by the Dreiser scale,¹⁶ assessing by 10 questions hand ability and pain in the common tasks of daily life. In this scale, each question is scored on a four-level scale with 0 = nodifficulty and 3 = inability; the total score ranges 0–30, with higher scores representing higher disability.

Pain (intended as the mean pain in the previous week) in the basal area of the thumb, scored by a numeric rating scale (NRS 0–10), was evaluated at T0, T1 and at the end of follow-up (T2) to assess long-term usefulness of the treatment.

Safety, adherence and satisfaction to treatment, analgesics consumption

Safety (adverse effects leading to drop outs), adherence to treatment (meant as waking hours in which the splint was worn) and the need for analgesics (over the follow-up period) were registered by the patients in a diary and checked by a physiotherapist (FS) at T1 and T2; the adherence to daily diary completion was checked at the seventh and 30th day during the first month and every 30 days during the follow-up period by the physiotherapist.

Participants were asked at T2 to answer a question about their overall level of satisfaction with the treatment on the basis of an NRS 0–10, with 0 = no satisfaction and 10 = the highest level of satisfaction.

The patients were assessed with a clinical examination by the physiotherapist after 1 week from the splint modeling, in order to check the eventual presence of points of compression on the splint potentially causing pain, and to correct them. After this revision, patients were asked to contact the therapist if pain at thumb base, spontaneous or movement-related, arose, and in this case, they were controlled for a potential de Quervain tenosynovitis or for other potential causes of local pain.

Statistics

Data are presented as mean \pm standard deviation and as numbers and percentages. *T*-test for unpaired data and chi-square test were used to compare for baseline characteristics. In order to detect effects on the outcome measures, analysis of variance (ANOVA) with Bonferroni Multiple Comparison Test (for pain) and paired *t*-test (for hand and pinch strength, Dreiser test) were used.

Data analysis was performed using SPSS statistical package 16.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

The baseline characteristics of the 50 Caucasian patients who were enrolled (44 women, six men, mean age: 60.72 ± 8.7 years; 27 manual workers, 23 non-manual workers; 27 [54%] with right, 11 [22%] with left and 12 [24%] with bilateral TMC joint OA) are presented in Table 1.

The time at assessment at T1 and T2 was 30.8 ± 4.5 days and 12.1 ± 1.4 months at T2, respectively.

Pain

In patients with symptomatic TMC joint OA, pain at the hands treated with a short opponens thermoplastic splint was reduced at T1 in respect to T0 in the whole group (P < 0.0001) and in manual (P = 0.0001) and non-manual workers (P < 0.0001).

In all the groups, at T2, the reduction of pain was maintained in respect to T1 (P = NS) and the perception of pain was lower in respect to T0 (P < 0.0001) for the whole group, manual workers (P = 0.0001) and non-manual workers (P < 0.0001) (Table 2).

Hand and pinch strength

At T1, in respect to T0, muscle strength was improved in the whole group (P < 0.0001), in manual (P < 0.001) and in non-manual workers (P < 0.001). Accordingly, pinch strength improved at T1 in the whole group, (P < 0.0001), in manual (P < 0.001) and non-manual workers (P < 0.05) (Table 2).

Dreiser scale

At T1, Dreiser scale scores, evaluating hand function and ability, were improved in the whole group (P = 0.0001), in manual (P < 0.05) but not in nonmanual workers (P = NS) (Table 2).

	Total	Women	Men
Number of patients	50	44 (88%)	6 (12%)
Age	60.72 ± 10.63	60.77 ± 10.72	60.33 ± 11.02
Non-manual workers	23 (46%)	18 (40.90%)	5 (83.33%)
Manual workers	27/50 (54%)	26 (59.09%)	1 (16.66%)
Right TMC joint OA	27 (54%)	23 (52%)	4 (67%)
Left TMC joint OA	11 (22%)	11 (25%)	0 (0%)
Bilateral TMC joint OA	12 (24%)	10 (23%)	2 (33.33%)
Symptomatic slow-acting	10 (20%)	8 (18.18%)	2 (33.33%)
drugs for OA (SYSADOA)			
NSAIDs/analgesics	26 (52%)	12 (27.27%)	1 (16.66%)

NSAIDs, non steroidal anti-inflammatory drugs; OA, osteoarthritis; TMC, trapeziometacarpal joint.

Table 1Baseline characteristics of OApatients

Table 2	Effects of splint on trapezio-
metacarp	al joint osteoarthritis

	Total sample	Manual workers	Non-manual workers
Pain (NRS 0–10)			
T0	5.99 ± 2.47	6.37 ± 2.52	5.49 ± 2.34
T1	2.61 ± 2.10	2.56 ± 2.24	2.68 ± 1.93
T2	3.22 ± 2.47	2.90 ± 2.25	3.65 ± 2.73
Overall effect (P)	< 0.0001	0.0001	< 0.0001
T1 vs. T0 (P)	< 0.0001	0.0001	< 0.0001
T2 vs. T0 (P)	< 0.0001	0.0001	< 0.0001
T2 vs. T1	NS	NS	NS
Muscle strength (kg)			
T0	37.46 ± 9.05	39.06 ± 9.35	35.33 ± 8.55
T1	49.64 ± 13.87	48.75 ± 10.72	50.83 ± 17.69
T1 vs. T0 (P)	< 0.0001	< 0.001	< 0.001
Pinch strength (kg)			
Т0	4.52 ± 1.22	4.50 ± 1.37	4.59 ± 1.02
T1	5.17 ± 0.90	5.14 ± 0.82	5.21 ± 1.03
T1 vs. T0 (P)	< 0.0001	< 0.0001	< 0.05
Dreiser test (0–30)			
Т0	6.80 ± 6.06	7.59 ± 6.15	5.38 ± 5.79
T1	4.42 ± 4.82	4.56 ± 4.90	4.16 ± 4.80
T1 vs. T0 (P)	0.001	< 0.05	NS

NRS, numeric rating scale; NS, not significant; T0, enrolment; T1, at the first month; T2, at the 12th month.

Safety, adherence and satisfaction to treatment, analgesics consumption

Compliance to the treatment was high (splint was worn 13.3 ± 2.5 h during waking hours at T1), no patient was lost during treatment and follow-up and no side effects were reported.

At T2, the overall satisfaction was high (8.9 \pm 1.2); the patients reported a reduced need for NSAIDs and analgesics during follow-up (14 patients at T2 *vs.* 26 at T0: *P* < 0.05). During the follow-up, the splint was worn 1.43 \pm 0.5 h daily.

DISCUSSION

Pain in the base of the thumb together with grip strength reduction and impairing of hand function are the main symptoms of TMC OA.

According to our data, in patients with TMC OA, the application of a custom-made splint (together with an educational program) significantly improved pain, hand and pinch strength and manual function. No differences were shown in these items between manual and non-manual worker subgroups. The reduction of pain was stable at follow-up, as also confirmed by the reduced consumption of analgesics.

In the literature, the beneficial effects of splinting on pain in patients with TMC OA has been partially demonstrated and the effects on pinch and hand strength and on hand function were not homogeneous.

The heterogeneity of the results reflects the scarce uniformity on the type of splints, the material used to build them or the timing of treatment (worn at rest, during the night or daily activities), the concurrent use of exercises, all limiting the possibility to compare results.^{9–18} Moreover, most of the studies include a limited number of patients and do not consider a follow-up period. Thus, the clinical evidence-based efficacy of splint treatment in TMC OA is still under evaluation.

A rapid effect on pain of the short opponens thermoplastic splint to be worn daily was shown by Gomes Carreira *et al.*,¹⁰ Weiss *et al.*¹⁷ and Wajon and Ada,¹⁸ all using a tool and a time schedule of splint wearing similar to our study. However, in the Weiss *et al.* study, the effect on pain of the thermoplastic splint was not different to that obtained by a neoprene splint.¹⁷ In the study by Wajon and Ada, the use of a splint was integrated with a cycle of hand exercises; this renders difficult to discriminate which effect may be related only to splint use.¹⁸ Interestingly, Wajon and Ada did not show better results in the group of patients wearing a short opponens thermoplastic splint compared to a group treated with a different thumb orthosis with a strap model.¹⁸ Moreover, the results on pain were confirmed in a longterm period only by Gomes (repeating the evaluations after 6 months of treatment), but not by Weiss *et al.*¹⁷ not executing a long intervention, and Wajon and Ada¹⁸, neither including a follow-up period. A failure in fast pain relief was shown also in the randomized controlled trial of Rannou *et al.*,⁹ evaluating a custommade neoprene splint worn at night for TMC joint OA. This study demonstrated an improvement of pain and disability only after 12 months.⁹

Our study, for the first time, shows that the significant results obtained by a 30-days splint application on thumb pain in a brief and long-term period also lead to a significant reduction of analgesics and NSAIDs consumption during follow-up. Thus, the occasional use of the splint, worn only when pain was present, can be a valid alternative in TMC OA to analgesic consumption and probably helps to prevent drug-related potential side effects. This datum contrasts with the results of Rannou *et al.*,⁹ that did not show significant changes in the consumption of analgesics and NSAIDs throughout the study.

Our data demonstrated that, in patients with symptomatic TMC joint OA, the application of a custommade thermoplastic splint for 30 consecutive days ameliorates not only pain after intervention and at 12 months follow-up, but, in the short term, significantly improved function, as assessed by the Dreiser test, hand strength and pinches. These results are prominent, because the amelioration of these outcome measures altogether has not been shown in a single study till now. In fact, the brief-term improvement of pinch and function was shown by Weiss et al.¹⁷ and Wajon and Ada¹⁸ but not by Gomes Carreira et al.¹⁰ In comparison, Rannou et al.9 found the amelioration of disability by Cochin Hand Function Scale, but not of pinch strength, only at 12 months, but not at the first month.

We first demonstrated the increase of muscle strength assessed by a Jamar dynamometer (not improved in the Gomes Carreira *et al.* study¹⁰), that evaluates the function not only of the extrinsic muscles of the hand, but also of the flexors inserting on the forearm. This result was probably obtained due to the particular type of splint that we used, that does not block wrist mobility and maintains a good muscle trophism. We have used this kind of splint since 1991 with good clinical results.^{19,20} In a study lasting 12 months, we showed that in a small group of patients with TMC OA a short opponens thermoplastic splint, worn at night and for

5 h in the first month and during more intensive manual activities in the following 11 months, decreased pain intensity and improved hand performance.^{19,20}

Our short opponens thermoplastic splint met with great compliance, with no side effects and no patients lost at follow-up, contrary to the long opponens splint holding the thumb in abduction utilized by Swigart *et al.*²¹ This tool, in around 30% of patients, was found to be restrictive and uncomfortable, especially in driving, writing and sports activities.²¹

A limit of our study could be the absence of a control group not treated with splints but, differently from other studies,^{9,10,18} it assesses the effects of a splint in daily clinical practice and not in a randomized controlled trial and implements the use of the splint with an educational program, including ergonomic principles. Thus, in our experience, the utilization of splints was comprised of a multidisciplinary management, the utility of which was already shown in treating OA patients in a clinical setting.¹³ The successful results of our study underline the need for a direct collaboration in the daily practice of rheumatologists and physiotherapists skilled in rheumatic diseases to improve the usefulness of a treatment, including both drugs and nonpharmacological interventions, in the management of patients with TMC OA.

Intentionally, a program of home exercises was not included in the treatment protocol in order to better evaluate the effects of the splint and to eliminate their possible synergism in improving strength, pain reduction and hand dexterity.²² However, despite the lack of a combined approach (splinting added to exercise), patients experienced high utility in reducing pain, and also in improving hand function and in reducing drug consumption.

In conclusion, the application in a clinical daily setting of a custom-made thermoplastic short opponens splint during waking hours implemented with an educational program, followed by its occasional use on pain exacerbation, resulted in an useful conservative treatment in symptomatic TMC OA in manual and non-manual workers and underlines the need for a tight collaboration between rheumatologists and physiotherapist skilled in rheumatic diseases in the daily clinical practice.

ETHICAL APPROVAL

The work was approved by the Ethics Committee of AOUC (Azienda Ospedaliera Universitaria Careggi).

CONFLICT OF INTEREST

The authors declare that there was no financial support or any other benefit which could create a potential conflict of interest with regard to the work.

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APPENDIX 1 THE EDUCATIONAL PROGRAM ADMINISTERED TO OA PATIENTS

Session 1 (2 h)

(A) Information on OA and its consequences (rheumatologist)

OA pathogenesis, causes, epidemiology, symptoms, diagnosis, involved joints

(B) OA treatment options (rheumatologist and physiotherapist)

OA non-pharmacological treatment: education, physical activity, rehabilitation, physical therapy; OA pharmacological therapy: symptomatic drugs, slow-acting drugs, their possible interaction and side-effects; surgery treatment in OA

(C) The multidisciplinary treatment for OA (rheumatologist)

The role of rheumatologist, OA patient, physiatrist, physical therapist, occupational therapist, psychologist, dietist in the treatment of OA.

Session 2 (2 h)

(A) Psychological and physical consequences of OA (rheumatologist)

How to cope with psychological problems, disability, impairment in daily activities and quality of life with OA

(B) Other interventions in OA (rheumatologist)

The role of weight reduction, different diets, supplements and complementary alternative therapies (herbal treatments, homeotherapy, body-mind techniques) in OA

(C) Ergonomic principles in OA (physiotherapist)

Education about ergonomic principles to prevent TMC overuse in OA