Effect of hyaluronate and splinting alone *versus* combined treatment (splinting and hyaluronate) on thumb carpometacarpal osteoarthritis

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Abstract

Thumb carpometacarpal osteoarthritis can lead to global hand dysfunctions and its symptoms are pain and inability.

The purpose of this study is to determine the effectiveness of hyaluronate in relieving these symptoms, and to compare it to orthosis and combined treatment (orthosis and hyaluronate).

We enrolled 39 patients, evaluated at the baseline by using numeric rating scale (NRS) for pain, Disability of the Arm, Shoulder and Hand (DASH) and Dreiser Scale for disability degree, and Digital Hydraulic Pinch Gauge for grip strength.

Eligible participants were randomly assigned to one of the three treatments: injection of hyaluronate (group I), combined treatment (hyaluronate and orthosis, Group II) and orthosis (hard-resting splint, Group III).

Patients of Group I and Group II were injected by low molecular weight Hyaluronate once a week for three consecutive weeks. Injections were performed by means of the so-called *blind* technique.

The data analysis indicated a significant decrease ($P<0.01$) of pain at week 4, further manifested at week 26 by all groups treated. The same occurred for functional symptoms, and grip strength.

This improvement appears more evident in group I that received HA.

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Introduction

The thumb carpometacarpal joint is a biconcave joint between the thumb metacarpal and the trapezium, that allows multiplanar motion.

Trapezio-metacarpal osteoarthritis is a disabling disease characterized by the destruction of normal articular joints.

Usual symptoms are pain, localized at the thumb base, and global hand dysfunctions, including weak pinch and inability to grasp large objects. Patients show a progressive instability and deformity of the articular joint leading to a restriction of their daily activities.

This pathology affects patients from 50 to70 years of age, especially women (8%-22%) performing manual activities; 10% of all cases of osteoarthritis involve the trapezio-metacarpal joint.[1]

Important pathogenetic factors are post-traumatic osteoarthritis, instability, malformations, ligamentous laxity, joint hypermobility, subchondral bone microcracks.[2]

The classification is based on a functional, radiological and clinical evaluation carried out on the basis of some scales, such as Disability of the Arm, Shoulder and Hand scale (DASH), Dreiser Scale, Eaton Glickel scale, and grip strength.

The Dreiser scale is an algofunctional index designed for the evaluation of patients with digital osteoarthritis. The index is based on a questionnaire on 10 daily activities involving the hands. The patient is asked to answer each item using a 4-point verbal scale, from *possible without difficulty* to *impossible*. This index was in a few clinical placebo-controlled trials and was found to be sensitive to change.[3]

The disabilities of the arm, shoulder and hand (DASH) questionnaire is a self-administered region-specific outcome instrument that has been developed as a measure of self-rated upper-extremity disability and symptoms and consists mainly of a 30-item disability/symptom scale.[4]

The Eaton Glickel scale, developed by Richard Eaton and William Littler in 1967 and subsequently modified in 1973, describes four progressive radiographic stages of thumb carpometacarpal arthritis. It is now the most commonly used radiographic classification system for thumb arthrosis.[5]

The initial treatments for trapezio-metacarpal osteo-arthritis are still controversial, and a number of options are available.

The most common conservative treatments for osteo-arthritis are analgesics, orthosis, injection (cortisone, hyaluronate), educational interventions, and physical therapy.

Surgery is indicated when the pathology is severe, however there are numerous complications associated with surgery and for this reason it is advisable to consider conservative options in the first place.[6]

Intra-articular corticosteroid injections or, alternatively,

hyaluronate are used in order to decrease pain and inflammation and to restore the viscoelasticity of synovial fluids. Some RCTs studied the effect of intra-articular injections, and Meenagh *et al*. concluded that there is no clinical difference between intra-articular steroid injections and placebo.[7]

Roux *et al*. observed 3 groups of patients receiving 1, 2, or 3 hyaluronate injections, and found out that there were no statistically significant differences among the groups regarding pain and function.[8]

A review published in 2015 highlights that there are only few high-quality studies addressing the conservative treatment of trapezio-metacarpal OA and attributes only some limited effects to orthoses and intra-articular hyaluronate or steroid injections.[9]

Furthermore, several guidelines recommend the use of orthosis to stabilize the thumb articular complex.[10] A randomized trial showed that wearing a splint decreases pain and disability after 12 months, but not after 1 month in patients with osteo-arthritis at the base of the thumb. The use of a splint during daily life activities decreases pain without having effects on functioning, grip strength and pinch strength.[11]

The aim

The purpose of this study is to determine the effectiveness of hyaluronate in relieving the symptoms of thumb arthritis and to compare it to orthosis and combined treatment, (orthosis and hyaluronate), evaluating pain relief, and functional outcomes among participants.

Materials and Methods

We enrolled 39 patients (Table 1), with painful thumb osteo-arthritis referred to our unit. The screening included a questionnaire and hands' x-rays.

All patients were evaluated at the baseline using: i) NRS scale (number rating scale) for pain intensity; ii) Dreiser and DASH scale for disability degree; iii) Eaton and Glickel scale for radiological evaluation; iv) Digital Hydraulic Pinch Gauge for grip strength. This was evaluated during pulp pinch, latero-terminal and sub-terminal motion.

Inclusion criteria included painful osteoarthritis of thumb, grade II-III of Eaton-Glickel scale. Exclusion criteria were systemic rheumatic disease, bleeding diatheses or anti-coagulation, allergies to steroids, current use of oral or intravenous steroids, active systemic malignancies, hyaluronan injection in CMC joint in the last 6 months, steroid or hyaluronan injection in any other joint in the last 6 months, insulin dependent diabetes mellitus (IDDM), active infection, comorbid hand conditions (such as carpal tunnel syndrome or De Quervain's tenosynovitis). Patients were asked not to take NSAIDS/COX-2s for pain relief during the study.

Eligible participants have been randomly assigned to one of three treatments: injection of hyaluronate (group I, HA treatment), combined treatment (hyaluronate and orthosis, Group II) and orthosis (Group III). For group I and II, in line with the literature, we used a hard-resting splint for 30 days.

Patients population

Patients Group 1 (HA treatment)

Patients of group 1 (HA treatment), were 15 (Table 2), 3 males and 12 females with a mean age of 65.2 years. The mean value of pain (NRS scale) at the baseline was 6.21, 10.26 according to the Dreseir scale and 34.33 according to the DASH scale. The mean value of grip strength was 7.2

Patients Group II (combined treatment)

The patients of group II (HA treatment and orthosis) were 12 (Table 3), 4 males and 8 females with a mean age of 63.08 years. The mean value of pain (NRS scale) at baseline was 5.75, the Dreiser index 11.8 and the DASH score 27.33. The mean value of grip strength was 8.33.

Patients Group III (orthosis treatment)

Patients of group III (orthosis treatment), were 12 (Table 4), males 3, females 9, mean age 67.41. Mean value of pain at the baseline was 6.5 (NRS scale), Dreiser Index 12.66, and DASH score 33.16. The mean value of grip strength was 7.1.

All patients were observed after 4 weeks and then after 26 weeks. They were evaluated according to NRS, Dreiser index and DASH score and Digital Hydraulic Pinch.

Injection technique

Some studies suggested that injections of hyaluronate (HA) may reduce pain and improve functioning in patients with osteoarthritis.

In our study the patients of Group I and Group II underwent one cycle of 3 weekly i.a. injections of 1 mL (10 mg/mL) of low molecular weight HA using a dorsolateral or infero-lateral approach, after palpating the TMC joint space. The volume of 1 mL of HA was the least painful when injected. The TMC joints were

Table 1. Patients.

Mean age	65.23
NRS	6.1
Dreiser	11.25
DASH	31.82
Male	10
Female	29
Left	19
Right	20
E.G. II	10
E.G. II-III	7
E.G. III	22

NRS, Numeric Number Scale; DASH, Disability of the Arm Shoulder and Hand; E.G., Eaton Glickel scale.

Table 2. Group 1 - HA treatment.

No. patients	15
Mean age	65.2
Males	3
Females	12
E.G. II scale	4
E.G III scale	11
Right TM OA	9
Left TM OA	6

E.G., Eaton Glickel scale; TM OA, trapezio-metacarpal osteoarthitis.

injected with a 25-gauge needle after skin cleansing with 10% povidone iodine.

The joint is very superficial, thus easy to palpate, therefore the injections were performed through a *blind technique* by using anatomic landmarks in order to guide the needle placement.

If the compression of the syringe met resistance, the needle was not in the joint space and it was repositioned until the HA could be injected freely.[12]

Data analysis

All analyses were performed using a statistical program. Pain, functioning, and strength were evaluated at the baseline (T_0), at the 4th week (T_1), and at the 26th week (Tf). These variables were compared using T-tests.

The primary end-point was changed to DASH score and Dreiser index at the 26th week. Secondary endpoints included improvement of NRS for pain, and grip strength at the 4th week.

Analyses were performed to observe any difference in the improvement in pain and functioning among the three groups: hyaluronate, orthosis and combined treatment.

Results

Group 1 - HA injection

Pain, functioning and strength were evaluated at the baseline (T_0) and also at the 4th week (T_1) and at the 26th week (Tf), after HA injection.

Pain scores and functional tests, expressed by using Numerical Rating Scale (NRS), Dreiser Index and DASH Score, showed relevant differences 4 weeks after the infiltration (T_1) in terms of reduction of pain scores (T_0 mean value 6.2; T_f mean value 0.93; P<0.01) and improvement of functioning scores (Dreiser Index: T_0 mean value 10.26 - T_f mean value 1.76 - P<0.01; DASH Score: T_0 mean value 34.33 - T_f mean value 20.13 - P<0.01).). Further improvement was observed 26 weeks after treatment (Figure 1).

Similarly, pulp pinch, lateral pinch and sub-terminal pinch strength, assessed by using a dynamometer (Figure 2), showed improvement after 4 and 26 weeks from the date of infiltration, compared with baseline (T_0 overall mean value 7.73 *Kp* -T_f overall mean value 13.45 kgp; P<0.01).

Therefore, assessment of the pinch power showed long-term effects of hyaluronic acid injection in osteoarthritis of the thumb in carpometacarpal osteoarthritis (CMC OA).

Group 2 - HA injection and orthosis

Pain, functioning, hand function and strength were evaluated at the baseline (T0) and also at the 4th week (T1) and at the 26th week (Tf), after HA injection, using orthosis to stabilize the thumb's articular complex.

A relevant difference was observed between pain scores before the treatment and after 26 weeks from it. The pain scores are expressed in mean values (T_0 mean value 5.75; T_f mean value 1.25; P<0.01), with a trend toward pain improvement at an early stage, 4 weeks after the treatment (Figure 3).

Relevant differences were noticed 4 weeks and 26 weeks after the treatment between Dreiser Index and DASH Scores (Dreiser Index: T_0 mean value 11.8 - T_f mean value 3.08 - P<0.01; DASH Score: T_0 mean value 27.33 - T_f mean value 14.25 - P<0.01).

Table 3. Group 2 - Combined treatment.

No. patients	12
Mean age	63.08
Males	4
Females	8
G.K. II scale	4
G.K. III scale	8
Right TM OA	5
Left TM OA	7

TM OA, trapezio-metacarpal osteoarthitis.

Table 4. Group 3 - Orthosis treatment.

No. patients	12
Mean age	67.41
Males	3
Females	9
G.K. Scale II	6
G.K. Scale III	6
Right TM OA	6
Left TM OA	6

TM OA, trapezio-metacarpal osteoarthitis.

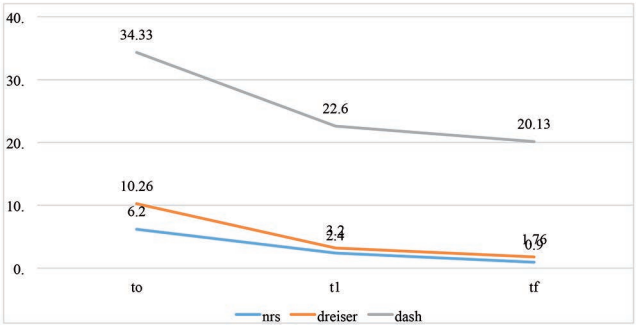

Figure 1. GROUP I: Pain and function. NRS, Numeric Rating Scale; DASH, Disability of the arm Shoulder and Hand.

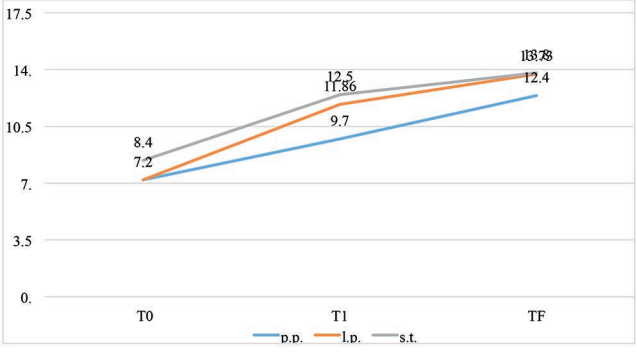

Figure 2. GROUP I: strength mean value. p.p., pulp pinch strength; l.p., latero-terminal strength; s.t., sub-terminal strength. Overall mean value: T_0 7.73 *Kgp*; T_f 13.45 kgp; ; P<0.01.

In addition, these results suggested an improvement of pulp pinch strength, measured by means of a dynamometer and expressed as mean value (Figure 4), with regard to significant differences at 4th and 26th weeks compared to the baseline (T_0 mean value 8.66 kg - T_1 mean value 12.02 kg - T_f mean value 12.83 - P<0.01).

Therefore, patients treated with intra-articular hyaluronate injection and using orthosis to stabilize the thumb articular complex showed a decrease in pain and functional disability and an improvement in hand functioning with an increase of grip strength.

Group 3 - Orthosis

Pain, functional disability, hand function and strength were evaluated at the baseline (T_0) and at the 4th week (T_1) and 26th week (T_f) after using orthosis to stabilize the thumb articular complex.

Some differences were noticed between pain scores (NRS: T0 6.5, Tf 2.58, P<0.01) after 4 weeks and 26 weeks from the use of orthosis (NRS: T_0 6.5, T_f 2.58, P<0.01), as seen in functional tests evaluated after using orthosis at 4 weeks (Dreiser Index: T_0 mean value 12.66 - T_1 mean value 7.66 - P<0.01; DASH Score: T_0 mean value 31.16 - T_1 mean value 24.83). However, at the 4th week, the improvement in the functional score was lower than the improvements observed in group 1 and in group 2 (Figures 5-6). Equality could be observed in functional tests at the 4th and 26th week after using the splint.

Pinch strength expressed as overall mean value showed a statistically non-significant increase in value 4 weeks after using orthosis compared to the baseline (T_0 mean value 7.38 - T_1 mean value 9.61). The analysis of mean values for each type of grip (pulp pinch, lateral pinch and sub-terminal pinch) showed improvement of pulp pinch only four weeks after using orthosis, which remained constant at 26 weeks after using the splint.

Discussion

In our study we investigated the effects of HA on the trapezio-metacarpal osteoarthritis, evaluating if splinting in combination with the hyaluronate treatment might be a valid alternative therapy.

This small open label study showed an effective improvement of conservative treatments.

The data analysis indicated a significant decrease (P<0.01) in pain at the 4th week, further shown at the 26th week, in all groups treated. By comparing pain scores at T.F (Figure 7), we observed that this improvement appeared more in group I that was receiving HA. In fact, in this group the pain score at baseline was 6.2 vs 0.3 at 26 weeks.

In group II, the pain score at the baseline was 5.75 vs 1.25 at the 26th week; in group III the pain score at the baseline was 6.5 vs 2.58 at the 26th week.

Function, as measured by the DASH index and the Dreiser score also improved significantly at week 26, especially in group I and II (P<0.01). Likewise, there was an improvement of grip strength, except for group 3, which did not achieve a statistically significant value (Figure 8). Our data in accordance with some stud-

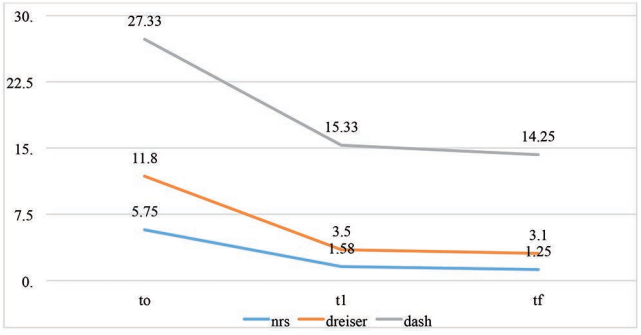

Figure 3. GROUP II: pain and function. NRS, numeric rating scale; DASH, Disability of the Arm Shoulder and Hand.

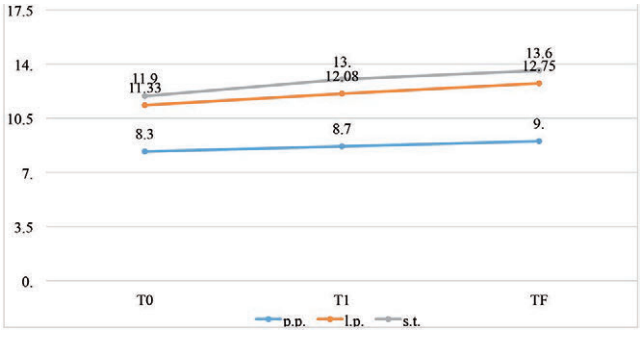

Figure 4. GROUP II: strength mean value. p.p., pulp pinch strength; l.p., latero-terminal strength; s.t., sub-terminal strength. Overall mean value: T_0 mean value 8.66 kg; T_f mean value 12.83; P<0.01.

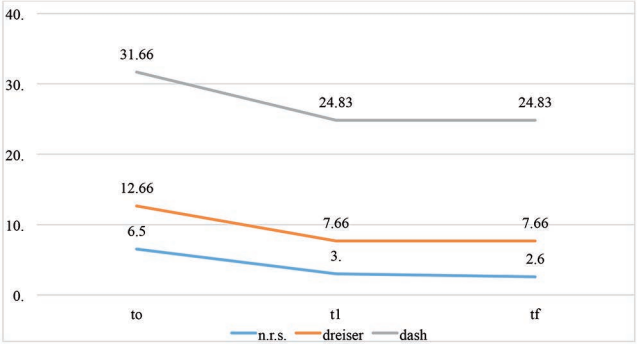

Figure 5. GROUP III: pain and function. NRS, Numeric Rating Scale; DASH, Disability of the Arm Shoulder and Hand.

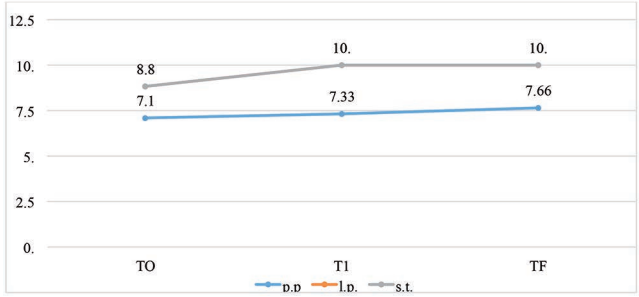

Figure 6. GROUP III: strength mean value. p.p., pulp pinch strength; l.p., latero-terminal strength; s.t., sub-terminal strength. Overall mean value: T_0 mean value 7.38; T_1 mean value 9.61.

ies prove that HA reduces pain and improves grip strength.[13] A randomized controlled trial of 56 patients showed *non-inferiority* of HA compared to steroids for pain relief at week 26.[14]

Regarding the use of orthosis, we observed that the splint did not lead to an improvement in functional symptoms. The data analysis showed a decrease in pain, which was lower in III group, and a lower effect in the combined treatment (group II); improvement in functional symptoms, such as grip strength, did not achieve a statistically significant value in group III.

Several guidelines recommend the use of orthosis in osteoarthritis of thumb, but no evidence of efficacy exists. A randomized trial showed that wearing a splint improves pain and disability after 12 months, but not at the first month. Its use during daily life activities results in the reduction of pain, but it is not effective in improving functioning or grip strength.[15] Usually, a client-centered approach is preferred.[16] Other authors point out that splinting can relieve pain in thumb arthritis and can potentially help patients avoid other treatments, such as drugs and steroid injections.[17]

In line with the literature, we used a hard resting splint for 30 days in group II (combined treatment) and group III (orthosis treatment).

As already observed by other authors,[18] the effect on pain is determined by a reduction of inflammation as a consequence of the use of a hard resting splint. Kortekaas *et al.* noted a significant positive correlation between pain and ultrasound-assessed inflammation in hand OA.[19]

As regards surgery, the literature highlights that it might be an option. A study of patients undergoing surgery showed that DASH scores improve,[20] but, despite this is effective in relieving pain, many older patients are not eligible for surgery, and HA injections may be an effective low-risk treatment in non-responders to standard medical therapy.

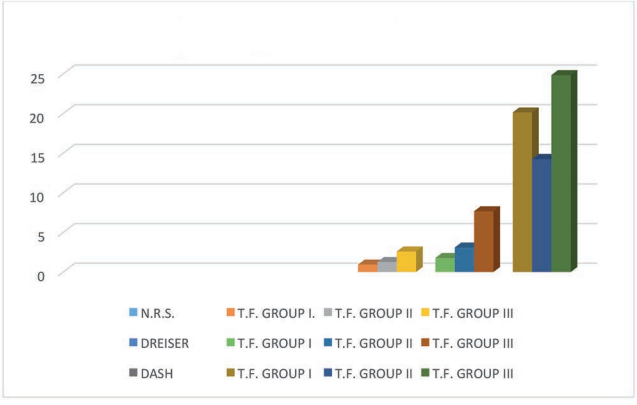

Figure 7. Mean value pain and function T.F.

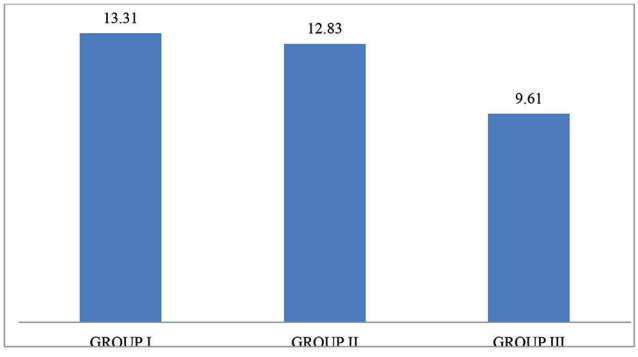

Figure 8. Mean value strength T.F.

Conclusions

Our analysis showed that hyaluronate is a valid treatment for trapezio-metacarpal osteoarthritis. Pain and functional symptoms improved like grip strength assessed at the 4th and 26th week.

Splinting reduces pain, but it does not have any significant effect on grip strength and functional symptoms, if used alone; the association with low molecular weight hyaluronate does not seem to have more effects.

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