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Three-dimensional printed customized versus conventional plaster brace for trapeziometacarpal osteoarthritis: a randomized controlled crossover trial

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Abstract

We investigated the non-operative management of trapeziometacarpal osteoarthritis with a three-dimensional (3-D) printed patient-customized brace compared with a conventional plaster brace. Fifty-two patients with symptomatic trapeziometacarpal osteoarthritis were enrolled in a 9-week crossover study, which was designed as a randomized controlled trial of two periods of 4-week brace therapies. The primary outcome was patient satisfaction measured with the Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology questionnaire survey. Secondary outcomes included pain, patient-reported function, functional hand strength measured by pinch and grip strength, and compliance assessed through a daily log of self-reported brace usage. The 3-D printed patient-customized brace had higher patient satisfaction and compliance than the conventional plaster brace. Patients preferred the 3-D printed customized brace (93%) rather than the conventional plaster brace (7%). This suggests that the 3-D printed patient-customized brace is effective in the non-operative management of trapeziometacarpal osteoarthritis.

Level of evidence: I

Keywords

Trapeziometacarpal osteoarthritis, brace, non-operative management, 3-D scanning and printing technology, thumb base

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Introduction

Trapeziometacarpal (TMC) joint osteoarthritis (OA) is commonly diagnosed in the elderly (Bijlsma et al., 2011; De Groot et al., 2011) with a radiographic prevalence of 33–36% among women above 50 years (Bijlsma et al., 2011; Marshall et al., 2011). Patients with TMC OA often experience basal thumb pain, have reduced pinch and/or grip strength, decreased thumb mobility and report functional hand limitations in daily life (Marshall et al., 2011; Martín-Merino et al., 2018). The number of patients with TMC joint OA is expected to increase because of the ageing population (Anandacoomarasamy and March, 2010). The initial therapy for TMC joint OA is non-operative treatment using a fixed orthotic TMC joint brace aimed to decrease pain and improve hand function. Treatment with these braces has resulted in increased patient satisfaction and improved ability to perform activities of daily life (Bertozzi et al., 2015; Grüschke et al., 2019; Kjeken et al., 2011; Poole and

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Pellegrini, 2000; Spaans et al., 2015; Wajon and Ada, 2005). However, despite the present improvements in the management of TMC joint OA, effective and comfortable TMC joint braces are still missing (Grüschke et al., 2019; Joseph et al., 2018; Spaans et al., 2015). Therefore, extensive research is done to optimize TMC joint braces by both academics and industry. Plaster braces are one of the treatment options of TMC joint OA. However, most of the these immobilize other joints besides the TMC joint, resulting in reduced degree of motion of the hand and thumb.

Recently, a conceptual design of a tailor-made TMC joint brace through three-dimensional (3-D) scanning and patient specific 3-D printing technology has been developed. It stabilizes the TMC joint and leaves the thumb in a functional position with an individualized fit. The goal of this study was to investigate the non-operative management for TMC joint OA with a 3-D printed patient-customized (3D PPC) brace or a conventional plaster (CP) brace.

Materials and methods

Two different orthotic braces were compared for their efficacy in treating patients with the TMC joint OA. Both were made in the plaster room of the hospital. The 3D PPC brace is personalized and custom-made using proprietary 3-D scanning and 3-D printing technology (Manometric, Delft, The Netherlands, Figure 1(a)). The 3-D scanner scans the patient's hand via multi-image photogrammetry taken from different angles to calculate point positions. The 3-D scans of the patient's hand and thereby the brace is modelled by the orthopaedic engineers. The 3D PPC brace stabilizes the TMC joint in a functional position and leaves the thumb interphalangeal joint and metacarpophalangeal joint free. The CP brace is made out of synthetic plaster and is removable due to its supplemental hood and loop fastener (Figure 1(b)). The plaster physicians/technicians manually applied plaster to the patient's hand. The position of both the braces were adjusted based on the conversation between the treating physician and the patient. The CP brace stabilizes the TMC joint and the metacarpophalangeal joint while leaving the thumb interphalangeal joint free, resulting in reduced freedom of thumb motion. The colour of both braces was adjusted according to patient preference. The cost of the 3D PPC brace is €590, whereas the CP brace is €400, both hospital prices.

Patients

Fifty-two patients with a confirmed diagnosis of TMC OA were enrolled. Physical examination of the TMC joint OA was assessed by a positive shear, a positive grind and a negative Finkelstein's tendovaginitis test (Sela et al., 2019), whereas its severity was classified in Grade 1, 2 or 3 according to the Kellgren–Lawrence radiographic scale (Kellgren and Lawrence, 1957). Patients with bilateral TMC joint OA were included with the side of their most symptoms. We excluded patients with a history of surgery for TMC joint OA, corticosteroid injection in the TMC joint in the preceding 6 months and medical conditions that might interfere with the study results, such as inflammatory rheumatoid arthritis, neurovascular disorder affecting the upper limb, radiocarpal OA and primary OA of the scaphoid-trapezium trapezoid joint. Patients with insufficient knowledge of the Dutch language and severe cognitive disorders were also excluded.

Figure 1. (a) Three-dimensional printed patient-customized brace and (b) conventional plaster brace.

Study design and protocol

The 3D PPC brace was compared with the CP brace in a 9-week randomized controlled crossover trial (Jones et al., 1996). The patients used the braces in a random order during 4-week treatment periods separated by a 1-week wash-out time (Haskett et al., 2004; Sillem et al., 2011; Woods et al., 1989). Group A started with the 3D PPC brace and then received the CP brace. Group B received the braces in reverse order.

The primary outcome of the study was patient satisfaction measured with the Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology (D-Quest) after each 4-week treatment period (Vegt et al., 2017; Wessels and De Witte, 2003). The D-Quest questionnaire valuates the degree of satisfaction of a patient with the assistive device. The survey consists of 12 items. Scores for each item range from 0 to 5, with higher scores indicating higher patient satisfaction. The total D-Quest score was calculated by adding the ratings of the valid responses and dividing this sum by the number of valid items.

The secondary study outcomes were patient-reported hand function, pain and compliance. The pain-related interference with daily activities was assessed by the QuickDASH (Beaton et al., 2005). Furthermore, pain was determined via the visual analogue pain scale (VAS) before and after both 4-week treatment periods (Collins et al., 1997). The anchors of the VAS were from extreme end points, such as 'no pain' (0) up to 'worst possible pain' (10).

Strength of the affected hand was evaluated by the pinch grip of index finger and thumb (pinch^1), the pinch grip of index, middle finger and thumb (pinch^2) and the key pinch grip tests, respectively, followed by a hand grip strength test (Fess, 1986; Mathiowetz et al., 1984). The Preston pinch gauge (Baseline® mechanical pinch gauge, Fabrication Enterprises Inc., White Plains, NY, USA) was used to measure the pinch force (Villafañe and Valdes, 2014), and the Jamar hydraulic hand dynamometer (Baseline® hydraulic hand dynamometers, Fabrication Enterprises Inc., White Plains, NY, USA) was used for grip strength measurements (Schmidt and Toews, 1970). To have comparable results, the grip handle of the Jamar hydraulic dynamometer was adjusted based on the patient's hand size in order to obtain an optimal grip position. During the strength assessments, the patients sat on a standard height chair with their shoulders adducted and neutrally rotated, elbow flexed at 90° and the forearm and wrist in neutral position. The patients were instructed to squeeze both the dynamometers as hard as possible for 2–3 seconds by avoiding pain. The pinch and grip strength measurements were done in triplicate with a 30-second rest in between to avoid fatigue. The calibration of both the dynamometers was tested periodically. Compliance was measured using a self-reported diary by each patient, in which they recorded the number of hours they wore the brace each day. After the second 4-week brace treatment, patients were asked for their preference and explanations for reason.

Statistical analysis

The primary outcome patient satisfaction with the D-Quest was used to estimate the sample size (Faul et al., 2009). As per this tool, a priori power calculation indicated that 42 patients were required to test the null hypothesis of a small difference in patient satisfaction between the two treatment groups. The calculation was based on a correlation quotient of 0.67 and a standard deviation of 0.5 points. Further, the minimally clinically important difference was set at 0.25 points on the 5-point outcome score, followed with an alpha level of 0.05, a power of 80% and a two-tailed test as the level of significance. Effect size was 0.5. In case of some incomplete cases (e.g. missing data), a possible dropout of 20% before study completion was taken into account. Thus 52 patients would ideally have to be included in this study, 26 in Group A and 26 in Group B.

Normality of each study outcome was determined using the Shapiro–Wilk test. A normal distribution could be assumed for all variables. Besides these, all the outcome results were tested for a potential presence of a carryover effect or a period effect. The presence of a carryover effect was tested comparing the sum of the results in Group A (i.e. the sum of the results of the D-Quest after the first and second 4-week brace period) to the sum of the results in Group B. A carryover effect was considered present when $p < 0.05$. Furthermore, the potential presence of a period effect was tested by comparing baseline results at the start of each 4-week brace period. Differences between both groups were determined with a (two-sample) *t*-test for normally distributed variables, whereas the Mann–Whitney *U*-test was done for not normally distributed variables. Normally distributed variables were presented as mean (SD), while not normally distributed variables as median (Q1–Q3). Patient preference is given in descriptive statistics as the percentage of participants who preferred a particular brace. Finally, *p*-values <0.05 were considered statistically significant.

Results

Forty-nine patients signed an informed consent and participated in the study. Two did not complete the follow-up assessment. In total, 47 patients were included in the analyses of the construct approach of responsiveness (Figure 2). Five patients missed the pinch and grip strength measurements due to the COVID-19 pandemic. The baseline sociodemographic and radiological characteristics of the included patients are presented in Table 1.

No carryover or period effects were present. According to the D-Quest results, patients were more satisfied while wearing the 3D PPC brace (50; SD 5.0) compared with the CP brace (41; SD 5.7) ($p < 0.05$). Compliance, measured as a wearing time of the brace, was higher with the 3D PPC brace (10.3 hours/day; SD 3.5 versus 8.9 hours/day; SD 3.4 for the CP brace) ($p < 0.05$). Patients preferred the 3D PPC brace (93%, $n = 44$) over the CP brace (7%, $n = 3$) ($p < 0.001$) (Table 2). The preference was that a better appearance, modern, smaller and the ability to do a wider variety of daily activities were the advantages of the 3D PPC brace. Actions for which the CP brace was taken off included opening bottles and activities that would cause the CP brace to get wet. Discomfort, odour-related problems, appearance and forgetting to put on the brace were often mentioned as reasons not to wear the CP brace.

After the 4-week brace treatments, QuickDASH and VAS improved both the CP brace and 3D PPC brace compared with baseline scores. However, there were no significant differences between the two braces in the post-treatment QuickDASH ($p > 0.05$) and VAS ($p > 0.05$) results. The 3D PPC brace showed a higher grip strength, 21.7; SD 10.3 kg than the CP brace, 19.4; SD 10.4 kg after 4 weeks of treatment ($p < 0.05$). However, there were no significant differences between the two braces in all three strength measurements when compared with the baseline ($p > 0.05$) and the post-treatment ($p > 0.05$) results.

Discussion

The initial therapy of TMC OA is non-operative management by splinting the joint, which results in

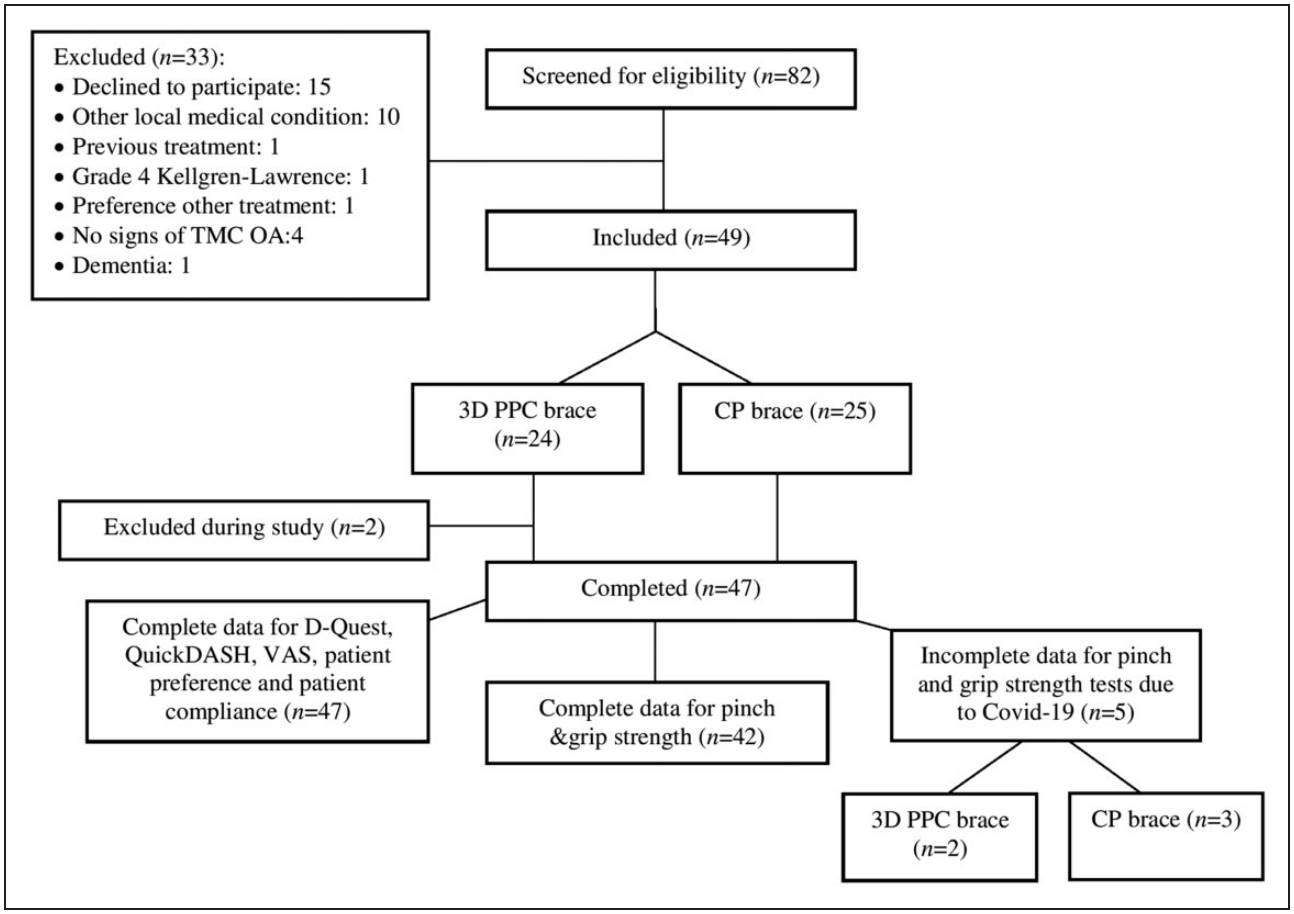

Figure 2. The flow of participated patients through the crossover clinical trial of the braces.

Table 1. Baseline sociodemographic and radiological characteristics.

Variable	3D PPC brace	CP brace	Total
Number	24	25	49
Mean age (years)	65 (SD 11)	61 (SD 11)	63 (SD 11)
Sex (male/female)	8/16	4/21	12/37
Affected side (left/right)	13/11	16/9	29/20
Dominant side (left/right)	3/21	1/24	4/45
Kellgren–Lawrence (total)	—	—	—
Kellgren–Lawrence Grade 1, number (%)	1 (4)	2 (8)	3 (6)
Kellgren–Lawrence Grade 2, number (%)	12 (50)	15 (60)	27 (55)
Kellgren–Lawrence Grade 3, number (%)	11 (46)	8 (32)	19 (39)

3D PPC: Three-dimensional printed patient-customized; CP: conventional plaster; SD: standard deviation.

Table 2. Primary and secondary outcomes.

	3D PPC brace		CP brace		*p*-value	
Outcomes	Baseline	Post-treatment	Baseline	Post-treatment	Baseline	Post-treatment
D-Quest (mean/SD)	—	50 (5.0)[b]	—	41 (5.7)	—	<0.001
QuickDASH (mean/SD)	45 (18.2)*	35 (17.9)[a]	44 (20.6)*	40 (17.9)[a]	0.361*	0.060
Pinch[1] (kg) (mean/SD)	2.4 (1.4)	2.7 (1.1)[a]	2.6 (1.9)	2.5 (1.2)	0.437*	0.092
Pinch[2] (kg) (mean/SD)	3.1 (1.9)	3.5 (1.7)	2.9 (1.4)	3.2 (1.5)[a]	0.315*	0.122
Key grip (kg) (mean/SD)	4.3 (2.4)	4.1 (1.9)	4.6 (2.2)	4.5 (2.2)	0.473*	0.512
Hand grip (kg) (mean/SD)	20.0 (10.8)	21.7 (10.3)	18.7 (9.6)	19.4 (10.4)[a]	0.064*	0.002
VAS (mean/SD)	5.7 (1.9)*	4.3 (1.9)[a]	5.4 (2.0)*	4.9 (2.0)[a]	0.297*	0.081
Patient preference (%)	93[b]		7		—	
Patient compliance (h/day) (mean/SD)**	10.3 (3.5)[b]		8.9 (3.4)		<0.001	

3D PPC: Three-dimensional printed patient-customized; CP: conventional plaster; D-Quest: Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology; SD: standard deviation: VAS: visual analogue pain scale.
[a]$p < 0.05$ compared with baseline.
[b]$p < 0.05$ compared with CP brace.
*no period effect was present.
**Patient compliance is shown as h/day.
Pinch[1]: pinch grip of index finger and thumb.
Pinch[2]: pinch grip of index, middle finger and thumb.

decreased pain and improvement of hand function (Spaans et al., 2015). We compared two braces regarding patient satisfaction measured with the D-Quest. Results showed that patients were more satisfied with the 3D PPC brace compared with a CP brace and preferred to use the 3D PPC brace. The optimal balance between stiffness and suppleness of the 3D PPC brace design and the thumb's functional position was described as this brace's biggest advantage.

Studies have shown that a randomized crossover of two 4-week treatment periods with a 1-week wash-out time in between is suitable for the investigation of novel orthotic braces since the TMC joint OA is a chronic disease (Bani et al., 2013; Buurke et al., 1999; Vegt et al., 2017; Weiss et al., 2000, 2004). It is essential to determine whether a carryover or period effect was present. The carryover effect is known as the effect of the brace therapy from the first 4-week period on the response at the second 4-week brace therapy. In contrast, the period effect is the change in disease over time, regardless of the treatment (Wellek and Blettner, 2012). In this study, the results showed neither a period effect nor a carryover effect, which was in accordance with the previous studies for braces in TMC joint OA management (Sillem et al., 2011; Haskett et al., 2004).

In this study, the CP brace and the 3D PPC brace significantly decreased pain of the TMC OA compared with baseline, and no significant differences between the two braces were found an effect on hand function (Spaans et al., 2015).

The designs of both braces are slightly different. However, the radiocarpal movement in the 3D PPC brace is comparable with the CP brace. With this information, it is essential to know which design of immobilization is most effective in which type and which degree of TMC joint OA. The TMC joint immobilization design is helpful to stabilize the first metacarpal while not immobilizing the thumb metacarpophalangeal and/or interphalangeal joints (Colditz, 2000). The 3D PPC brace allows the patient more natural functional use of the thumb since the patient contracts the thenar muscles in the brace during pinch with the TMC joint in a desirable position (Colditz, 2000; Ladd et al., 2013). Immobilization of the metacarpophalangeal thumb joint robs the hand of the valuable flexion, extension and radial and ulnar deviation (Colditz, 2000). Attention to this potential problem may prevent unnecessary discomfort and increase compliance with the CP brace.

Patients treated with the 3D PPC brace showed a clinically relevant increase in satisfaction and compliance compared with the CP brace. This might suggest that the 3D PPC brace is effective in the non-operative management of TMC OA. Although the results of patient-reported function and pain were comparable for both braces, further detailed research is needed to investigate these outcomes in a larger patient population.

A limitation of the study was that the patients were not blinded to the brace treatment conditions. However, it was thought this would not affect the study results as the same tests were repeated for each patient, irrespective of brace treatments. Nevertheless, the hand scanner's technical set-up might have influenced the participating patient's objectivity. Another limitation was that the research was not powered by pain and function, the study's secondary outcomes. Therefore, no robust conclusions can be drawn from these measures. Measuring pain and function outcomes is a first step in providing the value-based impact of the 3D PPC and CP braces, which future studies could investigate.

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Ethical approval The study was approved by the local Medical Ethical Committee (METC, 18-109) and is in accordance with the principles of the Declaration of Helsinki (version 7, October 2013).

Informed consent Written informed consents were obtained from all participating patients before the study. The study was registered in the database of the Netherlands Trial Register (NTR7542).

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