Journal of Oral Rehabilitation

Journal of Oral Rehabilitation 2015 **42**; 890–899

Efficacy of stabilisation splint therapy combined with non-splint multimodal therapy for treating RDC/TMD axis I patients: a randomised controlled trial

K. NAGATA, H. MARUYAMA, R. MIZUHASHI, S. MORITA, S. HORI, T. YOKOE & Y. SUGAWARA *Temporomandibular Disorders and Bruxism Clinic, Niigata Hospital, The Nippon Dental University, Niigata, Japan*

SUMMARY **Stabilisation splint therapy has long been thought to be effective for the management of temporomandibular disorders (TMD). However, the superiority of stabilisation splint therapy compared to other TMD treatments remains controversial. The aim of this study was to determine the efficacy of stabilisation splint therapy combined with non-splint multimodal therapy for TMD. A total of 181 TMD participants were randomly allocated to a non-splint multimodal therapy (NS) group (n = 85) or a non-splint multimodal therapy plus stabilisation splint (NS+S) group (n = 96). Non-splint multimodal therapy included self-exercise of the jaw, cognitive–behavioural therapy, self-management education and additional jaw manipulation. Three outcome measurements were used to assess treatment efficacy: mouth-opening limitation, orofacial pain and temporomandibular joint sounds. A two-factor repeated-measures analysis of variance (ANOVA) was used to evaluate the efficacy of the two treatment modalities (NS vs. NS+S), and Scheffe's multiple comparison test was used to compare the treatment periods. Subgroup analyses were performed to disclose the splint effects for each TMD diagnostic group. All three parameters significantly decreased over time in both groups. However, there were no significant differences between the two treatment groups in the total comparison or subgroup analyses; an exception was the group with degenerative joint disease. No significant difference between the NS and NS+S treatment approaches was revealed in this study. Therefore, we conclude that the additional effects of stabilisation splint are not supported for patients with TMD during the application of multimodal therapy.**

KEYWORDS: temporomandibular joint disorders, splint therapy, jaw exercise, jaw manipulation, cognitive–behavioural therapy, randomised controlled trial

Accepted for publication 11 June 2015

Background

Splint therapy has been a preferred modality for the management of temporomandibular joint disorders (TMD) since the 1960s, and many practitioners use splints as a primary care technique for patients with TMD. Although several randomised controlled trials (RCTs) demonstrating the positive effects of splints have been reported (1–3), others did not find evidence to support the proactive use of this modality (4–7).

When considering the complex effects of splint therapy combined with self-care, previous RCTs have failed to demonstrate a distinct positive effect of splints (6–8). In comparison with other TMD treatments, the effect of the splint was shown to be equal

The copyright line for this article was changed on 29 September 2015 after original online publication.

 doi: 10.1111/joor.12332

to (6, 9, 10) or weaker (11, 12) than the outcomes of other treatments. Three systematic reviews also arrived at similar conclusions, showing that splint therapy has a weak effect compared to no treatment and that splint therapy and other treatments, including non-occluding splints, acupuncture, bite plates, exercises and relaxation, are not significantly different with regard to outcome (13–15). However, two other systematic reviews supported the efficacy of stabilisation splints compared to no treatment (16, 17).

From the viewpoint of evidence-based medicine, the effectiveness of splint therapy for TMD has not yet been confirmed, and it no longer seems to be the most optimal treatment. Splints should be thoroughly tested and compared with other therapies intended to manage TMD, and such therapies should be non-invasive, low cost and safe. For this reason, we conducted an RCT to clarify whether splint therapy combined with non-splint multimodal therapy can reduce the signs and symptoms of TMD.

Methods

Participants

The participants were selected from among those who were admitted to The Nippon Dental University Niigata Hospital between June 2009 and July 2013. All participants had been diagnosed with TMD according to the criteria in the RDC/TMD axis I (18, 19). These participants provided written informed consent to participate in the study. The three exclusion criteria were as follows: (i) inability to attend our clinic during a set 2- to 4-week period; (ii) patient request for a particular treatment (e.g. drug, occlusal treatment) or declining our proposed treatment (e.g. splint, exercise); and (iii) the presence of any mental or physical problem that might interfere with the treatment (RDT/TMD axis II). Twenty participants withdrew from the study because they discontinued their treatment after the first visit, leaving a final total of 181 participants (63 males and 118 females) (Fig. 1).

The sample size of this study was selected using prior power analysis with G*Power software*.

The following parameters were used: input effect size $f = 0{\cdot}1$, α error = 0·05, power = 0·8, number of groups = 2, number of measurements = 7. The total sample size calculated was 456; finally, 456/7 = 65·1 participants were required for each group in this study. The number of participants in each group (85 in NS and 96 in NS+S) was increased slightly to account for possible dropouts.

Treatment groups

Participants were randomly assigned to the non-splint multimodal therapy group (NS) or to the multimodal therapy plus splint group (NS+S) with block randomisation to equalise the numbers of participants in the two groups (Table 1). The study was designed as a single blind RCT; participants in each group received detailed explanations for their individual treatment, but further information was not given to them to avoid education bias.

The NS participants were instructed to perform an improved self-exercise of the jaw (described below), underwent cognitive–behavioural therapy (CBT; e.g. guidance about clenching control during waking hours and coping with pain and stress) and received education about TMD self-management (i.e. a diet of soft foods, avoiding gum chewing and correcting bad posture). The participants with a mouth-opening limitation (under 35 mm) also underwent jaw manipulation (20) (Figure S1).

The self-exercise that all of the participants were instructed to perform was as follows: the participant pulled down on his or her bilateral lower last molars with their secondary fingers while opening his or her jaw to the greatest possible extent (Figure S2). This exercise was performed with 20 repetitions three times a day.

In the NS+S group, stabilisation splint therapy was added to the NS treatment at the second visit. The stabilisation splint was made of hard, clear, acrylic resin and was set to the upper teeth to provide equal contact for all of the lower teeth (Figure S3). An impression for the splint was made at the participant's initial visit, and the splint was applied to the upper teeth at the next visit approximately 2 weeks later. The splint was adjusted using habitual closing and light tapping of the jaw. The participants were instructed to wear the splint every night while sleeping, but daytime use was not required. If no change of symptoms was achieved by this treatment, the splint was altered to the bruxism-controlled type to disturb the eccentric movements of

*University Dusseldorf, http://www.gpower.hhu.de/

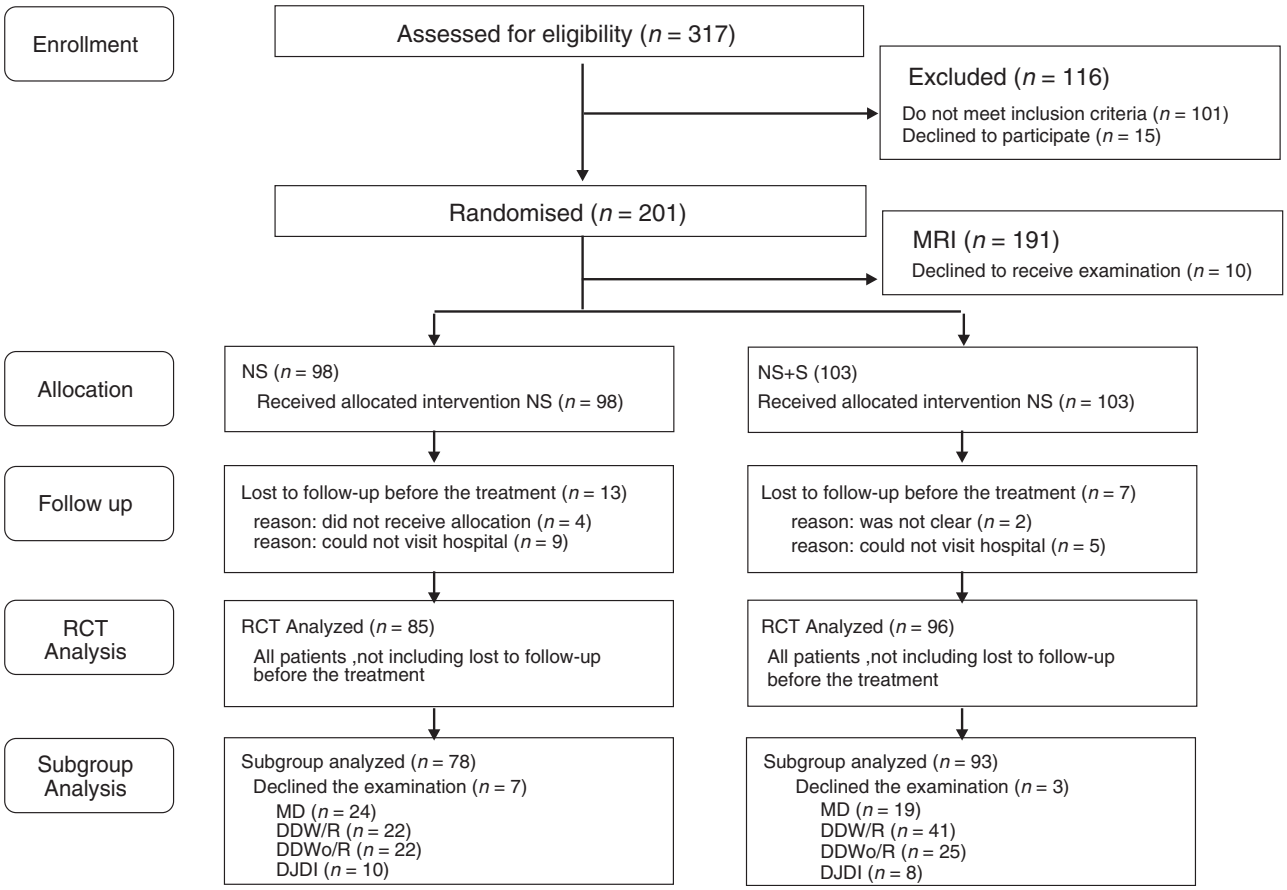

Fig. 1. Flow diagram of the RCT and subgroup analysis.

Table 1. Patient characteristics (Mean and s.d.)

	NS	NS+	Comparison
Participants	85 (33M, 52F)	96 (30M, 66F)	
Age	43·1 ± 17·6	41·1 ± 18·9	ns
Mouth-opening distance (mm)	36·3 ± 9·8	36·7 ± 8·9	ns
Oro-facial pain NRS	4·3 ± 2·8	4·4 ± 2·6	ns*
TMJ sound NRS	2·8 ± 2·9	3·0 ± 3·1	ns*

NS, non-splint multimodal therapy; NS+S, non-splint multimodal therapy plus splint; NRS, patient numerical rating scale (0–10); ns, not significant (Student's *t*-test); ns*, not significant (Mann–Whitney *U*-test).

the mandible with a steep obstacle located at the anterior teeth (Figure S4).

Examination and division for subgroup analysis

All participants included in the RCT were classified for subgroup analysis based on pathological type, which was determined by magnetic resonance imaging (MRI) (Excel ART Vantage XGV 1.5T†) of the primary symptom side of the jaw between the first and second visits. The pathological groups included muscular dysfunction (MD), disc displacement with reduction (DDW/R), non-reducing disc displacement (DDWo/R) and degenerative joint disease (DJD).

Participants without any temporomandibular joint (TMJ) problem detected by MRI were included in the MD group. Most participants have tenderness or spontaneous pain in the masticatory muscle, mylohyoid muscle or digastric muscle, and only five cases did not have these types of pain.

Participants with a side shift of the disc, posterior displacement of the disc at the maximum opening or partial displacement of the disc were included in the DDW/R group. Seven participants who refused the

†Toshiba CO., Tokyo, Japan.

MRI examination were diagnosed by clinical examination alone.

Evaluation parameters

Nineteen dentists, each of whom had more than 3 years of clinical experience with TMD treatment, were selected as the practitioners in this study. For the evaluation of treatment efficacy, the three TMD signs/symptoms of mouth-opening distance, oro-facial pain and TMJ sounds were recorded by the practitioners at seven time points: before and after treatment at the first visit and then 2, 4, 6, 8 and 10 weeks later (Figure S5). The mouth-opening distance between the upper and lower teeth was measured with a calliper. The participants were instructed to open their mouths as widely as possible, even if they felt pain. Oro-facial pain from the TMJ or masticatory muscles and TMJ sounds were estimated by the participants using a self-reported numerical rating scale (NRS) with scores ranging from 0 to 10.

If a muscle relaxant, acetaminophen or non-steroidal anti-inflammatory drug (NSAID) other than those in the pre-arranged protocol was given to a participant when no decrease in TMD signs/symptoms was achieved after several treatments, or if a participant discontinued treatment before the completion of this study, the participant's last TMD values were extended to fill in the post-assessment time points, according to the intention-to-treat concept.

Statistical analysis

A two-factor repeated-measures analysis of variance (ANOVA) was used to evaluate the efficacy of the two treatment modalities (NS vs. NS+S), and Scheffe's multiple comparison test was used to compare each treatment period.

The same analyses were performed in the subgroup analysis to clarify the pathological specificity of splint therapy. Excel add-in software[‡] was used for all analyses.

Results

All three parameters significantly improved over time in both treatment groups (Fig. 2). The mouth-opening limitation gradually improved after treatment during the first visit, and pain continuously decreased with time, although the most significant improvement was observed over the period from just after treatment to 2 weeks later. The TMJ sound score reduction was indistinct compared to the other parameters. However, ANOVA revealed no statistically significant differences between treatment groups with respect to changes in the mouth-opening limitation ($P = 0{\cdot}4715$), pain ($P = 0{\cdot}2699$) or sound ($P = 0{\cdot}2915$). There was no statistically significant interaction between time and treatment group for any of the outcome measurements ($P > 0{\cdot}05$). In addition, the results of Scheffe's test showed no differences between groups at any assessment time point (Fig. 2).

The results of the subgroup analysis were similar to those of the original RCT (Figs 3–5). ANOVA results for comparisons of the three parameters showed no difference between the two treatment groups, with the exception of the pain level in DJD participants ($P = 0{\cdot}0404$). Scheffe's analysis indicated that the change in the pain scores of DJD participants was greater for NS+S than NS from before treatment to 4 weeks after treatment.

Discussion

Several studies including RCT have shown that splint therapy can reduce the signs and symptoms of TMD (2, 3, 21, 22). However, as our RCT data did not reveal significant differences between the two treatment groups, our results are in disagreement with those findings. One reasons for the difference between the two conclusions is that RCTs supporting the effectiveness of splint therapy have typically employed a non-contact control splint (2, 3) for the control group, whereas we used a combination of other treatments as a control. Our findings are in accord with those of many RCTs (4, 6, 8–10) and systematic reviews (13–15) reporting no superiority of splint therapy over other treatments. Indeed, such studies used jaw self-exercise (11) and patient education (12) as a control. Therefore, we suggest that the inconsistencies among studies may be attributable to differences in control groups.

Although our RCT concluded that splint therapy was not effective based on comparisons of patients with TMD that included every pathological type, the

[‡]SSRI Co., Tokyo, Japan.

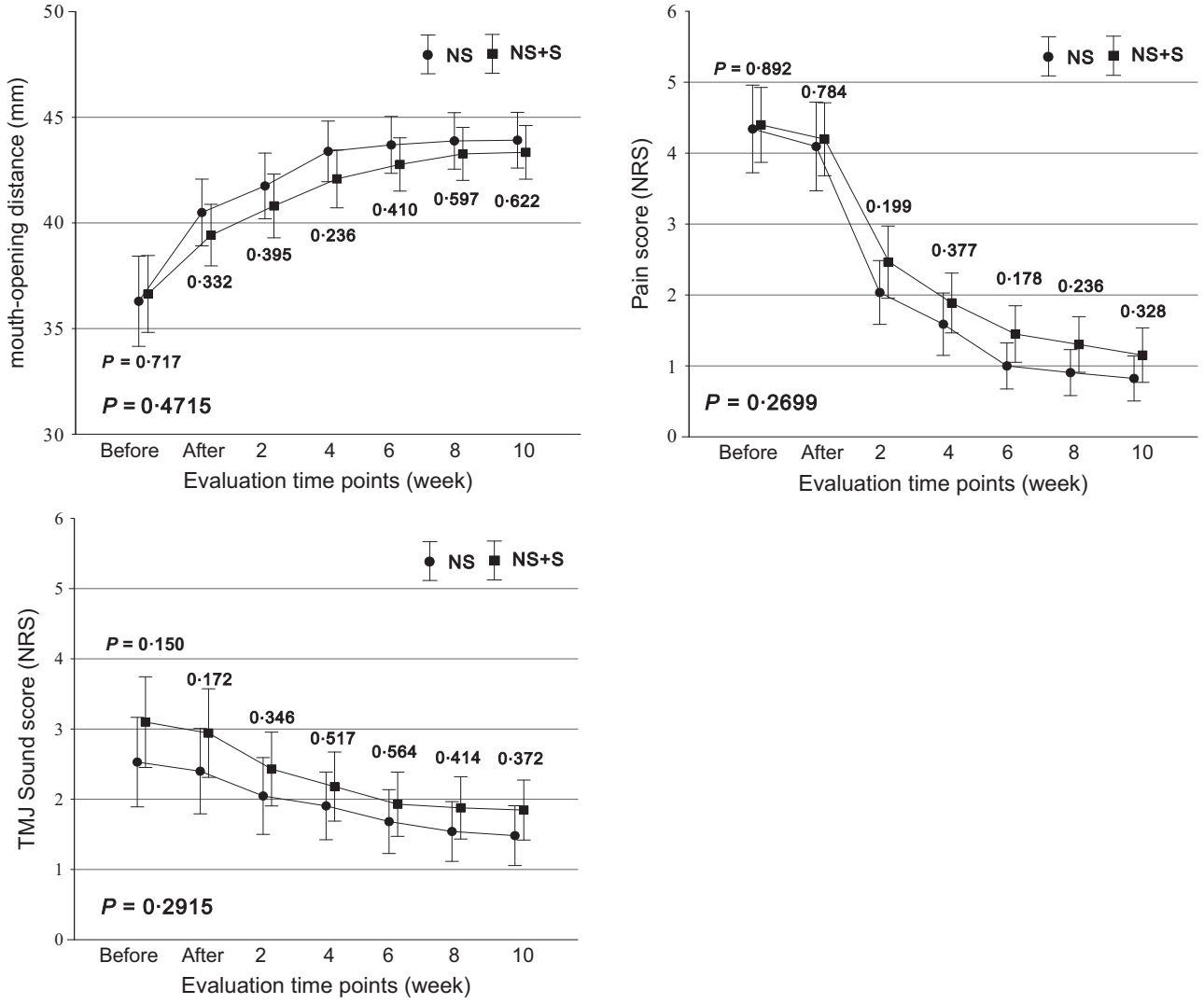

Fig. 2. Changes in mouth-opening distance (mm), pain score and sound score (NRS) in the RCT. Data points indicate the mean and 95% confidence interval; the results of ANOVA and Scheffe's multiple comparison are shown with *P*-value.

possibility remains that splint efficacy may be somewhat specific for particular pathological states of TMD. For example, splints may improve muscle-only disorders or disc displacement. For this reason, subgroup analysis was applied to clarify the pathological specificity of splint therapy. Contrary to our expectations, the results were similar to those of the RCT, with only significant differences shown for the pain of DJD participants from before the treatment to 4 weeks later. Moreover, this difference existed prior to treatment, indicating that this result should not be interpreted as the difference between two treatment groups, but as an advantageous inequality in the deviation of the participants caused by subgrouping.

Although the reliability of our subgroup analysis was limited by a small degree of inequality, these results did not confirm any pathological specificity of splint therapy.

The superiority of splint therapy over non-splint multimodal therapy was not demonstrated in our results. These findings suggest that the appropriateness and necessity of splint therapy as an initial treatment for TMD are limited. Instead, we suggest, in view of the cost and promptness of treatment, that multimodal therapy be recommended to treat oro-facial pain, mouth-opening limitation and TMJ sounds.

Multimodal therapies can be complex treatments that include CBT, patient education and additional

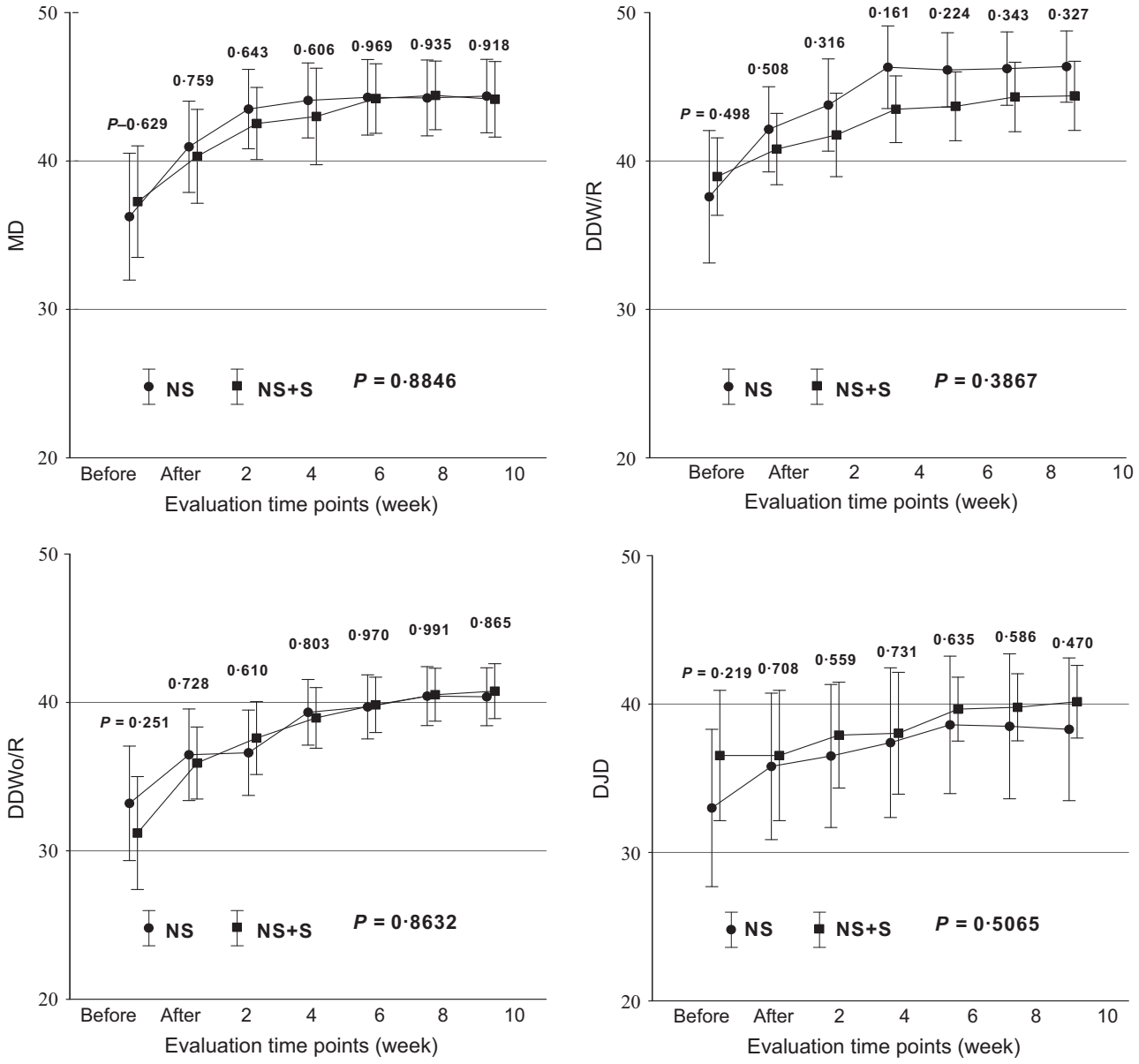

Fig. 3. Changes in mouth-opening distance (mm) for each pathological type evaluated in the subgroup analysis. MD, muscular dysfunction; DDW/R, disc displacement with reduction; DDWo/R, non-reducing disc displacement; DJD, degenerative joint disease. Data points indicate the mean and the 95% confidence interval; the results of ANOVA and Scheffe's multiple comparison are shown with *P*-value.

jaw manipulation. These therapies are selected for patients depending on their pathophysiological state, as TMD involves multiple factors and different causes. The effectiveness of CBT (23–25), patient education (12) and self-exercise (11) has been partially supported by the outcomes of previous RCTs, and we previously demonstrated the validity of jaw manipulation for the early treatment of mouth-opening limitation in another RCT (20). Each of the multimodal therapies was shown to be safe, available at low cost, and could be started immediately at the first visit. We therefore propose that comprehensive care using a combination of therapies represents an adequate and practical choice for primary TMD treatment.

The results of the present study revealed no superiority of splint therapy for TMD management, although this study had specific research design-related

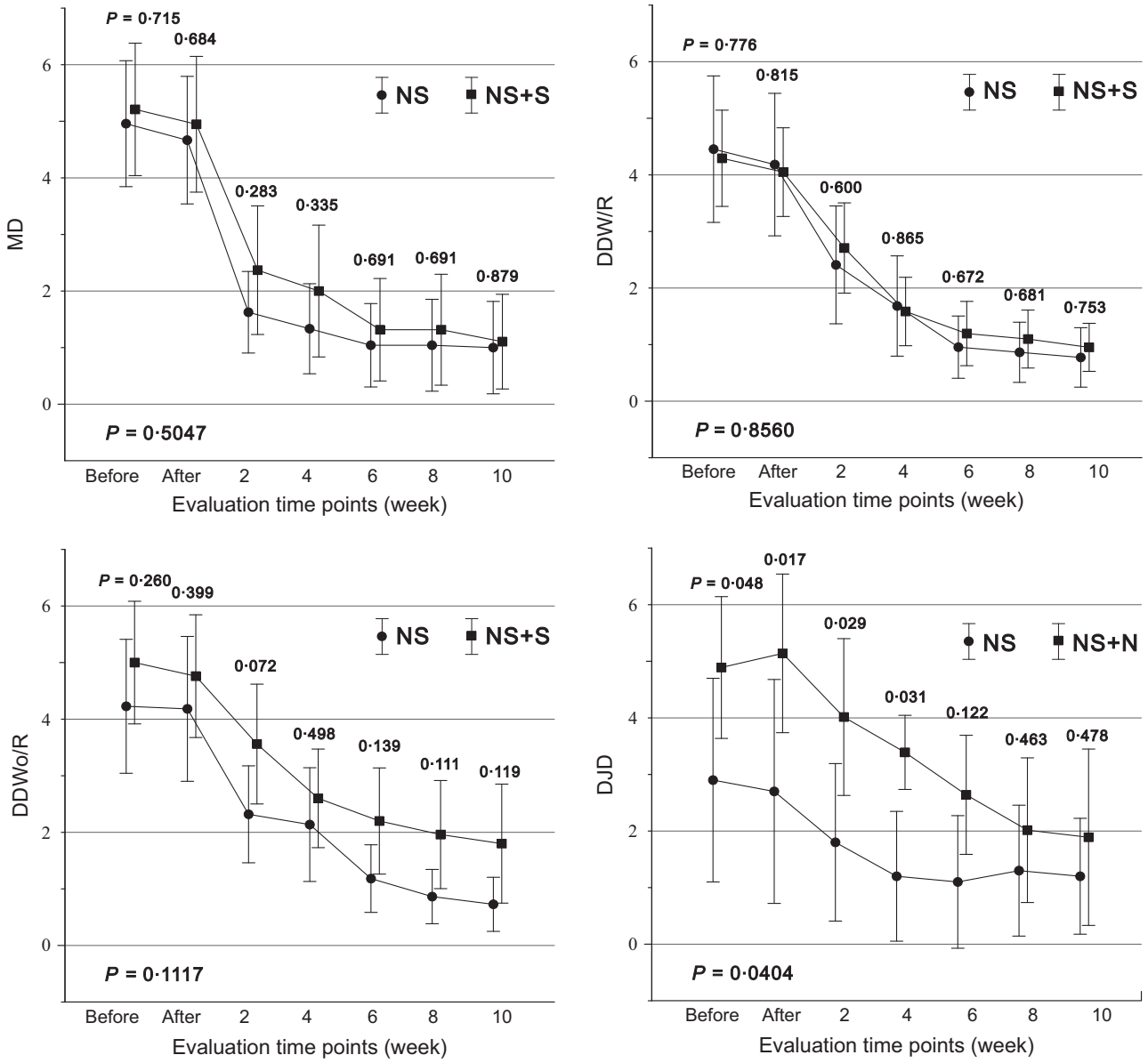

Fig. 4. Changes in the pain scores for each pathological type in the subgroup analysis. Data points indicate the mean and 95% confidence interval; the results of ANOVA and Scheffe's multiple comparison are shown with *P*-value.

limitations as follows, and the results should be interpreted with caution.

The first possible limitation was selection bias, as 20% of the participants were referred from general practices to our clinic, and some participants had already undergone unsuccessful splint therapy. These participants were potentially not suitable for splint therapy, and their data could have affected the results. Additional dental institutions should be involved in further investigations to eliminate this bias.

The second limitation was that only stabilisation splints were used, and other types of splints were not included in our RCT. Our results may therefore only be relevant to the stabilisation-type custom splints made in a laboratory. If other types of splints had been used, or if the timing had been different (e.g. the splint had been applied at the patient's first visit) (8), the conclusions might have been different. Additional investigation is necessary to evaluate the effectiveness of other types of splints (e.g. the anterior repositioning type).

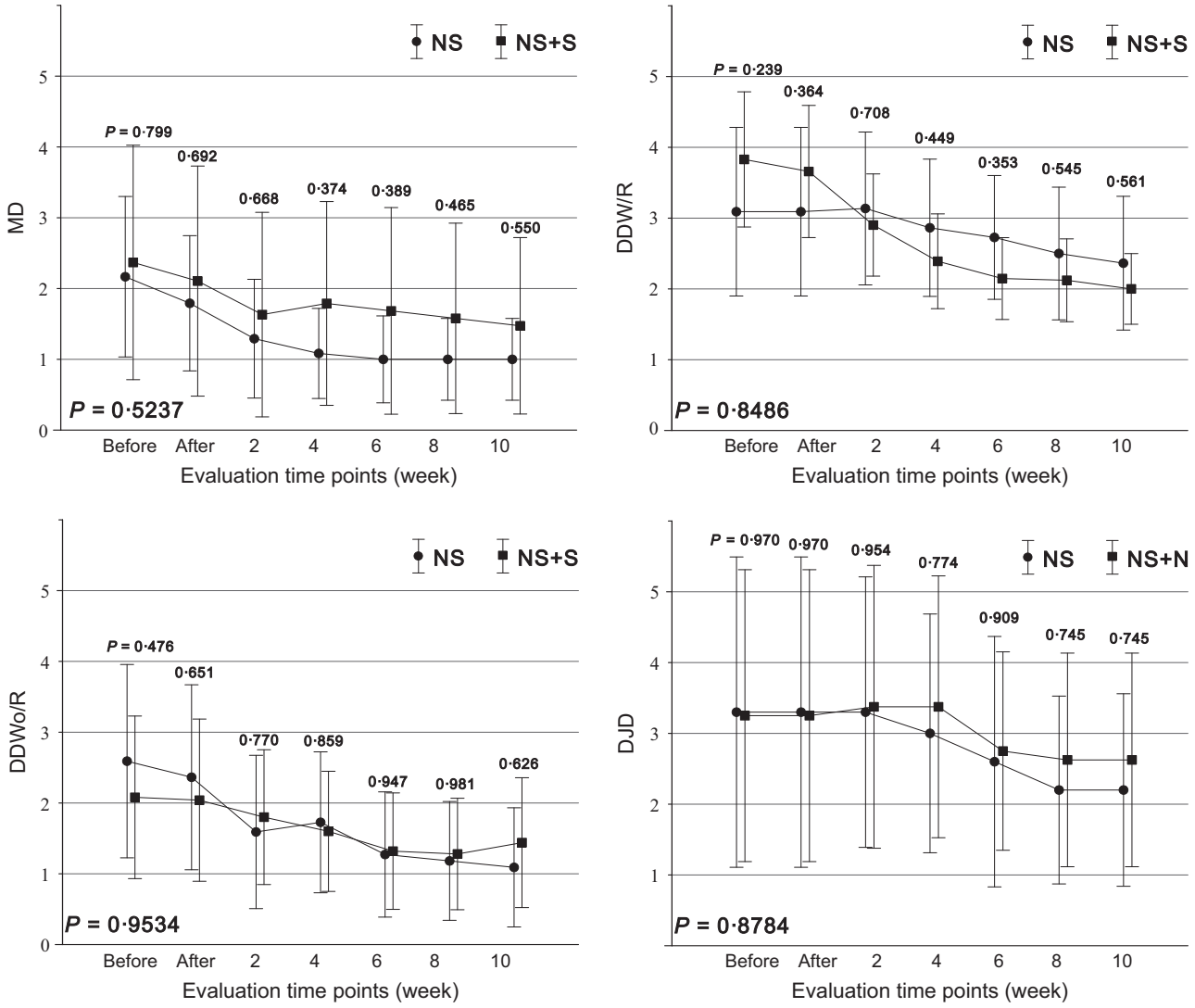

Fig. 5. Changes in the sound scores for each pathological type in the subgroup analysis. Data points indicate the mean and 95% confidence interval; the results of ANOVA and Scheffe's multiple comparison are shown with *P*-value.

The third limitation was that a non-treatment control group was not included in this study. Non-treatment subjects are necessary for strict evaluation of a treatment's effects. However, most patients with TMD indicated a desire for positive treatment during our explanation of this study, leading us to abandon the inclusion of a non-treatment group. Therefore, our results can only estimate the combined effect of splint therapy rather than the single effect.

However, the finding that perceptible sign and symptom improvements were achieved prior to splint setting during the participants' second visit should be emphasised (Fig. 2). Thus, we believe that the above-mentioned limitations did not affect our main finding concerning splint therapy in TMD treatment.

Conclusion

Our RCT and subgroup analysis revealed no significant differences between NS treatment and NS+S treatment with respect to mouth-opening limitation, oro-facial pain and TMJ sounds; the sole exception was a small difference in the subgroup analysis for one of the pathological states of TMD. These results did not confirm pathological specificity of splint therapy. We therefore conclude that splint therapy as an initial treatment for TMD is not supported when used

in combination with NS therapy. Given cost considerations and the desire for prompt treatment, comprehensive care rather than splint therapy alone might be considered to manage TMD.

Disclosure and acknowledgments

The study was conducted under the approval of the Ethical Review Board of the Nippon Dental University Niigata Hospital (ECNG-H-33) and under a petition for the University Hospital Medical Information Network in Japan (UMIN-CTR: UMIN000002711). None of the authors received support from a corporation or any funding for this study. We sincerely thank all the participants, practitioners and staff of the TMD and Bruxism Clinic, Niigata Hospital, Nippon Dental University for their cooperation in this long-term RCT. We are also grateful to Dr. Ikuo Miyagawa for advice regarding the statistical analyses.

References

1. Raphael KG, Marbach JJ. Widespread pain and the effectiveness of oral splints in myofascial face pain. J Am Dent Assoc. 2001;132:305–316.
2. Kuttila M, Le Bell Y, Savolainen-Niemi E, Kuttila S, Alanen P. Efficiency of occlusal appliance therapy in secondary otalgia and temporomandibular disorders. Acta Odontol Scand. 2002;60:248–254.
3. Ekberg E, Nilner M. Treatment outcome of appliance therapy in temporomandibular disorder patients with myofascial pain after 6 and 12 months. Acta Odontol Scand. 2004;62:343–349.
4. van der Glas HW, Buchner R, van Grootel RJ. Comparison of treatment options for myogenous temporomandibular dysfunction. Ned Tijdschr Tandheelkd. 2000;107:505–512.
5. Minakuchi H, Kuboki T, Matsuka Y, Maekawa K, Yatani H, Yamashita A. Randomized controlled evaluation of non-surgical treatments for temporomandibular joint anterior disk displacement without reduction. J Dent Res. 2001;80:924–928.
6. Truelove E, Huggins KH, Mancl L, Dworkin SF. The efficacy of traditional, low-cost and nonsplint therapies for temporomandibular disorder: a randomized controlled trial. J Am Dent Assoc. 2006;137:1099–1107; quiz 1169.
7. Niemelä K, Korpela M, Raustia A, Ylöstalo P, Sipilä K. Efficacy of stabilisation splint treatment on temporomandibular disorders. J Oral Rehabil. 2012;39:799–804.
8. Ficnar T, Middelberg C, Rademacher B, Hessling S, Koch R, Figgener L. Evaluation of the effectiveness of a semi-finished occlusal appliance–a randomized, controlled clinical trial. Head Face Med. 2013;9:5.
9. Magnusson T, Syrén M. Therapeutic jaw exercises and interocclusal appliance therapy. A comparison between two common treatments of temporomandibular disorders. Swed Dent J. 1999;23:27–37.
10. Glaros AG, Kim-Weroha N, Lausten L, Franklin KL. Comparison of habit reversal and a behaviorally-modified dental treatment for temporomandibular disorders: a pilot investigation. Appl Psychophysiol Biofeedback. 2007;32:149–154.
11. Haketa T, Kino K, Sugisaki M, Takaoka M, Ohta T. Randomized clinical trial of treatment for TMJ disc displacement. J Dent Res. 2010;89:1259–1263.
12. Michelotti A, Iodice G, Vollaro S, Steenks MH, Farella M. Evaluation of the short-term effectiveness of education versus an occlusal splint for the treatment of myofascial pain of the jaw muscles. J Am Dent Assoc. 2012;143:47–53.
13. Al-Ani MZ, Davies SJ, Gray RJ, Sloan P, Glenny AM. Stabilisation splint therapy for temporomandibular pain dysfunction syndrome. Cochrane Database Syst Rev. 2004;(1):CD002778.
14. Türp JC, Komine F, Hugger A. Efficacy of stabilization splints for the management of patients with masticatory muscle pain: a qualitative systematic review. Clin Oral Investig. 2004;8:179–195.
15. Forssell H, Kalso E. Application of principles of evidence-based medicine to occlusal treatment for temporomandibular disorders: are there lessons to be learned? J Orofac Pain. 2004;18:9–22.
16. Kreiner M, Betancor E, Clark GT. Occlusal stabilization appliances. Evidence of their efficacy. J Am Dent Assoc. 2001;132:770–777.
17. Fricton J, Look JO, Wright E, Alencar FG Jr, Chen H, Lang M *et al.* Systematic review and meta-analysis of randomized controlled trials evaluating intraoral orthopedic appliances for temporomandibular disorders. J Orofac Pain. 2010;24:237–254.
18. Schiffman EL, Truelove EL, Ohrbach R, Anderson GC, John MT, List T *et al.* The Research diagnostic criteria for temporomandibular disorders. I: overview and methodology for assessment of validity. J Orofac Pain. 2010;24:7–24.
19. Look JO, Schiffman EL, Truelove EL, Ahmad M. Reliability and validity of Axis I of the Research diagnostic criteria for temporomandibular disorders (RDC/TMD) with proposed revisions. J Oral Rehabil. 2010;37:744–759.
20. Gotou M, Nagata K, Sugawara Y. Short-term effectiveness of the jog-manipulation technique for temporomandibular disorder (TMD) patients with limited mouth-opening – a randomized controlled trial. J Jpn Soc TMJ. 2010;22:84–91.
21. Al Quran FA, Kamal MS. Anterior midline point stop device (AMPS) in the treatment of myogenous TMDs: comparison with the stabilization splint and control group. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2006;101:741–747.
22. de Felício CM, de Oliveira MM, da Silva MA. Effects of orofacial myofunctional therapy on temporomandibular disorders. Cranio. 2010;28:249–259.

23. Turner JA, Mancl L, Aaron LA. Short- and long-term efficacy of brief cognitive-behavioral therapy for patients with chronic temporomandibular disorder pain: a randomized, controlled trial. Pain. 2006;121:181–194.
24. Litt MD, Shafer DM, Kreutzer DL. Brief cognitive-behavioral treatment for TMD pain: long-term outcomes and moderators of treatment. Pain. 2010;151:110–116.
25. Ferrando M, Galdón MJ, Durá E, Andreu Y, Jiménez Y, Poveda R. Enhancing the efficacy of treatment for temporomandibular patients with muscular diagnosis through cognitive-behavioral intervention, including hypnosis: a randomized study. Oral Surg Oral Med Oral Pathol Oral Radiol. 2012;113:81–89.

Correspondence: K. Nagata, TMD and Bruxism Clinic, Niigata Hospital, The Nippon Dental University, 1-8 Hamaura-cho, Niigata City, Niigata, Japan.
E-mail: nagata@ngt.ndu.ac.jp

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Jog-type jaw manipulation technique. (a) A pivot made of gauze was set on the last molar. (b) The pivot closing type. (c) The side-to-side type. (d) The opening type.

Figure S2. Self-exercise of the jaw for TMD patients.

Figure S3. Stabilisation splint.

Figure S4. Bruxism controller. A bruxism controller was added to a stabilisation splint to disturb the eccentric movements of the mandible.

Figure S5. Evaluation and treatment chart.