The efficacy of traditional, low-cost and nonsplint therapies for temporomandibular disorder

A randomized controlled trial

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Background. Treatment recommendations for patients with painful temporomandibular disorders (TMDs) range from conservative treatments such as physiotherapy to aggressive and irreversible treatments such as restorative reconstruction and joint surgery.

Methods. The authors randomized 200 subjects diagnosed with TMD into three groups: usual conservative, dentist-prescribed self-care treatment without any intraoral splint appliance (UT); UT plus a conventional flat-plane hard acrylic splint (HS); and UT plus a soft vinyl (a low-cost athletic mouth guard) splint (SS). Subjects completed questionnaires and clinical examinations at three, six and 12 months.

Results. The authors observed no significant differences among the groups in TMD-related pain levels or other common signs and symptoms of TMD at baseline (BL) or at any follow-up. The changes from BL were comparable for all three groups. The authors did not note any significant differences at any follow-up for compliance with study protocols or for occurrences of adverse effects from either splint type. For HS versus SS, there were significant differences in rates of splint use, but these differences were not accompanied by differences in either self-reported symptoms or in clinical findings.

Conclusions. All patients improved over time, and traditional splint therapy offered no benefit over the SS splint therapy. Neither splint therapy provided a greater benefit than did self-care treatment without splint therapy.

Clinical Implications. These findings suggest that clinicians who treat patients with TMD should consider prescribing low-cost nonsplint self-care therapy for most patients.

Key Words. Temporomandibular disorders; myofascial pain; occlusal splint.

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Temporomandibular disorders (TMD) are associated with complaints of both acute and chronic orofacial pain.[1,2] Current concepts regarding the causes of TMD-related pain include excessive parafunctional jaw activities, behavioral stressors, and direct or indirect trauma to the jaws.[3,4] Treatment recommendations vary and range from rest and physiotherapy to more aggressive and irreversible treatments, including orthodontics, restorative care and joint surgery.[5-7] Situated in between are approaches characterized as reversible and conservative, involving the use of splints, physical therapy, self-care strategies and behavioral therapies.[8-10]

Self-care approaches include the use of heat and cold packs, jaw exercises, guidance in reduction of parafunctional jaw activities and progressive muscle relaxation. Outcomes from these interventions have demonstrated reductions in self-reported pain, pain on palpation, and improvements in range of motion and jaw function.[11-13]

Splint therapy, either alone or in combination with other

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treatments, is the most common form of TMD treatment used, even though data comparing splint and nonsplint therapy are not widely available.[14,15] Most studies of splint therapy have been limited by small sample size, lack of intent-to-treat analysis, use of short duration outcome (three months or less), inadequate control groups and failure to compare splint therapy with other forms of treatment (for example, customary and usual TMD care).[16-19]

Generally, studies focusing on splint therapy have shown a reduction in orofacial pain and other symptoms associated with TMD.[20-22] The types of splints studied, including choice of materials (for example, acrylic versus vinyl), have varied. It is difficult for dentists to make evidence-based decisions regarding splint therapy because few randomized controlled trials (RCT) comparing different splint designs have been conducted.[17,23,24] To complicate the matter further, several studies have suggested that the benefit of splint therapy may be through a placebo effect.[11,25]

The cost of splint therapy varies widely, depending on specific splint designs and fabrication methods (for example, jaw repositioning versus flat-plane designs; soft versus hard splint [HS] materials). The cost of splint therapy commonly ranges from several hundred to several thousand dollars.[14,26] The pattern emerging from the few well-conducted studies suggests that the mechanism of action of splints is unclear and possibly not dependent on specificity of design.

We conducted an RCT designed to compare self-care with higher-cost, heat-processed HSs; self-care with low-cost soft vinyl splints (SS); and self-care strategies alone. The primary objective of the study was to determine whether adding two types of splint therapy to self-care offered any advantage for reducing TMD-related pain and self-reported TMD symptoms over self-care strategies alone that included jaw relaxation, reduction of oral habits, heat packs, nonsteroidal anti-inflammatory drugs (NSAIDs) and jaw exercises.

SUBJECTS, MATERIALS AND METHODS

Subjects. We screened consecutive patients aged 18 to 60 years seen at the Orofacial Pain Clinic, Department of Oral Medicine, School of Dentistry, University of Washington, Seattle. All of the eligible subjects completed a survey that included the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)[27] questionnaire and additional questions about symptoms, treatment, and medical and behavioral status. The attending TMD clinical specialists (including E.T.) performed standardized RDC/TMD Axis I clinical examinations on the subjects at the initial visit; study personnel conducted these examinations at the research follow-up visits.

Inclusion criteria. We included subjects with a RDC/TMD Axis I diagnosis of myofascial pain (Group Ia or Ib) with or without a concurrent diagnosis of arthralgia (Group IIIa) or disk displacement with reduction (Group IIa), as well as an RDC/TMD Axis II Graded Chronic Pain score of Grade I (low pain) or Grade II (high pain), both of which had no or minimal pain-related psychosocial interference.[28]

Exclusion criteria. We excluded from the study subjects who had any other RDC/TMD Axis I diagnosis (for example, arthritis, disk displacement without reduction), any systemic arthritis or other serious medical complications, full dentures, major psychological disorders or the inability to communicate in English. We did not exclude patients who had a history of splint use, but we did exclude patients who used their current splints satisfactorily.

Study subjects provided written informed consent in accordance with human subjects requirements of the University of Washington, Seattle. We randomized the subjects into one of three study groups (Figure 1). We generated randomization assignments using randomly selected block sizes of six, nine or 12 and stratified them by provider. We concealed randomization to all study personnel until after we obtained the subjects' consent. The research dental hygienists conducting follow-up data collection were blinded to subject treatment group. The three groups were as follows:

- usual treatment (UT), n = 64: dentist-prescribed, conservative and reversible self-care strategies that required the dentist to follow a standardized treatment checklist that identifies all treatment recommendations (jaw relaxation, reduction of parafunction, thermal packs, NSAIDs, passive opening stretches and suggestions about stress reduction); we prescribed self-care strategies to all subjects, and we discouraged treatments such as narcotic analgesics, antidepressant medications and use of a nonstudy prescribed splint;
- HS, n = 68: UT plus fabrication of a hard

acrylic heat- (dental laboratory–) processed flat-plane maxillary splint, fitted by the treating dentist;

- SS, n = 68: UT plus fabrication at chairside of a soft thermoplastic vinyl athletic mouthguard splint (Figure 2) with the dentist supervising and directing the patient in splint fabrication.

Treatment protocols. At the baseline (BL) visit, we assessed all subjects, provided their first usual visit TMD clinic care (UT), enrolled them in the study and randomly assigned them to one of the three groups. For subjects in the HS group, we took impressions for splint fabrication. For subjects in the SS group, we took a bite registration using dental wax to provide an oral procedure of comparable duration. We instructed all of the subjects to return to the clinic in four weeks for follow-up and to call the study coordinator if any problems arose.

At the second visit, subjects in the HS group received the splint, which was a standard full-arch flat-plane maxillary acrylic splint adjusted to centric occlusion. Subjects in the SS group participated with the dentist in fabricating their splints according to the same criteria as for the HSs. We instructed subjects in both groups to wear their splints at night and two hours each day while awake throughout the three-month follow-up and 12-month follow-up, if possible or necessary. We also asked subjects to bring their splints to clinic visits and to discontinue using them if any problems developed. Subjects randomized to the two splint groups did not incur any splint-related costs or other out-of-pocket treatment costs beyond what subjects receiving UT alone incurred.

Follow-up data collection. We conducted follow-up visits at three, six and 12 months from the BL visit. These visits included having the subjects complete self-report questionnaires and receive an RDC/TMD clinical examination conducted by calibrated research dental hygienists blinded to study group assignment.

Study hypotheses and data analysis. We formed two hypotheses. The first was that at three months, the subjects in the HS and SS groups would demonstrate equivalent levels of short-term improvement in self-reported pain and in clinical measures such as range of motion, palpation pain and comparable use patterns of the appliance. The subjects in the UT group would show less short-term improvement than would those in the HS and SS groups.

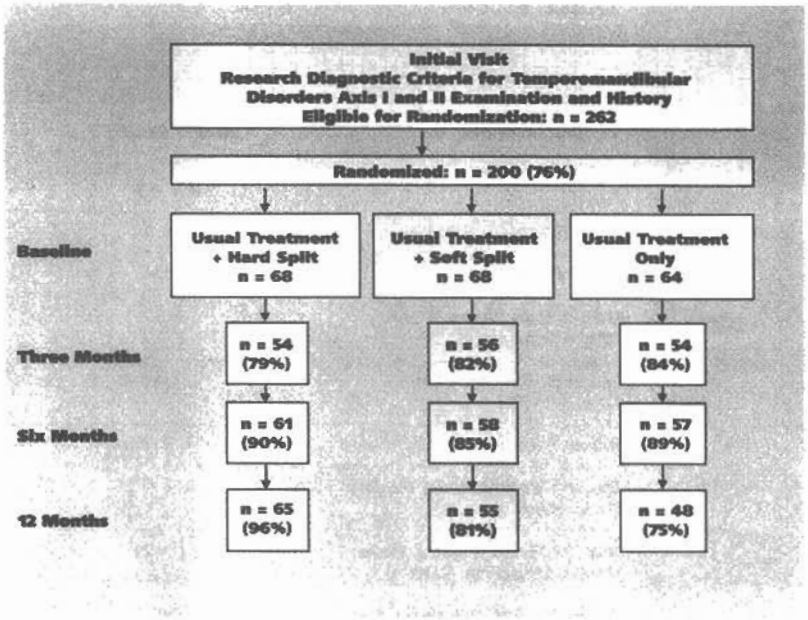

Figure 1. Study design.

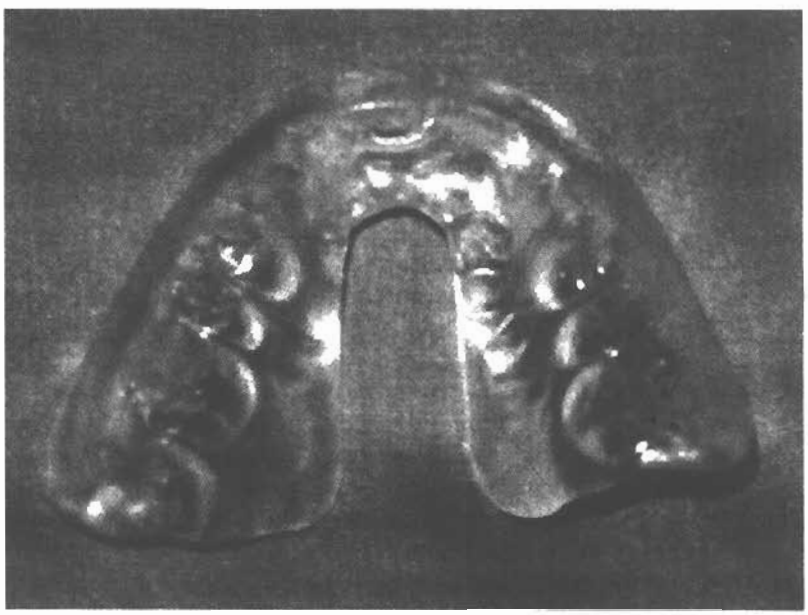

Figure 2. Soft splint. Image of Form Fit Regular mouthguard reproduced with permission of SafeTGard, Golden, Colo.

The second hypothesis was that at the six- and 12-month follow-up visits, subjects in the HS, SS and UT groups would show equivalent improvement in TMD-related pain and other clinical and self-report measures.

Statistical power. We based a priori sample size calculations for this trial on data from previous studies of patients at the Orofacial Pain Clinic, School of Dentistry, University of Washington, Seattle. Using the sample size calcula-

TABLE 1

Baseline demographics.

DEMOGRAPHIC	HARD SPLINT	SOFT SPLINT	USUAL TREATMENT	P
	n = 68	n = 68	n = 64	
Age (Mean ± SD*)	36 ± 11	35 ± 12	36 ± 11	.63
Female (%)	87	90	81	.41
Education More Than High School (%)	83	71	71	.20
Income $50,000 or Greater (%)	40	25	39	.04
Race Nonwhite (%)	8	13	4	.27
No. of Years With Facial Pain (Mean ± SD)	6 ± 9	5 ± 6	5 ± 5	.69
No. of Prior Facial Pain Visits (Median [IQR†])	2 (0-7)	3 (1-10)	3 (1-5)	.45
Prior Splint Therapy for Pain (%)	28	26	29	.94

* SD: Standard deviation.
† IQR: Interquartile range = 25th to 75th percentiles.

tions, we determined that 68 subjects per group would provide at least 80 percent power to detect a difference of 1.4 (or about a 35 percent difference) in characteristic pain intensity (CPI) levels between any two groups based on a one-way analysis of variance (ANOVA) at a .05 significance level, assuming a common standard deviation (SD) of 2.5.

Measures and data analyses. We included in our intent-to-treat analyses all randomized subjects for whom follow-up data were available, whether or not they actually received treatment. The primary outcome measure was CPI (the mean of present, average and worst TMD-related pain in the past two months).[29] Additional outcome measures included self-reported clenching, bruxing or both; limitations in jaw use; changes in clinical examination findings and diagnosis; pain duration; and compliance with treatment recommendations.

We used one-way ANOVA to compare the mean scores for the treatment groups at follow-up for continuous data measures, while we used χ^2 analysis to compare treatment proportions for categorical measures. We also used ANOVA to test for group differences based on change scores, and we conducted analysis of covariance (ANCOVA) to test for group differences at 12 months, adjusting for BL values. We noted that the findings using change scores and ANCOVA were similar to the ANOVA results; therefore, we present only the ANOVA results.

We collected data at three, six and 12 months. We reported short-term (three-month) and long-term (12-month) follow-up data because they are most relevant to study hypotheses, and because we typically found six-month data to be intermediate or equivalent to 12-month data.

RESULTS

Demographics. Table 1 shows the demographic and BL data. The average (± SD) age was 36 (± 12) years, and 86 percent of the subjects were female (data not shown). Through our analyses, we did not identify significant differences among the three treatment groups, except that there were fewer subjects in the SS group than in the HS and UT groups with mean incomes higher than $50,000.

Nonstudy participation and study dropouts. Of the 262 eligible patients, 200 (76.3 percent) agreed to enroll in our RCT. Thirty-seven (14 percent) of the 262 patients were ineligible because they already were using splints satisfactorily.

There were no statistically significant differences between study subjects and nonparticipants on demographic variables, ratings of facial pain or

self-reported jaw-related symptoms. Nonparticipants reported more prior health care visits for facial pain (median = 4.0) than did study subjects (median = 2.5; $P = .039$, Wilcoxon rank sum test). Follow-up rates were similar among groups at three and six months, but follow-up rates differed among groups at 12 months ($P = .004$, χ^2 test) (Figure 1). However, we observed no significant differences in the primary outcome measures or the demographic or clinical measures at BL, except that those who completed the study reported more prior health care visits for facial pain (median = 3.0) than did study dropouts (median = 1.0; $P = .059$), and those who completed the study reported more problems with joint clicking (90 percent) than did study dropouts (78 percent; $P = .062$, χ^2 test).

Self-report findings. *CPI.* At BL, the average CPI was comparable across groups (HS = 5.2, SS = 6.0, UT = 5.4; $P = .09$). The average score decreased significantly from a mean (± SD) of 5.5 (± 1.9) at BL to 3.1 (± 2.3) at 12-month follow-up ($P < .0001$). However, all of the groups showed comparable decreases in pain across the study ($P > .40$) (Figure 3).

Pain duration. All of the groups showed improvement over time for hours per day and days per month that the subjects were in pain. There were no differences among groups for pain duration at any follow-up (< .5 days versus ≥ .5 the days, $P = .12$) or for numbers of hours per day the subjects were in pain at BL or any follow-up ($P > .05$).

Self-reported TMD symptoms. There were no significant differences among groups at BL or at any follow-up in rates of any TMD symptoms reported (none/sometimes versus often/always) (Table 2). At the 12-month follow-up examination, subjects in the UT group reported the lowest rates of nocturnal clenching ($P = .076$), and subjects in the HS group reported the lowest rates of tinnitus ($P = .058$).

Clinical examination findings. *Range of motion.* There were no significant differences among groups at BL or at the three- and 12-month follow-up examinations for measurements of vertical jaw opening ($P > .2$) (Figure 4). We also found that measurements of lateral and protrusive jaw excursions were not statistically different across groups at any time ($P > .2$) (data not shown).

Joint sounds. We detected joint clicking on opening, closing or both in about one-half of all

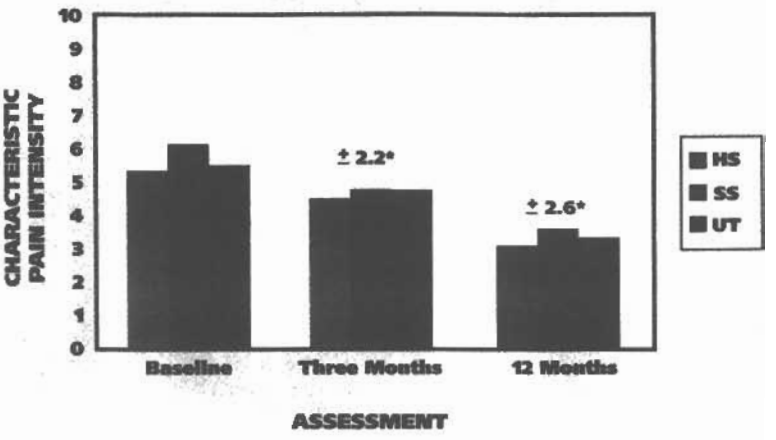

Figure 3. Characteristic pain intensity. HS: Hard splint. SS: Soft splint. UT: Usual treatment. * All other standard deviations = 1.9 to 2.1.

subjects (Table 3, page 1105) and found that it did not vary significantly among groups or over time ($P \geq .2$). Also, we detected no differences among groups in joint sounds during excursive movements either at BL or at the three- and 12-month follow-ups ($P > .2$) (data not shown).

Muscle and TMJ palpation pain. We observed no significant differences across groups in pain on clinician palpation of 16 extraoral masticatory muscle sites, four intraoral muscle sites or four TMJ sites at any time ($P > .2$) (Table 3). The number of painful palpation sites for extraoral muscles and the TMJ sites decreased from BL comparably for all groups, whereas the number of painful palpation sites for intraoral muscles did not change.

RDC/TMD diagnoses. Our study inclusion criteria required a Group I diagnosis of myofascial pain. There was a small difference in the distribution of subdiagnoses at BL (Table 4, page 1105), with the HS group having a higher rate of Group Ib diagnoses of myofascial pain with limited opening. At the three- and 12-month follow-ups, fewer subjects had a Group I diagnosis, with no differences among groups ($P > .3$). A Group IIa diagnosis (disk displacement with reduction) occurred in about one-third of each subject group at BL and decreased only modestly at 12 months, with no significant differences across groups ($P = .47$). At BL, 41 to 44 percent of subjects were diagnosed with arthralgia, but this percentage

TABLE 2

Self-reported TMD* symptoms present often/always.

TMD SYMPTOMS	ASSESSMENT	TREATMENT GROUP			P
		Hard Splint (%)	Soft Splint (%)	Usual Treatment (%)	
TMJ† Clicking/Popping Sounds	Baseline	66	53	65	.21
	Three-month	53	34	48	.11
	12-month	37	45	46	.54
TMJ Grating Sounds	Baseline	23	29	30	.64
	Three-month	19	13	13	.59
	12-month	14	17	19	.78
TMJ Locking/Catching	Baseline	19	19	17	.97
	Three-month	2	9	8	.21
	12-month	5	4	12	.15
Tinnitus	Baseline	17	37	22	.019
	Three-month	13	29	25	.12
	12-month	12	29	17	.058
Jaw Clenching-Diurnal	Baseline	40	28	43	.20
	Three-month	26	23	28	.93
	12-month	17	11	17	.59
Jaw Clenching-Nocturnal	Baseline	43	43	42	.98
	Three-month	50	41	37	.37
	12-month	42	41	23	.076
Limitations in Chewing	Baseline	22	16	19	.66
	Three-month	4	7	8	.70
	12-month	11	6	8	.59

* TMD: Temporomandibular disorder.
† TMJ: Temporomandibular joint.

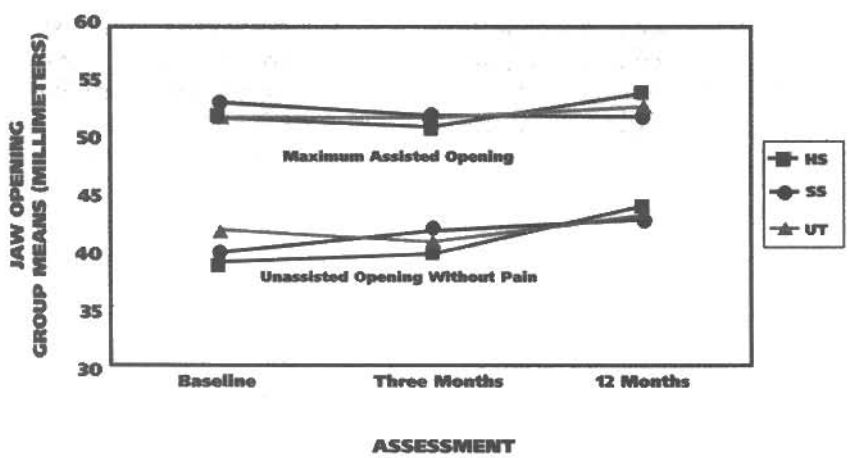

Figure 4. Jaw opening measurements. HS: Hard splint. SS: Soft splint. UT: Usual treatment.

was lower at follow-up visits, except for those in the UT group at 12 months. Few subjects (one or two per diagnosis) received a diagnosis of disk displacement without reduction (with or without limitation), osteoarthritis or osteoarthrosis at any follow-up.

Compliance with splint use. After the initial three months of use, self-reported compliance of HS or SS use was similar: 89 percent for HS and 75 percent for SS ($P = .059$). At 12 months, the subjects in the SS group reported lower splint use (30 percent) than the HS group (72 percent; $P < .001$). Three subjects in the HS group, six in the SS group and 10 in the UT group did not return to receive their study splint or to complete a second UT visit. No subjects reported an adverse effect with any of the treatments. Regardless, 10 subjects in the UT group (seven within 12 weeks of BL) and six subjects in the SS group (two within 12 weeks of BL) received a nonstudy HS during the 12 months of data collection. Analyses excluding these subjects or including them in the HS group improved the outcomes for the UT and SS groups but still did not result in differences among groups. The most common reasons for receiving a nonstudy-assigned splint were the

TABLE 3

Clinical examination findings.

CLINICAL FINDING	FOLLOW-UP	TREATMENT GROUP			P
		Hard Splint	Soft Splint	Usual Treatment	
TMD* Symptom					
Subjects' clicking on opening, closing or both (%)	Baseline	51	42	43	.53
	Three-month	52	51	50	.98
	12-month	57	46	64	.31
Pain on Palpation					
Mean (± SD†) number of extraoral muscle sites (0-16)	Baseline	7.3 (4.5)	6.7 (3.8)	6.1 (3.1)	.22
	Three-month	5.6 (5.4)	4.7 (4.1)	4.3 (4.0)	.45
	12-month	3.6 (4.1)	4.1 (4.4)	4.5 (4.5)	.69
Mean (± SD) number of intraoral muscles (0-4)	Baseline	3.0 (1.2)	3.0 (1.2)	2.7 (1.3)	.26
	Three-month	3.0 (1.4)	2.8 (1.6)	2.5 (1.6)	.37
	12-month	2.6 (1.6)	3.0 (1.4)	2.6 (1.4)	.41
Mean (± SD) number of TMJ‡ sites (0-4)	Baseline	1.5 (1.1)	1.2 (1.1)	1.5 (1.0)	.31
	Three-month	1.3 (1.5)	1.1 (1.4)	1.1 (1.3)	.64
	12-month	0.9 (1.1)	1.0 (1.0)	0.8 (0.9)	.74

* TMD: Temporomandibular disorder.
† SD: Standard deviation.
‡ TMJ: Temporomandibular joint.

TABLE 4

RDC/TMD* diagnoses.

GROUP DIAGNOSES	ASSESSMENT	TREATMENT GROUP			P
		Hard Splint (%)	Soft Splint (%)	Usual Treatment (%)	
Ia (Myofascial Pain)	Baseline	50	56	69	.08
	Three-month	19	32	21	.32
	12-month	32	39	48	.33
Ib (Myofascial Pain With Limited Opening)	Baseline	50	44	31	.08
	Three-month	16	14	14	.94
	12-month	25	21	21	.86
IIa (Disk Displacement With Reduction)	Baseline	38	32	37	.74
	Three-month	36	28	36	.71
	12-month	29	23	36	.47
IIIa (Arthralgia)	Baseline	41	43	44	.92
	Three-month	25	26	23	.94
	12-month	29	30	42	.46

* RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders.[27]

dentists' beliefs that the HS was necessary to decrease pain. There were no differences among groups for occlusal changes, either by self-report or by clinical evaluation using full-arch articulating paper.

Compliance with UT. Subjects reported compliance in following each recommendation of the standardized treatment checklist in equal proportions across all groups. We noted a modest difference among groups for decreasing clenching; 38 percent of subjects in the HS group reported "always" compared with 20 percent of subjects in the SS group and 40 percent of subjects in the UT group ($P = .049$).

Assessment of bias due to study dropouts. To assess for a potential bias from study dropout that may have been due to a deterioration of a subject's TMD condition, we took a conservative approach of carrying forward the last observation if the subject dropped out before month 12. None of our analyses demonstrated any differences among the three treatment groups on the primary outcome measures at 12 months. For example, the

mean CPI was similar between the treatment groups (HS = 3.0, SS = 3.5, UT = 3.4; P = .45), as well as for mean maximum unassisted opening (measured in millimeters) without pain (HS = 44, SS = 43, UT = 44; P = .72) and mean maximum assisted opening (HS = 54, SS = 52, UT = 53; P = .70).

DISCUSSION

We originally hypothesized that compared with UT alone, the UT plus HS or SS groups would demonstrate the most benefit after three months and that all groups would show equivalent levels of pain and symptom reduction by 12 months. In what we believe to be the largest RCT of evaluating efficacy of splints and self-care, we did not detect significant differences in any of the outcomes among the three treatment groups.

UT using self-care strategies alone was as effective in reducing characteristic TMD pain as UT plus HS or SS. We observed the same pattern of overall improvement, irrespective of treatment group, for all self-report and physical examination findings recorded. The equivalent improvement across the three groups is encouraging both for its clinical implications and because of the significant differences in cost and chair time required for the three treatment protocols. For example, the same amount of provider time was spent on UT, but there were additional time and costs associated with providing splint therapies. The over-the-counter soft vinyl splint blanks acquired from athletic suppliers for less than $1 took only eight chairside minutes (on average) to fabricate. The HS, by contrast, cost approximately $400 (including laboratory fees) and took 33 chairside minutes (on average), including time for creating study casts and for splint adjustment.

The results of the study may have been affected by a number of factors. While study research hygienists blinded to treatment groups collected all study measures, it was impossible to blind the clinicians treating the patients and to determine whether they inadvertently modified their treatment approach. We recorded specific UT components for each clinic visit and did not detect significant differences in treatments among groups in our ongoing monitoring. Another limitation of the study could be the decision to enroll patients with different types of TMD as long as they also had a concurrent diagnosis of myofascial pain.

Outcomes might have been different if we only included subjects with one type of TMD. It is well-known, however, that in clinical practice a large percentage of patients have more than one type of TMD, most typically a combination of myofascial pain, arthralgia and disk displacement with reduction (clicking). We designed our study to reflect that clinical reality. Furthermore, it appears that randomization was effective in distributing diagnostic subtypes of TMD comparably across groups. Additionally, we enrolled only subjects classified as "psychosocially functional" in our study, so we were not able to determine whether people experiencing more psychosocial dysfunction would have had the same outcomes.

CONCLUSIONS

The data from this RCT and others[12,13,25] lend support to even more conservative treatment protocols than have been advocated traditionally, since self-reported pain and symptoms and muscle and joint palpation scores decreased significantly across all three groups over time. Nonsplint, conservative treatments also appear to be as effective as the two splint types we included in our study in reducing self-reported parafunction. The apparent benefit of the nonsplint UT protocol suggests that patients of limited means and those without access to facilities that construct splints can be treated successfully with therapies that can be applied outside of traditional dental settings.

This study adds to our understanding of TMD and its treatments because, unlike most studies of splint therapy, we evaluated both splint and nonsplint treatments. To our knowledge, no study of TMD treatments has addressed both splint and nonsplint treatment outcomes in as large an RCT with long-term follow-up. ■

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