Effect of a Passive Jaw Motion Device on Pain and Range of Motion in TMD Patients Not Responding to Flat Plane Intraoral…

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ABSTRACT: This study was designed to compare the effectiveness of a passive jaw motion device, the Therabite, and wooden tongue depressors (WTD), in patients with temporomandibular joint and muscle disorders, who did not improve after manual manipulation of the mandible and flat bite plane therapy. Forty-three patients were enrolled in the study and were classified as joint or muscle groups according to the Research Diagnostic Criteria for TMD. Twenty-four were assigned to the joint group, and 19 patients were assigned to the muscle group. The patients were assigned at random to three treatment subgroups: 1. passive jaw motion device therapy (Therabite); 2. wooden tongue depressors therapy (WTD); and 3. control group. All subjects received flat bite plane appliance therapy throughout the treatment period. Mandibular range of motion was measured for maximum opening (MO), right and left lateral (Rt. Lateral, Lt. Lateral) and protrusive (Pr) movements. Pain level was also assessed at the beginning and at the end of the treatment. The results suggested that a passive jaw motion device is effective in increasing range of motion in both groups of temporomandibular disorder patients, joint (intra-capsular) and muscle (extracapsular). It also appears to decrease pain in patients with temporomandibular disorders. Pain was relieved to a greater degree in the muscle group than the joint group.

Limited joint mobility and joint pain are orthopedic conditions which are found frequently in patients who present to dental practitioners. This condition is referred to generally as mandibular hypomobility and can be of extracapsular or intracapsular origin.1-3 Intracapsular conditions include internal derangements, synovitis, osteoarthritis, and ankylosis. Extracapsular include myofascial pain dysfunction (MPD), muscle splinting or co-contraction, muscle contracture, trismus, fibrosis, infections, and tumors. Treatment choices may include bite plane therapy, physical therapy, occlusal adjustments and surgery.3-9 Costs for such treatments can range from moderate to high.

The need for early intervention by physical therapy for reduced TM joint range of motion in an acute condition has been stressed,10 and jaw hypomobility requires effective rehabilitation. A wide range of methods is used for TMJ mobilization therapy including the use of fingers, tongue depressors, and the use of mechanical or electrical devices.11-18

Conservative, noninvasive treatment should always be employed as initial therapy in these patients. Only after
such treatments have proven ineffective should more invasive approaches be undertaken. The Therabite (Therabite Corporation, Bryn Mawr, PA) is a patient operated passive jaw motion exercise device which is relatively inexpensive. Patient compliance and ease of use are important because these elements may contribute to the success of the treatment.

The objective of this study was to evaluate the effectiveness of the Therabite and standard wooden tongue depressors (WTD). Patients with restricted mouth opening and pain due to either an intracapsular or extracapsular etiology who did not respond to manual manipulation and bite plane therapy were studied.

Materials and Methods

Patients seeking treatment at the Gelb Orofacial Pain Center, Tufts University School of Dental Medicine, presenting with maximum interincisal openings (MO) of less than 35 mm were chosen initially. Based on the Research Diagnostic Criteria (RDC) guidelines, patients were then assigned to either intracapsular (Joint) or extracapsular (muscle) groups.

Manual manipulation of the mandible combined with flat bite plane therapy was provided as a first step for all patients for four weeks. Patients who exhibited a change in their maximal interincisal opening to a measurement greater than 35 mm were excluded from the study. The patients included in the study, 19 extracapsular and 24 intracapsular, were allocated randomly to three treatment groups. The three groups were the Therabite group, wooden tongue depressor group, and control group. MRI confirmed those patients whose clinical diagnosis indicated anterior disk displacement without reduction.

Measurements of MO, lateral left motion (Lt lateral), lateral right motion (Rt lateral), and protrusive motion (Pr) were measured prior to treatment using a standard plastic ruler. All measurements were recorded (in millimeters) at the end of each motion. All patients continued with flat bite plane appliances in addition to the passive jaw motion treatment: Therabite or wooden tongue depressors (WTD). Final measurements were taken after four weeks, at the conclusion of the study. The seven subjects in each control group received a total of eight weeks of flat bite plane therapy only.

The Therabite jaw motion rehabilitation device is a manually operated, patient controlled opening and closing device with an adjustable setting, set to the required vertical opening. Two tongue depressors were placed bilaterally between the upper and lower teeth, and tongue depressors were added to gently force mouth opening and achieve a moderate stretch.

Patients using the Therabite and the wooden tongue depressors were instructed to achieve and sustain a comfortable stretch of the jaw muscle. Patients were instructed to gently force their mouth open and hold the mouth open for one minute; then repeat this exercise three times in succession. This cycle of three openings was repeated five times per day.

Pain measurements were made using a 0 to 10 Numerical Rating Scale (NRS) with zero being no pain and 10 being the highest possible pain.

Results

The summary of the descriptive statistics of the data for the intracapsular group is presented in Table 1; the summary for the extracapsular group is presented in Table 2.

ANOVAs were performed on pre- and post-treatment differences in mean scores for both the intracapsular and extracapsular groups. Bonferroni tests were used to calculate significant changes between the three treatments (Therabite, WTD, and controls). Paired sample t-tests were used to compute changes in scores between the beginning and the end of the experiment.

Summary of ANOVAs, post hoc multiple comparisons and summary of paired t-tests for the intracapsular group are presented in Table 3 and for the extracapsular group, Table 4.

Intracapsular Group

Pain: ANOVA showed that the responses of the three treatment groups (Therabite, WTD, and control) were different (F=6.1, df=2, p=0.008). There was a significant reduction in pain for the subjects using the Therabite compared to subjects using wooden tongue depressors (p=0.013). The mean pain score difference between Therabite users and controls approached significance (p=0.053). There was no significant difference between the tongue depressors and the controls (p>0.05) (Table 3).

Pain from pre-experimental period to the fourth week was reduced significantly in the subjects using the Therabite (mean 5.6 to 2.7, t=4.2, p=0.002). No significant difference was found in the WTD (mean 4.0 to 4.0, t=0.0, p>0.05) or the control group (mean 4.4 to 3.9, t=0.7, p>0.05) (Table 3 and Figure 1).

Range of Motion: Maximum interincisal opening (MO): ANOVA showed different responses for the three
### Table 1
Mean, Range, and Standard Deviation of All Measures for Therabite, WTD, and Controls (Intracapsular Group)

<table>
<thead>
<tr>
<th>Intracapsular group</th>
<th>Therabite group (n=10)</th>
<th>WTD Group (n=7)</th>
<th>Controls (n=7)</th>
<th>Total (n=24)</th>
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treatment groups (F=13.8, df=2, p<0.000 1). Comparing the mean scores of the three groups, the Therabite group had greater increase than WTD (p=0.002) as well as controls (p<0.0001). There was no difference between the WTD group and controls (p>0.05) (Table 3).

For the subjects using the Therabite device, there was significant improvement in mouth opening after treatment (mean 27.2 to 35.4, t=-8.1, p<0.001). There was also significant improvement in the range of mouth opening for the WTD group (mean 29.3 to 32.0, t=-2.6, p=0.043). The control showed no significant change (mean 28.3 to 29.9, t=-1.9, p>0.05) (Table 3, Figure 2).

**Lateral movements:**

a. Right lateral: ANOVA showed no significant difference for the 3 groups (F=2.6, df=2, p=0.1) (Table 3, Figure 3).

b. Left lateral: ANOVA showed no different results for the 3 three treatment groups (F=1.7, df=2, p=0.22) (Table 3, Figure 4).

Protrusive movements: ANOVA showed no significant changes for the 3 groups (F=0.09, df=2, p=0.9) (Table 3, Figure 5).

**Extracapsular Group**

**Pain:** ANOVA showed that the responses of the three groups (Therabite, WTD, and controls) were different (F=9.2, df=2, p=0.002). Therabite produced significantly greater pain reduction than the WTD (p=0.050) and the control group (p=0.001). The mean of the pain scores for the WTD was not significantly different from that of the control group (p>0.05) (Table 4, Figure 1).

Pain was significantly reduced at the end of the

### Table 3

Summary of Analyses of Variance, Post Hoc Multiple Comparisons and Summary of Paired T-Tests for the Intracapsular Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>F tests</th>
<th>p-values</th>
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<td>Pain</td>
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<tr>
<td>Right lateral</td>
<td>F = 2.56</td>
<td>NS</td>
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<td>Left lateral</td>
<td>F = 1.66</td>
<td>NS</td>
</tr>
<tr>
<td>Protrusive</td>
<td>F = 0.90</td>
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<table>
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<tr>
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<th>Group</th>
<th>Mean difference</th>
<th>Sig. (p-value)</th>
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<td>Therabite vs. Control</td>
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<td>0.053</td>
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<td>WTD vs. Control</td>
<td>0.57</td>
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<td>Therabite vs. WTD</td>
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<td>Therabite vs. WTD</td>
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<table>
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<th>Mouth opening t-test p-value</th>
<th>Right lateral t-test p-value</th>
<th>Left lateral t-test p-value</th>
<th>Protrusive t-test p-value</th>
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<tr>
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<tr>
<td>Controls</td>
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**Table 4**

Summary of Paired T-Tests for the Extracapsular Group

<table>
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<tr>
<th>Group</th>
<th>Pain t-test p-value</th>
<th>Mouth opening t-test p-value</th>
<th>Right lateral t-test p-value</th>
<th>Left lateral t-test p-value</th>
<th>Protrusive t-test p-value</th>
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</thead>
<tbody>
<tr>
<td>Therabite</td>
<td>-4.20</td>
<td>0.002</td>
<td>8.13</td>
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<tr>
<td>WTD</td>
<td>0.00</td>
<td>NS</td>
<td>2.55</td>
<td>0.043</td>
<td>0.98</td>
</tr>
<tr>
<td>Controls</td>
<td>-0.73</td>
<td>NS</td>
<td>1.93</td>
<td>NS</td>
<td>1.00</td>
</tr>
</tbody>
</table>
study for subjects using the Therabite (mean 6.0 to 1.3, t=3.6, p=0.011). No significant change was observed for either the WTD (mean 4.2 to 2.8, t=1.9, p>0.05) or the control group (mean 4.5 to 4.3, t=0.8, p>0.05) (Table 4, Figure 1).

**Range of Motion**

Mean Maximum Mouth Opening (MO): ANOVA demonstrated a significant main effect (F=32.9, df 2, p<0.0001). Increase in MO for patients in the Therabite group was significantly greater (p<0.0001) than wooden tongue depressors as well as controls (p<0.001). WTD produced MO no different from the control group (p=0.23) (Table 4).

Subjects using the Therabite increased significantly (mean 25.3 to 41.6, t=7.1, p<0.001), as did the subjects using WTD (mean 29.6 to 34.4, t=-3.5, p=0.024) pre- and post-treatment. No significant change occurred in the control group (mean 26.5 to 27.3, t=-1.2, p>0.05) (Table 4, Figure 2).

**Lateral movements:**

a. Right Lateral: ANOVA showed that the responses for the three treatment groups were different (F=6.7, df 2, p=0.006). No significant change was found between the Therabite and the WTD (p=0.225). There was a significant change (p=0.005) between the mean of the Therabite and that of the control group. Between the mean of WTD and the control group there was no significant change (p=0.639) (Table 4).

There was a significant increase in the right lateral movement for Therabite (mean 6.4 to 10.6, t=-3.3, p=0.016) but no significant change in

---

Table 4
Summary of Analyses of Variance, Post Hoc Multiple Comparisons and Summary of Paired T-Tests for the Extracapsular Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>F tests</th>
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<th>Group</th>
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Variable Pain Mouth opening Right lateral Left lateral Protrusive
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<td>3.07</td>
<td>0.022</td>
<td>2.91</td>
<td>0.027</td>
</tr>
<tr>
<td>WTD (df=4)</td>
<td>-1.87</td>
<td>NS</td>
<td>3.54</td>
<td>0.002</td>
<td>2.09</td>
<td>NS</td>
<td>1.58</td>
<td>NS</td>
<td>0.41</td>
<td>NS</td>
</tr>
<tr>
<td>Controls (df=9)</td>
<td>-0.80</td>
<td>NS</td>
<td>1.24</td>
<td>NS</td>
<td>1.52</td>
<td>NS</td>
<td>2.25</td>
<td>NS</td>
<td>1.25</td>
<td>NS</td>
</tr>
</tbody>
</table>
the WTD (mean 6.8 to 8.6, t=-2.1, p>0.05) or the control group (mean 5.7 to 6.0, t=-1.2, p>0.05) (Table 4, Figure 3).

b. Left lateral: ANOVA showed that the responses for the 3 groups were different (F=6, df=2, p=0.01). While no significant change was found between the Therabite and the WTD (p=0.065), Therabite did show significant improvement over the control group (p=0.011). No difference was found between the WTD and the controls (p>0.05) (Table 4). There was a significant increase in the left lateral range of motion for subjects using the Therabite (mean 6.6 to 10.9, t=-3.1, p=0.022) but no significant change in both the WTD (mean 8.6 to 9.6, t=-1.6, p=0.189, and the controls (mean 5.5 to 6.1, t=-2.3, p=0.051). (Table 4, Figure 4).

Protrusive Movements: ANOVA showed that the three treatment groups made different responses (F=4.7, df=2, p=0.01). There was a significant increase of protrusion between Therabite and the WTD group (p=0.021) and Therabite with controls (p=0.032). No significant difference was found between the WTD and the controls (p>0.05) (Table 4).

A significant increase of protrusive movement was observed for the Therabite group (mean 4.7 to 7.9, t=-2.9, p=0.027) pre- and post-treatment and no significant change for the WTD (mean 5.8 to 5.6, t=-0.4, p>0.05) and the control group (mean 4.0 to 4.5, t=-1.2, p>0.05) (Table 4, Figure 5).

Discussion

The study was designed to determine whether the use of flat bite plane appliances in combination with either wooden tongue depressors (WTD), or the Therabite, could reduce pain and restore normal range of motion. In
order to standardize treatment and properly evaluate the Therabite device, flat plane appliances were used for all patients. Had the study been designed to evaluate appliance therapy only, the authors would have considered the use of repositioning appliances in some patients.

The results of this experiment demonstrated the effectiveness of the Therabite, while WTD and continued appliance therapy (control group) were significantly less effective. In extracapsular patients, mouth opening (MO) increased an average of 16.29 mm while in the intracapsular group an average increase of 8.2 mm occurred (Figure 2). Mean pain reduction was significantly greater in the Therabite group. The results were a pain reduction in the NRS score, from 5.6 to 2.7 in the intracapsular group, and from 6 to 1.3 in the extracapsular group (Figure 1). Lateral and protrusive measurements improved but to a smaller degree (Figures 3, 4, and 5).

Based on these findings, it was concluded that the Therabite device might be an effective adjunctive treatment for patients with mandibular hypomobility. Wooden tongue depressors are not as effective in improving the patients’ conditions.

These findings are consistent with those of a similar study by Karlis and Glickman, in which improvement of MO and pain measurements were found using the Therabite in patients with mandibular hypomobility over a 16-week period.

Lack of mobilization has profound effects on the TM joint and may contribute to the pathogenesis of TMJ disorders. The restoration of greater mobility has profound effects on the maintenance and integrity of the joint’s functional anatomy.

Mobilization of restricted joints is an accepted treatment that has proven to be effective in other joints in the body. Dramatic improvements have been reported in patients having restricted range of motion based on slow,
gentle mobilization of the restricted joints. Cartilage, lacking its own blood supply, depends upon the surrounding tissue to provide nutrition. This is accomplished by the movement of the joint causing pumping action to move synovial fluid into and throughout the joint space. Cohen, et al. in 1991 found that the use of the Therabite improved range of motion of postoperative patients at the rate of five times that of wooden tongue depressors over a sixty-day period. McCarty, et al. suggest the use of a mobilization regimen for postoperative care of joint surgery patients.

Bell described the use of the Therabite for post orthognathic cases in which the muscles of mastication have become tightened as a sequelae to surgery. In none of these cases, however, has there been any measurement of pain or lateral motion. The reasons for the effectiveness of this particular treatment may derive from the assisted opening, which follows the pathway defined by Posselt and allows for natural motion of the condyle in the fossa. Another reason for its success may include good patient tolerance of the device.

It may be simply that patient compliance is greater with Therabite than with wooden tongue depressors due to ease of use. The use of a patient diary detailing compliance may be helpful in clarifying this issue in future studies.

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