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

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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 (intracapsular) 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.

Dr. George E. Maloney graduated *Magna Cum Laude, Phi Beta Kappa* from the University of Massachusetts at Amherst with a B.S. in Biology. He received his D.M.D. from the University of Pennsylvania, and he completed a General Practice Residency at Worcester City Hospital. In 1990, he completed a program in the study of temporomandibular disorders and orofacial pain at the Gelb Orofacial Pain Center. He is currently an associate Clinical Professor at the center. His research interests include TMD-related ear pain, tinnitus and headache. Dr. Maloney is a Diplomate of the American Board of Orofacial Pain.

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.¹⁴ Patient compliance and ease of use are important because these elements may contribute to the success of the treatment.⁹

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,¹⁹ 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.²⁰

The wooden tongue depressors (WTD) used for this study were standard wooden tongue depressors measuring approximately 1.25 mm in thickness and 14 mm in

width.¹⁷ 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.²¹⁻²⁴

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)

Intracapsular group	Pain Pre	Pain Post	Mouth		Right		Left		Protrusive Pre	Protrusive Post	
			Opening Pre	Opening Post	Lateral Pre	Lateral Post	Lateral Pre	Lateral Post			
Therabite group (n=10)	Mean	5.6000	2.7000	27.2000	35.4000	6.9000	9.4000	6.4000	8.2000	6.3000	6.9000
	Minimum	.00	.00	22.00	30.00	3.00	7.00	5.00	5.00	3.00	3.00
	Maximum	9.00	5.00	31.00	41.00	10.00	11.00	10.00	11.00	10.00	11.00
	Range	9.00	5.00	9.00	11.00	7.00	4.00	5.00	6.00	7.00	8.00
	Std. Dev.	2.4129	2.0575	3.2592	3.9215	2.2336	1.3499	1.6465	2.2998	2.1108	2.5144
WTD Group (n=7)	Mean	4.0000	4.0000	29.2857	32.0000	5.8571	6.8571	8.0000	8.4286	6.1429	6.5714
	Minimum	.00	.00	25.00	27.00	4.00	4.00	5.00	5.00	4.00	4.00
	Maximum	8.00	8.00	34.00	42.00	8.00	12.00	12.00	12.00	10.00	10.00
	Range	8.00	8.00	9.00	15.00	4.00	8.00	7.00	7.00	6.00	6.00
	Std. Dev.	3.5119	3.3166	3.7289	5.0662	1.4639	2.9114	2.5820	2.9921	2.2678	2.5071
Controls (n=7)	Mean	4.4286	3.8571	28.2857	29.8571	6.8571	7.0000	4.1429	4.5714	3.5714	4.2857
	Minimum	.00	.00	20.00	20.00	4.00	4.00	2.00	3.00	1.00	1.00
	Maximum	10.00	7.00	35.00	40.00	10.00	10.00	5.00	7.00	6.00	6.00
	Range	10.00	7.00	15.00	20.00	6.00	6.00	3.00	4.00	5.00	5.00
	Std. Dev.	3.2071	2.4103	6.0474	6.4660	2.4785	2.3094	1.0690	1.2724	1.9881	1.7043
Total (n=24)	Mean	4.7917	3.4167	28.1250	32.7917	6.5833	7.9583	6.2083	7.2083	5.4583	6.0417
	Minimum	.00	.00	20.00	20.00	3.00	4.00	2.00	3.00	1.00	1.00
	Maximum	10.00	8.00	35.00	42.00	10.00	12.00	12.00	12.00	10.00	11.00
	Range	10.00	8.00	15.00	22.00	7.00	8.00	10.00	9.00	9.00	10.00
	Std. Dev.	2.9485	2.5353	4.2561	5.4212	2.0834	2.4223	2.3215	2.7972	2.3770	2.4931

Table 2
Mean, Range, and Standard Deviation of All Measures for Therabite, WTD,
and Controls (Extracapsular Group)

Extracapsular group		Pain Pre	Pain Post	Mouth Opening		Right Lateral		Left Lateral		Protrusive Pre	Protrusive Post
				Pre	Post	Pre	Post	Pre	Post		
Therabite group (n=7)	Mean	6.000	1.2857	25.2857	41.5714	6.4286	10.5714	6.5714	10.8571	4.7143	7.8571
	Minimum	2.00	.00	17.00	36.00	2.00	8.00	4.00	8.00	2.00	4.00
	Maximum	10.00	3.00	34.00	51.00	10.00	12.00	9.00	14.00	8.00	11.00
	Range	8.00	3.00	17.00	15.00	8.00	4.00	5.00	6.00	6.00	7.00
	Std. Dev.	2.9439	1.2536	6.3957	5.4423	2.6992	1.5119	1.9024	2.1931	2.1381	2.2678
WTD Group (n=5)	Mean	4.2000	2.8000	29.6000	34.4000	6.8000	8.6000	8.6000	9.6000	5.8000	5.6000
	Minimum	.00	.00	27.00	29.00	5.00	7.00	6.00	8.00	5.00	5.00
	Maximum	8.00	8.00	33.00	42.00	9.00	10.00	13.00	12.00	7.00	6.00
	Range	8.00	8.00	6.00	13.00	4.00	3.00	7.00	4.00	2.00	1.00
	Std. Dev.	2.8636	3.3466	2.3022	5.2249	1.4832	1.3416	2.9665	2.1909	.8367	.5477
Controls (n=10)	Mean	4.5000	4.3000	26.5000	27.3000	5.7000	6.0000	5.5000	6.1000	4.000	4.5000
	Minimum	.00	.00	20.00	20.00	3.00	3.00	3.00	3.00	2.00	2.00
	Maximum	8.00	8.00	35.00	36.00	9.00	8.00	8.00	8.00	6.00	8.00
	Range	8.00	8.00	15.00	16.00	6.00	5.00	5.00	5.00	4.00	6.00
	Std. Dev.	2.2730	2.4967	5.4620	5.1651	1.6364	1.6330	1.6499	2.0248	1.2472	1.7795
Total (n=22)	Mean	4.9091	3.0000	26.8182	33.4545	6.1818	8.0455	6.5455	8.4091	4.6364	5.8182
	Minimum	.00	.00	17.00	20.00	2.00	3.00	3.00	3.00	2.00	2.00
	Maximum	10.00	8.00	35.00	51.00	10.00	12.00	13.00	14.00	8.00	11.00
	Range	10.00	8.00	18.00	31.00	8.00	9.00	10.00	11.00	6.00	9.00
	Std. Dev.	2.6170	2.6547	5.3062	8.0813	1.9673	2.5162	2.3243	2.9866	1.6197	2.2601

Table 3
Summary of Analyses of Variance, Post Hoc Multiple Comparisons and
Summary of Paired T-Tests for the Intracapsular Group

Variable	F tests		p-values	
Pain	F _{df2} = 6.10		0.008	
Mouth opening	F _{df2} = 13.77		0.00001	
Right lateral	F _{df2} = 2.56		NS	
Left lateral	F _{df2} = 1.66		NS	
Protrusive	F _{df2} = 0.90		NS	

Variable	Group	Mean difference	Sig. (p-value)
Pain	Therabite vs. WTD	2.90	0.013
	Therabite vs. Control	2.33	0.053
	WTD vs. Control	0.57	NS
Mouth opening	Therabite vs. WTD	5.49	0.002
	Therabite vs. Control	6.63	<0.0001
	WTD vs. Control	1.14	NS
Right lateral	Therabite vs. WTD	1.50	NS
	Therabite vs. Control	2.36	NS
	WTD vs. Control	0.86	NS
Left lateral	Therabite vs. WTD	1.37	NS
	Therabite vs. Control	1.37	NS
	WTD vs. Control	0.0	NS
Protrusive	Therabite vs. WTD	0.17	NS
	Therabite vs. Control	0.11	NS
	WTD vs. Control	0.28	NS

Variable Group	Pain		Mouth opening		Right lateral		Left lateral		Protrusive	
	t-test	p-value	t-test	p-value	t-test	p-value	t-test	p-value	t-test	p-value
Therabite (df=9)	-4.20	0.002	8.13	0.0001	3.21	0.01	3.04	0.014	0.92	NS
WTD (df=6)	0.00	NS	2.55	0.043	0.98	NS	0.57	NS	0.70	NS
Controls (df=6)	-0.73	NS	1.93	NS	1.00	NS	1.44	NS	0.92	NS

treatment groups ($F=13.8$, $df=2$, $p<0.0001$). 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 4
Summary of Analyses of Variance, Post Hoc Multiple Comparisons and Summary of Paired T-Tests for the Extracapsular Group

Variable	F tests		p-values	
Pain	F _{df2} = 9.21		0.002	
Mouth opening	F _{df2} = 32.85		0.00001	
Right lateral	F _{df2} = 6.74		0.006	
Left lateral	F _{df2} = 5.96		0.01	
Protrusive	F _{df2} = 5.73		0.011	

Variable	Group	Mean difference	Sig. (p-value)
Pain	Therabite vs. WTD	3.31	0.05
	Therabite vs. Control	4.51	0.001
	WTD vs. Control	1.20	NS
Mouth opening	Therabite vs. WTD	11.49	<0.0001
	Therabite vs. Control	15.49	<0.0001
	WTD vs. Control	4.00	NS
Right lateral	Therabite vs. WTD	2.34	NS
	Therabite vs. Control	3.84	0.005
	WTD vs. Control	1.50	NS
Left lateral	Therabite vs. WTD	3.29	NS
	Therabite vs. Control	3.69	0.011
	WTD vs. Control	0.40	NS
Protrusive	Therabite vs. WTD	3.34	0.021
	Therabite vs. Control	2.64	0.032
	WTD vs. Control	0.70	NS

Variable Group	Pain		Mouth opening		Right lateral		Left lateral		Protrusive	
	t-test	p-value	t-test	p-value	t-test	p-value	t-test	p-value	t-test	p-value
Therabite (df=6)	-3.61	0.011	7.16	0.0001	3.33	0.016	3.07	0.022	2.91	0.027
WTD (df=4)	-1.87	NS	3.54	0.002	2.09	NS	1.58	NS	0.41	NS
Controls (df=9)	-0.80	NS	1.24	NS	1.52	NS	2.25	NS	1.25	NS

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

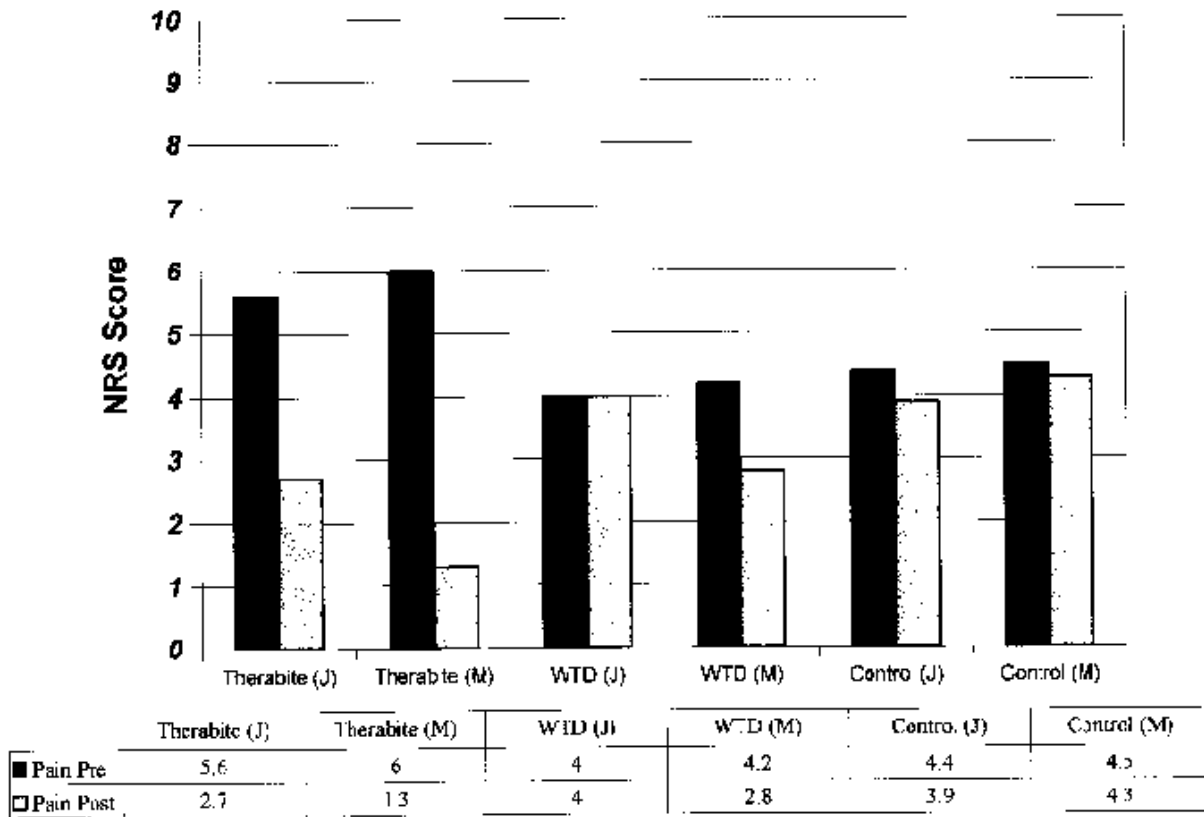


Figure 1
Mean pain scores pre- and post treatment for the intracapsular (J) and the extracapsular (M) groups.

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

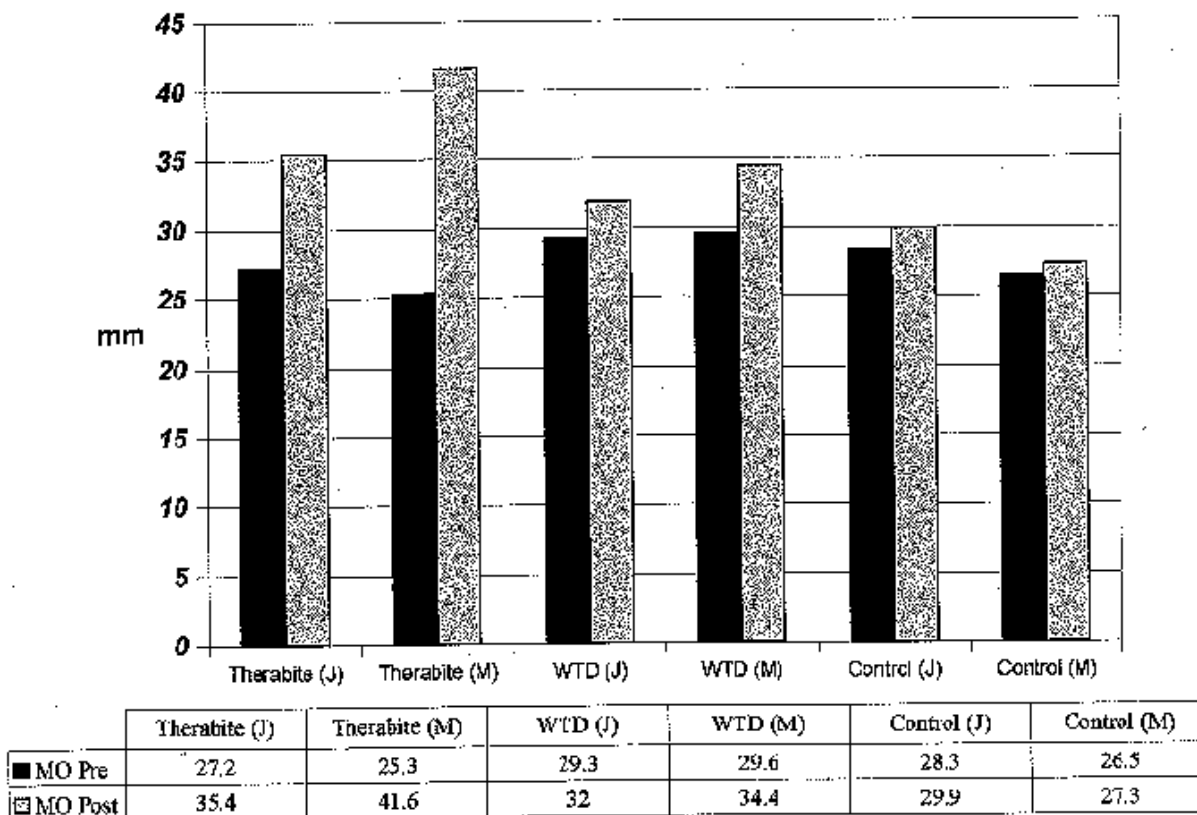


Figure 2
Mean mouth-opening pre- and post-treatment for the intracapsular (J) and the extracapsular (M) groups.

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,²⁵ 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 TMJ 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.^{11,26}

Mobilization of restricted joints is an accepted treatment that has proven to be effective in other joints in the body.²⁷ Dramatic improvements have been reported in patients having restricted range of motion based on slow,

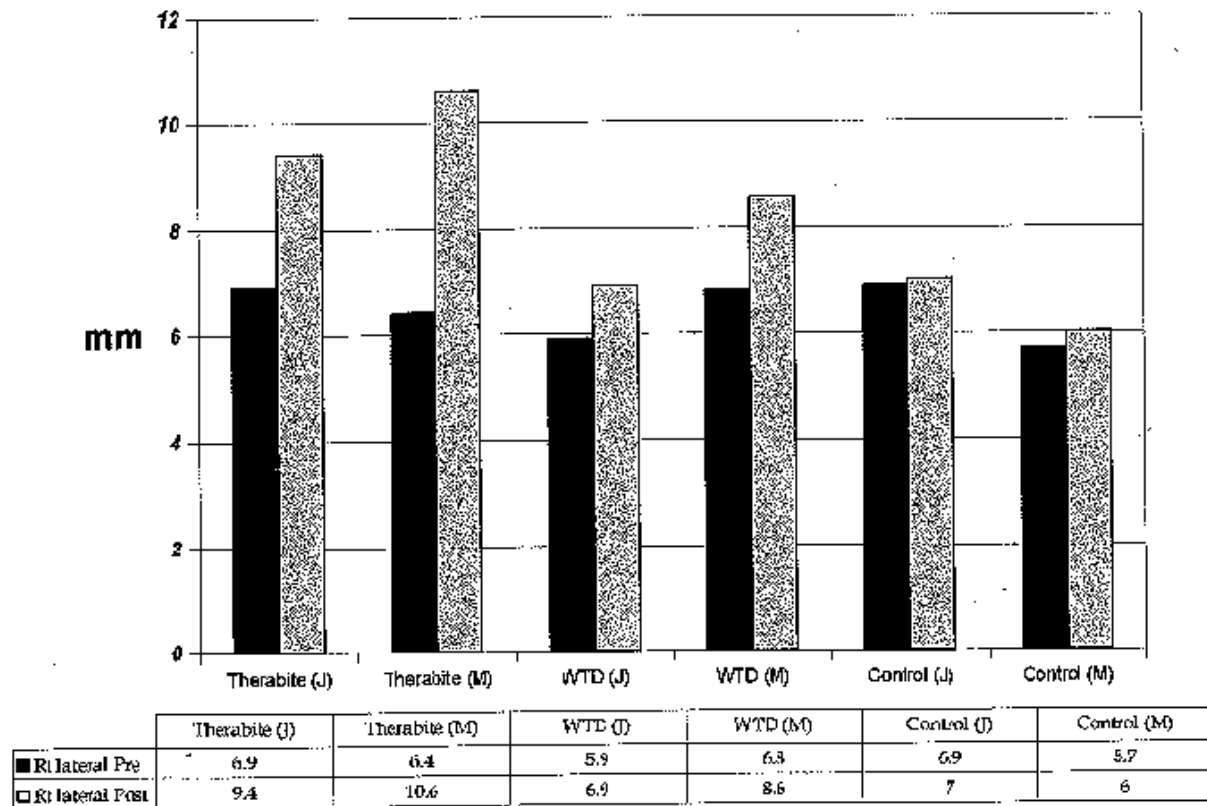


Figure 3
Mean right lateral movement measurements pre- and post-treatment for the intracapsular (J) and the extracapsular (M) groups.

gentle mobilization of the restricted joints.²⁸ 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.²⁹ Cohen, et al.²⁰ 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.²⁷ suggest the use of a mobilization regimen for postoperative care of joint surgery patients.

Bell^{12, 30} 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

Posselt³¹⁻³³ 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.

Acknowledgment

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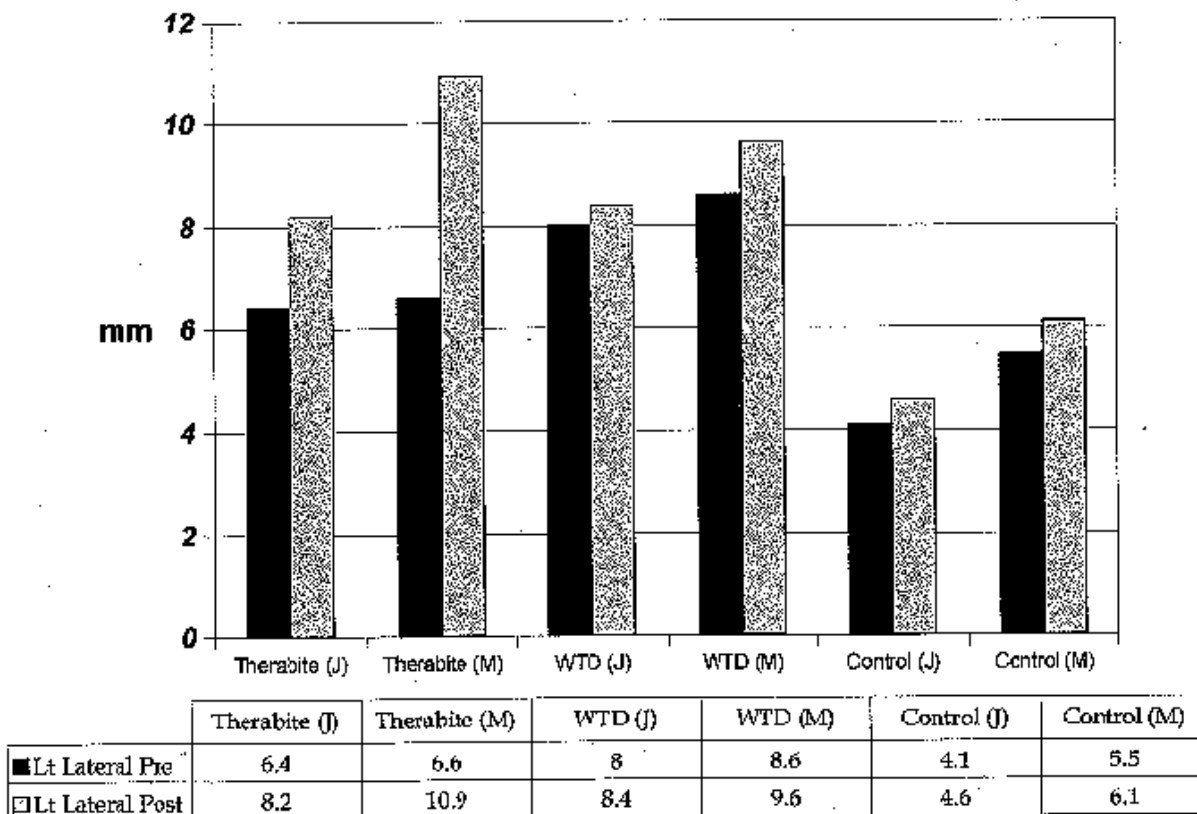


Figure 4
Mean left lateral movement measurements pre- and post-treatment for the intracapsular (J) and the extracapsular (M) groups.

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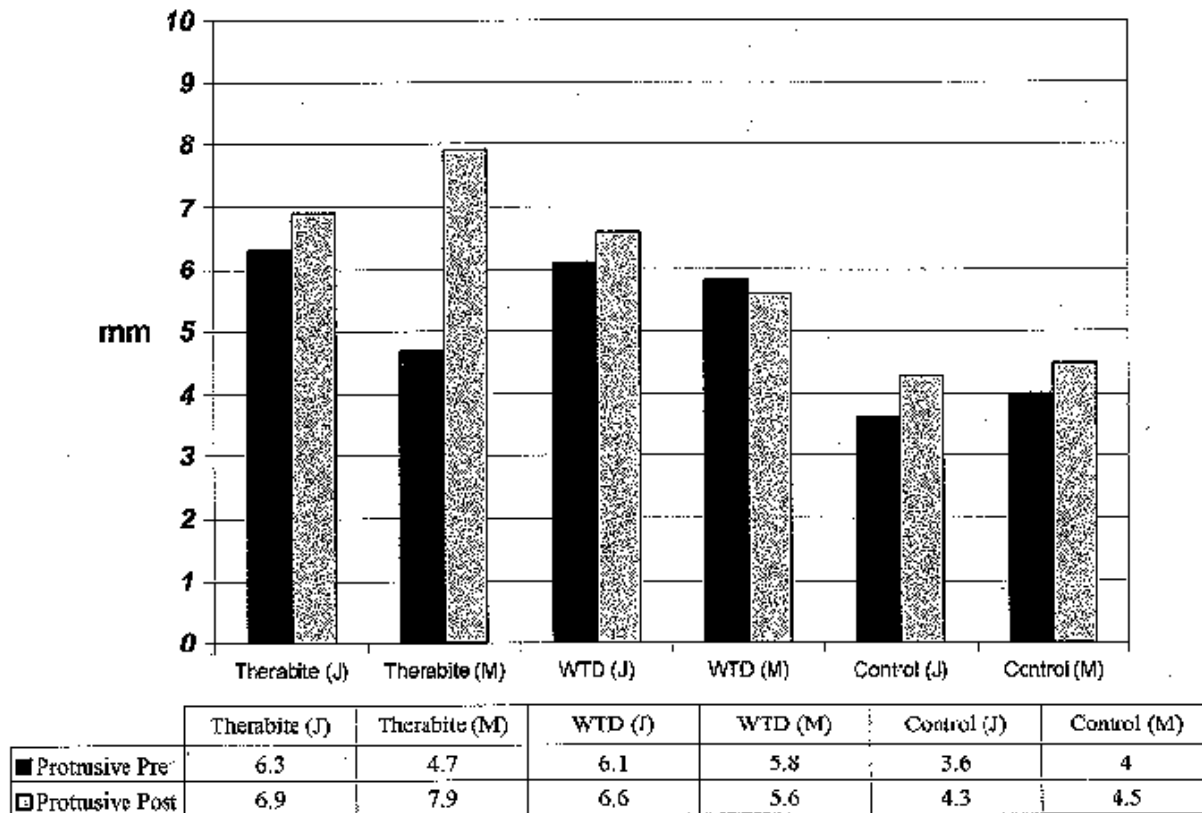


Figure 5
Mean protrusive movement measurements pre- and post-treatment for the intracapsular (J) and the extracapsular (M) groups.

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