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Mandibular Symphyseal Distraction Osteogenesis (MSDO): Association with Temporomandibular Dysfunction (TMD) Symptoms

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Mandibular Symphyseal Distraction Osteogenesis (MSDO): Association with Temporomandibular Dysfunction (TMD) Symptoms

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

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Abstract

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By Sheldon Anthony Bates, DMD

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Background: Transverse mandibular discrepancies are often overlooked during orthodontic treatment. MSDO is a treatment to address this issue, but much debate exists over the long-term implications on the temporomandibular joint (TMJ). Few studies have sample sizes sufficient to draw clear conclusions about the impact of MSDO on TMJ health. **Materials and Methods**: This study evaluated private practice records including 49 MSDO patients and 57 traditionally-treated controls. The subjects were assessed by TMD exams that evaluated jaw pain and discomfort using visual analog scales, range of motion for opening, right and left lateral, and protrusive movements, and the presence of clenching, bruxism, clicking, crepitus, and pain on TMJ and muscle palpation. **Results**: No significant changes between the groups were noted during treatment or follow-up. **Conclusions**: Compared to controls, MSDO patients did not

experience any increase in TMD symptoms. Distraction and control patients were not significantly different in any of the categories.

Introduction

Transverse skeletal discrepancies are routinely diagnosed and corrected during the course of orthodontic treatment. This form of correction is predictable in the maxillary arch but not in the mandibular arch. Because most transverse orthodontic correction occurs in the maxilla to accommodate the mandibular width, true transverse skeletal discrepancies in the mandible are often overlooked. Mandibular symphyseal distraction osteogenesis (MSDO) has emerged as a treatment modality for mandibular transverse discrepancies associated with severe crowding or for Brodie bites that cannot be corrected with traditional orthodontic therapies. Traditional methods of mandibular expansion generally focused on compensatory dental correction, including flaring of the incisors and using appliances such as the lip bumper, Schwarz and functional appliances. These dental changes are very difficult to maintain without long-term fixed retention.[1] The skeletal expansion obtained through MSDO has been shown to be quite stable even when additional dental corrections relapse.[2] Being a treatment in its relative infancy, few studies have been conducted on the effects of MSDO in humans and long-term follow-up studies are exceedingly rare. In fact, most research on the topic has been conducted within the last decade.

History

The concept of distraction osteogenesis was introduced in the early twentieth century (1905) by Alessandro Codivilla, and it was met with numerous complications. The primary application of this procedure at the time was for the lengthening of long bones, particularly lower limbs. Codivilla's first report was the case of a fractured femur. Unfortunately, these procedures involved significant infection, pain, and nerve and soft tissue damage. Gavril Abramovich Ilizarov improved the technique in the mid-twentieth century. Ilizarov developed an external fixator in 1934 which reduced the frequency and severity of complications. Infection, pain, and nerve and soft tissue damage still occurred but less frequently than without Ilizarov's device.

In 1927, Andrew H. Rosenthal first applied the concepts of osteodistraction to the mandible. The procedure was used for gradual anterior-posterior correction rather than a surgical advancement. Crawford in 1948 was the first to apply distraction osteogenesis to the widening of the mandible. In this case, the patient had a symphyseal fracture of the mandible and loss of a central incisor resulting in the subsequent collapse of the hemimandibles at the midline. The distractor was used to improve the alignment of the hemimandibular segments.

One of the first published descriptions of its use in intentional mandibular skeletal expansion in conjunction with orthodontic treatment was in the early 1990s by Cesar Guerrero.[3] Guerrero utilized mandibular symphyseal distraction osteogenesis to address mandibular transverse discrepancies. Today, distraction screws range from seven to eighteen millimeters. Since the introduction of the original distraction appliance, numerous iterations of the MSDO device have been developed.

Types of Distractors

Three types of distractors have been used to accomplish mandibular skeletal expansion—tooth-borne, bone-borne and hybrid (both tooth- and bone-borne). In a retrospective analysis of MSDO, Alkan et al[4] noted that most complications were observed in bone-borne appliances but also acknowledged that the complications could be due to type of distractor and surgeon's experience, as these were not controlled in the study. Some authors, such as Basciftci et al[5] and

Del Santo et al[2], suggested that tooth-borne appliances have a tendency to disproportionately expand at the alveolar crest while others, such as Alkan et al[4], maintained that as long as bony resistance was removed, even a tooth-borne appliance would transmit expansion forces to the skeletal base and cause even expansion along the osteotomy cuts.

Procedure

The mandibular distraction procedure consists of pre-distraction orthodontics, active distraction and post-distraction orthodontics. Initial alignment occurs in the maxillary arch with some alignment in the mandibular arch. In some cases mandibular incisors need root divergence in the pre-distraction phase to allow for the midline osteotomy during surgery. Depending on the type of distractor used, the appliance can be placed prior to surgery (tooth-borne distractor) or during surgery prior to the osteotomy (bone-borne or hybrid distractor). During surgery, typically a midline osteotomy is performed. Distraction is initiated after a 7-10 day waiting period to allow the bony callus to form. The rate of distraction is conducted at 1.0 mm per day until adequate expansion has been achieved. This is followed by a consolidation period of 8-12 weeks prior to active orthodontic tooth movement into the regenerate bone.

One important consideration in distraction osteogenesis is the rate at which the distraction occurs. If the bony callus is distracted too quickly, fibrous union of the segments will result. If it is distracted too slowly, then premature healing and fusion of the segments will result, in which case the required amount of distraction is not achieved. Al Ruhaimi et al[6] in 2001 found that in rabbit mandibles the distraction rate of 0.5 mm of distraction per day resulted in immature bone healing, 1.0 mm per day resulted in good healing, and 2.0 mm per day resulted in either incomplete osteogenesis or fibrous union of the bony segments. These results concur with those of Ilizarov's canine tibia distraction.

MSDO and tooth movement

As MSDO was developing, the ability, timing and stability of moving teeth into the newly-formed bone remained uncertain. Duran et al[7] evaluated the distraction site microscopically after obtaining bone biopsies of the site during the appliance removal surgery. They concluded that the bone that was formed was of the membranous or woven type and that movement of teeth into the area did not affect the bone formation, maturation, or regeneration. Some authors suggested that teeth could be moved quickly into the regenerate bone without deleterious effects.[8,9,10] Others, however, suggested waiting until radiographic evidence of bone formation is present prior to moving teeth into the regenerate bone.[11,12] Most studies in this area have evaluated tooth movement into regenerate bone in animal models with some limited studies examining human bone biopsies. One challenge with moving teeth into the regenerate is the occurrence of root resorption. In the beagle model, Nakamoto et al[13] moved teeth into regenerate bone at 2 weeks (Group 1) and 12 weeks (Group 2). Compared to controls, tooth movement was much more rapid in both study groups, and the teeth in Group 1 moved much more rapidly than those in group 2. Both groups experienced significant root resorption with group 1 having more. The authors opined that high cellular activity may explain the increase in resorption. Samchukov et al[14] described healing patterns of post-distraction regenerate bone and classified them from "absence of mineralization" to "reformation of both cortices." Chung et al[15] used this classification system to evaluate 11 patients during their MSDO treatment. They concluded that the healing patterns of those patients were varied but all patients showed evidence of mineralization within 3 weeks. The current consensus is that an 8-12 week waiting period is a reasonable time to wait prior to moving teeth into regenerate bone.

TMD

MSDO has been suggested by some authors[16] to cause harmful changes in the temporomandibular joint due to the suspected rotation of the mandibular condyles in their respective fossae. However, Landes et al[17] concluded that only minimal changes occur in condylar positioning in post-MSDO patients at 3 month follow up. This was further supported by Ploder et al[18] who concluded via three-dimensional analysis that the effects of expansion diminish from the symphysis to the gonial angle. Samchukov et al[19] suggested, based on a mathematical model, that 10 mm of expansion at the symphysis would result in approximately 3° of rotation at the condyle. Braun et al[20] suggested, however, that MSDO results in linear expansion from symphysis to condyle, but also stated that TMD symptoms did not seem to increase during MSDO. In this study superimpositions of submentovertex radiographs were measured prior to distraction and immediately after distraction using bilateral indexing wires as a reference. This study noted no increases in TMD symptoms in patients who started as asymptomatic and no increase in symptoms for those patients who presented with TMD. In a 6-year follow-up study by Sukurica et al[21] on a single patient with 8 mm of crowding and no prior TMD, no crowding and no TMD was noted at re-evaluation. In 2009 Gunbay et al[22] evaluated 7 patients with MSDO over the course of approximately 40 months. Using CT scans, the calculated rotation at the condyle was approximately 2.5-3.0°. During the distraction period, 3 patients experienced mild TMJ pain, but after the 3-year follow-up, no permanent TMD was noted in any patients. Though the sample size was small, this study demonstrated the longest multiple-patient follow-up period for any MSDO study. Gunbay et al did not, however, have a control group with which to compare the MSDO group to patients treated with other orthodontic techniques.

The aim of this study was to evaluate the effects of MSDO on the development of temporomandibular dysfunction symptoms as compared to a control group.

Materials and Methods

This project was submitted and approved under exempt status from the Virginia Commonwealth University Institutional Review Board.

Forty-nine patients from the office of Dr. John W. King included in this retrospective study were treated with mandibular symphyseal distraction osteogenesis. These patients were compared to fifty-seven control patients who were treated with traditional orthodontic methods (including archwire expansion, extraction regimen, etc.). Both groups had temporomandibular dysfunction exams completed on them pre- and post-treatment in addition to basic orthodontic records, including study models, lateral cephalometric radiographs and panoramic radiographs. The patients in the study group of mandibular distraction osteogenesis were offered MSDO as a treatment modality by Dr. King and opted for that course of treatment. Controls were selected from the normal patient pool of Dr. King's office with intention of matching the age range of study subjects.

The following patient characteristics were recorded at baseline: patient group (distraction or control), gender, race, banding date and age at banding, date of bracket removal and age at bracket removal. For the distraction patients, the following information was also collected: distraction osteogenesis (DO) date and age at distraction, mm of DO, use of rapid maxillary expander (RME, yes or no).

The following outcome measures were recorded at the pre-treatment baseline, 1 month, 3 months, 6 months, 1 year, 2 years, 3 years, 4 years, and 5 years: jaw pain using a visual analog pain scale (JP VAS), jaw discomfort using a visual analog pain scale (JD VAS), range of motion open (ROM-Open), right (ROM-R), left (ROM-L), and protrusive (ROM-Pro), and the presence or absence of the following: clenching, bruxism, clicking, crepitus, pain on TMJ palpation, and pain on muscle palpation.

With an $n \approx 50$ in each group, it was determined that the study had the ability to detect a SD=0.57 difference with 80% power at alpha = 0.05.

Statistical methods: Changes in the continuous outcome measures across time were compared between the groups using a repeated-measures mixed-model ANOVA (SAS mixed procedure with an unstructured covariance pattern that allowed each time point's results to be correlated to the other time points. SAS Institute Inc., Cary NC). Changes in binary outcome measures across time were compared between the groups using a repeated-measures logistic regression model (GEE analysis using the SAS genmod procedure with an unstructured covariance pattern).

Results

The results section first describes and compares the two groups of patients on the baseline characteristics and then answers the primary aim. The primary aim was to test if there was a different trend across time depending upon whether treatment was accomplished using MSDO or conventional orthodontic protocols.

Baseline comparison

There were a total of 106 patients in the study, n = 49 in the distraction group and n=57 in the control group. There was no difference in the gender between the groups; 57% female in the distraction group (n = 28) and 53% in the control group (Fisher's exact P = 0.3940). Both the distraction group and control group were comprised of Caucasian patients. The average age at banding overall was 15.1 years (SD = 5.1, range = 10 years 1 month to 40 years 11 months). The two groups were not significantly different in age at banding (distraction mean = 14.3 versus control mean = 15.8, t = 1.6, P = 0.1203). The average age at bracket removal was 17.2 (SD = 4.9, range = 12 years 7 months to 42 years 3 months). The distraction group was comprised of 75.5% (n=37) Class I and 24.5% (n=12) Class II patients, while the control group consisted of 66.6% (n=38) Class I, 31.6% (n=18) Class II and 1.8% (n=1) Class III patients. The groups were not different based on Angle classification (chi-square p = 0.445).

Jaw Pain

Jaw pain was measured on a 100 mm visual analog scale (VAS, from 0 = no pain to 1 = intense pain). The results of the jaw pain assessment for each group were reported as a percentage of the 100mm scale. Thus, a value of 0.108 corresponded to 10.8 mm on the VAS. The repeated-measures ANOVA results are shown in Table 1, and the means and 95% confidence intervals are shown in Table 2. The ANOVA results indicated that there was a significant change in jaw discomfort across time (P < .001) and the lack of significance in the time*group interaction indicated that the trend across time was not different between patients who underwent MSDO and those who did not (P = 0.118). Since this interaction was not significant, none of the post hoc tests could be interpreted.

Table 1: Jaw Pain VAS—Repeated Measures ANOVA Results

Source	NumDF	DenDF	F	P-value
time	5	102	7.06	<.001
Group	1	102	0.06	0.808
time*Group	5	102	1.81	0.118
Post hoc tests				
Group difference at Time =				
0-Pre	1	102	0.01	0.942
1-mo	1	102	0.01	0.929
3-mo	1	102	0.28	0.597
6-mo	1	102	0.15	0.696
12-mo	1	102	5.57	0.020
24-mo	1	102	0.60	0.439
Time trend within Group =				
Control	5	102	4.17	0.002
Distraction	5	102	4.45	0.001
Difference in changes =				
From Pre to 12 mo				
Difference in change			1.99	0.162
Controls, change			1.81	0.181
Distraction, change			9.48	0.003
From Pre to 24 mo				
Difference in change			0.38	0.538
Controls, change			10.13	0.002
Distraction, change			4.29	0.041

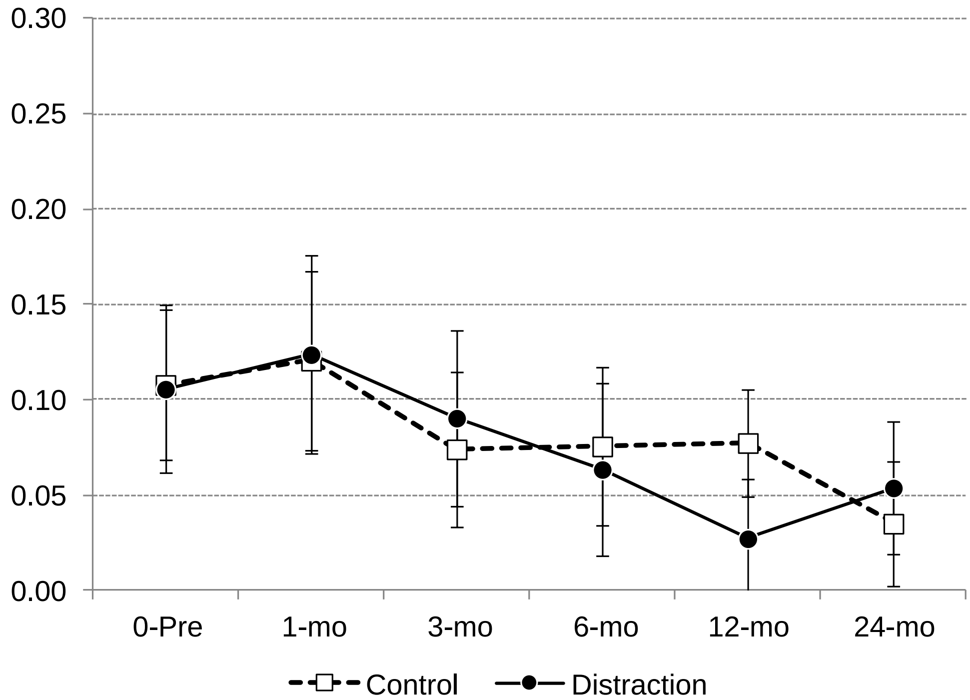
The table of means also show the number of patients with observations at that time point, the estimated mean value given by the analysis, the standard error of the estimate (SE), and a 95% confidence interval on the estimate. These estimates and confidence intervals (CIs) are shown in Figure 1. The white squares and dotted line for the control group means were decreasing, indicating a change across time. The black circles and solid line indicated that there was some difference across the three time points within the distraction group. The overlapping confidence intervals at each time point are consistent with there being no difference between the groups.

Figure 1

Table 2: Jaw Pain—Means and 95% CIs

		Jaw Pain - Visual Analog Scale					
Time	Group	n	Mean	SD	95% CI		SE
0-Pre	Control	54	0.108	0.147	0.068	0.147	0.02
	Distraction	43	0.106	0.144	0.061	0.15	0.022
1-mo	Control	49	0.121	0.168	0.074	0.168	0.024
	Distraction	40	0.124	0.164	0.072	0.176	0.026
3-mo	Control	54	0.074	0.147	0.034	0.115	0.02
	Distraction	40	0.09	0.145	0.045	0.136	0.023
6-mo	Control	53	0.076	0.153	0.034	0.117	0.021
	Distraction	44	0.063	0.153	0.018	0.109	0.023
12-mo	Control	54	0.077	0.103	0.049	0.105	0.014
	Distraction	42	0.027	0.104	-0.004	0.059	0.016
24-mo	Control	39	0.035	0.106	0.002	0.068	0.017
	Distraction	36	0.054	0.108	0.019	0.088	0.018

Figure 1: Jaw Pain—Visual Analog Scale



Jaw Discomfort

Jaw discomfort was measured on a visual analog scale (from 0 = no pain to 1 = intense discomfort). The repeated-measures ANOVA results are shown in Table 3, and the means and 95% confidence intervals are shown in Table 4. The ANOVA results indicated that there was a significant change in jaw discomfort across time ($P < .001$), and the lack of significance in the time*group interaction indicated that the trend across time was not different between the groups ($P = 0.445$).

Table 3: Jaw Discomfort VAS—Repeated Measures ANOVA Results

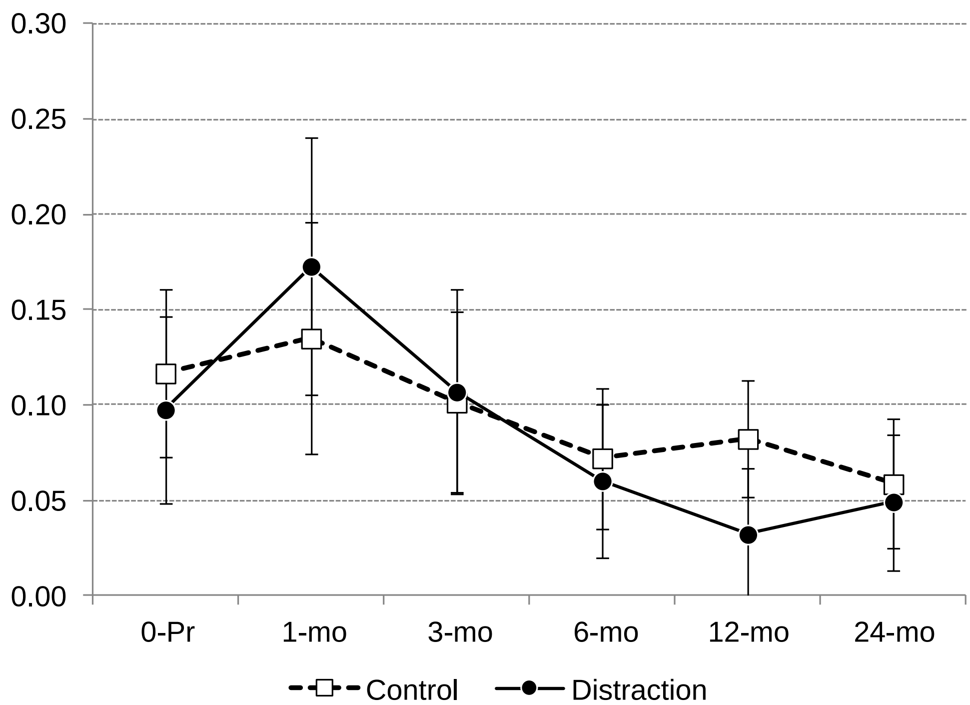
Source	NumDF	DenDF	F	P-value
time	5	102	6.28	<.001
Group	1	102	0.16	0.690
time*Group	5	102	0.96	0.445
Post hoc tests				
Group difference at Time =				
0-Pre	1	102	0.33	0.569
1-mo	1	102	0.68	0.411
3-mo	1	102	0.02	0.878
6-mo	1	102	0.19	0.667
12-mo	1	102	4.61	0.034
24-mo	1	102	0.14	0.708
Time trend within Group =				
Control	5	102	2.24	0.056
Distraction	5	102	4.70	<.001
Difference in changes =				
From Pre to 12 mo				
Difference in change			0.69	0.409
Controls, change			1.92	0.169
Distraction, change			5.45	0.022
From Pre to 24 mo				
Difference in change			0.06	0.804
Controls, change			4.83	0.030
Distraction, change			2.79	0.098

The table of means also shows the number of patients with observations at that time point, the estimated mean value given by the analysis, the standard error of the estimate (SE), and a 95% CI on the estimate. These estimates and CIs are shown in Figure 2. The white squares and dotted line for the control group means was relatively flat, indicating no change across time. The black circles and solid line indicated that there was some difference across the three time points within the distraction group. The overlapping confidence intervals at each time point are consistent with the absence of a difference between the groups.

Table 4: Jaw Discomfort—Means and 95% CIs

		Jaw Discomfort - Visual Analog Scale					
Time	Group	n	Mean	SD	95% CI		SE
0-Pre	Control	54	0.117	0.162	0.072	0.161	0.022
	Distraction	43	0.098	0.164	0.048	0.147	0.025
1-mo	Control	49	0.135	0.217	0.074	0.196	0.031
	Distraction	40	0.173	0.215	0.105	0.24	0.034
3-mo	Control	54	0.101	0.176	0.054	0.149	0.024
	Distraction	40	0.107	0.171	0.053	0.161	0.027
6-mo	Control	53	0.072	0.138	0.035	0.109	0.019
	Distraction	44	0.06	0.133	0.02	0.101	0.02
12-mo	Control	54	0.082	0.118	0.051	0.113	0.016
	Distraction	42	0.032	0.110	-0.003	0.067	0.017
24-mo	Control	39	0.058	0.106	0.025	0.092	0.017
	Distraction	36	0.049	0.108	0.014	0.085	0.018

Figure 2: Jaw Discomfort—Visual Analog Scale



Range of Motion—Opening

The average range of motion on opening was 48.1mm (SD = 5.86). There was a significant change across time (P < .001), but the time trends were not different between the two groups (P = 0.196, Table 5).

Table 5: Range of Motion—Opening, Repeated measures ANOVA Results

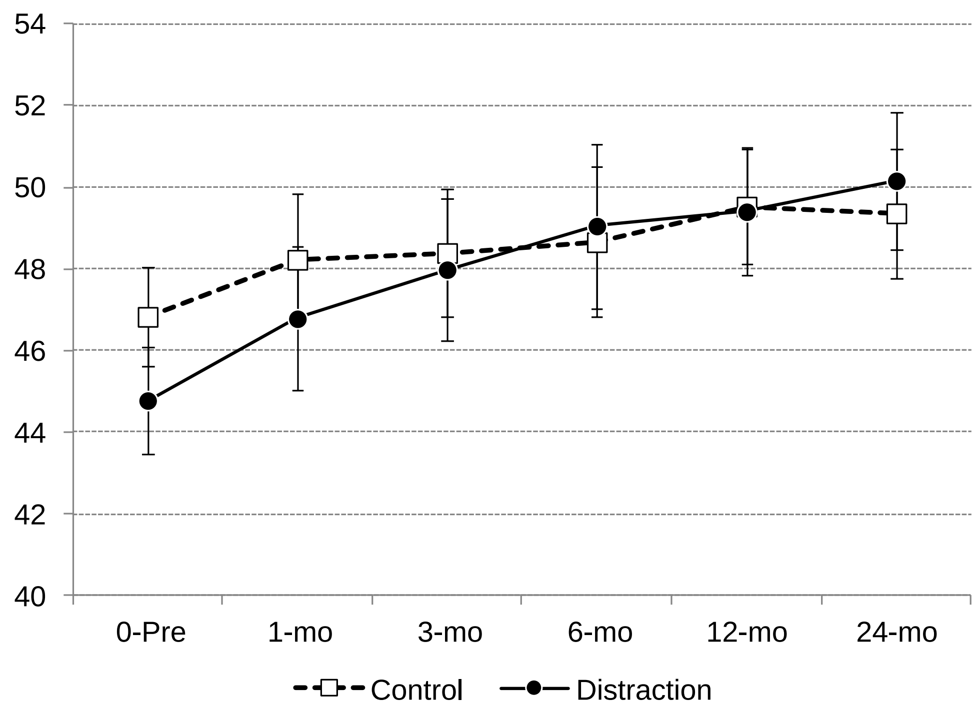
Source	NumDF	DenDF	F	P-value
time	5	102	12.74	<.001
Group	1	102	0.29	0.588
time*Group	5	102	1.50	0.196
Post hoc tests				
Group difference at Time =				
0-Pre	1	102	5.13	0.026
1-mo	1	102	1.44	0.233
3-mo	1	102	0.12	0.728
6-mo	1	102	0.08	0.774
12-mo	1	102	0.01	0.905
24-mo	1	102	0.47	0.496
Time trend within Group =				
Control	5	102	3.43	0.007
Distraction	5	102	10.18	<.001
Difference in changes =				
From Pre to 12 mo				
Difference in change			3.63	0.059
Controls, change			16.01	<.001
Distraction, change			37.91	<.001
From Pre to 24 mo				
Difference in change			5.81	0.018
Controls, change			9.88	0.002
Distraction, change			38.78	<.001

The means and 95% CIs are shown for each of the groups at the time point in Table 6 and Figure 3.

Table 6: Range of Motion—Opening, Means and 95% CIs

		Range of Motion - Opening					
Time	Group	n	Mean	SD	95% CI		SE
0-Pre	Control	54	46.833	4.519	45.614	48.052	0.615
	Distraction	46	44.781	4.510	43.462	46.101	0.665
1-mo	Control	49	48.231	5.684	46.62	49.842	0.812
	Distraction	40	46.785	5.635	45.018	48.553	0.891
3-mo	Control	54	48.396	5.754	46.843	49.949	0.783
	Distraction	40	47.988	5.502	46.261	49.714	0.87
6-mo	Control	53	48.66	6.756	46.819	50.502	0.928
	Distraction	44	49.057	6.746	47.038	51.075	1.017
12-mo	Control	54	49.533	5.225	48.124	50.943	0.711
	Distraction	43	49.407	5.161	47.846	50.968	0.787
24-mo	Control	39	49.367	4.977	47.787	50.948	0.797
	Distraction	36	50.166	5.118	48.474	51.858	0.853

Figure 3: Range of Motion—Opening



Range of motion—Right Lateral Excursion

There was no significant change across time for range of motion in right lateral excursions (P = 0.081), nor was there a difference in the trend between the groups (P = 0.286, Table 7).

Table 7: Range of Motion—Right Lateral Excursion, Repeated Measures ANOVA Results

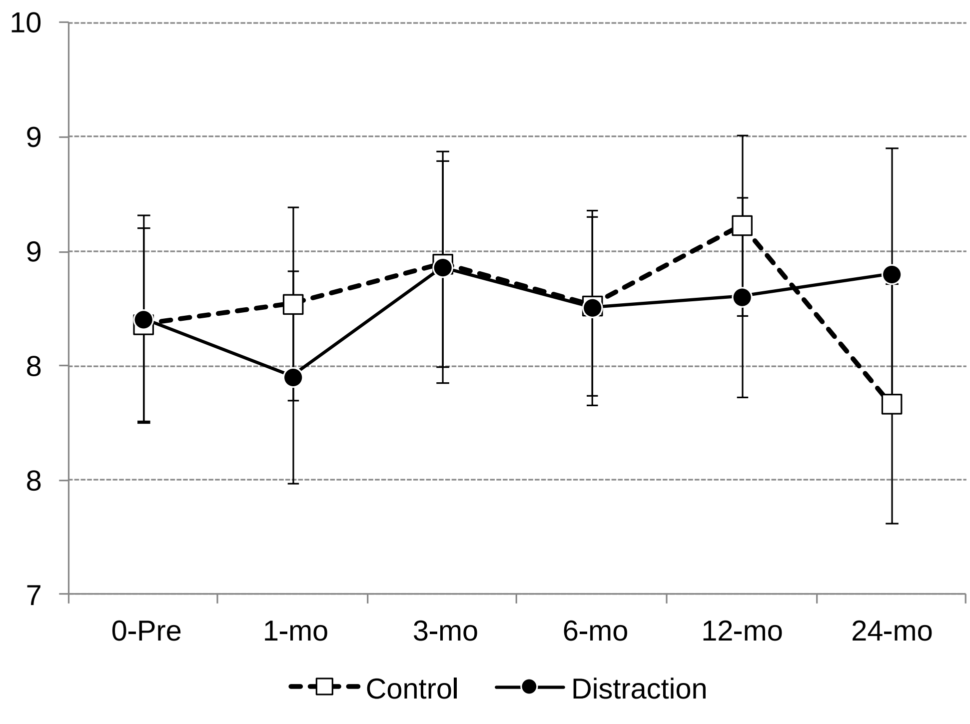
Source	NumDF	DenDF	F	P-value
time	5	102	2.02	0.081
Group	1	102	0.00	0.961
time*Group	5	102	1.26	0.286
Post hoc tests				
Group difference at Time =				
0-Pre	1	102	0.00	0.944
1-mo	1	102	1.01	0.317
3-mo	1	102	0.00	0.965
6-mo	1	102	0.00	0.978
12-mo	1	102	1.12	0.293
24-mo	1	102	2.19	0.142
Time trend within Group =				
Control	5	102	2.46	0.038
Distraction	5	102	0.92	0.469
Difference in changes =				
From Pre to 12 mo				
Difference in change			0.85	0.358
Controls, change			3.12	0.080
Distraction, change			0.13	0.716
From Pre to 24 mo				
Difference in change			1.43	0.235
Controls, change			1.23	0.270
Distraction, change			0.35	0.553

The means and 95% CIs are shown in Table 8 and Figure 4.

Table 8: Range of Motion—Right Lateral Excursion, Means and 95% CIs

		Range of Motion – Right Lateral Excursion					
Time	Group	n	Mean	SD	95% CI		SE
0-Pre	Control	54	8.182	1.565	7.76	8.605	0.213
	Distraction	47	8.205	1.570	7.751	8.658	0.229
1-mo	Control	49	8.271	1.498	7.847	8.695	0.214
	Distraction	40	7.952	1.486	7.485	8.419	0.235
3-mo	Control	54	8.447	1.661	7.999	8.895	0.226
	Distraction	40	8.432	1.613	7.926	8.939	0.255
6-mo	Control	53	8.264	1.434	7.873	8.656	0.197
	Distraction	44	8.256	1.433	7.828	8.685	0.216
12-mo	Control	54	8.616	1.462	8.222	9.011	0.199
	Distraction	43	8.302	1.443	7.865	8.739	0.22
24-mo	Control	39	7.835	1.649	7.312	8.359	0.264
	Distraction	36	8.402	1.668	7.85	8.954	0.278

Figure 4: Range of Motion—Right Lateral Excursion



Range of Motion—Left Lateral Excursion

There was no significant change across time for range of motion in left lateral excursion (P = 0.290), nor was there a difference in the trend between the two groups (P = 0.212). There was no significant change across time, and the trends were not different between groups (Table 9).

Table 9: Range of Motion—Left Lateral Excursion, Repeated Measures ANOVA Results

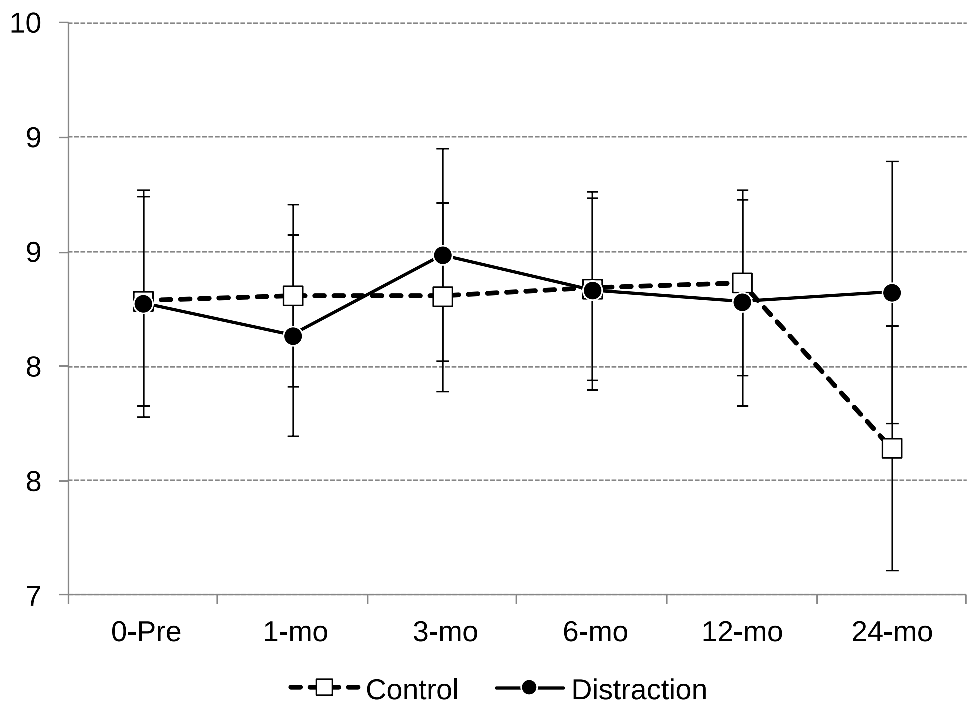
Source	NumDF	DenDF	F	P-value
time	5	102	1.25	0.290
Group	1	102	0.16	0.686
time*Group	5	102	1.45	0.212
Post hoc tests				
Group difference at Time =				
0-Pre	1	102	0.00	0.975
1-mo	1	102	0.35	0.558
3-mo	1	102	0.34	0.564
6-mo	1	102	0.00	0.983
12-mo	1	102	0.08	0.783
24-mo	1	102	2.95	0.089
Time trend within Group =				
Control	5	102	2.20	0.059
Distraction	5	102	0.52	0.764
Difference in changes =				
From Pre to 12 mo				
Difference in change			0.03	0.853
Controls, change			0.09	0.765
Distraction, change			0.00	0.982
From Pre to 24 mo				
Difference in change			2.28	0.134
Controls, change			4.22	0.042
Distraction, change			0.02	0.885

See Table 10 for means and 95% CIs. These estimates and CIs are shown in Figure 5.

Table 10: Range of Motion—Left Lateral Excursion, Means and 95% CIs

		Range of Motion – Left Lateral Excursion					
Time	Group	n	Mean	SD	95% CI		SE
0-Pre	Control	54	8.287	1.697	7.828	8.746	0.231
	Distraction	47	8.276	1.707	7.782	8.77	0.249
1-mo	Control	49	8.311	1.414	7.91	8.711	0.202
	Distraction	40	8.135	1.404	7.694	8.575	0.222
3-mo	Control	54	8.307	1.528	7.895	8.719	0.208
	Distraction	40	8.488	1.480	8.024	8.953	0.234
6-mo	Control	53	8.34	1.449	7.944	8.736	0.199
	Distraction	44	8.334	1.446	7.902	8.766	0.218
12-mo	Control	54	8.367	1.506	7.961	8.774	0.205
	Distraction	43	8.283	1.489	7.831	8.734	0.227
24-mo	Control	39	7.645	1.692	7.107	8.182	0.271
	Distraction	36	8.324	1.734	7.752	8.897	0.289

Figure 5: Range of Motion—Left Lateral Excursion



Range of motion—Protrusive

There was no significant change across time for range of motion in protrusion (P = 0.094), nor was there a difference in the trend between the groups (P = 0.064, Table 11). Means and 95% CIs are shown in Table 12. No change was noted across time or between the groups (See Figure 6).

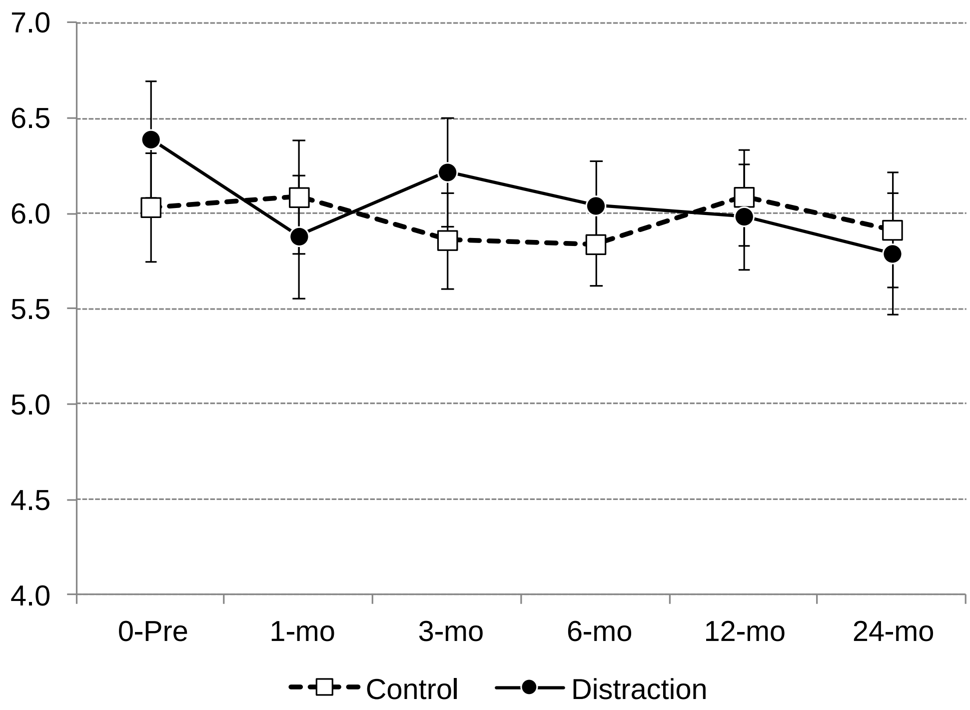
Table 11: Range of Motion—Protrusive, Repeated Measures ANOVA Results

Source	NumDF	DenDF	F	P-value
time	5	102	1.94	0.094
Group	1	102	0.34	0.561
time*Group	5	102	2.16	0.064
Post hoc tests				
Group difference at Time =				
0-Pre	1	102	2.94	0.090
1-mo	1	102	0.85	0.358
3-mo	1	102	3.50	0.064
6-mo	1	102	1.62	0.206
12-mo	1	102	0.29	0.591
24-mo	1	102	0.31	0.579
Time trend within Group =				
Control	5	102	1.35	0.249
Distraction	5	102	2.67	0.026
Difference in changes =				
From Pre to 12 mo				
Difference in change			3.50	0.064
Controls, change			0.11	0.746
Distraction, change			5.02	0.027
From Pre to 24 mo				
Difference in change			2.98	0.087
Controls, change			0.39	0.534
Distraction, change			8.77	0.004

Table 12: Range of Motion—Protrusive, Means and 95% CIs

		Range of Motion - Protrusive					
Time	Group	n	Mean	SD	95% CI		SE
0-Pre	Control	54	6.035	1.043	5.754	6.316	0.142
	Distraction	47	6.391	1.042	6.089	6.694	0.152
1-mo	Control	48	6.087	1.039	5.79	6.384	0.15
	Distraction	40	5.882	1.031	5.558	6.206	0.163
3-mo	Control	54	5.862	0.926	5.611	6.113	0.126
	Distraction	40	6.219	0.904	5.935	6.503	0.143
6-mo	Control	52	5.84	0.779	5.626	6.054	0.108
	Distraction	44	6.043	0.783	5.81	6.276	0.118
12-mo	Control	53	6.089	0.925	5.837	6.34	0.127
	Distraction	43	5.987	0.918	5.709	6.265	0.14
24-mo	Control	39	5.916	0.955	5.612	6.22	0.153
	Distraction	36	5.792	0.972	5.471	6.112	0.162

Figure 6: Range of Motion—Protrusive



Clicking

Clicking was noted overall on 28.5% of all evaluations performed (157/554). The repeated-measures logistic-regression results are shown in Table 13, and the proportions and 95% confidence intervals are shown in Table 14. The logistic regression results indicated that there was no significant change in jaw discomfort across time (P >0.486), and the lack of significance in the time*group interaction indicated that the flat trend across time was not different between the groups (P > 0.574).

Table 13: Clicking—Repeated measures logistic regression results

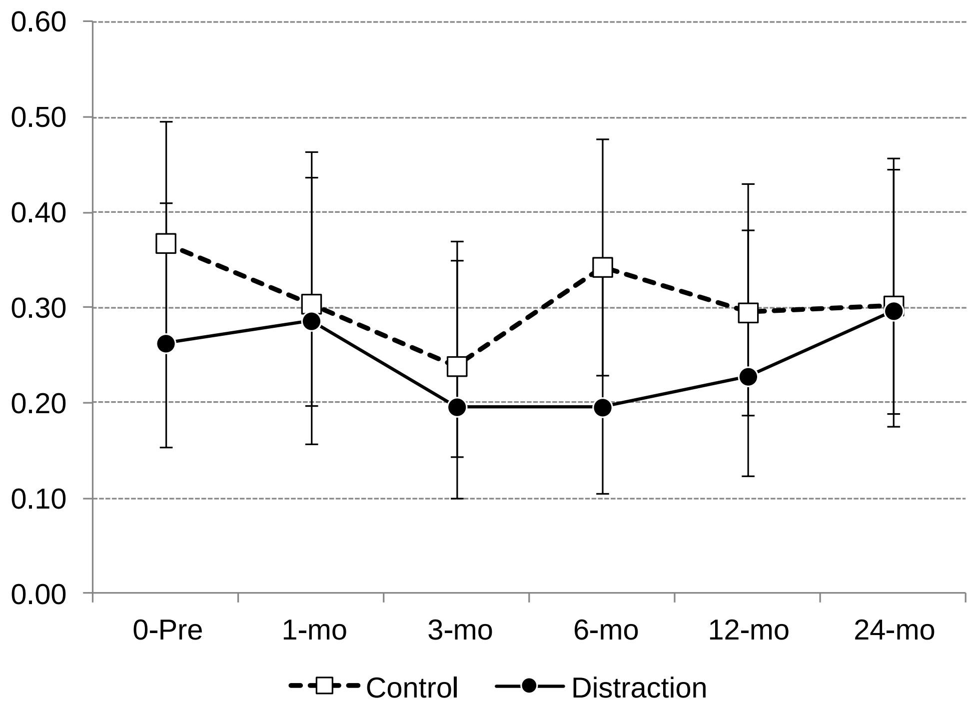
Source	DF	chi-sq	P-value
time	5	4.46	0.486
Group	1	0.95	0.329
time*Group	5	3.83	0.574
Post hoc tests			
Group difference at Time =			
0-Pre	1	1.28	0.259
1-mo	1	0.03	0.860
3-mo	1	0.24	0.625
6-mo	1	2.67	0.103
12-mo	1	0.52	0.471
24-mo	1	0.00	0.956
Time trend within Group =			
Control	5	5.85	0.321
Distraction	5	3.33	0.649
Difference in changes =			
From Pre to 12 mo			
Difference in change		0.06	0.806
Controls, change		0.87	0.351
Distraction, change		0.17	0.682
From Pre to 24 mo			
Difference in change		0.75	0.387
Controls, change		0.70	0.404
Distraction, change		0.18	0.675

The table of probabilities in each group also shows the number of patients with observations at that time point and the 95% CI. These estimates and the CIs are shown in Figure 7. The two groups had similar trends over time.

Table 14: Clicking—Proportions and 95% CIs

		Clicking			
Time	Group	n	Prob.	95% CI	
0-Pre	Control	55	0.368	0.256	0.497
	Distraction	47	0.263	0.155	0.410
1-mo	Control	49	0.304	0.198	0.436
	Distraction	40	0.286	0.157	0.464
3-mo	Control	54	0.239	0.143	0.370
	Distraction	40	0.196	0.100	0.350
6-mo	Control	53	0.343	0.230	0.477
	Distraction	44	0.196	0.105	0.335
12-mo	Control	54	0.295	0.188	0.431
	Distraction	43	0.228	0.124	0.382
24-mo	Control	39	0.302	0.189	0.446
	Distraction	36	0.297	0.175	0.456

Figure 7: Clicking—Proportions and 95% CIs



Clenching

Clenching was reported in 13% of all observations (72/552). The repeated-measures logistic-regression results are shown in Table 15, and the proportions and 95% confidence intervals are shown in Table 16. The logistic regression results indicated that there was no evidence for a change in clenching across time (P > 0.289), nor was there a difference in the trend across time between the two groups (P > 0.114).

Table 15: Clenching—Repeated Measures Logistic Regression Results

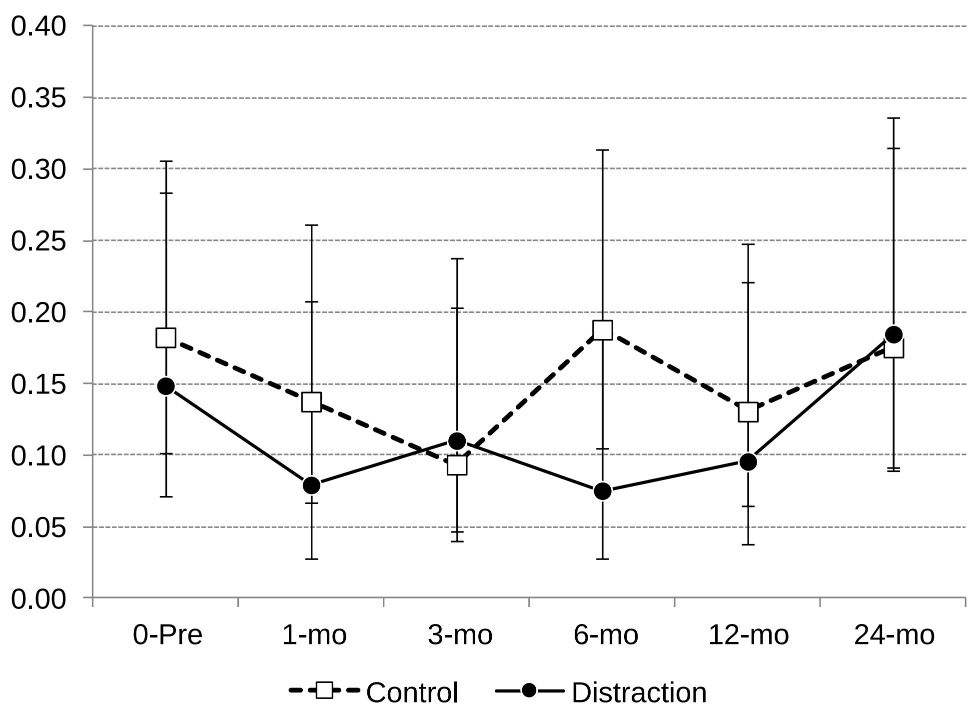
Source	DF	chi-sq	P-value
time	5	6.18	0.289
Group	1	0.63	0.427
time*Group	5	8.88	0.114
Post hoc tests			
Group difference at Time =			
0-Pre	1	0.20	0.651
1-mo	1	0.78	0.376
3-mo	1	0.08	0.780
6-mo	1	2.63	0.105
12-mo	1	0.30	0.586
24-mo	1	0.01	0.912
Time trend within Group =			
Control	5	6.73	0.242
Distraction	5	10.40	0.065
Difference in changes =			
From Pre to 12 mo			
Difference in change		0.02	0.891
Controls, change		0.87	0.351
Distraction, change		0.63	0.428
From Pre to 24 mo			
Difference in change		0.20	0.655
Controls, change		0.01	0.911
Distraction, change		0.23	0.630

The proportions are shown below in Figure 8.

Table 16: Clenching—Proportions and 95% CIs

		Clenching			
Time	Group	n	Prob.	95% CI	
0-Pre	Control	55	0.182	0.102	0.306
	Distraction	46	0.149	0.071	0.284
1-mo	Control	49	0.137	0.067	0.261
	Distraction	40	0.079	0.028	0.207
3-mo	Control	54	0.093	0.040	0.203
	Distraction	39	0.110	0.047	0.238
6-mo	Control	53	0.188	0.105	0.314
	Distraction	44	0.075	0.027	0.191
12-mo	Control	54	0.130	0.064	0.248
	Distraction	43	0.096	0.038	0.221
24-mo	Control	39	0.175	0.090	0.315
	Distraction	36	0.185	0.092	0.336

Figure 8: Clenching—Proportions and 95% CIs



Bruxism

Bruxism was reported in 11.8% of all observations (65/552). The repeated-measures logistic-regression results are shown in Table 17, and the proportions and 95% confidence intervals are shown in Table 18 and Figure 9. The logistic regression results indicated that there was no evidence of a change across time (P > 0.15) nor was there evidence of a difference in trends between the groups (P > 0.7).

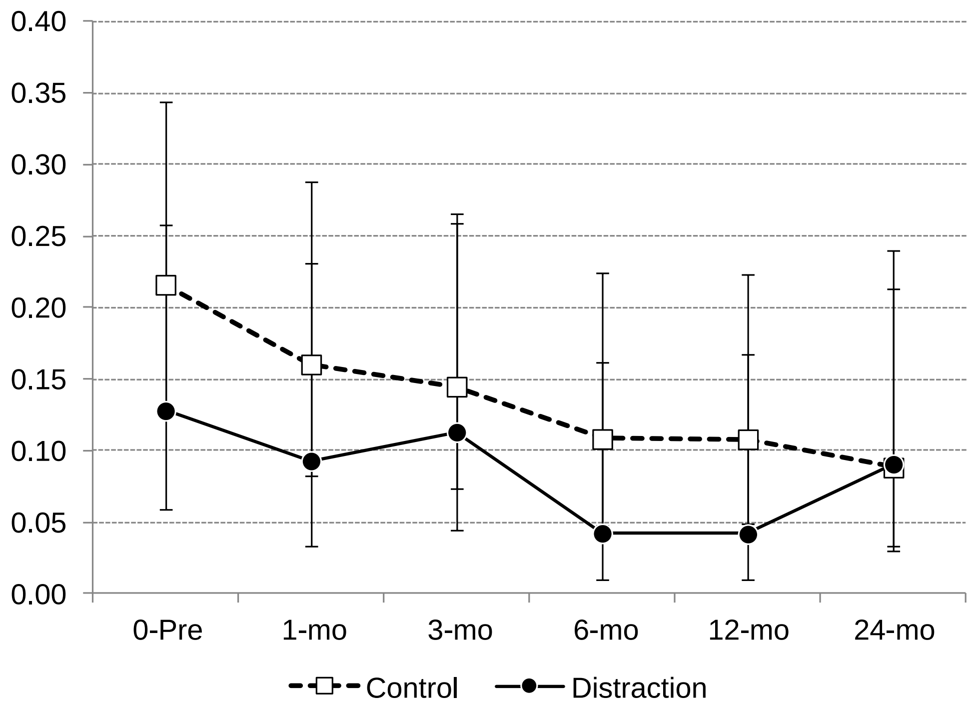
Table 17: Bruxism—Repeated Measures Logistic Regression Results

Source	DF	chi-sq	P-value
time	5	8.08	0.152
Group	1	1.47	0.225
time*Group	5	2.90	0.715
Post hoc tests			
Group difference at Time =			
0-Pre	1	1.33	0.249
1-mo	1	0.86	0.353
3-mo	1	0.19	0.659
6-mo	1	1.34	0.248
12-mo	1	1.31	0.253
24-mo	1	0.00	0.971
Time trend within Group =			
Control	5	7.98	0.157
Distraction	5	11.95	0.035
Difference in changes =			
From Pre to 12 mo			
Difference in change		0.24	0.625
Controls, change		3.45	0.063
Distraction, change		3.28	0.070
From Pre to 24 mo			
Difference in change		0.88	0.348
Controls, change		5.41	0.020
Distraction, change		0.52	0.472

Table 18: Bruxism—Proportions and 95% CIs

		Bruxism			
Time	Group	n	Prob.	95% CI	
0-Pre	Control	55	0.216	0.127	0.343
	Distraction	46	0.128	0.058	0.258
1-mo	Control	49	0.160	0.082	0.289
	Distraction	40	0.093	0.034	0.231
3-mo	Control	54	0.145	0.073	0.266
	Distraction	39	0.113	0.044	0.259
6-mo	Control	53	0.108	0.048	0.225
	Distraction	44	0.042	0.010	0.162
12-mo	Control	54	0.108	0.049	0.223
	Distraction	43	0.042	0.009	0.167
24-mo	Control	39	0.088	0.033	0.213
	Distraction	36	0.091	0.030	0.240

Figure 9: Bruxism—Proportions and 95% CIs



Crepitus

Crepitus only occurred three times: once in the distraction group at pre-test and in the control group at 6-mo and at 12-mo. No data analysis was possible.

Pain on TMJ Palpation

Pain on TMJ palpation was observed in 12.7% of all observations (69/543). The repeated-measures logistic-regression results are shown in Table 19, and the proportions and 95% confidence intervals are shown in Table 20. The logistic regression results indicated that there was no evidence for a change in clenching across time (P > 0.49), nor was there a difference in the trend across time between the two groups (P > 0.57).

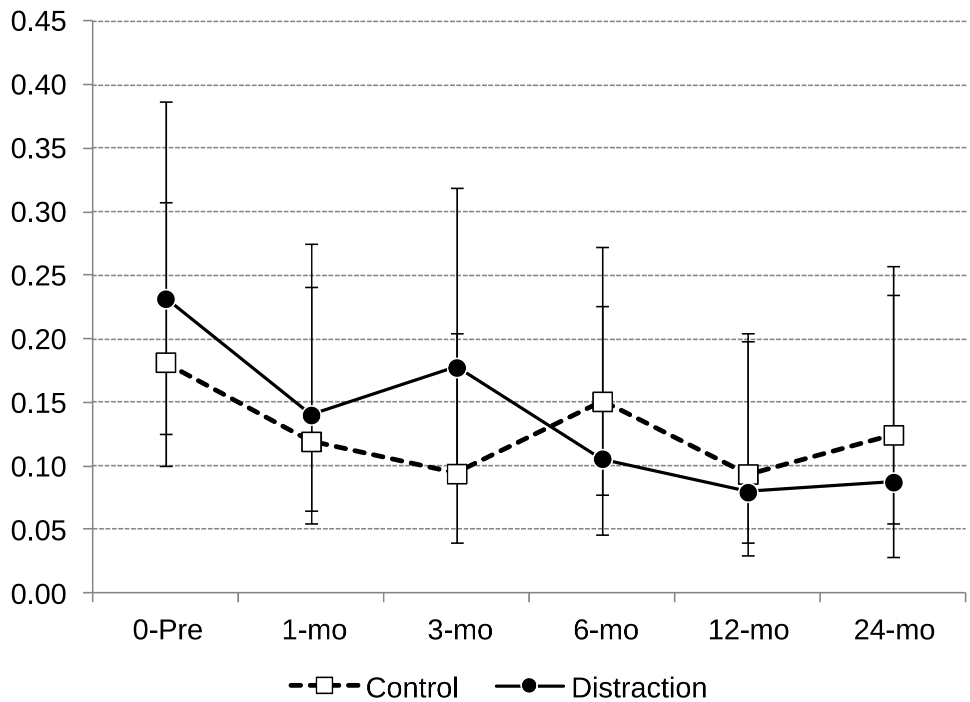
Table 19: Pain on TMJ Palpation—Repeated Measures Logistic Regression Results

Source	DF	chi-sq	P-value
time	5	7.99	0.157
Group	1	0.01	0.922
time*Group	5	2.80	0.732
Post hoc tests			
Group difference at Time =			
0-Pre	1	0.35	0.555
1-mo	1	0.09	0.764
3-mo	1	1.45	0.229
6-mo	1	0.47	0.495
12-mo	1	0.06	0.799
24-mo	1	0.28	0.596
Time trend within Group =			
Control	5	4.19	0.523
Distraction	5	8.17	0.147
Difference in changes =			
From Pre to 12 mo			
Difference in change		0.40	0.527
Controls, change		2.01	0.156
Distraction, change		5.20	0.023
From Pre to 24 mo			
Difference in change		0.67	0.413
Controls, change		0.75	0.386
Distraction, change		2.79	0.095

Table 20: Pain on TMJ Palpation—Proportions and 95% CIs

		Pain on TMJ Palpation			
Time	Group	n	Prob.	95% CI	
0-Pre	Control	54	0.182	0.100	0.308
	Distraction	37	0.232	0.126	0.387
1-mo	Control	49	0.120	0.055	0.242
	Distraction	40	0.140	0.066	0.275
3-mo	Control	54	0.094	0.040	0.204
	Distraction	40	0.178	0.090	0.320
6-mo	Control	53	0.151	0.078	0.272
	Distraction	44	0.106	0.046	0.226
12-mo	Control	54	0.094	0.040	0.204
	Distraction	43	0.080	0.029	0.199
24-mo	Control	39	0.125	0.055	0.257
	Distraction	36	0.088	0.029	0.235

Figure 10: Pain on TMJ Palpation—Proportions and 95% CIs



Pain on Muscle Palpation

Pain on muscle palpation occurred 34 times out of 538 evaluations (6%). Since the number of occurrences was zero (out of 36) in the distraction group at 24-months (and 3/39 in the control group), the repeated-measures analysis could not be performed. So, the analysis was done only on the observations through 12 months. The results showed no evidence for a change across time (P = 0.26) and no evidence for a difference between the two groups (P = 0.89). See Table 21, Table 22 and Figure 11.

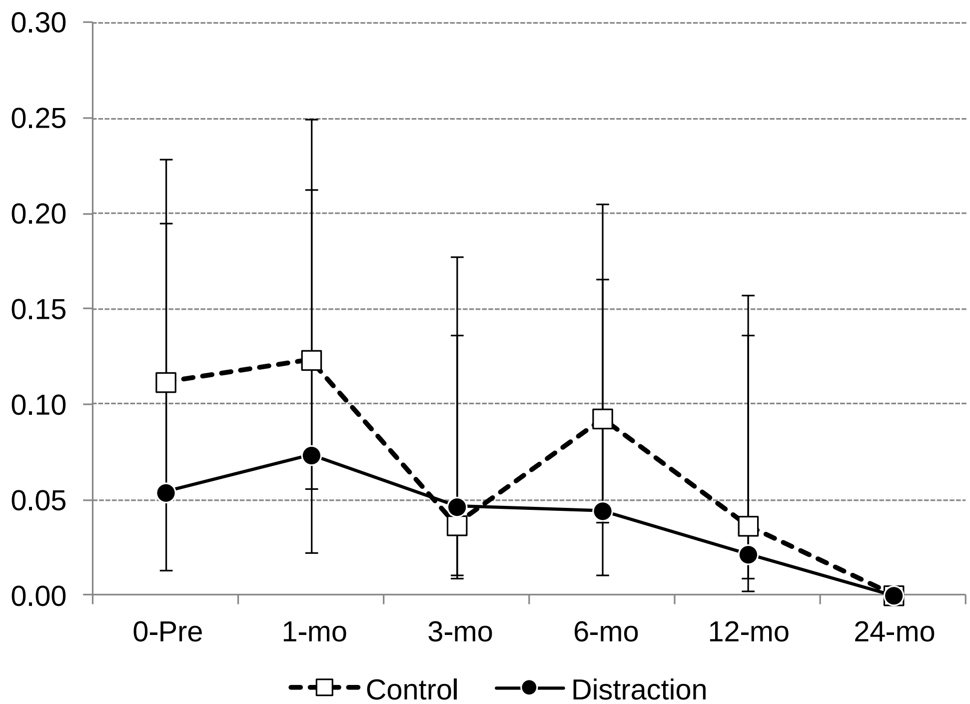
Table 21: Pain on Muscle Palpation—Repeated Measures Logistic Regression Results

Source	DF	chi-sq	P-value
time	4	5.31	0.257
Group	1	0.74	0.389
time*Group	4	1.16	0.885
Post hoc tests			
Group difference at Time =			
0-Pre	1	0.85	0.357
1-mo	1	0.56	0.453
3-mo	1	0.05	0.815
6-mo	1	0.80	0.370
12-mo	1	0.17	0.680
Time trend within Group =			
Control	4	4.15	0.386
Distraction	4	2.05	0.727
Difference in changes =			
From Pre to 12 mo			
Difference in change		0.03	0.872
Controls, change		1.86	0.173
Distraction, change		0.56	0.456

Table 22: Pain on Muscle Palpation—Proportions and 95% CIs

		Pain on Muscle Palpation			
Time	Group	n	Prob.	95% CI	
0-Pre	Control	53	0.112	0.051	0.229
	Distraction	36	0.054	0.013	0.195
1-mo	Control	48	0.123	0.056	0.250
	Distraction	38	0.073	0.023	0.213
3-mo	Control	54	0.037	0.009	0.136
	Distraction	40	0.046	0.011	0.178
6-mo	Control	53	0.093	0.039	0.206
	Distraction	44	0.044	0.011	0.166
12-mo	Control	54	0.036	0.009	0.137
	Distraction	43	0.022	0.003	0.158
24-mo	Control	39	0.083		
	Distraction	36	0.000		

Figure 11: Pain on Muscle Palpation—Proportions and 95% CIs



Mandibular Deviation

Mandibular deviation was not a binary outcome; it was coded as "none," "left," "right," or "both." The prevalence of each is shown in Table 23.

Table 23: Occurrences of Mandibular Deviation

		Mandibular Deviation					
time	Group	none	Left	Right	Both	(any)	% any
0-Pre	Control	45	8	2		10	18
	Distraction	33	6	4		10	23
1-mo	Control	38	6	5		11	22
	Distraction	34	3		1	4	11
3-mo	Control	10	44			44	81
	Distraction	32	5	3		8	20
6-mo	Control	50	3			3	6
	Distraction	38	2	3		5	12
12-mo	Control	44	7	3	1	11	20
	Distraction	37	2	3		5	12
24-mo	Control	33	2	4		6	15
	Distraction	30	3	3		6	17

Considering any form of mandibular deviation as an adverse outcome, logistic regression was performed, and the results are shown in Table 24. Some form of mandibular deviation was observed in 29% of all evaluations (123/424). The proportions and 95% confidence intervals are shown in Table 25. The logistic regression results indicated that there was no evidence for a change in clenching across time ($P > 0.49$), nor was there a difference in the trend across time between the two groups ($P > 0.57$). See Figure 12.

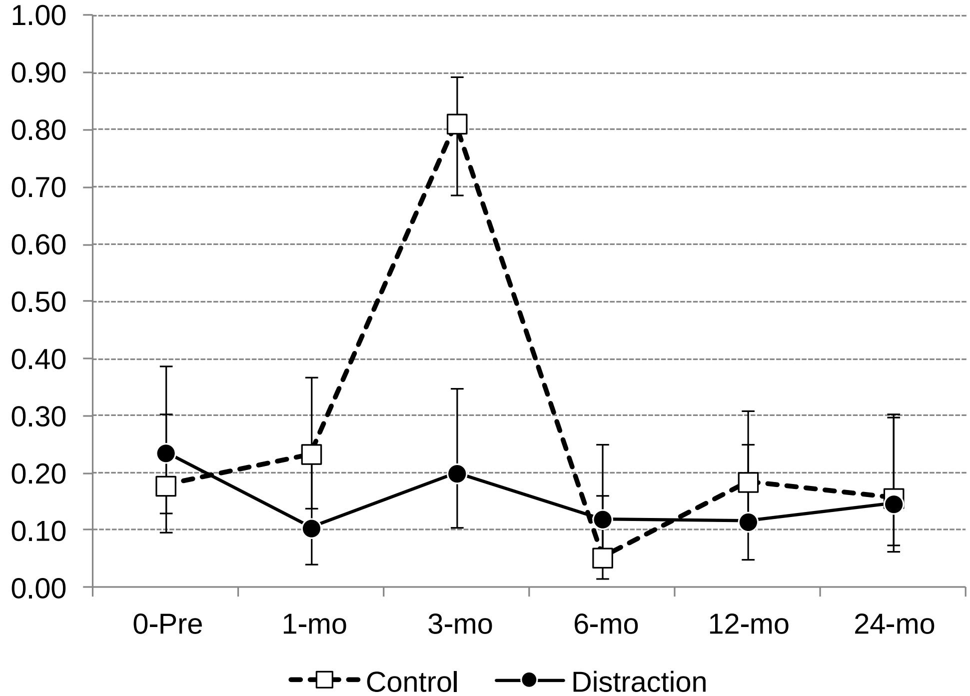
Table 24: Mandibular Deviation—Repeated measures logistic regression results

Source	DF	chi-sq	P-value
time	5	19.91	0.001
Group	1	1.82	0.177
time*Group	5	23.98	<.001
Post hoc tests			
Group difference at Time =			
0-Pre	1	0.48	0.489
1-mo	1	2.44	0.118
3-mo	1	30.20	<.001
6-mo	1	1.32	0.250
12-mo	1	0.87	0.352
24-mo	1	0.01	0.903
Time trend within Group =			
Control	5	68.54	<.001
Distraction	5	4.08	0.538
Difference in changes =			
From Pre to 12 mo			
Difference in change		1.54	0.214
Controls, change		0.02	0.900
Distraction, change		1.82	0.177
From Pre to 24 mo			
Difference in change		0.32	0.573
Controls, change		0.16	0.686
Distraction, change		0.79	0.374

Table 25: Mandibular Deviation—Proportions and 95% CIs

		Mandibular Deviation			
Time	Group	n	Prob.	95% CI	
0-Pre	Control	55	0.178	0.098	0.303
	Distraction	43	0.236	0.131	0.386
1-mo	Control	49	0.234	0.138	0.368
	Distraction	38	0.104	0.040	0.244
3-mo	Control	54	0.811	0.687	0.894
	Distraction	40	0.200	0.105	0.348
6-mo	Control	53	0.052	0.016	0.161
	Distraction	43	0.120	0.053	0.250
12-mo	Control	54	0.185	0.103	0.310
	Distraction	42	0.115	0.048	0.251
24-mo	Control	39	0.157	0.075	0.298
	Distraction	36	0.147	0.063	0.304

Figure 12: Mandibular Deviation—Proportions and 95% CIs



Five-Year Follow-Up

Although no five-year follow-up data for control group subjects was included in the database, means and standard deviations for each of the assessed variables at pretreatment and 5-year follow-up time points in the distraction group are included below in Table 26. Statistical analysis of these data was not completed as it was out of the scope of the comparison of the distraction and control groups. Without control data at the 5-year follow-up, such comparison was impossible.

Table 26: Pretreatment and 5-Year Follow-Up Means and Standard Deviations

Label	Time	n	Mean	SD
JP_VAS	0-Pre	48	0.107	0.145
JP_VAS	60-mo	32	0.021	0.041
JD_VAS	0-Pre	48	0.097	0.151
JD_VAS	60-mo	32	0.034	0.066
ROM_Open	0-Pre	48	44.674	4.238
ROM_Open	60-mo	32	50.469	5.559
ROM_R	0-Pre	48	8.191	1.650
ROM_R	60-mo	32	9.188	1.447
ROM_L	0-Pre	48	8.277	1.896
ROM_L	60-mo	32	8.969	1.675
ROM_Pro	0-Pre	48	6.383	1.190
ROM_Pro	60-mo	32	7.656	1.473
Click	0-Pre	48	0.298	0.462
Click	60-mo	32	0.258	0.445
Clench	0-Pre	48	0.152	0.363
Clench	60-mo	32	0.067	0.254
Brux	0-Pre	48	0.130	0.341
Brux	60-mo	32	0.133	0.346
Crep	0-Pre	48	0.022	0.147
Crep	60-mo	32	0.000	0.000
TMJ_Palp	0-Pre	48	0.243	0.435
TMJ_Palp	60-mo	32	0.065	0.250
Muscle_Palp	0-Pre	48	0.056	0.232
Muscle_Palp	60-mo	32	0.032	0.180
Mand_Dev	0-Pre	48	0.326	0.644
Mand_Dev	60-mo	32	0.063	0.246

Discussion

Since mandibular symphyseal distraction osteogenesis (MSDO) was introduced as an alternative treatment modality to address transverse mandibular deficiency and severe crowding, the impact of the procedure on the temporomandibular joint was questioned. Most studies investigating MSDO in patients have samples of limited size. Studies focusing specifically on the TMJ are rare and are very limited in their sample size. Absent from the literature, however, are studies comparing concomitantly-treated control patients to those with distraction. Perhaps one of the longest range studies was by Gunbay et al[22] who followed 7 patients for 36-48 (mean of 40) months. They conclude, however, that more multicenter studies and larger sample sizes were needed to more accurately assess the long-term effects of this procedure on the TMJ.[22] One of the strengths of the present study is its large sample size with the inclusion of 49 distraction patients and 57 control patients.

In total, this study included 106 patients (49 distraction and 57 control). Due to difficulty of follow-up over time, not all patients were followed at each time point which explains the differences in patient numbers at each time point. Statistical analyses were run based on the number of patients recorded at that time point. The database from which the TMD exam data were retrieved included some data for follow-up exams at the 2-, 3-, 4- and 5-year time points. However, due to scarcity of data in many of these long-term follow-ups, statistical analyses could not be completed. At the 5-year follow-up, TMD exam data were available for the majority of the distraction group. The control group, however, did not have such information available. Thus, statistical comparison between control and distraction groups was impossible at the 5-year mark.

Because the database included five-year follow-up TMD exams for distraction patients only, this study included the evaluation of the distraction group from pre-treatment to 5-year follow-up and noted no change in TMD symptoms over that period.

In line with most other studies[20, 22-23] following patients for TMD symptoms after distraction, our evaluation revealed no exacerbation of TMD symptoms in distraction patients over the course of the follow-up period. No other study included control data with which to compare which is a strength of this study. The results of the present study suggest that there is no different trend in any measure between the distraction group and the control group. In other words, with regard to TMD symptoms, both groups remained statistically the same.

It is reasonable to anticipate that rotation at the condyle could lead to issues with the temporomandibular joint since procedures such as bilateral sagittal split osteotomies and the resultant medial rotation of the condyles have been noted by some[24, 25] to be associated with TMD, though it has been controversial. Other studies[23, 26, 27] have not indicated an associated increase in TMD symptoms with altered condylar positions, whether rotational or linear, in the glenoid fossae. This led Kim et al[27] to suggest that often patients can adapt to non-ideal occlusion or condylar positioning.

MSDO has been suggested to cause a lateral rotation of the condylar head. The condylar rotation shown by Nishimura et al[26] ranged from 3.3°-5.1° with no associated TMD symptoms. This degree of rotation has not been shown to increase TMD symptoms in either the present study or preceding studies.[20, 22] Three authors have attempted to predict the degree of rotation at the condyle mathematically based on the amount of distraction performed at the symphysis.

Samchukov et al quantified the rotation as 0.34° of rotation at each condyle per millimeter of expansion at the symphysis. Orhan et al[28] estimated a 0.5° rotation for the same parameters based on indirect calculations. They measured intermolar and interpremolar distances at the end of expansion and after relapse of the expansion when the distractor was removed. These two studies were criticized by Landes et al[29] because they employed inadequate imaging techniques for assessing these values, which Orhan et al[28] also cited as a limitation of their calculations. Landes et al,[29] however, employed computed tomography to assess the magnitude of the condylar rotation after distraction. They determined that each condyle rotated 0.007° per millimeter of expansion at the symphysis—much less rotation than originally suggested by other investigators.

Rotational changes in the condyle have been suggested by Kundert et al[30] to cause the tissues of the temporomandibular joint to remodel. In fact, Harper et al[31] histologically evaluated the condyles of Macaca mulatta monkeys after distraction osteogenesis of 3-5 mm and noted that microscopic changes were most likely to be found on the posterolateral and anteromedial aspects of the condyle, which is consistent with a lateral rotation and with either a remodeling process of the condyles or a degenerative development. Due to the lack of TMD symptoms in the patients in this study and others, it is reasonable to conclude that the changes noted by Harper et al[31] signify an adaptive process of the condyles rather than a degenerative process. These results agree with Bell et al[32] who also studied histological changes in the condyles and concluded that the changes were minor. It appears, then, that the TMJ adapts to minor changes in condylar positioning. Currently no studies exist showing the threshold at which the TMJ can no longer adapt to the condylar position. Such a study in humans would be unethical.

The findings of this study agree with those of Gunbay et al,[22] who found that none of their 7 patients experienced permanent TMD symptoms after a mean of 40 months of follow-up, though one patient did experience pain in the TMJ that was resolved by physiotherapy. The mean distraction in their study was 6.48 mm which resulted in a condylar rotation measured to be 2.5°-3.0°. In the present study, the mean distraction was 6.36 mm. Though condylar rotation could not be measured given the records available, the amount of rotation is anticipated to be similar to Gunbay et al.[22]

Jaw pain and discomfort would be expected to be higher in the circum-distraction period due to patients recovering from surgery and adapting to additional intraoral orthodontic hardware. Thus, if a difference were to occur between distraction and control groups, it would be expected to occur at the time point closest to the surgery and active distraction. This corresponded with the 1 month follow-up observation, but no significant difference between the groups for any variables was noted even at this time point.

Regarding the sample used in this study, the patients were all treated in the same office by the same orthodontist and by the same oral surgeon. With a database of information such as the one utilized in this study, there is a potential risk of bias in collecting the sample. Patients who had the best outcomes could have been the only ones included in the database. While the authors believe that this is not a case, this potential bias still exists. In addition there was no blinding as to which patients had MSDO completed and which ones did not. Thus, a risk of bias at the follow-up exams does exist. The authors believe that the risk of this bias is low, but it must be mentioned.

Strengths of this study included the presence of a control group and the large number of patients in each group (n=49 for distraction and n=57 for control). One improvement in study design would be to evaluate patients who would benefit from MSDO and assign those who declined distraction to the control group to which to compare the distraction group. Additionally, the follow-up period for both control and study groups could be extended to 5 years. This study only had distraction group data available at the 5 year mark with no data for the controls. Studies currently available in the literature range from 1 patient and now to 49 patients who have undergone MSDO treatment with up to 5 year follow-up visits. Each study has concluded that TMD symptoms are neither created nor exacerbated by symphyseal distraction osteogenesis. Additional studies with large sample sizes and control groups should be conducted to verify the conclusions of this study and others. However, with the literature currently available addressing MSDO, the procedure seems to be biologically safe for all structures of the mandible, including the TMJ, provided that careful case selection and proper surgical techniques are employed.

Conclusions

- Compared to controls, subjects treated with MSDO did not experience any increase in TMD symptoms.
- The distraction group and control group were not different in any of the following measures at any time point:
    - Jaw pain
    - Jaw discomfort
    - Maximum opening
    - Maximum right and left lateral excursions
    - Maximum mandibular protrusion
    - The presence of: clenching, bruxism, clicking, crepitus, headaches, and TMJ palpation.

List of References

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Vita

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