

MRI-based determination of occlusal splint thickness for temporomandibular joint disk derangement: a randomized controlled clinical trial

Ayman F. Hegab, PhD,^a Ahmed Hossni Youssef, PhD,^b Hossam I. Abd Al Hameed, PhD,^c and Khaled Said Karam, PhD^c

Objective. This prospective study examined a method using magnetic resonance imaging (MRI) to assess the appropriate effective occlusal splint vertical thickness in the management of disk derangement.

Study Design. Patients were diagnosed as having internal disk displacement of the temporomandibular joint and were divided into 2 groups. Group I (disk displacement with reduction) was subdivided randomly into 2 subgroups: subgroup IA (control group) comprising patients treated with 3-mm-thick splints; and subgroup IB (study group) comprising patients treated with MRI-based splint thickness. Group II (disk displacement without reduction) was subdivided randomly into 2 subgroups: subgroup IIA (control group) comprising patients treated with 3-mm-thick splints; and subgroup IIB (study group) comprising patients treated with 3-mm-thick splints; and subgroup IIB (study group) comprising patients treated with 3-mm-thick splints; and subgroup IIB (study group) comprising patients treated with MRI-based splint thickness. The primary outcome variables were maximum voluntary mouth opening and visual analogue scale scores for pain. The secondary outcome variable was joint sound. The final sample was composed of 162 patients (Group I = 90 and Group II = 72).

Results. Statistical analysis showed significant improvement of the clinical outcomes in subgroups IB and IIB compared with that in subgroups IA and IIA.

Conclusions. On the basis of MRI measurements and clinical outcome, the present study we recommend 4-mm and 6-mm vertical splint thickness for disk displacement with reduction and disk displacement without reduction, respectively, for 1 year. (Oral Surg Oral Med Oral Pathol Oral Radiol 2018;125:74–87)

Internal derangement of the temporomandibular joint (TMJ) has been defined as an abnormal positional relationship of the disk relative to the condylar head, fossa, and/or articular tubercle and is the major cause of jaw pain, clicking, and/or crepitation and limitation of opening.^{1,2}

Different treatment modalities have been proposed for the management of internal derangement of the TMJ, including occlusal splints, physiotherapy, psychological treatment, medications, and surgical procedures.³⁵ Of these modalities, splint therapy is considered a reversible nonsurgical treatment modality for the management of internal derangement⁶ because it reduces the pain in the TMJ caused by excessive occlusal pressure from external forces. Thus, the splint restores blood circulation to the TMJ by maintaining a wide gap between the mandibular condyle and the mandibular fossa.^{7,8}

Although the effectiveness of occlusal splints for treating temporomandibular internal derangement continues to be debated,⁹⁻¹¹ the use of splints is presently considered the most common treatment modality for temporomandibular disorders (TMDs).^{12,13}

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Occlusal splint therapy is used for the treatment of TMDs for many reasons, in addition to its placebo effect⁶; it leads to adjustments of occlusion, enhancement of jaw muscle function, and new positioning of the disk–condyle relationship.^{4,8,14-17} The treatment goal is to achieve harmonious relationships among teeth, joints, and muscles. However, the effect of occlusal splint therapy on the disk–condyle relationship is still controversial.^{7,18-22}

Published studies have described different vertical thicknesses ranging from 1 to 8 mm.²²⁻²⁸ The best method to measure and select the accurate vertical thickness of the occlusal splint has not been determined yet. Therefore, improvement of the internal derangement of the TMJ after the application of a splint may vary among patients and among different studies. Hence, the selection of the vertical thickness of the occlusal splint should be based on scientific evidence.

To our knowledge, no previous studies have thoroughly investigated the changes in the disk-condyle relationship with use of different vertical thicknesses of

Statement of Clinical Relevance

To our knowledge, no previous studies have thoroughly investigated the changes in the disk–condyle relationship with use of different vertical thicknesses of the occlusal splint during magnetic resonance imaging acquisition to select the most accurate vertical thickness (evidence based) for the treatment of internal derangement.

^aDepartment of Oral & Maxillofacial Surgery, Faculty of Dental Medicine, Al-Azhar University, Cairo, Egypt.

^bProsthodontics, Faculty of dentistry Al-Azhar University, Cairo, Egypt. ^cDiagnostic Radiology, Al-Azhar University, Faculty of Medicine for Men, Cairo, Egypt.

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the occlusal splint by using magnetic resonance imaging (MRI) to select the most accurate and effective vertical thickness for the treatment of disk displacement with and without reduction. The present study aimed to investigate a new method of using MRI to assess the most effective vertical thickness of the occlusal splint for the management of TMJ internal derangement.

MATERIALS AND METHODS

The present study was approved by the institutional review board, and all patients gave written informed consent according to the ethics of our clinical research committee. The study population was composed of patients seeking treatment for TMDs.

Inclusion criteria

Patients were included if they were older than 18 years and diagnosed with disk displacement with or without reduction, as confirmed by MRI findings and the research diagnostic criteria (RDC) for TMDs.

Exclusion criteria for this study included systemic diseases (the presence of polyarthritis or other rheumatic diseases), contraindications for MRI (e.g., implanted metal or medical devices, claustrophobia), the presence of neurologic disorders, head and neck cancer, oral submucous fibrosis, a history of TMJ surgery, and a history of previous treatment with occlusal splints. Completely or partially edentulous patients were also excluded. Patients with normally positioned disks, patients who had a history of an open/closed lock, trauma patients with subcondylar fracture, and patients with congenital and developmental disorders of the TMJ were also excluded from the study.

The sample originally included patients who provided consent to participate in this study and who ultimately underwent treatment for the TMJ internal derangement between 2014 and 2017. During the study interval, 200 patients were screened for eligibility. Eight patients did not meet the inclusion criteria (7 had rheumatoid arthritis and 1 had psoriasis), and 22 were unwilling to participate in the study. Eight patients could not undergo the MRI because of claustrophobia and were excluded from the study. The final sample was composed of 162 patients.

RDC for TMD assessment

We used the RDC, not the diagnostic criteria (DC), because we began our study before the DC were recommended. The RDC have 2 assessment components. Axis I describes the image analysis of TMJ disk displacement using arthrography and MRI, and osteoarthritis based on the computed tomography (CT). Axis II evaluates the patient's psychological status and pain-related disability.²⁹ Axis I of the new DC involves expanded taxonomy for all the TMDs, and the criteria are derived from pertinent clinical signs and symptoms. For Axis II, the protocol has been expanded by adding new instruments to evaluate pain behavior, psychological status, and psychosocial functioning.³⁰

For clinical assessment, we used a standardized clinical protocol, including evaluation of patient history, palpation of the TMJs, auscultation of joint sound, and measurement of mandibular range of motion. The study patients were instructed to open their mouths as wide as they could without discomfort. According to the RDC,²⁹ cases with disk displacement with reduction were associated with the following: reciprocal clicking in the TMJ, reproducible in 2 of 3 consecutive trials; clicking of the TMJ in the vertical range of motion (either opening or closing), reproducible in 2 of 3 consecutive trials; and clicking during lateral excursion or protrusion, reproducible in 2 of 3 consecutive trials.

Cases of disk displacement without reduction were associated with a history of clicking sounds, contralateral excursion less than 7 mm, uncorrected deviation to the ipsilateral side on opening, and a history of significant limitation in opening; maximum unassisted opening less than 35 mm, and increased passive stretch opening less than 4 mm over the maximum unassisted opening.

Imaging studies

Panoramic radiography. Orthopantomography was used to screen all patients enrolled in this study as part of the regular protocol used in the respective clinics.

Magnetic resonance imaging. MRI scans were examined by 2 radiologists with more than 12 years of experience in maxillofacial radiology, especially in the study of TMJ disorders. Disk position was categorized as disk displacement with reduction (DDR) and disk displacement without reduction (DDNR).^{31,32}

The 90 patients in group I (DDR) were randomly assigned to 1 of 2 equal subgroups of 45 patients, each using sealed opaque sequentially numbered envelopes. The patients in subgroup IA (the control group) were treated with a 3-mm-thick occlusal splint. The patients in subgroup IB (the study group) were treated with an MRIbased splint thickness, and the thickness of the occlusal splint was selected according to the optimal effect of the splint on the condyle and disk movement, as described below.

The 72 patients in group II (DDNR) were randomly assigned to 1 of 2 equal subgroups of 36 patients, each using sequentially numbered envelopes. The patients in subgroup IIA (the control group) were treated with a 3-mm-thick occlusal splint. The patients in subgroup IIB (the study group) were treated with an MRI-based splint thickness.

MRI was performed in the following sequence: The first MRI was performed before treatment without splint insertion for the diagnosis of the TMD for all patients

enrolled in the study. The second MRI was performed only for patients in subgroups IB and IIB, with the splints in situ. For this MRI examination, occlusal splints of differing vertical thicknesses were inserted for each scan, with the goal of selecting the splint thickness that resulted in the optimal effect on the condyle and disk movement as described below. A third MRI was performed 12 months after treatment without splint insertion for the evaluation of the treatment results for all the patients enrolled in the study.

Pretreatment MRI

MRI examinations were performed using a 1.5 T unit (Magnetom Vision; Siemens, Erlangen, Germany) with a dual TMJ surface coil. A multislice examination was performed on each patient with 9 slices for each joint in multiple planes (slice thickness 2.5 mm). All patients had bilateral oblique sagittal T1-weighted spin echo scans (repetition time [TR] = 550 ms; echo time $[TE] = 13 \text{ ms}; \text{ field of view } [FOV] 14 \times 14 \text{ cm}) \text{ in both}$ open- and closed-mouth positions. The other available images for review included T2-weighted spin echo images in oblique sagittal (TR = 3570; TE = 67) and in closedand open-mouth positions. Proton density-weighted images with spin echo sequence (TR = 3570; TE = 22) were obtained in the oblique sagittal plane in both closedand open-mouth positions. T1-weighted oblique coronal images were acquired in the closed-mouth position only (TR = 550 ms; TE = 13 ms).

To prepare for closed-mouth MRI, the clinician instructed the participants to keep the posterior teeth together in a position where the teeth fit the best. The clinician then visually verified this position. The same instructions were reviewed by the radiology technologist, who read them to the patient before the MRI. During openmouth MRI, the clinician instructed the participants to open their mouths as wide as determined previously in the clinic. The patients were instructed to open their mouths as wide as they could without discomfort. The clinician then placed a mouth-opening device between the patient's teeth and opened the mouth to the maximum that the participant could tolerate. The amount of opening was recorded by the clinician, and this information was given to the radiology technologist.

Splint fabrication

Maxillary full-arch hard stabilization splints were fabricated with fluid resin. In the control subgroups (IA and IIA), the occlusal vertical dimension between the posterior molar teeth of the maxilla and mandible was maintained at 3 mm. In the study subgroups (IB and IIB), the occlusal vertical dimension between the posterior molar teeth of the maxilla and mandible was maintained at 2, 3, 4, 5, and 6 mm. Thus, 5 occlusal splints were constructed for the patients in subgroups IB and IIB. The selection of the splint thickness that produced the optimal results with regard to condylar and disk movements was based on the MRI study, according to the criteria of changes in condylar and disk positions described below.

MRI measurements

To standardize the technique, MRI analyses were performed by the 2 radiologists, who were blinded to the clinical diagnosis. To prevent errors during the MRI measurements, no hand-tracing was used. The software Siemens Syngo fastView for DICOM images was used for all MRI measurements. Analysis of the MRI scans was performed according to the method of Kurita et al.³³ (Figure 1A and 1B). The 2 radiologists worked together, and the lines as illustrated in Figure 1A and 1B were created by both of them. The measurements were performed in a blinded manner by the radiologists, and the average of the results was determined. Based on these measurements, the optimal splint thickness was selected for patients in subgroups IB and IIB, based on criteria described below.

To evaluate the anteroposterior condylar and disk positions, 3 lines were drawn. The first line was tangential to the inferior edge of the articular tubercle (T) and the superior edge of the external auditory meatus (P). This is the TP line. The second line was tangential to the posterior border of the mandibular condyle, perpendicular to the TP line. The point of intersection of this line and the TP line was defined as C. The third line was tangential to the posterior edge of the disk, perpendicular to the TP line. The point of intersection of this line and the TP line was defined as D. The anteroposterior condylar position was then expressed by the ratio of the distance between T and C and the distance between T and P (TC/ TP). The anteroposterior disk position was expressed as the ratio of the distance between T and D and the distance between T and P (TD/TP).

Two other lines parallel to the TP line were drawn to evaluate the vertical movement of the mandibular condyle. The first line was tangential to the roof of the mandibular fossa (point F). The second line was tangential to the superior surface of the condyle (point S). The vertical change of the condyle was defined as the ratio of the shortest distance between these 2 lines (FS) and the distance between T and P (FS/TP).

MRI study with splint in situ

An MRI examination was performed with the splint placed in the upper jaw. When the splint was in place, the patients were asked to make light contact with the splint with their teeth. The positions with and without the appliance were practiced before the examination. This procedure was repeated with splints of different thicknesses (2, 3, 4, 5, and 6 mm), with the patients maintaining



Fig. 1. **A**, Measurement of anteroposterior positions of the condyles and disks: *T*: Inferior edge of the articular tubercle. *P*: Superior edge of the external auditory meatus. *F*: Roof of the mandibular fossa. *S*: Superior edge of the condylar head. *Line TP*: Line tangent to points T and P. A second line was drawn perpendicular to TP, tangent to the posterior border of the mandibular condyle. The point of intersection of this line and TP was defined as C. A third line was drawn perpendicular to TP, tangent to the posterior condylar posterior edge of the disk. The point of intersection of this line and the TP line was defined as D. The anteroposterior condylar position was then expressed by the ratio of the distance between T and C and the distance between T and P (TC/TP). The anteroposterior disk position was expressed as the ratio of the distance between T and D and the distance between T and P (TD/TP). Measurements of the vertical movement of the condyles: Two lines parallel to the TP line were drawn. The first line was tangent to the roof of the mandibular fossa (point F). The second line was tangent to the superior surface of the condyle (point S). The vertical change of the condyle was defined as the ratio of the shortest distance between these 2 lines (FS) and the distance between T and P (FS/TP). **B**, Changes that occurred with the splint inside the mouth are marked with (–).

the same occlusal position for each splint. Reference points with a mark (-) represented the positions when a splint was in situ (see Figure 1B). There was no metal clasp in the splint during the MRI examination to prevent image distortion.

Data analysis

The anteroposterior movement of the condyle caused by the splint was evaluated by subtracting $T^{-}C^{-}/T^{-}P^{-}$ (with the splint in situ) from TC/TP (without the splint).

The anteroposterior movement of the disk was evaluated by subtracting $T^{-}D^{-}/T^{-}P^{-}$ (with the splint in situ) from TD/TP (without the splint).

The vertical movement of the condyle was evaluated by subtracting F'S'/T'P' (with the splint in situ) from FS/ TP (without the splint).

The measurements were done 3 times for each image, and the average was calculated. The post-treatment MRI study was preformed 12 months after the splint therapy for all of the patients in this study, without the splint in situ.

Criteria for selection of the appropriate thickness of the splint

The splint that fulfilled the following requirements was used:

1. Increased anterior movement of the mandibular condyle (TC/TP – T⁻C⁻/T⁻P⁻)

- 2. Increased movement of the articular disk (TD/TP T⁻D⁻/T⁻P⁻)
- 3. Increased vertical movement of the mandibular condyle $(FS/TP F^{-}S^{-}/T^{-}P^{-})$.

The splint thickness that had the greatest change in each of the 3 parameters was selected. In cases when different splint thickness produced the same average measurements, the least thick was used (if the same average measurements produced a splint thickness of 4, 5, and 6 mm, then a splint thickness of 4 mm was used).

Splint-wearing regimen

The selected splint was adjusted, and 2 ball clasps were added on each side of the splint to increase retention. In both study groups, the occlusal splint was worn 24 hours a day for 12 months, except when eating and brushing the teeth or during other oral hygiene care. The patients were asked to return to the clinical setting for monthly follow-up or when needed.

Medications/conservative therapy prescribed included analgesics (diclofenac potassium 50 mg) and muscle relaxants to be taken 3 times daily for 1 week.

Clinical outcomes

The primary outcome variable was treatment effectiveness based on the assessment of maximum nonassisted (voluntary) mouth opening (MVMO) in millimeters. The pain index score was measured using a 10-point visual analogue scale (VAS), with 0 indicating absence of pain and 10 indicating the worst pain.

The secondary outcome variable was joint sound. To evaluate joint sound, the patients were asked to open their mouths as widely as possible, and the joint sound was then determined by combining 3 means: (1) palpation of the TMJ zone by the clinician, (2) the patient's selfreporting regarding whether the joint sound could be heard, and (3) auscultation of the TMJ zone with the stethoscope. The absence of joint sound was confirmed when no sound was detected or reported when the above 3 means were employed. Joint sound was considered to be present if it was detected/reported with use of the above 3 means or a result was undetermined.

All outcome variables were assessed and compared between the groups at baseline and 1, 3, 6, and 12 months later. Age and gender were considered the third category of variables and correlated with the outcome variables. Adjustment variables included baseline MVMO and the pain index score. For statistical purposes, VAS pain levels and jaw range-of-motion values were managed as continuous variables. For all variables, repeated measures analysis of variance was performed to assess the existence of significant within-group and between-group treatment effects. Adjustments for age and gender were performed to assess the influence of demographic features on treatment effectiveness.

Statistical analysis

A post hoc power analysis was designed to determine the study's power. The power was found to be 0.97 (97%), indicating that the sample size was adequate. The sample size calculation was performed using G^*Power version 3.1.9.2.

The numerical data were explored for normality by examining the distributions of the data, calculating the means and medians, and using tests of normality (e.g., the Kolmogorov-Smirnov and Shapiro-Wilk tests). The age data exhibited a parametric distribution, but the interincisal opening data exhibited a nonparametric distribution. The VAS scores were also treated as nonparametric data. The age data, presented as mean and standard deviation (SD) values, were compared using the Student t test. The nonparametric data are presented as median and range values. The Mann-Whitney U test was used for between-group comparisons. The Friedman test was used to study the changes in each group over time. Wilcoxon signedrank tests were used for pairwise comparisons when Friedman tests yielded significance. The joint sound data (qualitative data) are presented as frequencies (n) and percentages (%). The χ^2 test was used to compare these data between the 2 groups. The significance level was set at 0.05. The data were analyzed using InStat statistical software (GraphPad Software, Inc., La Jolla, CA). Interobserver reliability was measured using the intraclass correlation coefficient.

RESULTS

In group I, 90 patients enrolled and were subdivided randomly into 2 equal subgroups of 45 patients each; and 72 patients enrolled in group II with 36 patients in each subgroup (Figure 2). The follow-up period ranged from 1 year and 9 months to 3 years and 3 months, with an average of 2 years and 4 months. The splint was used for 12 months in all patients enrolled in the study.

Interobserver reliability/consistency (95% confidence interval [CI]) for MRI measurements was 0.87 (0.79-0.90), with an excellent level of correlation among the observers.

Results of group I (DDR)

MRI measurement results in group IB. With regard to anteroposterior condylar movements, statistical analysis of the changes in the condylar positions with different splint thicknesses in comparison with the measurements of the condylar position without a splint in situ showed that there was no significant difference between the condylar position without a splint in situ and the condylar position changes with splint thicknesses of 2 and 3 mm (P = .323 and .91, respectively). There were highly significant changes in the anteroposterior condylar positions with splint thicknesses of 4, 5, and 6 mm (P < .001) (Table I).

Statistical analysis of the anteroposterior condylar position changes between the different splint thicknesses (the differences between each successive thickness) showed that there was a highly significant difference in the condylar position changes between 4 mm and 3 mm thicknesses (P < .001). The difference in the anteroposterior condylar position between 4 mm and 5 mm was not significant (P = .329). Furthermore, there was a large significant difference between the 4-mm and 6-mm thicknesses (P < .001).

With regard to disk movements, statistical analysis of the changes in the disk position with different splint thicknesses in comparison with the measurements of the disk position without a splint in situ showed that there was no significant difference between the disk position without a splint in situ and the disk position changes with splint thicknesses of 2 and 3 mm (P = .159 and .125, respectively). There were highly significant changes in the disk positions with splint thicknesses of 4, 5, and 6 mm (P = .013, .007, and .002, respectively) (see Table I).

Statistical analysis of the disk position changes for the different splint thicknesses showed that there was a significant statistical difference in the anteroposterior disk positions among the 2-, 3-, and 4-mm vertical thicknesses,



Fig. 2. Flow chart for the patients enrolled in the study.

with more disk movement associated with 4-mm vertical thickness (P = .021). There was no significant difference among the 4-, 5-, and 6-mm thicknesses (P = .071).

With regard to the vertical condylar movements, statistical analysis of the vertical position with different splint thicknesses in comparison with the measurements of the vertical position without a splint in situ showed nonsignificant change with a splint thickness of 2 mm (P = .16). Significant changes were associated with the splint thickness of 3 mm (P = .045). Highly significant changes were observed with splint thicknesses of 4, 5, and 6 mm (P < .001) (see Table I).

Statistical analysis of the vertical position changes among the different splint thicknesses showed that there was a large significant difference in the vertical positions of the condyle among the 2-, 3-, and 4-mm thicknesses, with more disk movement associated with 4-mm vertical thickness (P < .001). There was a significant difference among the 4-, 5-, and 6-mm thicknesses, with more vertical movement associated with 6-mm vertical thickness (P = .002).

On the basis of the results of the MRI measurements, the 4-mm vertical splint thickness was selected for use in subgroup IB. The same average measurements of the 3 parameters (anteroposterior condylar movements, anteroposterior disk movements, and vertical condylar movements) were produced by splint thicknesses of 4, 5, and 6 mm, so a splint thickness of 4 mm was used.

Details regarding the statistical analyses of the relationship of age, gender, and the affected side (unilateral/ bilateral) on the condylar, disk, and vertical movements are summarized in Table II. There were significant differences in anterior disk position as a result of age and gender; younger age and female gender were associated with higher movements. There was a significant difference in vertical condylar position as a result of

Table I. Changes in the anteroposterior condylar position, anteroposterior disk position, and vertical condylar position in subgroup IB with the 5 splints

	2 mm	3 mm	4 mm	5 mm	6 mm
Group IB: Anteroposterior condyle position changes	$Mean \pm SD$	$Mean \pm SD$	$Mean \pm SD$	$Mean \pm SD$	$Mean \pm SD$
Change (in mm)	16.2 ± 1.45	16.1 ± 1.42	10.9 ± 1.06	10.5 ± 1.06	10.1 ± 1.10
Lower 95% CI of mean	0.623	0.619	0.398	0.396	0.384
Upper 95% CI of mean	0.672	0.667	0.434	0.431	0.421
<i>P</i> value	.323 ^{ns}	.091 ^{ns}	<.001*	<.001*	<.001*
Group IB: Anteroposterior disk position changes					
Change (in mm)	12.0 ± 0.889	11.9 ± 0.894	11.4 ± 1.1	11.4 ± 1.05	11.3 ± 1.05
Lower 95% CI of mean	0.432	11.7	0.423	0.421	0.418
Upper 95% CI of mean	0.465	12.2	0.457	0.455	0.452
<i>P</i> value	.159 ^{ns}	.125 ^{ns}	.013†	.007‡	.002‡
Group IB: Vertical condylar position changes					
Change (in mm)	3.84 ± 0.629	4.01 ± 0.608	4.51 ± 0.678	5.16 ± 0.531	5.29 ± 0.406
Lower 95% CI of mean	0.128	0.132	0.161	0.191	0.198
Upper 95% CI of mean	0.157	0.161	0.199	0.211	0.214
<i>P</i> value	.16 ^{ns}	.045†	<.001*	<.001*	<.001*

CI, confidence interval; ns, not statistically significant.

Table II. Effect of age, gender, and affected side onanteroposterior condylar, anteroposterior disk, andvertical condylar movements in subgroup IB

	Age	Gender	Side (UNI/BI)
Anteroposterior condylar movements	0.614 ^{ns}	0.266 ^{ns}	0.372 ^{ns}
Anteroposterior disk	0.022*	0.003*	0.894 ^{ns}
Vertical condylar movements	0.424 ^{ns}	0.023*	0.548 ^{ns}

ns, not statistically significant; UNI/BI, unilateral/bilateral. $\ast P < .05.$

 $^{\dagger}P < .01.$

gender, with the female gender associated with greater vertical movements.

Statistical analysis for the correlations among the anteroposterior disk movements, anteroposterior condylar movements, and vertical condylar movements showed highly significant correlations between the anteroposterior disk movements and both anteroposterior and vertical condyle movements (P = .007 and P = .001, respectively). In addition, there was a significant correlation between vertical and anteroposterior condyle movements (P = .013).

Clinical results. In subgroup IA, 12 cases were bilateral DDR, and 33 were unilateral DDR, whereas in subgroup IB, 13 cases were bilateral DDR, and 32 were unilateral DDR. Table III shows the comparisons of the demographic features and the baseline values of the outcome variables between subgroups IA and IB. There were no significant differences between the subgroups for any of the variables.

Table III. Comparison of demographic features andbaseline values in outcome variable between thesubgroups IA and IB

Study variable	Subgroup IA Subgroup IB		P value	
Sample size	n = 45	n = 45	Not applicable	
Gender				
Male	13 (29%)	14 (31%)		
Female	32 (71%)	31 (69%)	.929	
Mean age	30.2 ± 5.7	32.5 ± 5.8	.973	
Mouth opening (mm)	35.5 ± 1.8	34.3 ± 2.4	.056	
Pain (0-10 on VAS)	6.8 ± 0.84	7.1 ± 1.13	.088	
Joint sound	45 (100%)	45 (100%)	Not applicable	

VAS, visual analogue scale.

Maximum voluntary mouth opening. At 1 month after treatment, there was no significant difference in MVMO between subgroups IA and IB (P = .122). Subgroup IB exhibited significantly higher MVMO compared with subgroup IA after 3, 6, and 12 months (mean \pm SD MVMO: 38.84 \pm 1.678 mm; 39.96 \pm 1.846 mm; and 41.02 \pm 1.725 mm; respectively) (P < .001). With regard to the changes over time in subgroup IB, there was a significant increase in the median MVMO through all periods.

Pain (VAS scores). The baseline median (range) pain scores were 7.0 (5.0-8.0) in subgroup IA and 7.0 (4.0-9.0) in subgroup IB.

Subgroup IB exhibited significantly lower pain scores than subgroup IA after 1, 3, 6, and 12 months (P < .001). With regard to the changes over time in subgroup IB, a significant decrease in median pain scores was observed across all periods (P < .001).

Joint sound. At 1 month after treatment, there was no statistical difference between IA and IB. In subgroup IB,

^{*}*P* < .001.

 $^{^{\}dagger}P < .05.$

 $^{^{\}ddagger}P < .01.$

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MVMO	Subgroup IA	Subgroup IB	
(months)	$Mean \pm SD$	$Mean \pm SD$	P value
1	36.0 ± 1.71	36.6 ± 1.86	.122 ^{ns}
3	36.7 ± 1.65	38.8 ± 1.68	<.001*
6	37.3 ± 1.57	39.9 ± 1.85	<.001*
12	37.5 ± 1.36	41.0 ± 1.73	<.001*
VAS			
1	5.13 ± 1.01	5.13 ± 1.01	<.001*
3	3.64 ± 1.30	1.67 ± 1.38	<.001*
6	1.98 ± 1.25	0.22 ± 0.52	<.001*
12	1.67 ± 1.02	0.13 ± 0.344	<.001*
Joint sound			
1	1.000 ± 0.0	1.000 ± 0.0	Not applicable
3	0.867 ± 0.344	0.467 ± 0.505	<.001*
6	0.644 ± 0.484	0.111 ± 0.318	<.001*
12	0.644 ± 0.484	0.111 ± 0.318	<.001*

MVMO, maximum voluntary mouth opening; *ns*, not statistically significant; *VAS*, visual analogue scale.

*P < .001.

 $^{\ddagger}P < .01.$

there was a significant decrease in the prevalence of joint sound after 3, 6, and 12 months (P < .001).

Details regarding the clinical outcomes of subgroups IA and IB are summarized in Table IV.

The effects of age, gender, and the affected side on the clinical outcomes among the study groups were not significant (P > .05).

An MRI study at 12 months after treatment without the splint in the mouth showed complete disk recapture in 11 cases of subgroup IB, whereas there was no disk recapture in subgroup IA (Figures 3 and 4, respectively).

An MRI study was repeated for the 11 patients with recaptured disks after another year beyond the 1-year posttreatment MRI (in other words, 2 years after the beginning of the project), and the disks had maintained their recaptured positions.

Results of group II (DDNR)

With regard to the anteroposterior condylar position, statistical analysis of the changes in the condylar position with different splint thicknesses in comparison with the measurements of the condylar position without a splint in situ showed that there was no significant difference in the condylar movement with use of 2-, 3-, and 4-mm splints in comparison with the measurements without the splint in situ (P = .324, .160, and .094, respectively). There was a significant difference in the anteroposterior condylar position for 5-mm splints (P = .002). Moreover, the 6-mm splint thickness was associated with a large significant difference (P < .001) (Table V).

Statistical analysis of the anteroposterior condylar position changes between the different splint thicknesses showed that there was no statistically significant difference in the anteroposterior condylar movement among the 2-, 3-, and 4-mm thicknesses (P = .239). There was a large significant difference between the 4- and 5-mm thicknesses (P < .001) and between the 5-and 6-mm thicknesses (P < .001).

For anteroposterior disk movements, statistical analysis of the changes in the disk position with different splint thickness in comparison with the measurements of the disk position without a splint in situ showed that there was no significant difference in the disk movement with the use of 2-, 3-, and 4-mm splints in comparison with the measurements without the splint in situ (P = .324, .173, and .089, respectively). There was a significant difference in the anteroposterior disk position for 5-mm splints (P = .048). Moreover, the 6-mm splint thickness was associated with a large significant difference (P < .002) (Table V).

Statistical analysis of the anteroposterior disk position changes among the different splint thicknesses showed that there was no statistically significant difference among the 2-, 3-, 4-, and 5-mm vertical thicknesses (P = .118). A vertical thickness of 6 mm showed a large significant difference compared with the other vertical thicknesses (P < .001).

For vertical condylar movements, statistical analysis of the changes in the vertical condylar position with different splint thicknesses in comparison with the measurements of the vertical condylar position without the splint in situ showed that there was no significant difference in the vertical condylar movement with the use of 2-, 3-, and 4-mm splints in comparison with the measurements without the splint in situ (P = .324, .163, and .087, respectively). There was a significant difference in the anteroposterior disk position for 5-mm splints (P = .027). The 6-mm splint thickness was associated with a large significant difference (P < .001) (Table V).

Statistical analysis of the vertical position changes among the different splint thicknesses showed that there was no statistically significant difference in the vertical condylar movement among the 2-, 3-, and 4-mm thicknesses (P = .234), and there was no significant difference between the 4-and 5-mm thicknesses (P = .135). A 6-mm vertical splint thickness showed a large significant difference compared with the other vertical splint thicknesses (P < .001).

The 6-mm splint thickness had the greatest change in each of the 3 parameters (anteroposterior condylar movements, anteroposterior disk movements, and vertical condylar movements). On the basis of the results of the MRI measurements, the 6-mm vertical splint thickness was selected for use in subgroup IIB.

Details regarding the statistical analyses of the effects of age, gender, and the affected side (unilateral/bilateral) on the anteroposterior condylar movements, anteroposterior disk movements, and vertical movements are summarized in Table VI. There were significant

 $^{^{\}dagger}P < .05.$



Fig. 3. Case 1 (subgroup IB): magnetic resonance imaging (MRI) evaluation of the changes of the anteroposterior condylar position, anteroposterior disk position, and vertical condylar position with different splint thicknesses and post-treatment disk recapture. A, T1-weighted image on pretreatment MRI in the closed-mouth position showing anterior disk displacement. B, T1-weighted image on MRI with 4-mm vertical splint thickness in the mouth. D, T1-weighted image on post-treatment MRI in the closed-mouth position showing a reduction of the anteriorly displaced disk. C, T1-weighted image on MRI with 4-mm vertical splint thickness in the mouth. D, T1-weighted image on post-treatment MRI in the closed-mouth position showing disk recapture without a splint in the mouth. E, T1-weighted image 1 year after treatment on MRI in the closed-mouth showing disk recapture without a splint in the mouth.



Fig. 4. Case 2 (subgroup IA): Pretreatment and post-treatment magnetic resonance imaging (MRI) evaluation of a case of disk displacement with reduction with no disk recapture after treatment. **A**, T1-weighted image on pretreatment MRI in the closed-mouth position showing anterior disk displacement. **B**, T1-weighted image on pretreatment MRI in the open-mouth position showing a reduction of the anteriorly displaced disk. **C**, T1-weighted image on post-treatment MRI in the closed-mouth showing no disk recapture without a splint in the mouth. **D**, T1-weighted image on post-treatment MRI in the open-mouth position showing a reduction of the anteriorly displaced disk.

differences in anteroposterior condylar and disk positions as a result of age, with greater changes occurring in younger patients. Significantly greater anteroposterior and vertical condylar movement was detected in females.

Statistical analysis of the correlations among the anteroposterior condyle, anteroposterior disk, and vertical movements showed that there was a highly significant correlation between disk movements and anteromedial and vertical condyle movements (P = .001 and P < .001, respectively). In addition, there was a significant correlation between anteroposterior and vertical condyle movements (P < .001).

Clinical results. In subgroup IIA, 10 cases were bilateral DDNR, and 26 were unilateral DDNR, whereas in

Table V. Changes in the anteroposterior condylar position, anteroposterior disk position, and vertical condylar position in the subgroup IB with the 5 splints

	2 mm	3 mm	4 mm	5 mm	6 mm
Group IIB: Anteroposterior condyle position changes	Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD
Change (in mm)	3.63 ± 0.759	3.69 ± 0.839	3.76 ± 0.914	3.89 ± 0.957	4.31 ± 0.786
Lower 95% CI of mean	0.105	0.106	0.108	0.111	0.138
Upper 95% CI of mean	0.131	0.132	0.134	0.138	0.163
P value	.324 ^{ns}	.160 ^{ns}	.094 ^{ns}	.002*	<.001 [†]
Group IB: Anteroposterior disk position changes					
Change (in mm)	6.03 ± 0.971	6.00 ± 0.934	5.93 ± 0.942	5.87 ± 0.921	5.50 ± 0.854
Lower 95% CI of mean	0.221	0.221	0.219	0.219	0.206
Upper 95% CI of mean	0.254	0.253	0.251	0.249	0.233
<i>P</i> value	.324 ^{ns}	.173 ^{ns}	.089 ^{ns}	.048‡	.002*
Group IB: Vertical condylar position changes					
Change (in mm)	3.63 ± 0.759	3.69 ± 0.839	3.76 ± 0.914	3.89 ± 0.957	4.31 ± 0.786
Lower 95% CI of mean	0.105	0.106	0.108	0.111	0.138
Upper 95% CI of mean	0.131	0.132	0.134	0.138	0.163
<i>P</i> value	.324 ^{ns}	.163 ^{ns}	.087 ^{ns}	.027‡	<.001*

CI, confidence interval; ns, not statistically significant.

 $^{\ddagger}P < .05.$

Table VI. Effect of age, gender, and affected side onanteroposterior condylar, anteroposterior disk, andvertical condylar movements in subgroup IIB

	Age	Gender	Side (UNI/BI)
Anteroposterior	0.002*	0.05†	0.003*
condylar	(greater in	(greater in	(more in UNI)
movements	younger age)	females)	
Anteroposterior	0.001*	0.503 ^{ns}	0.956 ^{ns}
disk movements	(greater in		
	younger age)		
Vertical condylar	0.075 ^{ns}	0.001*	0.609 ^{ns}
movements		(greater in	
		females)	

ns, not statistically significant; UNI/BI, unilateral/bilateral.

*P < .001 (highly significant).

 $^{\dagger}P < .05$ (significant).

subgroup IIB, 8 cases were bilateral DDNR, and 28 were unilateral DDNR. Table VII illustrates the comparisons of the demographic features and the baseline values of the outcome variables between subgroups IIA and IIB.

Maximum voluntary mouth opening. Subgroup IIB exhibited significantly higher median MVMO compared with subgroup IIA throughout the follow-up period (at 1, 3, 6, and 12 months postoperatively). At 12 months postoperatively, subgroup IIB exhibited a significantly higher median MVMO (39 mm) compared with subgroup IIA (34 mm) (P < .001). With regard to the changes over time in subgroup IIB, there was a significant increase in the median MVMO through all periods.

Pain (VAS scores). The baseline median (range) pain scores were 8.0 (6.0-9.0) in subgroup IIB and 8.0 (5.0-9.0) in subgroup IIA.

Table VII. Comparison of demographic features and
baseline values in outcome variable between the
subgroups IIA and IIB

Study variable	Subgroup IIA	Subgroup IIB	P value
Sample size	n = 36	n = 36	Not applicable
Gender			
Male	12 (33%)	15 (42%)	.590
Female	24 (67%)	21 (58%)	
Mean age	32.1 ± 7.3	32.9 ± 5.9	.215
Mouth opening (mm)	27.4 ± 3.7	27.2 ± 3.1	.309
Pain (0-10 on VAS)	8.0 ± 0.9	8.1 ± 0.9	.933
Joint sound	4 (11%)	1 (0.3%)	Not applicable

VAS, visual analogue scale.

Subgroup IIB exhibited significantly lower median pain scores than subgroup IIA after 1, 3, 6, and 12 months (P < .001). With regard to the changes over time in subgroup IIB, a significant decrease in median pain scores was observed across all periods.

Joint sound. At 1 and 3 months after treatment, there was no significant difference between subgroup IIA and IIB (P = .183 and P = .083, respectively).

In subgroup IIB, there was a significant increase in the prevalence of joint sound after 6 and 12 months. At 12 months after treatment, there was a significant difference in joint sound between both subgroups, with a greater increase in the prevalence of joint sounds in subgroup IIB (P < .001).

An MRI study at 12 months after treatment without a splint in the mouth showed disk recapture in

^{*}*P* < .01.

 $^{^{\}dagger}P < .001.$



Fig. 5. Case 1 (subgroup IIB): magnetic resonance imaging (MRI) evaluation of the changes of the anteroposterior condylar position, anteroposterior disk position, and vertical condylar position with different splint thicknesses and disk recapture postoperatively in the open mouth position only (case change from DDNR to DDR). **A**, T1-weighted image on pretreatment MRI in the closedmouth position showing anterior disk displacement. **B**, T1-weighted image on pretreatment MRI in the open-mouth position with the disk still displaced (DDNR). **C**, T1-weighted image on post-treatment MRI in the open-mouth position showing disk recapture without a splint in the mouth. **D**, T1-weighted image, 1 year after treatment, on MRI in the open-mouth position showing disk recapture without a splint in the mouth. There is greater posterior movement of the articular disk with an increase in the width of the bilaminar zone, indicating an increase in the range of mandibular movement during mouth opening (*black arrow*).

7 cases of subgroup IIB but no disk recapture in subgroup IIA.

Of the 7 cases of disk recapture in subgroup IIB, complete disk recapture in the closed- and openmouth positions occurred in only 3 cases. In the other 4 cases, disk recapture occurred in the open-mouth position only (the cases changed from DDNR to DDR) (Figures 5 and 6). MRI was repeated once more for the patients with disk recapture (7 cases) another year after the 1-year post-treatment MRI (in other words, 2 years after the beginning of the project), and the disks maintained their recaptured positions.

Details regarding the clinical outcomes of both subgroups IIA and IIB are summarized in Table VIII.

With regard to the effects of age, gender, and the affected side on the clinical outcomes, VAS was significantly affected by age, gender, and the affected side (P = .025, .027, and .029, respectively). Male gender, younger age, and unilateral DDNR were associated with lower VAS scores.

The effects of age, gender, and the affected side on joint sound were not significant (P = .222, .155, and .161, respectively).

MVMO was significantly affected by gender and the affected side (P = .041 and .031, respectively). Male gender and unilateral DDNR were associated with greater mouth opening. The effect of age on mouth opening was not significant (P = .057).

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MVMO (months)	Subgroup IIA Mean ± SD	Subgroup IIB Mean ± SD	P value
1	28.0 ± 4.64	30.7 ± 2.85	0/1*
3	20.9 ± 4.04 30.5 ± 4.36	30.7 ± 2.83 34.4 ± 2.09	< 001 [†]
6	32.2 ± 3.62	34.4 ± 2.09 38.4 ± 1.50	<.001 [†]
12	32.4 ± 3.45	38.8 ± 1.09	<.001*
VAS			
1	6.89 ± 1.01	5.00 ± 1.01	<.001*
3	5.58 ± 1.63	1.83 ± 0.971	<.001*
6	4.17 ± 2.08	0.167 ± 0.378	<.001*
12	3.61 ± 1.68	0.139 ± 0.351	<.001*
Joint sound			
1	0.111 ± 0.3187	0.0278 ± 0.167	.183 ^{ns}
3	0.0833 ± 0.280	0.250 ± 0.439	.083 ^{ns}
6	0.0556 ± 0.232	0.528 ± 0.506	<.001*
12	0.0556 ± 0.232	0.528 ± 0.506	<.001*

MVMO, maximum voluntary mouth opening; *ns*, not statistically significant.

*P < .05.

 $^{\dagger}P < .001.$

 $^{\ddagger}P < .01.$

DISCUSSION

Vertical thicknesses of occlusal splints range from 1 to 8 mm in published studies, with different treatment outcomes and results.²²⁻²⁸ Piper found that splints with a thickness ranging from 12 mm to 15 mm can alleviate clenching.³⁴ Manns et al. indicated that, for the treatment



Fig. 6. Case 2 (subgroup IIB): magnetic resonance imaging (MRI) evaluation of the changes of the anteroposterior condylar position, anteroposterior disk position, and vertical condylar position with different splint thicknesses and post-treatment disk recapture. **A**, T1-weighted image on pretreatment MRI in the closed-mouth position showing anterior disk displacement. **B**, T1-weighted image on MRI with 6-mm vertical splint thickness in the mouth. **D**, T1-weighted image on post-treatment MRI in the closed-mouth position showing disk recapture without a splint in the mouth. **E**, T1-weighted image on post-treatment MRI in the open-mouth position showing disk recapture without a splint in the mouth. **F**, T1-weighted image, 1 year after treatment, on MRI in the closed-mouth showing disk recapture without a splint in the mouth. **G**, T1-weighted image 1 year after treatment on MRI in the open-mouth position showing disk recapture without a splint in the mouth.

of bruxism and myofascial pain dysfunction, 4.4- and 8.2mm-thick splints can relax the masticatory muscles more satisfactorily than 1-mm-thick splints.²⁷ Dylina concluded that splints with a thickness of at least 4 mm can prevent bruxism.³⁵ Thus, the vertical thickness of occlusal splints is a key factor in the success of the treatment.

The selection of the vertical thickness of occlusal splints in these reports was based on personal experience and the clinical results of different studies without evidencebased research. In the present study, the selection of the vertical thickness of the occlusal splint based on the condylar and disk movements observed during MRI acquisition could be considered an evidence-based method.

The findings of our study suggest that an increase in the vertical thickness of the occlusal splint is associated with better clinical outcomes for patients with internal derangement of the TMJ. The final results of the MVMO, VAS, and joint sound evaluations showed significant improvement in the study group compared with the control group in patients with DDR and DDNR. These clinical results are supported by the MRI changes of the condyle–disk–fossa complex associated with an increase in the splint thickness from 2 mm to 6 mm. In the present study, MRI measurements of the anteroposterior condylar movements, anteroposterior disk movements, and vertical condylar movements in the DDR group were significant with vertical thicknesses of 4, 5, and 6 mm, whereas movements were not significant with smaller vertical thicknesses. The reason for selecting a vertical thickness of 4 mm was that there was no significant difference among the movements associated with 4-, 5-, and 6-mm thicknesses besides patient tolerance, which decreased with increasing vertical thickness. Therefore, using a vertical thickness of 5 or 6 mm in the DDR group is of no benefit because a 4-mm thickness produces almost the same movements.

The MRI results were supported by the clinical outcomes of the present study demonstrating significant improvement in subgroup IB (MRI-based splint thickness) compared with subgroup IA. Moreover, disk recapture occurred in 11 patients in subgroup IB, and this can be explained by the 4-mm vertical splint thickness that leads to an increase in the condylar and disk movements, which can help with disk recapture.

The MRI measurements in subgroup IIB (with DDNR) showed that the movements were significant only with

splint thicknesses of 5 and 6 mm, with a significant difference between the movements associated with 5- and 6-mm splint thicknesses. Hence, we chose the 6-mm vertical splint thickness; it provided the best condylar and disk movements.

The clinical results of the present study supported the MRI results. The clinical outcome of the DDNR group showed significant improvement in subgroup IIB (MRI-based splint thickness) in relation to subgroup IIA. Complete disk recapture occurred in only 3 cases, whereas in the other 4 cases, disk recapture occurred in the openmouth position only (the cases changed from DDNR to DDR). In subgroup IIA, no changes occurred in the disk position. This can be explained by the condylar and disk movements; they were only significant with a vertical thickness of 6 mm (subgroup IIB), and there were no significant changes with a vertical thickness of 3 mm (subgroup IIA), as confirmed by the MRI study and measurements.

It is thought that the posterior attachment of the anteriorly displaced disk is often elongated and thinned. Numerous investigators rely on the fact that this deformed and stretched tissue will not regain its original form or function, even when the disk is properly repositioned over the condyle.³³

The possibility of disk recapture depends on many factors, including the degree of disk displacement, disk shape, the integrity of the posterior attachments, the degree of the degenerative change of the condyle, the amount of load on the joint, the tissue repair capabilities, and the patient's age. Moreover, the vertical thickness of the occlusal splint plays an important role in the disk recapture as confirmed by MRI in this study.

The results of our study are supported by those of Manns et al.,²⁷ who concluded that thinner splints took longer to reduce pain in patients with internal derangement of the TMJ. The results of the present study are supported by the results of the Jolanta et al.,³⁶ who found a statistically significant correlation between vertical thickness of the splint and treatment effectiveness as well as between the vertical jaw separation at which the first minimum bite force generated in patients was measured and the vertical jaw separation for the vertical thickness of the splint with maximum therapeutic effectiveness.

The ability of the occlusal splint to alter the disk– condyle relationship remains controversial. The literature suggests that normal disk–condyle relationships are reestablished after occlusal splint therapy, either by repositioning of the condyle or recapturing of the disk.³⁷

These findings are in agreement with our results showing both repositioning of the condyle and disk recapturing after using the splint, which was confirmed by MRI with the splint in the mouth. However, the present study found that changes in the disk–condyle relationship were not uniform among patients and among the different thicknesses of the occlusal splint.

One of the limitations of our study was that the movement of the disk was evaluated only in the anteroposterior direction. Kurita et al.³³ measured the central, medial, and lateral movements to provide a 3-dimensional corelation of disk movement. In our sample and with the use of our methods, evaluation of the medial and lateral depth measurements was associated with longer duration of MRI, which is difficult for patients. At the same time, aim of our study was to evaluate the effect of increasing the occlusal splint thickness on movement rather than to study the movement itself.

Some patients wanted a thinner splint that was more acceptable and less inconvenient. Compliance with wearing of the occlusal splint required personal psychological adaptation as well as physiologic rehabilitation of pronunciation and all oral activities, especially after the change of the vertical dimension, which affects the relationship between the maxilla and the mandible, swallowing activities, and the tongue's position in the oral cavity. The social adaptation of the patient and his or her ability to continue social activities while wearing the occlusal splint 24 hours a day (except during eating) for at least 12 months (at school, university, work, or with family) played an essential role in treatment success and depended on different factors.

CONCLUSIONS

The present study demonstrated that an increase in splint thickness was associated with an increase in anteroposterior condylar movements, anteroposterior disk movements, and vertical condylar movements and led to improved clinical outcomes. Although the results of this study may suggest that the thicker splint is effective in TMD cases with DDNR, it is difficult to determine the best thickness of a splint. On the basis of MRI measurements and clinical outcomes in our study, we recommend a 4-mm vertical splint thickness for DDR and a 6-mm vertical splint thickness for DDNR cases and at least 1 year of treatment.

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Reprint requests:

Ayman F. Hegab, PhD Department of Oral & Maxillofacial Surgery Faculty of Dental Medicine Al-Azhar University Cairo Egypt hegab@mail.com; prof.aymanhegab@yahoo.com