

2023

Evaluation of pain perception associated with maxillary first molars distalization in the presence of maxillary third molars versus extracted third molars using infra-zygomatic mini-screws: A randomized clinical trial

Nadeen H. Hafez

B.D.Sc Faculty of Dentistry, Ain shams University, Cairo, Egypt., 20172999@fue.edu.eg

Yehya A. Mostafa

Professor and chairman, Department of Orthodontics, Faculty of Oral and Dental Medicine, Future University in Egypt, Cairo, Egypt., yehia.ahmed@fue.edu.eg

Amr E. El-Dakroury

Professor and chairman, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt., amrdakroury61@yahoo.com

Mostafa M. El-Dawlatly

Associate professor, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt., Mostafa.eldawlatly@fue.edu.eg

Follow this and additional works at: <https://digitalcommons.aaru.edu.jo/fdj>



Part of the [Orthodontics and Orthodontology Commons](#)

Recommended Citation

Hafez NH, Mostafa YA, El-Dakroury AE, El-Dawlatly MM. Evaluation of pain perception associated with maxillary first molars distalization in the presence of maxillary third molars versus extracted third molars using infra-zygomatic mini-screws: A randomized clinical trial. *Future Dental Journal*. 2024; 9(2).

This Article is brought to you for free and open access by Arab Journals Platform. It has been accepted for inclusion in Future Dental Journal by an authorized editor. The journal is hosted on [Digital Commons](#), an Elsevier platform. For more information, please contact rakan@aarj.edu.jo, marah@aarj.edu.jo, u.murad@aarj.edu.jo.

**Evaluation of pain perception associated with
maxillary first molar distalization in the presence of
maxillary third molars versus extracted third molars
using infra-zygomatic mini-screws:
A randomized clinical trial**

Nadeen H. Hafez ^a, Yehya A. Mostafa ^b, Amr E. El-Dakrouy ^c,
and Mostafa M. El-Dawlatly ^d.

^a B.D.Sc Faculty of Dentistry, Ain shams University, Cairo, Egypt.

^b Professor and chairman, Department of Orthodontics, Faculty of Oral and Dental Medicine, Future University in Egypt, Cairo, Egypt.

^c Professor and chairman, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt.

^d Associate professor, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt.

Introduction:

Class II malocclusions have a significant prevalence in most populations[1–3] and have always been a point of interest to orthodontists. Non-extraction treatment protocols for the correction of dental Class II malocclusions can be accomplished by various techniques. Distalizing the maxillary molars and utilizing the gained space to alleviate crowding and/or decrease overjet is an integral part of these methods.

The success of the treatment plan for Class II malocclusion is highly affected by the means of anchorage. However, during distalizing the maxillary molars into a Class I relationship, they move slowly, and anchorage loss frequently happens [4,5].

Despite the availability of multiple approaches and techniques for controlling anchorage, the use of mini-implants for absolute anchorage has become more prevalent in recent years[6]. These temporary anchorage devices have several advantages, including ease of insertion and removal, low cost, small size, various insertion locations, patient cooperation limited to maintaining good oral hygiene, and immediate loading, shortening the treatment duration[7,8].

Due to the variety of screw types and their applications, only a few generalizations can be made about the pain and distress associated with mini-screws insertion [9]. Previous research revealed that drilling a pilot hole is as painful as the pressure that self-drilling screws exert on the bone. Patients report even higher pain levels when flap surgery or soft tissue puncturing is included in the treatment. When flap surgery or soft tissue puncturing is included in the treatment, patients report even higher pain levels [7,10]. It was demonstrated that patients anticipate the placement of mini-screws buccally to be more excruciating than it actually is: [11].

In recent decades, certain researchers have proposed the infra-zygomatic crest (IZC) as an anchorage area for maxillary molar distalization using mini-implants [12]. The advantage of IZC is that it has a thick cortical bone that can withstand high strains, and the approach utilized was both cost-effective and non-invasive since no surgery was required. However, there is a lack in the literature concerning the pain and discomfort of patients being treated with mini-implants inserted in the infra-zygomatic region.

In accordance with previous studies [13] more anchorage loss is anticipated when distalizing the maxillary first molar after the complete eruption of the maxillary second molar. They also recommended a germectomy of the third molars before distalization. In adults, extracting fully erupted third molars is not a problem and may even be advised so that the extraction site may accommodate more distalization amount. On the contrary, adolescents usually have unerupted third molars; therefore, the surgical extraction might be painful and traumatic [14]. Patients may avoid orthodontic treatment due to fear of discomfort and trauma.

To the best of our knowledge, no prior clinical trial has compared the pain perception and patient discomfort throughout the entire treatment duration while distalizing the maxillary first molars in the presence and absence of maxillary third molar buds using infra-zygomatic mini-implants.

Consequently, the objective of this clinical trial was to assess and compare the pain encountered at the insertion site of the infra-zygomatic mini-implant and the pain associated with distalizing maxillary first molars with the presence versus extraction of unerupted third molars in a group of adolescent female patients.

Material and methods:

The Research Ethics Committee of Future University approved this single-centre, 2-arm, parallel-group, randomized clinical trial with a 1:1

allocation ratio. Before treatment, all participants and their parents signed the written informed consent form. Calculation of the sample size was based on a comparison of pain on a numeric rating scale between the third molar extraction (TME) and third molar presence (TMP) groups. According to a prior study[15], the minimal clinically significant difference in the numerical rating scale (NRS) was 1.7 with a standard deviation of 1.43. Using Student's t-test for independent samples, the minimum sample size required to reject the null hypothesis with 80% power at $\alpha = 0.05$ was 12 participants per group. Sample size calculation was done using PS Power and Sample Size Calculations Software, version 3.1.2 for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA). To Account for any missing data, the sample size was increased to 15 per group.

During the recruitment period, the eligibility of sixty-seven patients was determined. From this sample, 35 subjects were eliminated because they did not meet the selection criteria, and two others declined to participate. Thirty patients were assigned in a ratio of 1:1. The inclusion criteria included: (1) Female patients aged 16-19 years old (2) Class II molar relationship, (3) normal vertical dimension; (4) All permanent dentition has erupted except the maxillary third molars. Exclusion criteria included: (1) a skeletal Class II or Class III relationship; (2) past orthodontic treatment; (3) bad oral hygiene; (4) para-functional habits (5) history of systemic disease. The randomization process was carried out via the Randomization.com website (<http://www.randomization.com>). The treatment allocation cards were concealed in consecutively numbered, opaque, and sealed envelopes with sequential numbers. Following the randomization sequence, the group name was written on Each envelop

In the third molar extraction group (TME), the third molars were surgically removed four weeks prior to the commencement of the intervention. The same treatment protocol was then applied to all patients in both groups.

After levelling and alignment stage, two self-tapping mini-screws, 10 mm in length and 1.6 mm in diameter (Tomas-pin EP, Dentaaurum, Germany) were inserted in the infra-zygomatic region (2 mm above the mucogingival junction and opposing to the mesiobuccal root of the maxillary first molar) [16] (Fig. 1). 0.12% chlorhexidine mouth rinse was prescribed prior to implantation of the Mini-screw [11]. All mini-screws were implanted under the effect of local anaesthesia (2% lidocaine hydrochloride, 1:100,000 epinephrine). On the day of the mini-implant implantation procedure, the patient was provided with a written pain assessment form. This form contained a numeric pain rating scale [17] (Fig 2), which was filled out by each patient and given to the operator at his first 2-week follow-up appointment. Pain assessment was done by providing the patient with a written form on the day of the mini-implant insertion. This form comprised a numeric pain rating scale (Fig 2), which was completed by each patient and handed out to the operator on his first follow-up visit after 2 weeks.

The Numeric Pain Rating Scale was explained to the patient to assess the pain intensity in the postoperative period; immediately after the Mini-implant insertion, 1 day, 3 days and 1 week after the installation procedure. Paracetamol analgesic was only prescribed in case of severe unbearable pain.

The mini-screws were loaded two weeks after insertion (Fig. 3). The force applied was 350 gm per side. Each patient responded to a written form comprising a numeric pain rating scale to assess the pain intensity on the same day of mini-screw loading, 3 days, 1 week, and 2 weeks after appliance fixation. Three copies were given to every patient, and the same pain response was required for the first, third, and sixth appliance activations.

Distalization continued until achieving class I molar relation. Follow up was done every 4 weeks for force activation and checking screw stability.

Data were analyzed blindly by an external assessor and statistically described in terms of mean and standard deviation. Numerical data were tested for the normal assumption using Shapiro Wilk test. Comparison between the

study groups was done using Mann Whitney U test for independent samples. Two-sided *P* values less than 0.05 was considered statistically significant. IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows was used for all statistical analyses.

Results:

At the mini-implant site, the mean pain scores in the TMP and TME on the same day for screw insertion were 5.27 ± 2.08 and 4.89 ± 1.99 , respectively. After 24 hours, the TMP and TME had mean pain scores of 3.87 ± 1.95 and 4.13 ± 2 , respectively. After 3 days of mini-implant insertion, the mean pain score in the TMP and TME groups was 1.87 ± 1.45 and 2.12 ± 1.7 , respectively. After one week, the mean pain score in the TMP and TME was 0.93 ± 1.12 and 0.8 ± 1.12 , respectively. Table 1 shows that there was no significant difference between the trial groups at any time of pain assessment.

Throughout the distalization phase, the average pain severity at the maxillary molar site on the day of mini-implant loading was 4.2 ± 1.46 in the TMP group and 4.13 ± 2.2 in the TME group. There was no significant difference between the two groups. ($P > 0.05$). After three days of force application, the average pain score in the TMP and TME groups was 3.17 ± 1.11 and 3.08 ± 1.05 , respectively. At one week, the TMP group's average pain score was 1.37 ± 0.86 , and the TME group's average pain score was 1.44 ± 0.78 . The TMP and TME groups had an average pain score of 0.44 ± 0.48 and 0.5 ± 0.33 after two weeks of loading respectively, which were found to be statistically insignificant.

At the first, third, and sixth activation points, there were no significant differences between trial groups. Also, there were no significant differences in the average activation times on the day of mini-implant loading, after three days, one week, and two weeks (Table II).

Table I: Comparison of pain scores at the different assessment times at the mini-implant insertion site

Group	Third molar presence	Third molar extraction	
Time of assessment	Mean (SD)	Mean (SD)	P value
On the day of insertion	5.27(2.08)	4.87(1.99)	0.55
After 24 hours	3.87(1.95)	4.13(2)	0.86
After 72 hours	1.87(1.45)	2.13(1.7)	0.75
After 1 week	0.93(1.1)	0.8 (1.12)	0.91

(SD) standard deviation

Table II: Comparison of pain scores at the different activation times at the maxillary molars site

Group	Third molar presence	Third molar extraction		
Time of assessment	Mean (SD)	Mean (SD)	P value	
First activation				
Same day of loading	4.2(2.2)	3.9(2.7)	0.585	
After 72 hours	3.6(1.95)	3.46(2.32)	0.85	
After 1 week	1.53(1.45)	1.8(1.74)	0.732	
After 2 weeks	0.73 (0.8)	0.8(0.77)	0.686	

Third activation			
Same day of loading	4.33(2.38)	4.13(2.2)	0.983
After 72 hours	2.86(1.4)	3(1.77)	0.915
After 1 week	1.26(1.38)	1.46(1.12)	0.415
After 2 weeks	0.33(0.6)	0.46(0.74)	0.643
Sixth activation			
Same day of loading	4.06(2.12)	4.6(1.9)	0.529
After 72 hours	3.06(1.8)	2.8(1.69)	0.658
After 1 week	1.33(1.17)	1.06(0.96)	0.588
After 2 weeks	0.26(0.59)	0.26(0.59)	0.121
Average pain score in all activations			
Same day of loading	4.2(1.46)	4.22(1.4)	0.983
After 72 hours	3.17(1.11)	3.08(1.05)	0.504
After 1 week	1.37(0.86)	1.44(0.78)	0.818
After 2 weeks	0.44(0.48)	0.51(0.37)	0.356

(SD) standard deviation

Discussion:

Pain is a subjective experience that may be difficult to evaluate and is influenced by several factors. It often varies depending on a number of variables, including gender, age, the location of the mini-implant, and the subject's prior pain history[18]. Tradition suggests that females are 'fragile' and sensitive to pain, whereas males are more enduring and can withstand more pain[19]. In our research, only female participants were chosen to minimize such confounders.

In orthodontic treatment, comparing the 'effect of age' on pain perception is challenging. This is primarily because patients of varying ages are treated differently. However, research on this topic has yielded contradictory results. The majority believe that adult patients experience more discomfort than young patients [20,21]. Comparing pain perception with a pain rating index in pre-adolescents, adolescents and adults, Brown and Morenhout [21] revealed that adolescents reported a greater level of pain than pre-adolescents and adults. In our investigation, female adolescents aged 16 to 19 were selected as participants.

The fundamental aim of all minimally invasive surgical procedures is to achieve absolute anchorage utilizing patient-friendly approaches; consequently, patients' feedback was of the most importance. All patients were asked to assess their pain levels on the day of the mini-implant insertion procedure and after 24 hours, 72 hours, and 1 week using a numeric pain rating scale[17]; a highly reliable tool compared to the visual analogue scale (VAS) and the verbal rating scale (VRS). Hjerstad et al.[22] conducted a systematic review to compare the three forementioned pain scales. They recommended the use of the numeric pain rating scale on the basis of higher compliance rates, better responsiveness, ease of use and good applicability relative to the VAS & VRS. The severity of pain experienced by patients in both groups ranged from minimal to moderate and rapidly subsided after one week. Nevertheless, the mean pain scores obtained in

this study were greater than those reported by Sreenivasagan et al.[23]. The implant site pain perception did not differ significantly between both groups.

Similar to the research conducted by Nur et al. [24] and El-Dawlatly et al. [25], a distalization force of 300 gm/side was applied. Comparing the two trial groups, the pain induced by the distalization procedure was comparable in both groups, ranging from moderate on the day of activation to mild by the third day and fading gradually thereafter.

Conclusions:

To recapitulate the findings of the current randomized clinical trial, the pain experienced by the patient during maxillary molar distalization, whether the third molar was extracted or present, is comparable. Infra-zygomatic screw insertion evolved moderate to mild pain in both groups. Distalization procedure was associated with moderate or slight discomfort that faded away gradually after the loading day. Generally, the pain experienced at the mini-implant site was higher than that caused by the distalization force in both groups.

References:

1. El-Mangoury NH, Mostafa YA. Epidemiologic panorama of dental occlusion. *Angle Orthod.* 1990;60(3):207–14.
2. E-Erum ,, Fida M. Pattern of malocclusion in orthodontic patients: a hospital based study [Internet]. Vol. 20, *Journal of Ayub Medical College.* 2008. Available from: <http://ecommons.aku.edu/>
3. Bilgic F, Gelgor IE, Celebi AA. Malocclusion prevalence and orthodontic treatment need in central Anatolian adolescents compared to European and other nations' adolescents. *Dental Press J Orthod.* 2015 Nov 1;20(6):75–81.
4. Ghosh J, Nanda RS. Evaluation of an intraoral maxillary molar distalization technique. *American Journal of Orthodontics and Dentofacial Orthopedics.* 1996;110(6):639–46.
5. Patel MP, Janson G, Henriques JFC, de Almeida RR, de Freitas MR, Pinzan A, de Freitas KMS. Comparative distalization effects of Jones jig and pendulum appliances. *American journal of orthodontics and dentofacial orthopedics.* 2009;135(3):336–42.
6. Papadopoulos MA, Tarawneh F. The use of miniscrew implants for temporary skeletal anchorage in orthodontics: a comprehensive review. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology.* 2007;103(5):e6–15.
7. Kuroda S, Sugawara Y, Deguchi T, Kyung HM, Takano-Yamamoto T. Clinical use of miniscrew implants as orthodontic anchorage: success rates and postoperative discomfort. *American Journal of Orthodontics and Dentofacial Orthopedics.* 2007;131(1):9–15.
8. Lee JS, Park HS, Kyung HM. Micro-implant anchorage for lingual treatment of a skeletal Class II malocclusion. *J Clin Orthod.* 2001;35(10):643–7.
9. Reynders R, Ronchi L, Bipat S. Mini-implants in orthodontics: a systematic review of the literature. *American Journal of Orthodontics and Dentofacial Orthopedics.* 2009;135(5):564-e1.
10. Lehnen S, McDonald F, Bourauel C, Baxmann M. Patient Expectations, Acceptance and Preferences in Treatment with Orthodontic Mini-implants. *Journal of Orofacial Orthopedics/Fortschritte der Kieferorthopädie.* 2011;72(2).

11. Lee TCK, McGrath CPJ, Wong RWK, Rabie ABM. Patients' perceptions regarding microimplant as anchorage in orthodontics. *Angle Orthod.* 2008;78(2):228–33.
12. Lin JJJ, White LW. *Creative orthodontics: blending the Damon System & TADs to manage difficult malocclusions.* Yong Chieh Company; 2007.
13. Kinzinger GSM, Wehrbein H, Diedrich PR. Molar distalization with a modified pendulum appliance—in vitro analysis of the force systems and in vivo study in children and adolescents. *Angle Orthod.* 2005;75(4):558–67.
14. Lee YJ, Kook YA, Park JH, Park J, Bayome M, Vaid NR, Kim Y. Short-term cone-beam computed tomography evaluation of maxillary third molar changes after total arch distalization in adolescents. *American Journal of Orthodontics and Dentofacial Orthopedics.* 2019;155(2):191–7.
15. Farrar JT, Young Jr JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain.* 2001;94(2):149–58.
16. Liou EJW, Chen PH, Wang YC, Lin JCY. A computed tomographic image study on the thickness of the infrazygomatic crest of the maxilla and its clinical implications for miniscrew insertion. *American journal of orthodontics and dentofacial orthopedics.* 2007;131(3):352–6.
17. McCaffery M, Beebe A. *Pain: Clinical manual for nursing practice.* (No Title). 1989;
18. Serogl HG, Klages U, Zentner A. Pain and discomfort during orthodontic treatment: causative factors and effects on compliance. *American Journal of Orthodontics and Dentofacial Orthopedics.* 1998;114(6):684–91.
19. Bergius M, Kiliaridis S, Berggren U. Pain in orthodontics. A review and discussion of the literature. *J Orofac Orthop.* 2000;61(2):125–37.
20. Jones ML, Richmond S. Initial tooth movement: force application and pain—a relationship? *Am J Orthod.* 1985;88(2):111–6.
21. Brown DF, Moerenhout RG. The pain experience and psychological adjustment to orthodontic treatment of preadolescents, adolescents, and adults. *American Journal of Orthodontics and Dentofacial Orthopedics.* 1991;100(4):349–56.
22. Hjerstad MJ, Fayers PM, Haugen DF, Caraceni A, Hanks GW, Loge JH, Fainsinger R, Aass N, Kaasa S, (EPCRC EPCRC. Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. *J Pain Symptom Manage.* 2011;41(6):1073–93.

23. Sreenivasagan S, Subramanian AK, Selvaraj A, Marya A. Pain Perception Associated with Mini-Implants and Interventions for Pain Management: A Cross-Sectional Questionnaire-Based Survey. *Biomed Res Int.* 2021;2021.
24. Nur M, Bayram M, Pampu A. Zygoma-gear appliance for intraoral upper molar distalization. *Korean J Orthod.* 2010;40(3):195–206.
25. El-Dawlatly MM, Abou-El-Ezz AM, El-Sharaby FA, Mostafa YA. Zygoma-Miniimplantate zur Korrektur von Klasse-II-Anomalien bei heranwachsenden Patientinnen. *Journal of Orofacial Orthopedics.* 2014;75(3):213–25.

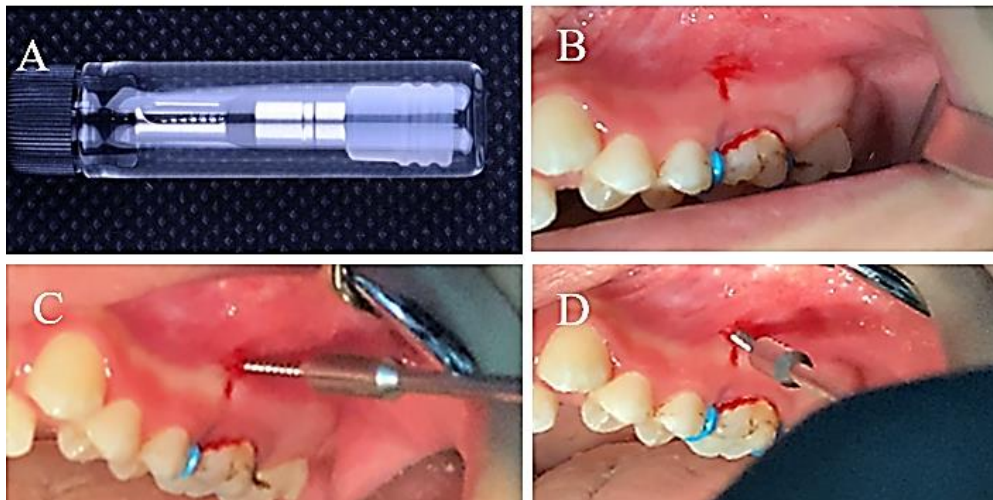


Figure 1: A) 10 mm dentaurum mini screw B) Bleeding point to mark the area of insertion of the screw C) Insertion of the screw tip perpendicular to bone surface D) The screwdriver was turned clockwise about 55° to 70° to the maxillary occlusal plane.

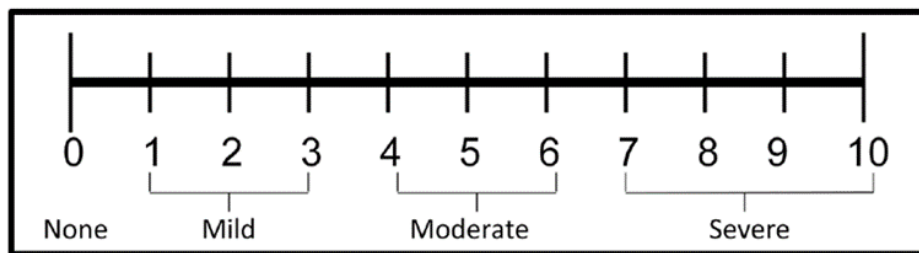


Figure2: The numerical pain rating scale

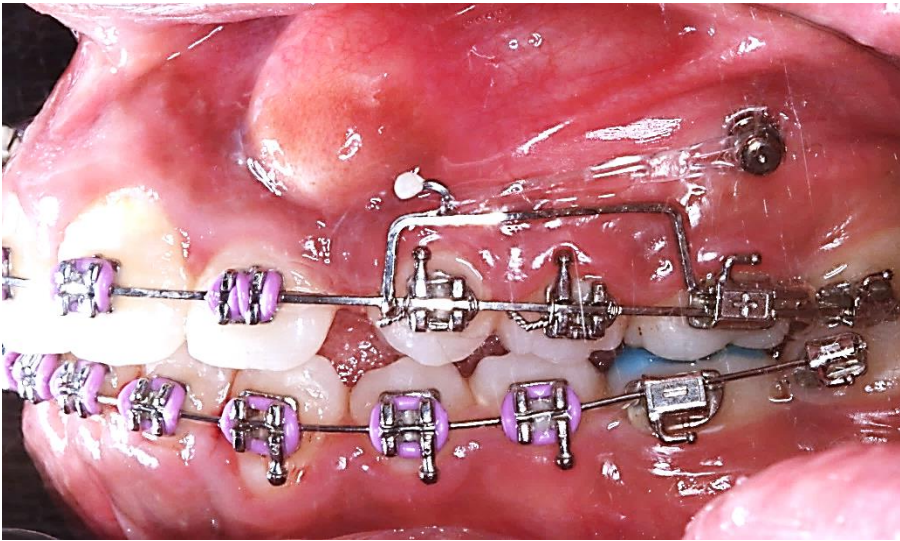


Figure 3: Sliding jig appliance for maxillary molar distalization.