

## **Oral Mucosal and Periodontal Changes of Patients under Treatment with Manual Invisalign and Fixed Labial Orthodontic Appliances**

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**Abstract:** Today's orthodontic appliance has a move toward more aesthetic designs and materials. Thus, the purpose of this study was to investigate the adverse effects of two orthodontic treatment modalities - manual invisalign and fixed labial orthodontic appliances on the oral mucosa and periodontal health status.

**Patients and Methods:** The study sample comprised 60 healthy patients (48 female and 12 male) attended an orthodontic private clinic in Sulaimani city- Iraq. This study was implemented to analyze and compare the adverse effects of two treatment modalities; manual invisalign (MIA) and fixed labial orthodontic appliances (FLOA) on oral health status using T-tests. Plaque index (PI), gingival index (GI) and probing pocket depth (PPD) were used for a periodontal evaluation, whereas oral mucosal lesions were evaluated via a thorough oral examination and a questioner based assessment.

**Results:** Patients with manual invisalign appliances (MIA) presented significantly lower GI, PI and PPD compared to those with fixed labial orthodontic appliances (FLOA) (0.63, 0.83 and 1.66 mm) against (0.97, 1.21 and 1.98 mm) respectively. Furthermore, FLOA recorded total of (21) traumatic ulcers (70%) in opposition to 6 (20%) for MIA; these ulcers were mainly recorded from check and lips. Check and lip traumatic ulcers caused by FLOA were (15, 5) respectively against (2, 1) for MIA. Number of aphthous ulcers also found to be higher with FLOA than MIA (10 to 4) respectively. Additionally, the study recorded (3) cases of hyperkeratotic lesions beside (4) cases of mucosal overgrowth of the check for patients wearing FLOA.

**Conclusions:** Patient treated with manual invisalign orthodontic appliances presented significantly fewer periodontal and oral mucosa lesions than patients with fixed labial orthodontic appliances.

**Keywords:** fixed labial orthodontic appliance, Manual invisalign, oral mucosal changes, and periodontal status.

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### **I. Introduction**

The numbers of patients demanding orthodontic appliances increased in the last few decades due to improving patient's standard of living and quality of life or perhaps as a result of modern innovation that has distinguished the field of orthodontics. This change attracted orthodontists to improve the quality of their orthodontic appliances from aesthetic and functional point of view<sup>[1]</sup>. Hence, today's orthodontic appliance has a move toward more aesthetic designs and today's orthodontic patients not only concerning about improvement of their dental appearance, they also concerning about the aesthetic of the appliances that they are going to use for several months or years. Furthermore, the numbers of adult patients under 40 years seeking periodontal treatment are considerably increased, and the majority is preferring lingual or invisalign treatment as an aesthetic choice<sup>[2,3]</sup>.

It is acknowledged that orthodontic therapy has many adverse effects/negative influences on the oral health status including the hard and soft apparatus of the oral cavity. Oral mucosa and periodontal soft and hard tissues are the two most frequent oral tissues affected by the orthodontic appliances. Complications might occur, and some are considered to be serious complications. However, they could happen for many reasons, some related to the patient attitude and behavioral factors, whereas others related to the orthodontic treatment/orthodontist's skill and experience in designing the right appliance and performing the appropriate treatment plan for each individual case. Adverse effects and complication can be avoided or reduced by intelligent treatment plan and employing the most appropriate treatment modality for each case. Patient's compliance can contribute to a high standard outcome of the treatment with minimum side effects<sup>[4]</sup>.

The potential hazards of orthodontic therapy on the oral health status can be divided into soft tissue and hard tissue risk. The soft tissue lesions including reactive lesions, periodontal lesion, loss of pulp vitality and nickel allergy, whereas hard tissue lesions include dental caries, root resorption, dentin hypersensitivity, tooth fracture and alveolar bone loss. Moreover, pain is one of the frequent symptoms during the orthodontic

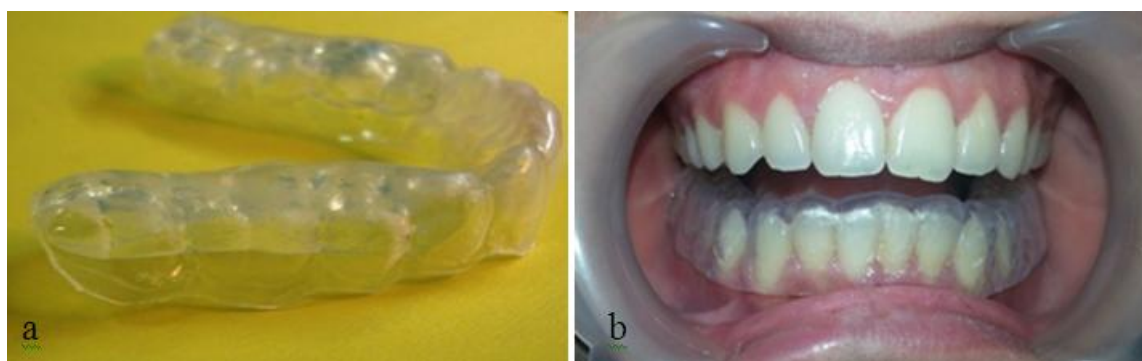
therapy<sup>[5]</sup>. Furthermore, other problems has been reported such as ill-fitting, rough or broken appliances, brackets and band tubes which might cause physical irritation to contacting oral tissues which might end up with proliferative, ulcerative and keratotic lesions. Traumatic ulcers are a frequent clinical finding in the oral mucosa caused by acute trauma from orthodontic appliances<sup>[6]</sup>. It is also acknowledged that the injury may lead to ulceration in individuals susceptible to aphthous stomatitis<sup>[5]</sup>. Persistent low-grade injury causes proliferative or keratotic changes in the oral mucosa<sup>[7]</sup>.

Periodontal lesion is such a major concern during orthodontic treatment. Periodontal disease is not a single pathologic entity but comprises a number of inflammatory and degenerative lesions of the periodontal supporting structures including gingivitis, gingival recession, gingival bleeding and gingival hyperplasia as well as alveolar process damage, these have a very high prevalence among children and young adults<sup>[8]</sup>.

The majority of the complications mentioned above reported with fixed orthodontic appliance as a result of its complicated design and mechanics that might cause a direct trauma to the regional mucosa. Moreover, the design of fixed appliance helps plaque accumulation and hampers plaque control using conventional oral hygiene methods. It is well accepted that oral hygiene is the key element of maintaining periodontal tissues health during the entire period of orthodontic therapy<sup>[9]</sup>.

Today many orthodontists started to use invisalign appliances to overcome problems of plaque control, irritation to the oral mucosa, as well as the aesthetic concern of the patients. Invisalign is an invisible modern orthodontic appliance used for orthodontic tooth movement without adopting the old metallic braces and wires and the complicated mechanics. The appliance accomplishes gradual and sequential teeth movement using clear customized aligners that are fabricated either using a computer assisted technology (ALIGN TECHNOLOGY INC)<sup>[10]</sup> or a manual type which requires a high technical skill at fabrication and has been adopted in the present study (Fig 1).

Invisalign aligners are removable appliance permitting unimpeded oral hygiene. Furthermore, periodontal health and malodorous can improve during orthodontic treatment using the Invisalign system because patients can remove the aligners to brush and floss normally as well as cleaning the inner surface of the appliance. In contrast, fixed appliances create numerous plaque-retention sites that increase a patient's risk to develop demineralization (white spot), carious lesions and/or periodontitis<sup>[11]</sup>.



**Figure (1): a:** photographic pictures for manual invisalign appliances MIA.

**Figure (1): b:** photographic pictures for patient with manual invisalign appliances MIA

Aligner perhaps has a similar performance to that of fixed orthodontic appliances in certain cases with minimum adverse effects on the oral health status and better aesthetics. Patients treated with invisalign aligners recorded significantly lower scores of plaque index, gingival index, furthermore significantly less mucosal irritation, teeth tenderness and few other potential discomforts were accounted for invisalign when compared to fixed appliances<sup>[12,16]</sup>. Online search showed limited data on gingival inflammation and other oral symptoms for using Invisalign<sup>®</sup> aligners. Therefore, the present study aimed at investigating and comparing the adverse effect of two orthodontic treatment modalities – the manual invisalign (MIA) and fixed labial orthodontic appliances (FLOA) on the oral mucosa and periodontal health status.

## II. Patients and Methods

### 2.1 The sample

This prospective study conducted between October 2014 to January 2015 and the study sample was recruited from a private orthodontic center in Sulaimani city – Iraq. The study recruited sixty (60) systemically healthy participants - 12 male and 48 female, their age ranged between 13 and 44 year with a mean of 20.6 years. Females comprised 80% of the total sample as shown in Table (1). Patients were under orthodontic treatment at least for five months<sup>[17]</sup> when they had been assigned to participate in this prospective clinical assessment. The study conducted to investigate the adverse effects of both manual invisalign (MIA) and fixed

labial orthodontic appliances (FLOA) on the oral health status. The study sample comprised 30 patients with MIA (27 female and 3 male) and an identical number of FLOA (21 female and 9 male) (Table 1).

**Table (1): Gender and age distribution with percentage of the sample according to types of appliances.**

Type of App	Male	Female	Total	Age range
FLOA	9	21	30	15-26 y
MIA	3	27	30	13-44 y
<b>Total</b>	<b>12</b>	<b>48</b>	<b>60</b>	
<b>% of the sample</b>	<b>20%</b>	<b>80%</b>		

FLOA: is fixed labial orthodontic appliances; MIA: is manual invisalign

## 2.2 Periodontal examination

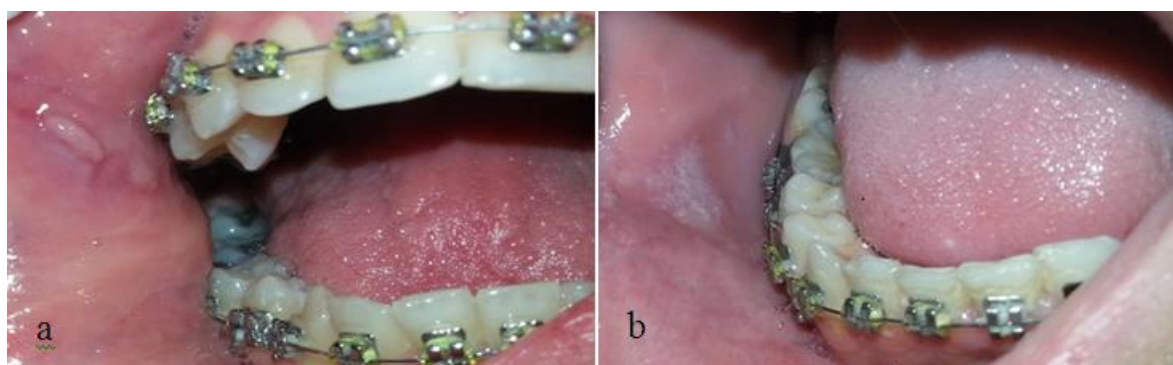
The periodontal condition was evaluated using the following indices:

- 1- Plaque Index(PI) – This parameter was estimated on a scale of 0-3 according to Silness and Loe (1964) [18].
- 2- Gingival Index(GI) – This parameter was estimated on a scale of 0-3 according to Loe and Silness (1963) [19].
- 3- Probing pocket depth (PPD) , determined by measuring the distance from the free gingival margin to the bottom of the sulcus or pocket in millimeters (mm) [20].

All measurements were undertaken from mesial, distal, buccal and lingual sides for each tooth by a single well-trained examiner. The periodontal condition of all permanent, fully erupted teeth was examined using a manual periodontal probe – William’s probe. Third molars and teeth covered by crowns were excluded. Moreover, the orthodontic treatment also performed by one expert orthodontist.

## 2.3 Mucosal Examination

Patients were examined for evaluation and detection of any oral mucosal lesions - traumatic ulcers (TA), aphthous ulcers (AU), mucosal overgrowth (MO) and hyperkeratotic lesions (HK). Besides, a questionnaire-based study was used, questioning the participants about the history of TA, AU, MO and HK. They have also been questioned if those lesions appeared at the time of using the appliances and their emergence had any relation to the appliances or not. Moreover, all subjects were informed about the nature of their participation in this study and a consent form was signed by the participants after reading the content carefully. Ethical approval has been obtained from the University Research Ethics Committee, School of Dentistry –University of Sulaimani for conducting this clinical study.



**Figure(2):a:**photographic picture from current study shows mucosal overgrowth.

**Figure(2):b:** photographic picture from current study shows hyperkeratotic lesion HK associated with FLOA.

## 2.4 Statistical Analysis

Descriptive statistics – tables, figures, percentages and inferential statistics using T- test was applied to present the results of the current study. The data was input and analyzed by using statistical packages SPSS-18 (Statistical Packages for Social Sciences version 18) in order to determine relevancy and significance.

## III. Results

Results showed a significant difference in the female – male ratio (80% - 20%) respectively. Furthermore, statistically a significant reduction ( $p \leq 0.05$ ) in mean PI, GI and PPD were recorded for MIA group against FLOA group (0.63, 0.83 and 1.66 mm) against (0.97, 1.21 and 1.98 mm) respectively (Table 2).

**Table (2): Comparison of mean values of (PI), (GI) and (PPD) with both treatment modalities MI and FLOA.**

Periodontal indices	Type of App	Mean	Std. Deviation	Std. Error	p-value
				Mean	
PI	FLOA	0.97	0.35	0.06	0.000*
	MIA	0.63	0.28	0.05	
GI	FLOA	1.21	0.25	0.04	0.000*
	MIA	0.83	0.30	0.05	
PPD	FLOA	1.98 mm	0.26	0.04	0.001*
	MIA	1.66 mm	0.45	0.08	

\*P-value is significant at  $P \leq 0.05$ ; PI: is Plaque Index; GI: is Gingival Index;  
 PPDI: is Probing pocket depth Index; FLOA: is fixed labial orthodontic appliances;  
 MIA: is manual invisalign

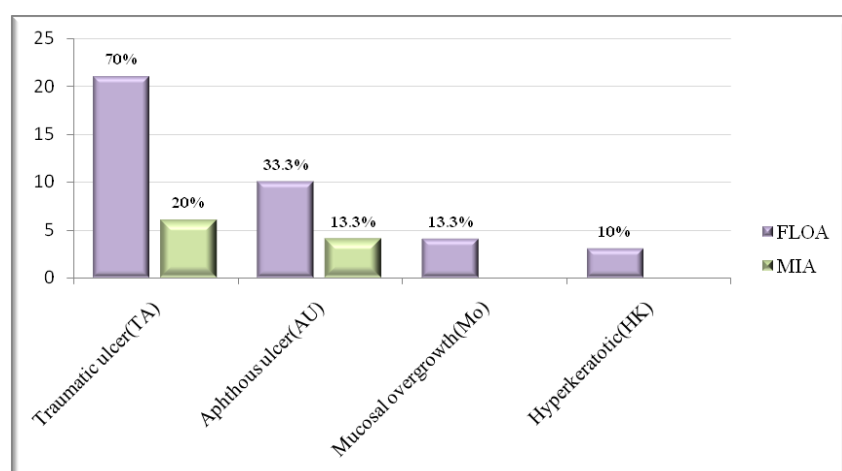
Results of oral mucosal examination and the questioner based analysis about the history of traumatic ulcers (TA), aphthous ulcers (AU), mucosal overgrowth (MO) and hyperkeratotic lesions (HK) are presented in Table (3). A total of (21) TA was recorded for FLOA, whereas MIA group had recorded only (6). Patients with FLOA listed significantly ( $p < 0.05$ ) a history of higher number of TA than MIA especially at two designated sites in the current study - check and lips. The maximum number of TA was reported on check for FLOA compared to MIA (15 against 2) followed by TA of the lips (5 against 1) as seen in Table (3). Also Table (3) demonstrates (10) AU that associated with FLOA while there are (4) AU in MIA group. However, the patients have not related these ulcers to presence of appliances. Additionally, the study recorded (3) cases of HK lesions beside (4) cases of MO lesions for patients wearing FLOA (Table 3) and Fig (2).

**Table (3): Frequency and distribution of oral mucosal lesions with MIA and FLOA.**

type of App	Type of mucosal lesion	Sex	Check		Palate		Tongue		Lips		Floor of the mouth		Total	
			M	F	M	F	M	F	M	F	M	F	M	F
TA														
FLOA	21		6	9	-	-	-	1	1	4	-	-	7	14
MIA	6		-	2	-	1	-	1	-	1	1	-	1	5
AU														
FLOA	10		2	3	-	-	-	-	1	4	-	-	3	7
MIA	4		-	4	-	-	-	-	-	-	-	-	-	4
MO														
FLOA	4		2	-	-	-	-	-	-	2	-	-	2	2
MIA	-		-	-	-	-	-	-	-	-	-	-	-	-
HK														
FLOA	3		1	2	-	-	-	-	-	-	-	-	1	2
MIA	-		-	-	-	-	-	-	-	-	-	-	-	-

FLOA: is fixed labial orthodontic appliances; MIA: is manual invisalign; TA: is traumatic ulcers; AU: is aphthous ulcers; MO: is mucosal overgrowth; HK: is hyperkeratotic lesions; M: is male; F: is female.





**Figure (3):** frequency distribution and percentage of oral mucosal lesions associated with MIA (manual invisalign) and FLOA (fixed labial orthodontic appliances)

#### IV. Discussion

This prospective, clinical study designed to determine and compare the adverse effect of two different models of orthodontic appliances on oral mucosa and periodontal apparatus. The study involved patients using fixed labial orthodontic appliances and manual invisalign treatment options for at least five months at a private orthodontic center in Sulaimani city. We believe that five month period is enough for both treatment modalities to manifest their adverse effects on oral mucosa/periodontal tissues<sup>[17]</sup>.

The present study designed to investigate the oral and periodontal status in a single visit and a questioner based records for verification of periodontal and mucosal lesions rather than looking at the patients in a regular follow up schedule and indexing multiple records throughout the entire therapy time. This can provide an inclusive and précised vision on the adverse effects of both treatment modalities employed in the current study.

It is acknowledged that bacterial aggregation in dental plaque is the primary etiologic agent of periodontal disease<sup>[19]</sup>. Orthodontic treatment with fixed appliances is known to enhance plaque accumulation and render an increased plaque volume on the teeth surfaces and the appliance components. However, fixed orthodontic appliances alter the microbial flora toward more virulent species<sup>[20]</sup>. An increase in anaerobic organisms and a reduction in facultative anaerobes around the bands was reported by Travess et al (2004). This indicates an alteration in the composition of plaque toward more pathogenic species<sup>[21]</sup>. Therefore, fixed orthodontic treatment may result in localized gingivitis in the majority of the cases<sup>[22]</sup>, however, this can be determined by the level of oral hygiene during the entire period of the orthodontic therapy. Therefore, before starting the treatment, orthodontic patients should be properly guided to meticulous plaque control and plaque control method should be modified and reinforced at each visit after wearing the appliances.

This study recorded significantly lower mean periodontal indices: PI, GI and PPD in MIA than FLOA, which points to as a lower risk of developing periodontal lesions all through the treatment course, our result is consistent with Miethke and Brauner (2007)<sup>[11]</sup>. This is because MIA is a removable appliance thus better plaque control and cleaning the inner surface of the appliance can be achieved by the patients, unlike FLOA which has a complicated mechanics makes oral hygiene difficult even for the most motivated patients and consequently the majority of patient with fixed appliances reveal different grades of gingival inflammation. Also, the small size with smooth edges of the MIA reduces the mucosal lesions and adds substantially to the patient's quality of life compared with fixed appliances<sup>[11]</sup>. Hu Longa et al. (2013) reported a similar prevalence of gingival bleeding and bad taste between the two treatment modalities that is conflicting the result of the current study<sup>[25]</sup>.

Based on the results of the current study, oral mucosal lesions were significantly less with MIA than FLOA. The result of the present study was consistent with numerous recent reports, Shalish (2011) recorded significantly lower levels of oral symptoms in the Invisalign™ appliances compared to the fixed buccal and the lingual appliances<sup>[26]</sup>. Another study evaluated the levels of discomfort among aligner group and fixed appliance group, the study found that aligner causes much less patient discomfort compared to fixed appliances regarding mucosal irritation, soreness of the teeth, and several other areas of potential discomfort usually experienced by patients during orthodontic treatment with fixed appliances.

Mainali reported; the oral problems encountered during fixed orthodontic treatment were oral ulcerations 40.8%, problems to dental hard tissues 29.2%, periodontal problems 25.8% and TMJ pain 9.2%.

Amongst oral ulcerations, the most frequent ulceration was traumatic ulcerations (60.80%) followed by aphthous ulcerations (8.30%)<sup>[27]</sup>. This result agrees with the outcome of the current study that reported percentages of traumatic and aphthous ulcerations with FLOA group (70% and 33.33%) respectively as seen in Fig (3).

Online databases showed no reports on manual invisible appliances; however the current study reported (3) cases of HK lesions in addition to (4) cases of MO lesions related to FLOA that is a result of low-grade irritants of the fixed appliance components.

Based on data collected in this study one can predict that invisalign is less traumatic to the oral mucosa and causing less harm to the periodontal apparatus than fixed appliance, this is because manual invisalign aligner is a removable appliance with fewer complicated mechanics, renders less plaque and irritation to the oral mucosa. Furthermore, it is considered aesthetically as an acceptable treatment options for most patients attending orthodontic clinics.

## V. Conclusions

Patient treated with manual invisalign presented significantly fewer periodontal lesions and oral mucosal lesions than patients with fixed labial orthodontic appliances.

## References

- [1] Impellizzeri A, Palaia G, Carpentieri F, et al. Secondaries problems of the oral mucosa during orthodontic treatment. *Prevent Res*, 2014;65. Available from <http://www.preventionandresearch.com/>
- [2] Hohoff A, Stamm T, Goder G, Sauerland C, Ehmer U, Seifert E. Comparison of 3 bonded lingual appliances by auditive analysis and subjective assessment. *Am J Orthod Dentofacial Orthop*. 2003 Dec; 124(6):737-45.
- [3] Nedwed V, Miethke RR. Motivation, acceptance and problems of Invisalign® patients. *J Orofac Orthop*. 2005 Mar;66(2):162-73
- [4] Preoteasa C.T, Ionescu.E and Preoteasa.E (2012). Risks and Complications Associated with Orthodontic Treatment, InTech, Available from:<http://www.intechopen.com/books/orthodontics-basic-aspects-and-clinical-considerations/risks-and-complications-associated-with-orthodontic-treatment>
- [5] Jyothi B.M, Rakesh B.C, Pandey B. Brackets--A boon or a bane? Undesirable effects of Orthodontic Treatment. *Journal of Dental Peers*, 2013 Apr; 1(1):58-68.
- [6] Arruda EP, Trevilatto PC, Camargo ES, Woyceichoski IE, Machado MA, Vieira I, Lima AA. Preclinical alterations of oral epithelial cells in contact with orthodontic appliances. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub*. 2011 Sep;155(3):299-303.
- [7] Regezi JA, Sciubba J, Jordan PC. *Oral pathology: Clinical-pathologic correlations*. 6th ed. St. Louis, Saunders Elsevier; 2012.
- [8] Sheibaninia A, Saghiri MA, Showkatbakhsh A, Sunitha C, Sepasi S, Mohamadi M, Esfahanizadeh N. Determining the relationship between the application of fixed appliances and periodontal conditions. *Afr J Biotechnol*. 2011; 10(72): 16347-16350.
- [9] Talic NF. Adverse effects of orthodontic treatment: A clinical perspective. *Saudi Dent J*. 2011 Apr;23(2):55-9
- [10] Naik VR and Chavan P. Invisalign: The invisible braces. *Int. Journal of Contemporary Dentistry*. 2010; 1(2):54-57.
- [11] Miethke RR, Brauner K. A comparison of the periodontal health of patients during treatment with the Invisalign® system and with fixed lingual appliances. *J Orofac Orthop*. 2007 May;68(3):223-31.
- [12] Boyd RL. Periodontal and Restorative considerations with clear aligner treatment to establish a more favorable restorative environment. *Compend Contin Educ Dent*. 2009 Jun;30(5):280-2, 284, 286-8 passim.
- [13] Miller KB, McGorray SP, Womack R, Quintero JC, Perelmutter M, Gibson J, Dolan TA, Wheeler TT. A comparison of treatment impacts between Invisalign aligner and fixed appliance therapy during the first week of treatment. *Am J Orthod Dentofacial Orthop*. 2007 Mar;131(3):302.e1-9
- [14] Clements KM, Bollen AM, Huang G, King G, Hujoel P, Ma T. Activation time and material stiffness of sequential removable orthodontic appliances. Part 2: dental improvements. *Am J Orthod Dentofacial Orthop*. 2003 Nov;124(5):502-8.
- [15] Taylor MG, McGorray SP, Durrett S, et al. Effect of Invisalign on periodontal tissues. *J Dent Res*. 2003; 82(A):1483.
- [16] Tuncay O, Bowman SJ, Amy B, Nicozisis J. Aligner treatment in the teenage patient. *J Clin Orthod*. 2013 Feb;47(2):115-9.
- [17] Zanatta F, Moreira C, Rösing C. Association between dental floss use and gingival conditions in orthodontic patients. *Am J Orthod Dentofacial Orthop*. 2011 Dec;140(6):812-21.
- [18] Silness J, Loe H. Periodontal disease in pregnancy II Correlation between oral hygiene and periodontal condition. *Acta Odontol Scand*. 1964 Feb; 22:121-35.
- [19] Loe H, Silness J. Periodontal disease in pregnancy I. Prevalence and severity. *Acta Odontol Scand*. 1963 Dec; 21:533-51.
- [20] Zanatta FB, Ardenghi TM, Antoniazzi RP, Pinto TM, Rösing CK. Association between gingival bleeding and gingival enlargement and oral health-related quality of life (OHRQoL) of subjects under fixed orthodontic treatment: a cross-sectional study. *BMC Oral Health*. 2012;12:53.
- [21] Sanders NL. Evidence-based care in orthodontics and periodontics: a review of the literature. *J Am Dent Assoc*. 1999 Apr; 130(4):521-7.
- [22] Petti S, Barbato E, Simonetti D'Arca A. Effect of orthodontic therapy with fixed and removable appliances on oral microbiota: a six-month longitudinal study. *New Microbiol*. 1997 Jan; 20(1):55-62.
- [23] Travess H, Roberts-Harry D, Sandy J. Orthodontics. Part 6: Risks in Orthodontic treatment. *Br Dent J*. 2004 Jan 24; 196(2):71-7.
- [24] Van Gastel J, Quirynen M, Teughels W, Coucke W, Carels C.. Influence of bracket design on microbial and periodontal parameters in vivo. *J Clin Periodontol*. 2007 May; 34(5):423-31.
- [25] Long H, Zhou Y, Pyakurel U, Liao L, Jian F, Xue J, Ye N, Yang X, Wang Y, Lai W. Comparison of adverse effects between lingual and labial orthodontic treatment: A systematic review. *Angle Orthod*. 2013 Nov; 83(6):1066-73.
- [26] Shalish M, Cooper-Kazaz R, Ivgi I, Canetti L, Tsur B, Bachar E, Chaushu S. Adult patients' adjustability to orthodontic appliances. Part I: a comparison between labial, lingual, and Invisalign. *Eur J Orthod*. 2012 Dec; 34(6):724-30.
- [27] Mainali A: Occurrence of Oral Ulcerations in Patients undergoing Orthodontic Treatment: A Comparative study. *Orthodontic Journal of Nepal*, December 2013; 3(2):32-35.