Prospective Study of Oral Health, Pain and Discomfort and Success Rates Following Insertion of Orthodontic Mini-Implants

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Abstract

Objectives: To evaluate oral health and compare the experience of pain and discomfort after the insertion of mini-implants TADs (temporary anchorage device) and to analyze potential factors associated with the stability of TADs used for orthodontic treatment in a sample of Erbil city orthodontics patients.

Methods: The sample included 47 patients of both genders (24 females, 23 males) between (13-35) years with mean ages 23.73 years. The patients were treated with fixed orthodontic appliance and TADs were inserted to reinforce anchorage as the cases required. The patients recall was performed for examination and recording through a questionnaire at baseline, few hours (evening), one day, one week and two weeks after TADs insertion. The inserted side of TADs was recorded by the researcher in anterior maxilla or mandible and posterior maxilla or mandible.

Results: The overall success rate was 85.1%. There were no significant relations in failure rates among the TADs related to the following variables: gender, pain (discomfort), implantation site (maxilla, mandible), location (anterior or posterior), and type of soft tissue (keratinized or non- keratinized mucosa). In the second week of TADs insertion females that complain from no pain was 43.3% versus 56.6% of males while moderate pain complain in the females was 64.7% versus 35.3% for males The success rates for non-inflamed gingiva around TADs were 96.3% in the second week post- insertion with significant differences during 1st and 2nd weeks post-insertion (P=0.020 and P=0.042 subsequently). An increased failure rate was noted for those presented with local inflammation of the surrounding soft tissue, especially those cases which loaded within 2 weeks after TADs insertion.

Conclusions: Inflammation of soft tissue surrounding a TADs and immediate loading (within 2 weeks) after insertion were the most significant factors affecting TADs failure. Gender, pain, age, jaws, soft tissue management, and placement sites are not related to the success of TADs.

Keywords: *TADs, Mini-implants, Orthodontics, Pain, Discomfort.*

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Introduction

Orthodontic treatment is often correlated with discomfort and pain. Soreness and aching are certainly reported after insertion of the initial arch wire[1]. Anchorage is a prerequisite for orthodontic treatment with fixed appliances. Orthodontic mini-implants or so-called TADs are an excellent alternative to traditional orthodontic anchorage methodologies and increased in popularity[2]. Since TAD has become a common technique in orthodontics, another potentially painful procedure has become part of the orthodontic treatment plan including; which the type of screw, where to insert, whether anesthesia and pre- or postoperative medication are required[3]. Pain or discomfort is experienced by up to 95% of patients during orthodontic treatment and has been cited as a reason for discontinuing Treatment[4]. The drilling of a pilot hole for TADs was reported to be as uncomfortable as the pressure that self-drilling screws cause in the bone[5], and when treatment includes flap surgery or soft tissue punching, patients report even higher pain levels[6]. The clinical use of TADs accompanies some risks and complications, which occur during screw insertion, under orthodontic loading, and during removal[7]. Lee et al showed that patients expect the buccal placement of TADs to be more painful than another site within the oral cavity[8]. Insufficient primary stability of the TADs causes deficient healing and premature loss of the TADs (failure). Therefore, the primary stability observed during implantation plays an important role in the success rates of the TADs[9,10].

The success rate of orthodontic TADs is usually influenced by certain factors, such as implant-related, patient-related, location-related, orthodontic-related, and implant-maintenance factors. Implant-related factors include the type of TADs. Patient-related factors are related to sex, age, and type of malocclusion. Location related factors are related to the jaw of insertion, the site of insertion, the bone quality around the insertion site, and the type of soft tissue around the insertion site. Orthodontic-related factors include the timing of force application. An implant-maintenance factor was related to local inflammation around a TAD[11].

The purposes of this prospective study were to evaluate and compare the experience of pain and discomfort after the insertion of TADs and to analyze potential factors associated with the stability of TADs used for orthodontic treatment among Orthodontists in this region.

Patients and methods

The sample includes 47 patients in Erbil City of both genders, the age ranged between 13-35 years old, all patients treated with fixed orthodontic appliance and TADs was inserted to reinforce anchorage as the case necessary. The patients recall for examination and recording was done through a questionnaire at baseline, the evening after (D1), one day after (D2), one week after (D3) and two weeks (D4) after TADs insertion.

The study protocol and informed consent were approved by the Ethical committee at the college of dentistry /Hawler medical university. Additionally, Informed consents gained from patients and parents (underage patients).

The inclusion criteria were patients need orthodontic treatment with the fixed appliance, the treatment plan including TADs insertion for orthodontic patients that need anchorage reinforcement, permanent occlusion. Whereas, exclusion criteria included: patients who had completed a previous course of orthodontic treatment; patients who were unable to comprehend or complete the questionnaire; patients with craniofacial syndromes.

The inserted side of TADs was recorded in anterior maxilla or mandible and posterior maxilla or mandible (Figure 1). The patient's record contains the following: patient's name, date, age, and gender. The Orthodontic mini- implant system used in this study was (Bio-Tack, BIO CETEC Company, (Korea). The length and diameter of TADs recorded. The TADs were inserted in keratinized or non-keratinized mucosa and oral hygiene of the patients recorded as acceptable or non-acceptable. Also, the stability and failure of TADs were recorded during the patient's visits.

Inflammation evaluation criteria were modified from the gingival index. Definition of the degree of inflammation: 0 for the absence of any signs of inflammation; 1 for mild inflammation around TAD; 2 for moderate inflammation around TAD; and 3 for severe inflammation around TAD with marked redness, swelling, and a tendency to bleed[12]. Complications associated with the TADs were evaluated during each patient's visits.

Pain and discomfort were recorded by the patient through a VAS (Visual analogue Scale for pain). The pain VAS questionnaire is a combination of faces pain rating scale or Comparative pain scale chart; patients use an 11-point numeric scale (NRS 11) (Numeric pain

Rating Scale) with 0 representing “no pain” and 10 representing the “worst pain imaginable” (Figure 2).

All TADs were inserted by one orthodontist according to the following protocol:

1. Topical anesthesia with 5% lidocaine gel (APL).

2. Buccal infiltration of 0.3 mL of local anasthesia per site (lidocaine hydrochloride 20 mg/mL, adrenaline 12.5 lg/mL, Dentsply Pharmaceutical)

3. Chlorhexidine mouth rinse for 60 seconds (Kin Gingiva 2 mg/mL, Laboratorios Kin S.A, Barcelona,Spain) as disinfection.

4. Insertion of TADs (Hex head (CHH) Bio tack from BIO CETEC Company (Korea)), buccally and interdentally with 30–45 degree of angulation.

5. Periapical radiographs

6. Immediate loading of the TADs as direct anchorage with an orthodontic force less than 200 grams was applied by orthodontic force gauge[15].

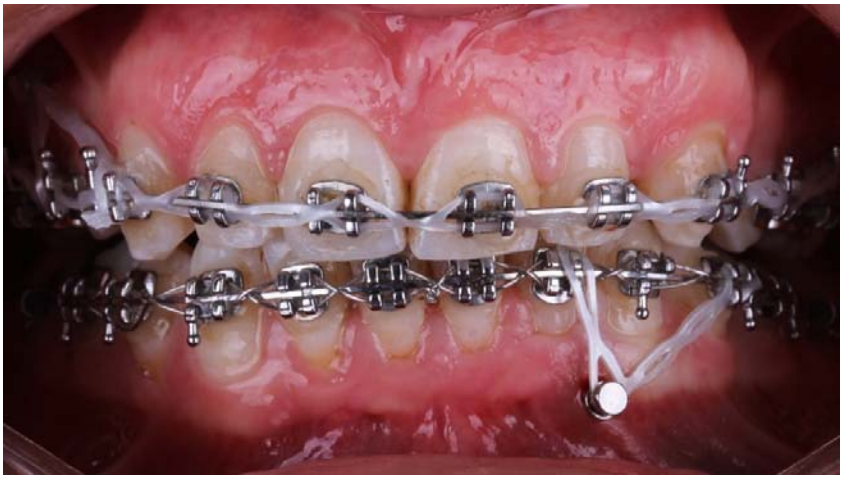

Figure 1: Mini-screw placed in anterior mandible.

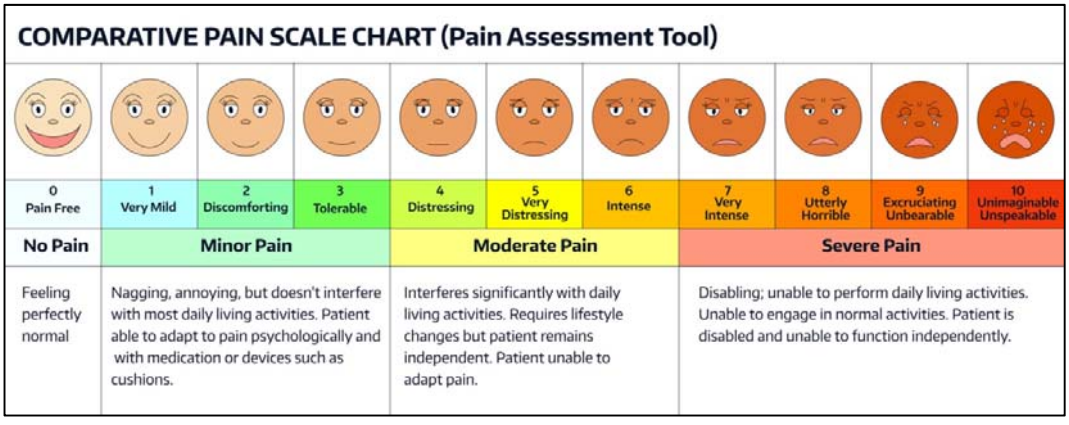

Figure 2: Commonly used one-dimensional pain intensity scales: the 11-point NRS, the VAS from no pain (= 0) to worst pain imaginable [= 10 (or 100)] and the four-point categorical verbal rating scale (VRS).

Results

Fifty-two patients were invited to participate in this investigation which matched the inclusion criteria, but 5 patients declined to participate. Therefore, informed consent was collected from 47 patients before they were participating in the research.

Patients who received the TADs were mainly young adults. Among them, the number of females (24) was more than the number of males (23). The mean age was 23.73 years and the range was 13-35 years. The success rate for females (87.5%) was higher than males (82.6%) without a statistically significant difference (P= 0.638). Patients ≤ 20 years of age showed more TAD stability (86.7%) than patients of > 20 years of age (84.4%) with no significant difference (P= 0.837) Table 4.

The descriptive information about the sample showed in Table 1. TAD's lengths were (8mm, 10mm) with 3 TAD's width 1.4 mm, 1.6 mm and 1.8 mm were used. The higher TAD stability recorded in width of 1.6 mm (86.9%) and length of 8 mm (88.2%). There was no significant relation between TADs success and TADs dimensions (length, width) (P= 0.330,P= 0.873 consequently) Table 4. The TAD was inserted in 8 locations in the upper and lower jaw as shown in table 1 according to the orthodontic indications. More than half of TADs were placed in the posterior region of maxilla 28 (59.5%), and the next most common location was the anterior region of mandible 9 (19.1%). TADs inserted in the posterior site the maxilla showed highest stability success rate 23 TADs (82.14%), the right and left side showed comparative TADs stability (right = 84%, left= 86%). As observed, there were no statistically significant relations according to TADs locations table 4.

About 38 TADs (80.9%) were inserted in the Keratinized mucosa. Keratinizes mucosa showed more TADs success rate (86.8 %) than non-keratinized (77.8%) with no significant relations (P= 0.492) (Table 4).

Patient-reported pain intensity is presented in Figure 3 and Table 2 Pain decreased with time, in the 1st day of TADs insertion 32 (68.1%) patients recorded minor pain (Table 2) and reported higher success rate (81.25%) (Table 4), in this table, pain not related to the success of TADs. Statistically there were no significant relations. The rate of females that complain of no pain is 43.3% versus 56.6% of males complaining while moderate pain complains in the females was 64.7% versus 35.3% for males.

Table 1: Descriptive information of the sample.

Factors	variables	No.	%
Gender	Male	23	48.9
	Female	24	51.1
	total	47	100.0
TAD length	8	34	72.3
	10	13	27.7
	Total	47	100.0
TAD width	1.4	14	29.8
	1.6	23	48.9
	1.8	10	21.3
	Total	47	100.0
location	Anterior Max Left	2	4.3
	Anterior Max Right	3	6.4
	Posterior Max Left	15	31.9
	Posterior Max Right	13	27.7
	Anterior Mand Left	4	8.5
	Anterior Mand Right	5	10.6
	Posterior Mand Left	1	2.1
	Posterior Mand Right	4	8.5
	Total	47	100.0
Soft tissue	Keratinized	38	80.9
	Non- Kertinaized	9	19.1
	Total	47	100.0

Table 2: Pain categories related to the gender.

Variables	Gender	D1*		D2		D3		D4	
		No.	%	No.	%	No.	%	No.	%
No pain	male	1	14.2**	3	75	12	52.1	17	56.6
	female	6	85.7	1	25	11	47.8	13	43.3
	total	**7**	**14.9**	**4**	**8.5**	**23**	**48.9**	**30**	**63.8**
Minor pain	male	19	59.3	17	50	11	52.3	6	35.3
	female	13	40.6	17	50	10	47.6	11	64.7
	total	**32**	**68.1**	**34**	**72.3**	**21**	**44.7**	**17**	**36.2**
Moderate pain	male	3	37.5	3	42.8	0	0.0	0	0.0
	female	5	62.5	4	57.1	3	100	0	0.0
	total	**8**	**17.0**	**7**	**72.3**	**3**	**6.4**	**0**	**0.0**
Severe pain	male	0	0.0	0	0.0	0	0.0	0	0.0
	female	0	0.0	2	100	0	0.0	0	0.0
	total	**0**	**0.0**	**2**	**4.3**	**0**	**0.0**	**0**	**0.0**

*D1= day of TAD insertion, D2= evening of TAD insertion, D3= one week after TAD insertion, D4 = two weeks after TAD insertion. ** Percentage within column.

On the 1st day, 2nd day and one week after TADs insertion (D1, D2, D3), all patients had acceptable oral hygiene and only 4 patients at 2nd week (D4) had unacceptable oral hygiene. The results showed that the patient's oral hygiene has no significant relations to TADs success rate (Table 4).

Implant mobility was found for 7 cases (14.8%) implants after 2 weeks (D4). One of them failed after 1 week of TAD insertion. The other 40 (85.1%) TADs sustained the orthodontic load satisfactorily without any detectable mobility or significant inflammation.

In terms of inflammation of the gingiva around TAD, the results showed in table 3. The inflammation around TADs was increased from mild inflammation at the beginning (D1) (14.89%) to moderate inflammation after two weeks (D4) (21.27%). The success rates of TADs were 92.9% with none inflamed gingiva around TADs, 81.3% with mild inflammation & 33.3% with moderate inflammation in the 1st week of TADs insertion and success rate of TADs were 96.3% for non inflammation gingiva, 77.8% with mild inflammation & 63.6% with for moderate inflammation in the 2nd week of TADs insertion. And there are significant relations during 1st and 2nd weeks (p=0.020 and P=0.042 subsequently) (Table 5).

Table 3: Inflammation categories around TADs.

Variables	D1		D2		D3		D4	
	No.	%	No.	%	No.	%	No.	%
No inflammation *	40	85.10	31	65.95	28	59.57	31	65.95
mild inflammation	7	14.89	15	31.91	16	34.04	5	10.6
moderate inflammation	0	0	1	2.12	3	6.38	10	21.27
severe inflammation	0	0	0	0	0	0	1	2.12

* A score from 0.1-1.0 = mild inflammation; 1.1-2.0 = moderate inflammation , and 2.1-3.0 signifies severe inflammation.

Table 4: The success and failure of screws according to sex, age, placement site, soft tissue management, TADs measurements, pain, and oral hygiene.

Factors	Variables	Success Classes				Chi-Square P-Value
		Yes		No		
		No.	%	No.	%	
Age	≤ 20	13	86.7	2	13.3	0.837
	> 20	27	84.4	5	15.6	
gender	Male	19	82.6	4	17.4	0.638
	Female	21	87.5	3	12.5	
location	Anterior Max Left	2	100.0	0	0.0	0.871
	Anterior Max Right	2	66.7	1	33.3	
	Posterior Max Left	12	80.0	3	20.0	
	Posterior Max Right	11	84.6	2	15.4	
	Anterior Mand Left	4	100.0	0	0.0	
	Anterior Mand Right	4	80.0	1	20.0	
	Posterior Mand. Left	1	100.0	0	0.0	
	Posterior Mand Right	4	100.0	0	0.0	
Soft tissue	Keratinized	33	86.8	5	13.2	0.492
	Non- Keratinized	7	77.8	2	22.2	
TAD Length	8	30	88.2	4	11.7	0.330
	10	10	76.9	3	23.07	
TAD width	1.4	12	85.7	2	14.2	0.873
	1.6	20	86.9	3	13.04	
	1.8	8	80	2	20	
pain D1	Pain Free	6	85.7	1	14.3	0.736
	Minor pain	26	81.25	6	18.75	
	Moderate pain	8	100	0	0.0	
	Severe pain	0	0.0	0	0.0	
pain D2	Pain Free	3	75.0	1	25.0	0.135
	Minor pain	30	88.23	4	11.7	
	Moderate pain	6	85.71	1	14.28	
	Severe pain	1	50	1	50	
pain D3	Pain Free	20	87.0	3	13.0	0.192
	Minor pain	17	85	3	15	
	Moderate pain	2	66.66	1	33.33	
	severe pain	0	0.0	0	0.0	
pain D4	Pain Free	27	90.0	3	10.0	0.458
	Minor pain	13	76.47	4	23.52	
	Moderate pain	0	0.0	0	0.0	
	severe pain	0	0.0	0	0.0	
oral hyg. D1	Acceptable	40	85.1	7	14.9	Not applicable
	Un-Acceptable	0	0.0	0	0.0	
oral hyg. D2	Acceptable	40	85.1	7	14.9	Not applicable
	Un-Acceptable	0	0.0	0	0.0	
oral hyg. D3	Acceptable	39	84.8	7	15.2	0.672
	Un-Acceptable	1	100.0	0	0.0	
oral hyg. D4	Acceptable	36	85.7	6	14.3	0.734
	Un-Acceptable	4	80.0	1	20.0	

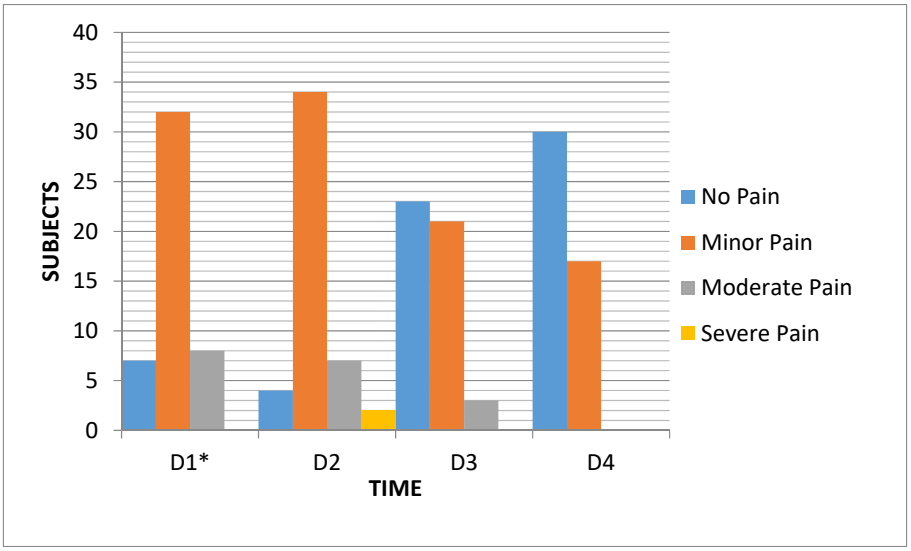

Figure 3: Most of pain feeling was minor, and in second week of TADs insertion showed no pain category.

Table 5: Success and failure of screws according to inflammation of the gingiva around TADs.

Factors	Variables	Success Classes				Chi-Square P-Value	t-test P value
		Yes		Yes			
		No.	%	No.	%		
Inflam. D1	No inflammation	34	87.2	5	12.8	0.378 df=1	0.504
	Mild inflammation	6	75.0	2	25.0		
	moderate inflammation	0	0.0	0	0.0		
	severe inflammation	0	0.0	0	0.0		
Inflam. D2	No inflammation	28	90.3	3	9.7	0.289 df= 2	0.291
	mild inflammation	11	73.3	4	26.7		
	moderate inflammation	1	100.0	0	0.0		
	severe inflammation	0	0.0	0	0.0		
Inflam. D3	No inflammation	26	92.9	2	7.1	0.020 df= 2	0.012
	mild inflammation	13	81.3	3	18.8		
	moderate inflammation	1	33.3	2	66.7		
	severe inflammation	0	0.0	0	0.0		
Inflam. D4	No inflammation	26	96.3	1	3.7	0.042 df=3	0.014
	mild inflammation	7	77.8	2	22.2		
	moderate inflammation	6	63.6	4	36.4		
	severe inflammation	1	100	0	0.0		

Discussion

This study was performed with prospective results; therefore, some bias was unavoidable that would result in selecting certain patterns of TADs for different orthodontic treatment purposes.

The question of anchorage in orthodontics has attracted considerable interest and remained a major problem since the introduction of fixed appliances.

The total success rate of TAD in this study was 40 (85.1%) out of 47 TADs which was comparable to Lee et al (83.6%)[20] and higher than the 78.6% reported by Moon et al[21]. However, it was lower than the 94.8% reported by Lai and Chen[12]. The Dislodgement of TADs occurred most frequently in 2nd weeks of immediate loading. The variations in success rates between literatures and this study may be due to the: types of mini-implants used, the age ranges and the site of TADs insertions.

In this study, patient gender was not related to the success rate P= 0.638 (females 87.5% more than males 82.6%) (Table 4), which was in accordance with the results of Moon et al[15] and Miyawaki et al[22]. Therefore, we assumed that sex was not related to the clinical success of the TADs. The patient's ages more than 20 years old showed less success rate (>20 years 84.4%, ≤ 20 years 86.7%), which was statistically not significant and this is in agreement with Lai et al[12] and disagree the results of Aly et al[23].

Regarding TADs location, the left side had a higher success rate (86%) than the right side (84%) and this is in accordance to Lai et al[12], and this is according to Park et al due to that maybe the left side received better hygiene because most patients were right-handed [24]. Most of the TADs are inserted in the maxillary jaw around upper first permanent molar (27 TADs out of 47) however the space between the roots of the maxillary second premolars and first molars is the preferred site for TADs insertion because it is wider than other inter-radicular spaces, particularly after leveling with Roth prescription brackets[25,26]. Although most of the TADs are inserted in the posterior side of the jaws, TADs located in the posterior region of the jaws are more prone to failure (5 TADs failure in posterior versus 2 TADs failure in the anterior side of the jaw) without significant associations, probably this is due to their reduced amount of keratinized gingiva, greater hygiene difficulty and surgical access difficulty[26].

Temporary anchorage device's length and width factors (Implant-related factors) are summarized in Table 4. The success rate of TADs with 1.6 mm diameter (86.9%) seemed to be higher than those with 1.4 mm diameter (85.7%) and 1.8 mm (80%), but there was no statistically significant relationship between the successes rate and TADs width (P= 0873) and this was in accordance with most studies[12,26]. The results of this study concerning TADs diameter may be due to the type TADs used or sample size.

The success rate of TADs with 8-mm length (88.2%) seemed to be higher than those with 10-mm length (76.9%), but there were no statistically significant relations between them and this is coincident with other studies[12,27].

For the soft-tissue component, the success rate of TADs in the keratinized mucosa was (86.8%) which has been reported to be higher than that for TADs surrounded by non-keratinized mucosa (77.8%). The reason may be due to movable, non-keratinized alveolar mucosa and is easily irritated, thin keratinized tissue seen in the dento-alveolar or mid-palatal region is ideal for TADs placement[28]. In this study, there is no statistically relation between TADs failure and soft tissue type and this is in accordance with Cerroni et al[29] and Sharma et al[30]. This is may be due to the sample size between this study and other studies.

Numeric rating scale is now widely regarded as the fifth vital sign[13,14]. These questionnaires have been found to be reliable and with sufficient internal consistency in earlier studies[15-17] The baseline questionnaire was administrated after the randomization process and comprised questions about treatment motivation and expectation, pain and discomfort, and limitations in daily activities[18]. The NRS and the VAS have been shown to give almost identical values in the same patient at various times after surgery, whereas the four-point (no, minor, moderate and severe pain) VRS (Verbal Rating Scale) seemed to underestimate the most intense pain compared with the VAS[19]. An NRS with numbers from 0 to 10 ('no pain' to 'worst pain imaginable') is more practical than a VAS, easier to understand for most people, and does not need clear vision[31]. The reported pain intensity and discomfort levels in this study were generally minor (D1= 68.1%, D2= 72.3%, D3= 44.7%) and in the second week the pain due to TADs obviously decreased to no pain category (D4= 63.8%) in table 2, Figure 3, the pain intensity reported by Ganzer et al[32] was moderate. This homogeneity of the study population might also explain why we found no significant correlations between the baseline questionnaire and later experiences of pain and discomfort[32]. There is no statistically significant relation between TAD's success rate and patients feeling of discomfort in any pain questioner stages; although the patients with pain-free feeling showed higher TADs success rates (Table 4).

Gender differences concerning the experience of pain and discomfort during and after TADs insertion, the results of this study showed that females experience pain and discomforts more frequently than males with statistically no association to the TADs success and this is in accordance with the Valieri et al study[33]. This is may be due to sample size differences.

Optimal oral hygiene is imperative to minimize TADs complications[34,35]. Most patients in this study maintained acceptable oral hygiene during the whole time of the study for this reason we reported high success TADs rate with good oral hygiene. There is no statistically relation between oral hygiene and success rate of TADs and this is in contrary to many studies[36,37].

This is may be due to sample size and time duration of this study.

Healthy peri-implant tissue plays an important role as a biologic barrier to bacteria, tissue inflammation, minor infection, and peri-implantitis can occur after TADs placement[38]. Certain previous studies showed that inflammation around TADs is one of the most important factors to predict implant failure, and this study yielded similar results[39, 40, 41]. The results of this study showed significant relations between TADs failure (mobility) and inflammation around it and this is apparent in the first week D3 (P= 0.020) and second week of TADs insertion D4 (P = 0.42). Moreover, the results revealed that there is a significant difference between the TADs that is a success and that's of failure in D3 and D4 (P = 0.012, P = 0.014 subsequently in Table 5). Gingival inflammation around the TADs are one of the most common TADs complications, this is probably related to the accumulation of bacterial plaque around TADs resulting from the patient's inadequate oral hygiene[42].

Conclusions

Installation of TADs in general causes mild to moderate pain and discomfort. Beside that soft-tissue health directly affects implant stability that requires proper TADs home care of oral hygiene by the patients and requires proper placement of TADs by the orthodontist. Gender, age, jaw, soft tissue management, and placement side were not related to the success rate of TADs.

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