

Assessment of Pain and Discomfort after Insertion of Temporary Anchorage Devices – A Single-Group Prospective Cohort Study

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ABSTRACT

Introduction: The primary objective of this study was to compare the anticipated pain levels reported by patients with the actual pain experienced on the first day after the insertion of TADs. The secondary objective was to evaluate the pain and discomfort levels reported by orthodontic patients during the first week following TADs placement, as well as identify the factors associated with this pain and discomfort.

Materials and Methods: A single-group prospective cohort study was conducted at a tertiary care hospital with a sample size of 33 patients. The normality of the data was assessed using the Shapiro-Wilk test, revealing a non-normal distribution. Friedman test was applied to assess mean pain and discomfort scores at different time intervals. Wilcoxon signed rank test was used for pairwise comparison of pain and discomfort at different time intervals. Generalized estimating equation analysis utilizing linear regression was applied to assess the factors (Arch, site of insertion, length of miniscrew etc.) associated with pain and discomfort after insertion of TADs.

Results: On the basis of patients' responses, insignificant differences were found between the pain anticipated and actual experienced pain on the first day after TAD insertion. The pain started to decrease significantly on the second and third day ($p \leq 0.001$). Generalized estimating equation analysis showed a significant positive association of age with pain experienced during TAD insertion.

Conclusions: TAD insertion increased pain and discomfort on the first day, but it decreased dramatically on the second and third days. A positive association was observed between age and the levels of patient-reported pain and discomfort after the insertion of TADs. Furthermore, immediate loading of miniscrew after insertion resulted in greater pain as compared to delayed loading. Based on the patients' responses, it can be inferred that miniscrews are a well-accepted option in orthodontic treatments.

Keywords: Miniscrew; TAD; Temporary Anchorage Device; Orthodontics; Pain

Introduction

Effective orthodontic planning is imperative for achieving desired treatment outcomes and minimizing the undesirable effects of mechanotherapy [1,2]. Reciprocal effects of orthodontic forces need to be carefully analyzed, evaluated and controlled by adequate anchorage preparation before initiating orthodontic treatment [3]. Anchorage can be defined as resistance to undesired tooth movement [4]. Loss of anchorage is an alarming sign, particularly during the process of space closure after premolar extraction [5]. There are a number of conventional techniques in orthodontics for reinforcement of anchorage. These can be broadly classified into extra-oral and intra-oral methods [6]. Headgears can be used extra-orally for anchorage control; intra-orally, transpalatal arches, Nance buttons, inter-maxillary elastics, and using differential moments of multiple teeth at the anchorage segment can provide good biomechanical control [7]. Adolescent patients are less compliant with the conventional methods of reinforcing anchorage, especially the use of headgears, because of discomfort or esthetic concerns. A lack of compliance can cause prolonged duration of treatment, and lead to unpredictable and compromised treatment outcomes [8]. In an endeavour to mitigate such complications, orthodontic treatment has increasingly integrated absolute anchorage.

It refers to a form of anchorage in which the anchor units offer maximum resistance to unwanted displacement and minimize undesirable tooth movement [9]. It can be achieved by using ankylosed teeth or placing miniscrews or miniplates into the alveolar bone to take advantage of skeletal units as absolute anchors [10]. Among all the methods of gaining absolute anchorage, temporary anchorage devices (TADs) are the most common, because of their convenience and atraumatic method of insertion. They provide exceptional outcomes and exhibit remarkable durability, even when subjected to immediate loading [10-12]. Anxiety, pain and discomfort are some of the disadvantages of TAD insertion [13,14]. Pain is an undesirable sensory experience correlated with definite or probable tissue damage [15]. Hashem, et al. [16] reported that the insertion of miniscrews produces mild to moderate pain and can also cause pre-operative anxiety. Studies have shown that patients in whom the degree of pain perception during TAD placement was neglected, encountered increased levels of discomfort during the procedure [16-18]. It has also been documented that because of the pain experienced during orthodontic treatment, every tenth orthodontic patient fails to complete full course of treatment. Mirhashemi, et al. [1] who used visual analog scale (VAS) to evaluate the perception of pain after first week of TAD placement reported the mean value for pain after one hour and one day of TADs insertion as 48.79 ± 35.57 and 13.74 ± 22.05 , respectively.

Therefore, consideration of the pain and discomfort experienced during placement of TADs is critical for patient satisfaction and desired post-operative outcomes. The primary objective of this study was to compare the anticipated pain levels reported by patients with

the actual pain experienced on the first day after the insertion of TADs. The secondary objective was to evaluate the pain and discomfort levels reported by orthodontic patients during the first week following TADs placement, as well as identify the factors associated with this pain and discomfort.

Material & Methods

After obtaining an approval from the ethical review committee (ERC) of institution (2022-7614-22191), a single-group prospective cohort study was conducted at a tertiary care hospital. The sample size was calculated with WHO software (version 7.1) by using the findings of Mirhashemi, et al. [1], who reported the difference in pain proportion after the insertion of TADs as 48% and 13% for 12 hours and 24 hours, respectively. With this difference in proportion, keeping α as 5% and the power of study as 80%, the sample size of 26 (N) was required. To address the sample attrition, we inflated the sample size by 30%, reaching the final sample size of 33 (N) subjects in the study. Data were collected from 33 patients undergoing orthodontic treatment, with ages ranging from 18 to 35 years. The research team determined the age range that included a research assistant, two orthodontic residents and one orthodontist. The purpose of establishing this age range was to ensure inclusivity for the adult population seeking orthodontic care. The inclusion criteria were as follows: patients aged between 18-35 years, patients undergoing fixed orthodontic treatment who require miniscrew placement in the dental arches as a part of their proposed treatment plan, patients with good oral hygiene (plaque score 1, bleeding score 0 and gingivitis score 1) with no evidence of periodontal disease and all patients signing the informed consent form.

Patients with the presence of uncontrolled periodontal disease, history of smoking, any craniofacial/dental anomaly, syndrome, trauma or previous history of orthodontic treatment were excluded from the study. Patients visiting the orthodontic clinic at the Aga Khan University Hospital Karachi were included in this study. Treatment plans of all orthodontic patients were formulated by a team that involve consultants, residents and instructors after evaluating complete pre-treatment orthodontic records.

TAD Installation

The TADs used in this study were Titanium based self-drilling implants (Forestadent, orthoeasy pin system, Germany), sized 6x1.7 mm, 8x1.7 mm, and 10x1.7 mm (slot 0.22"). The location of TADs was determined according to the treatment need and proposed treatment plan of the patients. Before inserting the TADs, a mouth rinse of 0.12% chlorhexidine mouthwash was prescribed [19]. All the procedures were performed by a single operator under local anesthesia using 2% lidocaine hydrochloride with 1:100,000 epinephrine (Octacaine, Novocol, Canada). Following the administration of local anesthesia, the TADs were manually placed through the attached gingiva. Patients were instructed to inform the operator if they experienced

any pain or discomfort during the procedure. Subsequently, periapical radiographs were taken to verify the correct positioning of the TADs. In this study, after obtaining consent on the first visit of TAD insertion, all participants were asked to rate the pain anticipation on a 100 mm unmarked horizontal VAS with 0 being no pain and 100 being severe pain, pre-operatively. TADs were inserted under local anesthesia and patient's perception regarding discomfort during the insertion of TADs was assessed again on VAS. Patients were provided with log sheets and were asked to fill those log sheets on first, third and seventh post-operative days. Those log sheets involved data regarding pain, discomfort, and usage of analgesics after TAD insertion.

Responses for pain and discomfort were recorded using VAS, whereas analgesic information was recorded as "yes" or "no" along with the name of the analgesic used.

Data Analysis

Data analysis was conducted using SPSS (version 23.0) and STATA (version 12.0). The normality of the data was assessed using the Shapiro-Wilk test, revealing a non-normal distribution. Descriptive statistics such as median and interquartile ranges were reported for the age of patients. Friedman test was applied to assess mean pain and discomfort scores at different time intervals. Wilcoxon signed rank test was used for pairwise comparison of pain and discomfort at different time intervals. Generalized estimating equation analysis utilizing linear regression was applied to assess the factors (Arch, site of insertion, length of miniscrew etc) associated with pain and discomfort after insertion of TADs. A p-value < 0.05 was considered as statistically significant.

Results

The total sample size was 33, with a gender distribution of 14 males and 19 females were included in this study. The median and interquartile range for the age of the patients recruited was 21.58 (18.91-27.47) years (Table 1). From the sample of 33, in 20 patients the miniscrews were placed bilaterally. Whereas, in 10 and 3 patients, they were placed on right and left quadrants, respectively. In 20 patients, the miniscrews were placed buccally and in 10 patients they were placed palatally. 26 miniscrews were placed in maxilla and 7 in mandible. 11 were loaded immediately and 22 were loaded after one week. On the basis of patients' responses, the median and interquartile ranges for the expected pain and the actual pain experienced on first day after insertion of TADs were 47.00 (21.55-52.00) and 34.00

(14.00-59.00), respectively (Table 2). We found insignificant differences between the pain anticipated and actual experienced pain on first day after TAD insertion. The pain started to decrease significantly on second and third day (Table 3). Out of 33 patients, 20 utilized analgesics for their pain on the first day after the placement of TADs. However, on seventh day, no one from the sample utilized analgesics (Table 4). Prescription-free compositions of paracetamol or ibuprofen were used for pain management. The highest reported discomfort was observed on first day after insertion of TADs 48.00 (23.00-67.50) (Table 2). On third and seventh day, there was a reduction in the discomfort scores (Table 3).

Table 1: Demographics.

Age of patients	Median (IQR)
Age (N:33)	21.58 (18.91-27.47)
Male (n:14)	19.75 (18.08-25.00)
Female (n:19)	26.42 (19.08-31.08)

Note: N: Total number of patients, n: number of patients per group

IQR: Interquartile range

Table 2: Comparison of pain and discomfort at different time intervals.

Variables	Time interval	Median and IQR	p-value
Pain	Expected pain	47.00 (21.55-52.00)	≤ 0.001**
	First day	34.00 (14.00-59.00)	
	Third day	9.00 (0.00-17.75)	
	Seventh day	0.00 (0.00-9.50)	
Discomfort	During TAD insertion	27.00 (6.25-53.50)	≤ 0.001**
	First day	48.00 (23.00-67.50)	
	Third day	10.00 (0.00-32.50)	
	Seventh day	4.00 (0.00-13.00)	

Note: N: 33, IQR: Interquartile range, TAD: Temporay anchorage devices

Friedman test, p ≤ 0.001**

Table 3: Pairwise comparison of pain and discomfort at different time intervals.

Variables	Time interval	Median and IQR	p-value
Pain	Expected pain VS during TAD	47.00 (21.55-52.00) 15.00 (3.50-46.75)	0.004*
	Expected pain VS first day	47.00 (21.55-52.00) 34.00 (14.00-59.00)	0.387
	First day VS third day	34.00 (14.00-59.00) 9.00 (0.00-17.75)	≤ 0.001**
	First day VS seventh day	34.00 (14.00-59.00) 0.00 (0.00-9.50)	≤ 0.001**
	Third day VS seventh day	9.00 (0.00-17.75) 0.00 (0.00-9.50)	≤ 0.001**
Discomfort	During TAD VS first day	27.00 (6.25-53.50) 48.00 (23.00-67.50)	0.045*
	First day VS third day	48.00 (23.00-67.50) 10.00 (0.00-32.50)	≤ 0.001**
	First day VS seventh day	48.00 (23.00-67.50) 4.00 (0.00-13.00)	≤ 0.001**
	Third day VS seventh day	10.00 (0.00-32.50) 4.00 (0.00-13.00)	≤ 0.001**

Note: N: 33, IQR: Interquartile range, TAD: Temporary anchorage devices

Wilcoxon signed rank test, $p \leq 0.05^*$, $p \leq 0.001^{**}$

Generalized estimating equation analysis utilizing linear regression was applied to assess the factors associated with pain and discomfort after placement of TADs. It showed a significant positive association of age with pain experienced during TADs insertion. With increasing age there seemed to be an increase in reported pain values. Immediate loading of miniscrew after insertion resulted in greater pain as compared to delayed loading (Table 5).

Table 4: Frequency of analgesic taken at different time intervals.

Time	Number of patients using analgesics		Kind of analgesic	
	Yes	No	Paracetamol	Ibuprofen
Pre-treatment	13	20	10	3
First day	20	13	16	4
Third day	3	30	2	1
Seventh day	0	33	0	0

Table 5: Factors associated with pain after insertion of temporary anchorage devices.

Variables		Beta Coefficient	95% CI	p-value
Age		0.982	0.405, 1.559	≤ 0.001**
Gender (F)		1.866	-6.820, 10.552	0.674
Length		-0.364	-5.461, 4.733	0.889
Loading (DL)		-11.442	-19.696, -3.189	0.007*
Cortical surface (P)		-4.676	-13.905, 4.553	0.321
Quadrant	Right	-1.516	-10.423, 7.391	0.739
	Left	15.438	1.199, 29.676	0.034*
Arch (Mn)		-2.463	-12.958, 8.032	0.646

Note: N: 33, CI: Confidence interval, F: Female, DL: Delayed loading, P: Palatal, Mn: Mandible

Generalized estimating equation utilizing linear regression, $p \leq 0.05^*$, $p \leq 0.001^{**}$

Discussion

Patients' acceptance of orthodontic treatment is proportional to the degree to which they experience pain and discomfort during or after treatment. Pain and discomfort induced by orthodontic appliances have a negative impact on the patients' acceptance of treatment and cooperation. Therefore, it is crucial to take into account the pain and discomfort experienced by patients during TAD placement in order to achieve the ideal post-operative outcomes. We found insignificant differences between the pain anticipated and actual experienced pain on first day after TAD insertion. The highest reported discomfort was observed on first day after insertion of TADs. Generalized estimating equation analysis utilizing linear regression showed a significant positive association of age with pain and discomfort experienced during TADs insertion. Furthermore, immediate loading of TAD after insertion resulted in greater pain and discomfort as compared to delayed loading. The results of the current study demonstrated that anticipated pain was greater than actual pain experienced during TAD insertion and one day after insertion. Always, anxiety plays a crucial role in the perception of pain [20]. Thus, through appropriate counselling and explanation of the upcoming procedure, one should always attempt to alleviate the anxiety of patients. In the current study the patients included had no prior negative history related to dental procedures and the patients who were included in the sample were given comprehensive instructions on TADs insertion before their visit, in order to reduce procedure-related anxiety, therefore, reducing the anxiety-related bias on pain perception.

The findings of this study indicate that the level of pain and discomfort experienced during TAD insertion at the palatal site was comparatively lower than that observed in the buccal site. This may be attributable to the fact that the local anaesthesia injection pain in the palatal region was intense, and the patient did not experience the TAD insertion pain in this region after the area was anaesthetized. This finding contradicts the previous research conducted by Sreenivasagan, et al. [21], which documented a higher pain score in the palatal region compared to other sites of TAD insertion. When examining the pain levels experienced in the left and right quadrants of the maxillary arch, it was seen that there was a reduction in discomfort during and after the insertion of TADs specifically in the right quadrant. The findings of this study indicate that the clinician's position at the chair may potentially impact the insertion of TADs. This result contradicts a recent study that found no influence of clinical position on TAD insertion, and also revealed that the difference in resultant pain between the right and left sides of the quadrant was not significant [22]. The present study revealed that the implementation of delayed loading of TADs led to a reduction in discomfort and pain.

This observation can be attributed to the phenomenon wherein the inflammation surrounding the TADs diminishes after a few days after insertion, leading to a decrease in pain sensitivity upon the ap-

plication of load. Nevertheless, when considering effectiveness, there is a general agreement among several experimental models that the immediate loading of TADs is suitable [23]. Moreover, the findings of the present study indicate that a significant proportion of the patients experienced elevated levels of discomfort on the initial day following the insertion of TADs, leading them to seek analgesic medication for relief. On the seventh day following the placement of the TADs, there was a notable decrease in both pain and discomfort levels. Hence, it is postulated that the loading of TADs could be delayed by one week to alleviate the pain and suffering experienced by patients. The feeling of pain is subjective and exhibits variability among individuals [24]. The results of our study align with previous studies about the impact of gender on pain, specifically indicating that female patients had higher pain scores as measured on the VAS [25]. Moreover, certain research suggests that the perception of pain can be altered by the age of the patient [26]. In our investigation, it was observed that individuals with younger ages experienced greater levels of pain and discomfort both during and after the insertion of TADs.

This suggests that the effects of age and sex on pain perception may be modulated by various factors, including biophysiological, psychological and physical aspects [27]. The current body of orthodontic literature exhibits a dearth of studies that yield inconclusive findings when examining the correlation between the perception and actual experience of pain and discomfort subsequent to the insertion of TADs [1,18]. This research endeavour will provide a comprehensive examination of the variables linked to pain and discomfort subsequent to the placement of TADs. The aim is to identify these characteristics in order to implement effective measures that can mitigate discomfort and enhance the overall comfort throughout orthodontic treatment. Furthermore, this study may elucidate specific characteristics linked to the discomfort that can be mitigated during and following the insertion of TADs, perhaps resulting in enhanced patient acceptability of miniscrews as orthodontic anchorage devices over conventional alternatives. This study possesses certain limitations as it will be conducted at a single centre, specifically a tertiary care hospital, and may be prone to the influence of pain perception subjectivity.

Conclusion

1. On the first day following TAD insertion, there were no significant differences between the pain anticipated and the actual experienced pain.
2. TAD insertion increased pain and discomfort on the first day, but it decreased dramatically on the second and third days.
3. On the first day after TAD insertion, the majority of patients utilised analgesics for their discomfort. On the seventh day, no sample member took analgesics.
4. A positive correlation was observed between age and the levels of patient-reported pain and discomfort after the in-

sersion of TADs. Furthermore, immediate loading of miniscrew after insertion resulted in greater pain as compared to delayed loading.

5. Based on the patients' responses, it can be inferred that miniscrews are a well-accepted option in orthodontic treatments.

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