EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
VOL. 70, 2181:2188, JULY, 2024
PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360
ORTHODONTICS, PEDIATRIC AND PREVENTIVE DENTISTRY
Submit Date : 22-03-2024 • Accept Date : 08-05-2024 • Available online: 01-07-2024 • DOI : 10.21608/EDJ.2024.278569.2988

CORRELATION BETWEEN DIFFERENT INTRUSION FORCE MAGNITUDES AND PAIN INTENSITY IN A GROUP OF ADOLESCENT FEMALES (A RANDOMIZED CLINICAL TRIAL)

Aya Ahmed El Faham*, Mohamed Amgad Kaddah*,
Marwa Magdy Saad Abbass** *and* Fady Hussein Fahim*

ABSTRACT

Background: Pain resulting from orthodontic tooth movement is one of the annoying issues to the patient. This randomized clinical trial was conducted to determine the intensity of the pain that the patient experience upon teeth intrusion with different force magnitudes.

Subjects and methods: fourteen female patients aged 15-18 years were selected randomly from the clinic of Orthodontic department of Faculty of Dentistry, Cairo University. Participants were divided into two equal groups (n=7). Group 1 where 25 grams of intrusive force were applied, Group 2 where 100 grams of intrusive force were applied. Via a paper visual analogue scale (VAS) distributed to each patient after the end of the three months of intrusion to assess their pain score.

Results: For patients undergone 25 grams intrusive force, the mean VAS score was 1.8±0.4 with a median 2.0 and interquartile range (IQR):(2.0 to 2.0) vs. 4.4±0.5 with a median 4.0 and IQR:(4.0 to 5.0) for patients undergone 100 grams, indicating a statistically significant increased pain score among patients subjected to the higher intrusive force (absolute mean difference = 2.6, $p < 0.001$).

Conclusion: There is a positive correlation between force magnitude and pain. Pain intensity and its perception increases by increasing the intrusive force magnitude.

KEYWORDS: intrusive force magnitude, Visual Analogue Scale, Pain intensity, tooth intrusion, Orthodontic force.

* Orthodontic Department, Faculty of Dentistry, Cairo University, Cairo, Egypt.
** Oral biology Department, Faculty of Dentistry, Cairo university, Cairo, Egypt.

INTRODUCTION

Over the course of orthodontic therapy, patients wearing orthodontic appliances reported varied degrees of pain and discomfort. One of the primary reasons people refuse orthodontic treatments is pain. Therefore, pain management is essential for both patients and orthodontists (Atta *et al*., 2020). Orthodontic pain is generally defined as dental discomfort brought on by orthodontic tooth movement; however, a more comprehensive definition of orthodontic pain includes any uncomfortable feeling brought on by orthodontic appliances, such as mucosal ulcers, tongue soreness, and gingival lesions (Long et al., 2016).

There is a high degree of uncertainty regarding the appropriate force level that should be applied during orthodontic tooth movement (OTM) (Theodorou *et al*., 2019).

It has been difficult to assess pain effectively since it is a complex, subjective sensation. According to Karoly's Pain Context Model, verbal reports of pain, pain behavior, pain intensity, pain location, and pain effect are only a few of the components that make up the concept of pain. The construct is deduced from other people's observations rather than being directly observable. Although it is crucial to recognize this construct's multidimensionality, doing so makes it more difficult to develop a straightforward quantitative assessment of the pain experience.

Multidimensional pain questionnaires have been established, like the Wisconsin Brief Pain Questionnaire and the McGill Pain Questionnaire, however completion of them requires proficient language skills. Patients may select terms that they are accustomed to rather than ones that accurately describe their level of discomfort, which can lead to a significant cultural and educational bias. Some experts also believe that these kinds of surveys are excessively lengthy, requiring the pain patient to focus for extended periods of time(Briggs and Closs, 1999). Therefore, acute pain research continues to use unidimensional scales that measure solely the sensory aspect of the pain experience (Briggs and Closs, 1999).

The researchers in these experiments are looking for a shift in the sensory perception of pain intensity. When patient self-report is utilized to collect data, the visual analogue scale (VAS) has strong construct validity and reliability. A lot of different types of subjective experience, including pain, are studied using the VAS. Subjects are asked to mark a (typically) 100-mm-long horizontal line with the labels "no pain" at one end and "worst pain possible" at the other end to indicate the degree of their pain when utilizing a VAS. This necessitates that the patient be able to relate the degree of pain they are feeling to the line's length (measured from the left to the indicated location). It is thought to be responsive to therapies that change the perception of pain (Lai *et al*., 2020).

The primary advantage of the VAS is that, if the data are normally distributed, the scores seem to have the characteristics of ratio data and may be handled as such statistically (Briggs and Closs, 1999).

SUBJECTS AND METHODS

Trial Design

The design of this randomized controlled trial is a parallel group two arm trial with 1:1 allocation ratio. No changes were made to the methods after trial commencement.

Participants

The inclusion criteria for the participants were: Adolescent female patients with age ranging between 15- 18 years, with full set of permanent dentition, no previous orthodontic treatment, cases of malocclusion that are indicated for extraction of maxillary first premolars as part of their treatment

plan and having good oral hygiene and periodontal condition. The exclusion criteria for the participants were patients with systemic diseases, bad Oral hygiene, missing permanent teeth (except for third molars), and uncontrolled pathological conditions that may contra-indicate immediate orthodontic treatment (caries, gingivitis, periodontitis). The patients were selected from the outpatients of clinic of Orthodontic Department, Faculty of Dentistry, Cairo University, Cairo government, Egypt.

Interventions

The study time lasted for 3 months. All included patients completed their orthodontic treatment by the same operator. All subjects received a straight wire appliance on their lower arches, when needed. The brackets were bonded to the mandibular teeth surface using orthodontic light cured composite resin. However, the upper arch leveling and alignment was postponed after the 3 months of intrusion.

Two Self-drilling temporary anchorage devices (TADs) (1.6 × 10 mm) were placed. One as laced buccally between first and second premolars (figure 1), and the other, placed palatal between canine and first premolar (figure 2). A button is bonded on the buccal surface of the first premolar and another button is bonded to the palatal surface of the same tooth, miniscrews are placed diagonally to allow for a pure intrusive force.

Immediately after miniscrew placement and bonding, the buttons on the first premolar on the right side of the patient were intruded by a power chain with 25 grams of force for 7 patients, and 100 grams of force for another 7 patients, using a force gauge, whereas the left side was considered as a control side. The patients are brought for follow up visits every 10 days, to assure the continuity of the force applied with the predetermined amount whether 25 grams or 100 grams, until the end of the 3 months of intrusion.

Re-activation of the power chain was done when necessary to maintain 25 grams' force delivery for the first group, and 100 grams for the second group. TADs stability was also regularly checked. The study time was continued for 3 months. During the study time, the patients received treatment in the opposing arch using the same type of brackets. Extraction or non-extraction conventional treatment in the lower arch was performed according the treatment plan of each case separately. By the end of 3 months of intrusion, each patient received the VAS sheet to state the intensity of pain they had experienced during the three months of intrusion period.

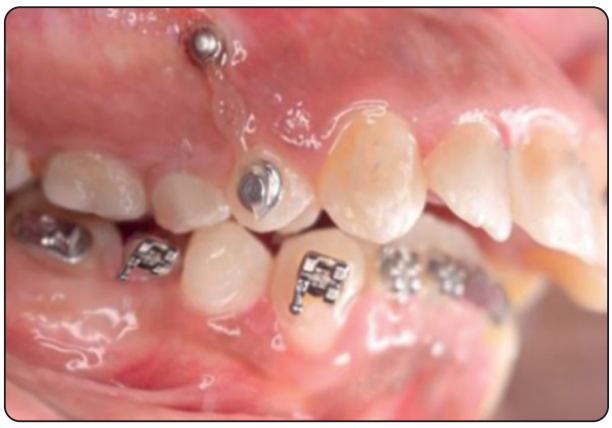

Fig. (1) Buccally placed miniscrew between first and second premolars (distally)

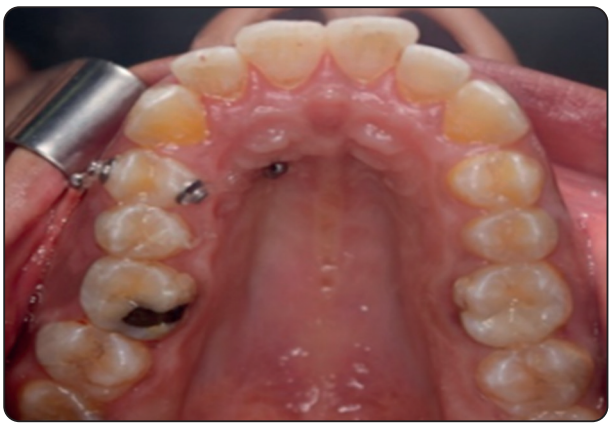

Fig. (2) Buttons at the palatal surface of the first premolar, between the canine and the first premolar (mesially).

Outcomes

The outcome of the study was to determine the correlation between pain intensity and increasing orthodontic force magnitude. patients were asked to mark the VAS (figure 3) to represent the average pain they had experienced during the whole duration of force application.

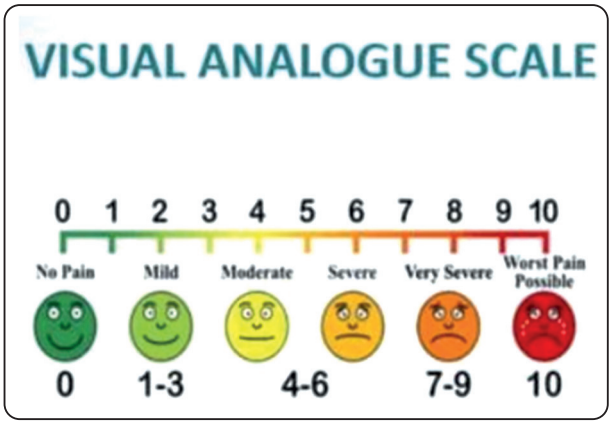

Fig. (3) Visual Analogue Scale

Sample Size

Sample size calculation was done using R statistical package, version 3.3.1 (21-06-2016). Copyright (C) 2016. The R Foundation for Statistical Computing. One-way analysis of variance power calculation for two groups was used to detect the proper sample size. Means and standard deviations were determined according to (Kereshanan, Stephenson and Waddington, 2008). The results showed that, at a power of 80% and a two-sided significance level of 5%; a total sample size of 14 participants will be adequate to reject the null hypothesis that the group means are equal. This means with equal allocation to two arms, there will be 7 participants in each group.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

The study design was a randomized controlled trial. Computer generated random numbers using Microsoft Office Excel 2007 sheet by a person who was not involved in the clinical trial. the right sides of patients were randomly assigned to intrusion, either 25 or 100 grams of force. The numbers of the subjects (1-14) were written on papers inside opaque sealed envelopes, and kept in a box until the commencement of premolar intrusion. At time of intervention, the subject was allowed to choose one of the envelopes to detect her number in the randomization sequence and thus the operator know which amount of force her right upper premolar will undergo, whether 25 grams or 100 grams.

Blinding

Blinding of operator was impossible; however, the pain assessment was blind. Since the patients were assigned to amount of intrusion by random number, the outcome assessor did not know which one had 25 grams or 100 grams of intrusive force.

Ethics approval

This study protocol was approved by the Ethical Committee, the Faculty of Dentistry, Cairo University, approval number (18-10-3).

Trial Registration

www.clinicaltrials.gov (NCT03644537).

Statistical analysis

After discussing the protocol and the objective of the study and after data collection and verification, the VAS results for study groups were fed to statistical analysis using R Software version 4.2.2 "Innocent and Trusting". Descriptive statistics had been carried out using mean, standard deviation (SD), median, IQR and range for quantitative data, while frequency and percentage were applied for qualitative categorical ones. Normality assumptions for the continuous scores had been detected using Shapiro–Wilk test. Comparative analysis had been performed using Two-Sample t-Test for continuous scores and Fisher's exact test for score categories.

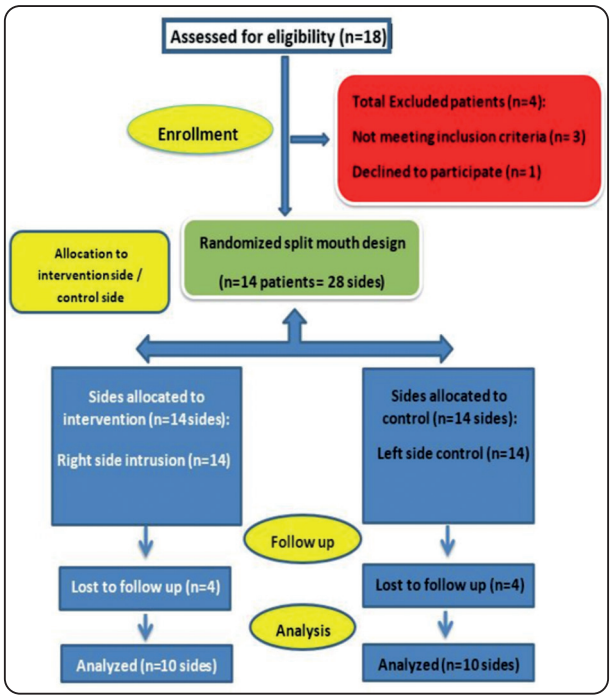

Fig. (4) CONSORT flow diagram

Spearman correlation coefficient had been used for the correlation between the applied forces in grams and the resulted pain score. P value ≤ 0.05 was considered statistically significant.

RESULTS

There were two drop outs in each group, accordingly, the study had been conducted on 10 patients, 5 patients were subjected to 25 grams of intrusive force and another 5 patients were subjected to 100 grams of intrusive force. The mean VAS score was 1.8 ± 0.4 with a median 2.0 and IQR:(2.0 to 2.0) for patients undergone 25 grams intrusive force vs. 4.4 ± 0.5 with a median 4.0 and IQR:(4.0 to 5.0) for patients undergone 100 grams indicating a statistically significant increased pain score among patients subjected to the higher intrusive force (absolute mean diff. = 2.6, p <0.001). (Table 1 & Figure 4)

TABLE (1) The visual analogue scale scores among study groups:

	Patient Groups		Absolute mean difference	P value
	25 grams of intrusive force (n = 5)	100 grams of intrusive force (n = 5)		
Mean (SD)	1.8 (0.4)	4.4 (0.5)		
Median (IQR)	2.0 (2.0 to 2.0)	4.0 (4.0 to 5.0)	2.6	**<0.001*** **
Min - Max	1 - 2	4 - 5		

Data are represented as mean, standard deviation (SD), median, interquartile range (IQR) and range.

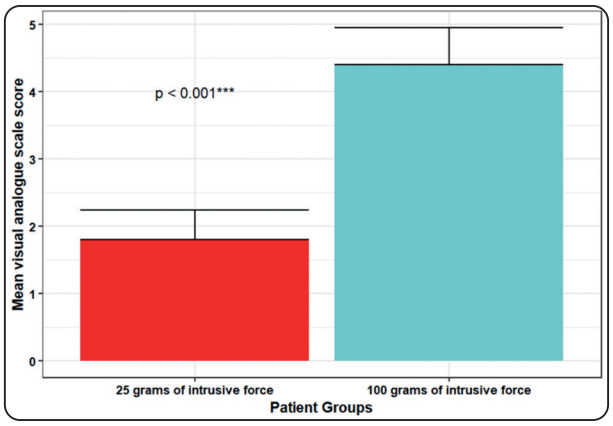

Fig. (4) Comparative analysis for visual analogue scale scores among study groups.

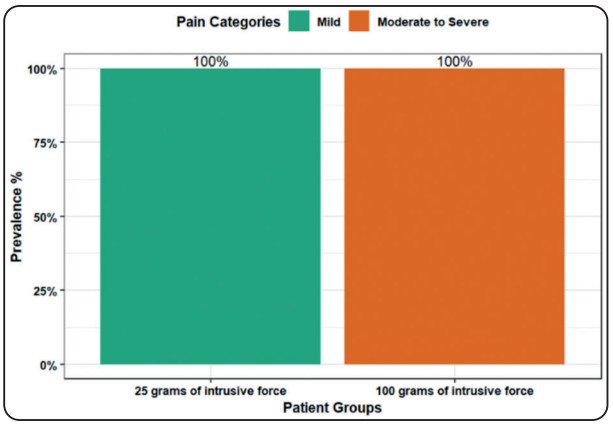

Fig. (5) Comparative analysis for visual analogue scale score categories among study groups.

TABLE (2) The visual analogue scale score categories among study groups:

Visual analogue scale score categories		Patient Groups		P value
		25 grams of intrusive force (n = 5)	100 grams of intrusive force (n = 5)	
Pain score categories	Mild pain	5 (100%)	0 (0.0%)	0.008**
	Moderate to Severe pain	0 (0.0%)	5 (100%)	

Also 100% of patients undergone 25 grams intrusive force showed a mild level of pain, while 100% of patients undergone 100 grams showed a moderate to severe pain level showing a statistically significant difference (p = 0.008). (Table 2 & Figure 5)

Figure 6 also showed a statistically significant very strong positive correlation between the applied intrusive forces in grams and patients visual analogue scale scores (r = 0.91, p < 0.001).

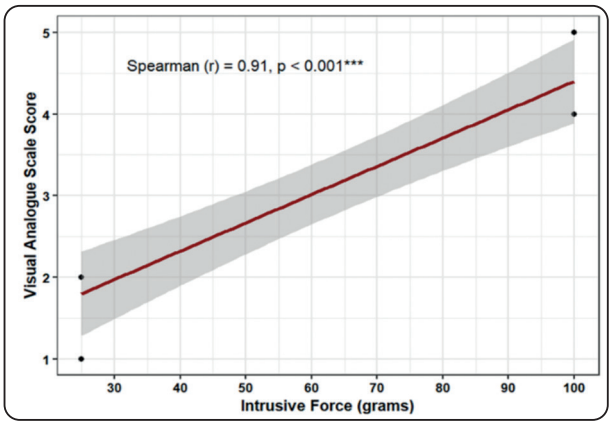

Fig. (6) Correlation between applied intrusive force in grams and the resulted pain score.

DISCUSSION

According to the Medical Bio Statistical Unit of Faculty of Dentistry, Cairo University, at a power of 80% and a two-sided significance level of 5%, a total sample size of fourteen participants will be adequate to reject the null hypothesis stating that mean value for both groups are equal. Therefore, with equal allocation to two arms, each group will confine seven participants. The number of patients in each group was 7 patients (5 main participants and 2 case subjects to replace any dropouts) as per (Kereshanan, Stephenson and Waddington, 2008) study.

The recommended force for intrusion (25 grams) was initially applied, where group 2 suffered a force value 4 times (100 grams) higher than group 1. The big difference between both force values will give room for the expected changes to be demonstrated more vividly (Gonzales *et al*., 2008).

The initial magnitude of force for group 1, 25 grams, was chosen in accordance with (Chan and Darendeliler, 2005) study and(Harris, Jones and Darendeliler, 2006) study, whereas the second magnitude of force (100 grams) was selected in accordance with (Han *et al*., 2005) study, (Carrillo *et al*., 2007) study and (Wan Hassan *et al*., 2012) study.

For the study, the maxillary arch was the arch of choice. The mandible was less likely to be used in the study due to the inaccessibility of the lingual side for mini-screw placement and the nature of the hard and compact mandibular bone subjecting the mini-screw to a risk of fracture(Kuroda and Tanaka, 2014). Any case with malocclusion was accepted as long as the treatment plan enlists extraction of the upper first premolars. Miniscrews, rather than any other mechanics, was selected since miniscrews provide pure intrusion forces unlike other archwire mechanics. Diagonal, rather than same side (mesial or distal), placement of miniscrews was attempted to avoid teeth tilting during intrusion.

Miniscrews diameter value was a minimum of 1.6 mm which I ordered to avoid the risk of fracture upon application. Miniscrews were 10 mm threads length to avoid screw failure (Kuroda and Tanaka, 2014).

A button rather than a bracket was used to hang over the memory chain, since a button allows better centralization thus providing one point of application. A memory chain rather than a NiTi spring was selected to deliver forces since NiTi closed springs' shortest length failed to provide the required force.

Also the duration of force application (3 months) was selected in accordance with (Carrillo *et al*., 2007) study.

Due to the usage of a memory chain for force delivery, a ten-day follow-up period was mandatory to make sure that the same magnitude of force is provided over the intended interval of time.

One of the most widely utilized tools for assessing subjectively perceived pain during fixed orthodontic therapy is the VAS (Lai *et al*., 2020). Additionally, the VAS contains many response categories compared to measures with fewer responses, which implies that it is thought to be more sensitive to changes in pain intensity. It has been shown, therefore, that although the VAS might be sensitive to the effects of treatment if the same person rates their pain before and after the intervention, it might not generate accurate ratings across various patient groups since different patients might interpret the scale in different ways(Lai *et al*., 2020).

The VAS's conceptual complexity and need for the ability to convert a sensory experience into a linear format are other drawbacks. The main causes of the problems with the VAS are either inadequate instructions from the researcher or a lack of understanding on the part of the patient, and these issues seem to be more common in patient populations who are older (Briggs and Closs, 1999). Using a photocopier to duplicate the VAS is another way to introduce error. Every time they make a copy, some photocopiers have a tendency to slightly enlarge the image (Briggs and Closs, 1999). Consequently, if the VAS is duplicated, the final VAS can be longer than 100 mm. The VAS is nevertheless appreciated for its simplicity of use and the minimum demands it places on sick patients, despite these drawbacks, and is utilized in a range of clinical and research settings (Lai *et al*., 2020) (Briggs and Closs, 1999).

The correlation between increasing force magnitude and pain intensity is evidently positive , as displayed in (figure 4,table 1, figure 5 ,table 2 and figure 6) and as ascertained by (Theodorou *et al*., 2019) study.

The level of pain experienced during orthodontic treatment varies depending on the patient and treatment strategy. Orthodontists should use a patient's susceptibility assessment when developing treatment plans for pain management and prevention, and patients should be informed as part of informed consent. (Atta *et al*., 2020).

The overall results of the present research clearly demonstrate that there is a correlation between increasing intrusive force magnitude and pain intensity. In addition, the higher the force value applied (100 grams), the greater the pain level.

CONCLUSION

From the findings of this study, it was concluded that:

1- There is a positive correlation between force magnitude and pain.

2- Pain intensity increases by increasing the intrusive force magnitude.

Funding

Non-financial competing interests: This study was a part of the Masters' degree in Orthodontics, Faculty of Dentistry, Cairo University. The study was self-funded by the principal investigator.

Conflict of Interest

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

I am deeply grateful and forever indebted to Dr. Esraa Ahmed Radwan, Associate Professor of Oral Biology, Faculty of Oral and Dental Medicine, Cairo University, for her continuous encouragement and advice throughout this work, this work would not be accomplished without her efforts and advice.

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