Research Journal of Medical Sciences 10 (5): 545-550, 2016
ISSN: 1815-9346

Fabrication and Evaluation of a Diagnostic Device for the Measurement of Mechanical Allodynia

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Abstract: Acute inflammation of periradicular tissues such as acute apicalabscess, acute periradicular periodontitis, etc. is detected by reduction of the mechanical pain threshold which is defined as allodynia. It is essential to design a standard method to assess the mechanical allodynia in patients with dental pain. Thus, the aim of this study was to evaluate a device converting the bite force to a recordable figure based on newton in order to measure mechanical allodynia. In this cross-sectional study which was investigated in 40 volunteered dental students, by one researcher, mechanical allodynia device was used. In the first phase, the device was placed between the mesiopalatal cusp of maxillary first molar and mandibular first molar. This process was followed for the contra lateral teeth. This process was performed four times with a frequency of one minute for each side. The maximum forces were recorded and these measurements were performed againin 2 and 4 weeks again (totally 960 measurements). Data were analyzed by SPSS Software (version 21).The maximum force in the right and left sides in different testing times were 290.97 and 278.84 N, respectively, which is statistically significant ($p<0.0001$). The mean of forces for women in the right and left sides were 22.6 N and 29.3 N lower than those of the men, respectively, which was statistically significant in both sides ($p<0.0001$). The mean of forces in the three periods obtained through the analysis of linear effect of age showed that 0.33 and 2 N less forces were exerted for each year increase in age in the right and left sides, respectively. This change, however was statistically significant in the left side ($p<0.04$). The interclass correlation coefficient (rho) in the right side was 0.6 ($p<0.0001$) and in the left side was 0.56 ($p<0.0001$). This device has the potential to be used for the repeatable measurement of bite force in every individual at different periods.

Key words: Allodynia, dental pain, diagnostic device, SPSS Software, statistically

INTRODUCTION

Accurate diagnosis is the first step for the successful treatment of dental pain. However, diagnosis of pulp and periradicular conditions can be a complex and vague process. The status of periradicular such as acute periradicular periodontitis is often evaluated by diagnostic tests without accuracy or validity (Khan *et al*., 2007a).

Acute inflammation of periradicular tissues such as acute apicalabscess, acute periradicular periodontitis, etc. is detected by reduction of the mechanical pain threshold, probably as a result of peripheral or central mechanisms (Khan *et al*., 2007b; Owatz *et al*., 2007). An intrinsic characteristic of acute apical inflammation condition is mechanical allodynia which is defined as reduction of mechanical pain threshold (Khan *et al*., 2007;a, b; Owatz *et al*., 2007).

Masticatory system is highly complicated. It consists of bones, muscles, ligaments and teeth. The movements of this system are mediated by a complex process of neural control. In the proper movements of mandible

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by muscles, the teeth are so appropriately in contact with each other that the optimum efficiency is obtained for mastication (chewing and softening), (Okeson, 2008). Measurement of bite force is often necessary to evaluate the function of the jaw muscles (Tortopidis *et al*., 1998).

Percussiontest is a common clinical method to measure mechanical allodynia (reduction of mechanical pain threshold) which is often performed by a mirror handle and compared with the adjacent normal tooth. This technique generates a variant force that is often determined as a simple positive or negative response.

In another clinical test, a hard instrument such as tooth slooth is placed on the patient'stooth and if the patient feels the pain, this test is confirmed. Although, both tests have been used for many years by the dentists, none of them has a definite numerical value and their sensitivity and specifity are unknown and intrinsically variant.

Thus, it is essential to design a standard method to assess the mechanical allodynia in patients with dental pain. Using a quantitative technique to measure the mechanical pain threshold can remarkably enhance the clinical diagnostic accuracy of periradicular conditions in root therapy and provide the possibility of measuring the efficacy of the treatment (Khan *et al*., 2007a, b). Calculation of bite force to evaluate the function of jaw muscles is also necessary, but this measurement is often difficult and depends on several factors:

- The location of the device to record the masticatory force that can be placed inunilateral, bilateral, posterior or anterior positions
- Patients may not tend to press their teeth on each other due to the fear of dental injury or pain especially when the instrument that the teeth are pressed on is made of metal
- The size of the recording instrument may largely distract the condyle
- Inflexibility of the components of the instrument may interfere with the patient's reluctance to press the teeth at maximum level
- Inability to record the dynamic conditions of the jaw as well as the instrument's accuracy
- The sensitivity of the teeth, muscles and temporomandibular joint (Braun *et al*., 1995)

In addition to the above factors, other elements with the most bite force include the muscular force that closes the jaw, teeth condition, pain threshold and opening of the mouth (Tortopidis *et al*., 1998).Moreover, several studies have considered the role of gender as an influential element and have shown higher sensitivity to the pain for women (Fillingham *et al*., 1999; Usui *et al*., 2007). However , quantitative evaluation of the biteforce can be used in the following areas:

- Evaluation of the efficiency of sedatives
- Evaluation of the accuracy of anesthetic injection (whether the tooth has been anesthetized or not)
- Evaluation of the accuracy of the patient's report about legal issues and forensics
- Evaluation of the effect of non-pharmaceutical endodontic therapies on patients
- Evaluation of the bite force following orthognathic surgery
- Evaluation of the bite force following orthodontic therapies (Khan *et al*., 2007a, b; Norholt *et al*., 1998)

Thus, the main objectives in the present study were to fabricate a device with ability to quantitatively evaluate the mechanical allodyniaand to determine whether this measurement device of bite force has sufficient reliability or not.

MATERIALS AND METHODS

This study (with the grant no: K/87/54) was approved by the ethical committee of Kerman University of Medical Sciences.

In this cross-sectional study which was carried out in the endodontics department at Kerman University of Medical Sciences,mechanical allodynia device was usedby one researcher (Fig. 1). The validation of it was confirmed by a formerly calibrated microfile machine (made in Switzerland) according to the application of specific forces.

The masticatory function of the molars was investigated in 40 volunteered dental students with the following conditions:

- Criteria for inclusion in this study was having maxillary and mandibular first molars. The healthy tooth was the one with vital pulp, no largefilling (that is lack of involvement in the marginal ridge of the teeth under study) in the crown and asymptomatic in periapical tests (percussion and palpation)
- Criteria for exclusion from in this study was the volunteers withperiodontalproblems and those with systemic disease and consuming any drugs especially painkiller

Fig. 1: Measurement device for mechanical allodynia

This clinical study was carried out in three phases (0, 2 and 4 week). First, the following text was completely read for each participant in order to inform them about their proper cooperation.

"I insert this device between your upper and lower teeth to evaluate your ability in closing your teeth, then, you need to put your teeth on each other slowly. When a resting condition is provided for you, press your teeth on each other as much as possible as I gesture. As soon as you feel pain, quickly stop pressing your teeth. Some patients indicate this feeling of maximum ability to close the mouth by pinching, burning or high pressure. Measurement of your maximum bite force begins with my gesture and continues until you open your mouth, which lasts almost 5 seconds".To control the infection, disposable plastic covers were used for part of the device that was placed inside the mouth.

In the first phase, the device was placed between the mesiopalatal cusp of maxillary first molar and mandibular first molar. This process was followed for the contralateral teeth. This process was performed four times with a frequency of one minute for each side. The second, third and fourth phases were done like the first phase. The maximum forces obtained in these stages were recorded and measured again two times with intervals of 2 and 4 weeks (Khan *et al*., 2007a, b). All measurements were performed in specific times of the day (9:30-11:00) to prevent muscular fatigue in the participants (Okeson, 2008).

Owing to the effect of head position on the efficiency of muscular strength during the application of force, the bite force was measured in the sitting position with the vertical head (Okeson, 2008). The given numberswere calculated based on newton and their accuracy was confirmed by a machine. The stages and obtained forces along with the date of application for each stage were recorded in the following form.

RESULTS

The means of the recorded forces in different stages of the experiment for three patient referrals are presented in Table 1. To compare the forces in the right and left sides, paired t-test was applied. The findings indicated that the mean forces in the right and left sides in testing times were 281.2 N and 268.9 N, respectively which indicated a statistically significant difference ($p<0.0001$). The maximum figures obtained in the right and left sides were 324 and 322 N, respectively and the minimum registered number in the right and left sides were 130 and 108 N, respectively.

Table 1: The means of the recorded forces in different stages of the experiment

Referral time	Maximum force in right side	Maximum force in left side
Gender		
Male		
First	296.41	288.36
Second	301.18	292.18
Third	297.95	285.27
mean	298.52	288.61
Female		
First	273.44	263.06
Second	287.83	273.39
Third	283.94	264.28
mean	281.74	266.91
Mean of maximum force	290.97±20.45	279/84±24/03

To compare the maximum force in the right and left sides, paired t-test was applied and results showed that the maximum force in the right and left sides in different testing times were 290.97 and 278.84 N, respectively, which is statistically significant ($p<0.0001$).

The mean of the forces in the three periods obtained by random regression model indicated that women significantly generated less force in the left and right sides compared to men. The mean of forces for women in the right and left sides were 22.6 and 29.3 N lower than those of the men, respectively, which was statistically significant in both sides ($p<0.0001$).

The mean of forces in the three periods obtained through the analysis of linear effect of age showed that 0.33 and 2 N less forceswere exerted for each year increase in age in the right and left sides, respectively. This change, however, was statistically significant in the left side ($p<0.04$). The age range of the participants was 20-40 years with the mean age of 24.

Table 2: The results of random regression model

	Right		Left	
Random regression	Coefficient	p-value	Coefficient	p-value
Gender				
Man	-	-	-	-
Woman	-22.60	>0.0001	-29.3	>0.0001
Age	-0.33	0.7200	2-.00	0.0400
Referral time	2.86	>0.0001	2.40	0.0010
(Rho)	0.60	>0.0001	0.56	>0.0001

The analysis of the linear effect of the testing time from the first round to the fourth round indicated that on average 2.86 N in the right side and 2.4 N in the left side were added from one round to another round, which showed a statistically significant difference in both sides (Right: $p<0.0001$) (Left: $p<0.001$).

The correlation between the recorded forces in different testing times was high, 0.6 N for the right side and 0.56 for the left side, indicating a statistically significant correlation ($p<0.0001$). Also, the Cronbach's alpha coefficients for the right and left sides were 0.82 and 0.8, respectively (Table 2).

The results of random regression model with regard to the mean of the maximum forces acquired in the three periods indicated that women generated significantly less force in the right and left sides than men. The means of maximum forces for women in the right and left sides were 17.1 N and 24.1 N lower than those of the men, respectively which revealed a statistically significant difference (Right: $p = 0.02$) (Left: $p<0.0001$).

The analysis of the linear effect of age according to the mean of the maximum forces obtained in the three time periods showed that 0.23 and 1.6 N less forces were exerted in the right and left sides for every year of age increase, which was not statistically significant for both sides (Right: $p=0.72$) (Left: $p=0.06$).

The analysis of the linear effect of referral time from the first round to the third round indicated that on average, 2.8 N was added in the right side from one time to another which was statistically significant (Right: $p = 0.01$). In the left side, however, -0.56 N was added which was not statistically significant (Left: $p = 0.69$).

The correlation between the forces in various times of the experiment was high, 0.73 N in the right side and 0.63 N in the left side, indicating a statistically significant correlation ($p<0.0001$).

DISCUSSION

The present study was conducted tomanufacture a device converting the bite force to a recordable figurebased on newton in order to measure mechanical allodynia in endodontic clinical studies. The findings confirmed the reliability and correlation of figures obtained by the device *in vitro*.

The interclass correlation coefficient (rho) in the right side was 0.6 ($p<0.0001$) and in the left side was 0.56 ($p<0.0001$). It is important to note that the high correlation of obtained numbers and Cronbach's alpha coefficient in registration of occlusal force is indicative of the ability of the fabricated device in repeating the acquired numbers, which consequently facilitates the following experiments. These findings show that this device has the potential to be used for the repeatable measurement of bite force in every individual at different periods.

Mechanical allodynia is an important characteristic of periradicular pain, which is probably the result ofnociceptors'sensitivity in the Periodontal Ligaments (PDL) that are acutely inflamed. However, clinical studies that have investigated the mechanism of mechanical allodynia are limited in strength because of inability to be replicated and lack of quantifiable methods for mechanical allodynia (Khan *et al*., 2007a, b).

Similar studies have measured the highest bite force by a similar device. (Khan *et al*., 2007a, b; Usui *et al*., 2007) . The following features were different in the present study:

- Using tooth slooth to findthe proper location of the teeth allowing us to locate, it in its correct position. However, other studies have used stainless steel transducer (Bonakdarchian *et al*., 2009; Vardimon *et al*., 2007)

The height of device in the tooth position, where the height of our device was 16 mm and in other studies was different given the design type of device. Various studies have reported different measurements for the maximumbite force in human (Proffit *et al*., 1983; Hellsing and Hagberg, 1990; Ferrario *et al*., 2004). The means of the maximum bite force in the present study in the right andleft sideswere 290.97±20.45 and 278.84±24.03, respectively. However, in some studies a higher bite force has been reported than in the present study (Khan *et al*., 2007a, b; Regalo *et al*., 2008) whereas in some other studies, the mean of the maximumbite force is similar to that of the present study (Ferrario *et al*., 2004; Mackenna and Tu, 1983).

Lower mean of the maximum bite force can be due to the training that is given to patients to stop pressing their teeth in case they feel any pain. This, however can unconsciously induce less pressure. (Khan *et al*., 2007a, b) It has been argued that the maximum bite force is obtained when the intraocclusal distance between incisors is 17±3 mm (Mackenna and Tu, 1983).

The height of our device was 16 mm which caused an opening of around 22 mm in the incisor region. The pressing ability and the maximumbite force are decreased

by increasing the jaw angle and lower jaw movement clockwise, (Braun *et al*., 1995) which may consequently decrease the mean of figures for maximum bite force in the present study compared to some other studies (Kamegai *et al*., 2005).

In this study, tooth slooth was utilized to record thebite force. It was only in contact with the tooth by a cusp while in other studies (Tortopidis *et al*., 1998; Braun *et al*., 1995), there was a larger contact area between the tooth and force transmitter. Since, the contact area affects the maximum recorded force (Khan *et al*., 2007a, b), higher forces may have been reported in previous studies (Tortopidis *et al*., 1998; Braun *et al*., 1995; Mohmmadi *et al*, 2014).

CONCLUSION

The bite force is measured unilaterally and bilaterally. Higher forces, however, have been reported in the bilateral approach. But the study carried out by Tortopidis *et al*. (1998) indicated that bilateral measurement yielded much more difference in the measurement intervals; therefore, only unilateral recording was applied to measure the masticatory force in the present study.

In the study conducted by Usui *et al*. (2007) on five age groups from 8.5-25 years, the maximum bite force rose as the age increased. However, due to lack of such extensive age range in the present study, the effect of age on the maximum bite force was not significant.

As many studies have reported a significant role in maximum bite force for gender, (Miyaura *et al*., 1999; Hatch *et al*., 2001).the present study indicated women have significantly less force than men. This may probably be due to larger muscle mass and longer muscles in men. (Hatch *et al*., 2001).On the other hand, there was a significant difference between the left and right sides in the recorded cases, which has been confirmed by a similar study (Bonakdarchian *et al*., 2009).

Another important point to be considered is that this device should not be used in patients with large composite restorations, because it may cause composite deboning. Furthermore, using this device in patients with masticatory muscles'problems may intensify the symptoms of the patients; therefore, it needs to be avoided in this group of patients.

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