# The Development of a Diagnostic Instrument for the Measurement of Mechanical Allodynia

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#### **Abstract**

Mechanical allodynia, defined as a reduction in mechanical pain threshold, is an essential diagnostic feature of inflammation of the periodontal ligament. Traditional methods for measuring mechanical allodynia in a tooth are not quantitative. This study evaluated the reliability of a new bite force transducer to measure mechanical pain thresholds, which might have application as a quantitative diagnostic aid for measuring mechanical allodynia in patients with apical periodontitis. To determine inter-observer reliability, subjects (n = 40) were given standardized instructions before generating maximal bite force on maxillary first molars; readings were then recorded by three examiners for a total of ten readings per examiner. To determine the test-retest reliability, the initial examiner then retested at two different sessions. The intraclass correlation coefficient was fair to substantial for inter-observer reliability (0.3-0.64) and substantial for intra-observer reliability (0.63-0.68). Thus, the force transducer used in our study is a reliable method to measure mechanical pain thresholds in endodontic patients. (J Endod 2007; 33:663-666)

#### **Key Words**

Bite force transducer, inflammation, mechanical allodynia, pain threshold, periodontal ligament

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Accurate diagnosis is the first step towards the successful management of odontalgia. However, the diagnosis of pulpal and periradicular conditions can be a very complex and imprecise procedure. Inferences about the periradicular status are often made with diagnostic tests having limited or unknown precision and validation. An essential feature of acute apical inflammatory conditions (e.g. acute exacerbation of chronic periradicular periodontitis, acute periradicular periodontitis, acute apical abscess, etc.) is mechanical allodynia, as defined by reduced mechanical pain thresholds. Mechanical allodynia shows a high sensitivity for detecting periradicular pain as compared to pulpal pain [odds ratio (OR) of 6.9; p < 0.01] (1).

However, the most common clinical method for measuring mechanical allodynia in a tooth is a percussion test, often conducted using a mirror handle (2). To establish a baseline for comparison, the test is also conducted on adjacent normal teeth. This technique applies a variable and unknown amount of force, and is often scored simply as a positive or negative response. Another clinical test is to have the patient bite down on a hard object, such as a Tooth Slooth. If the patient reports pain, then the test is considered to be confirmatory. Although both these tests have been used by clinicians for a number of years, they are not quantitative, have unknown levels of sensitivity and specificity, and are inherently variable. It is important to develop and validate a standardized method for assessing mechanical allodynia in patients with odontalgia.

Using a quantifiable method to measure mechanical pain thresholds might substantially improve accurate clinical diagnoses of periradicular conditions in endodontics and will also provide us with a measure of the effectiveness of the treatment provided. Potential applications of this method include mechanistic studies evaluating the development of mechanical allodynia and efficacy studies evaluating different analgesics and anesthetics. Previous studies have demonstrated that the reduction in bite force in subjects who underwent extraction of their third molars is highly correlated with reports of postoperative pain (3) and the use of ibuprofen attenuates this decrease in bite force (4). Thus, quantitative measurement of biting force appears to provide a measure of masticatory mechanical allodynia.

One method of assessing mechanical allodynia in a tooth with periradicular periodontitis is to measure the maximal bite force that can be exerted before the patient reports pain and to compare that bite force to the threshold value exhibited by a corresponding control tooth. However, before using a force transducer to assess mechanical allodynia in this manner, it is imperative to first determine whether the instrument measures bite force in a reliable fashion. Therefore, the purpose of this clinical trial was to examine the test-retest and inter-rater reliability of a newly developed bite fork with a built in digital force transducer.

#### **Materials and Methods**

This study was approved by the Institutional Review Board of the University of Texas Health Science Center at San Antonio and the informed consent of all human subjects who participated in the experimental investigation was obtained. Inclusion criteria were the presence of left and right maxillary and mandibular first molars. Subjects with large carious lesions on their first molars, a history of recent orofacial injuries, or current orofacial pain of any etiology were excluded from the study.

The bite fork (Occlusal Force-Meter, GM10, Nagaro Keiki, Tokyo, Japan) was modified by attaching the head of a Tooth Slooth (Professional Results, Inc., Laguna

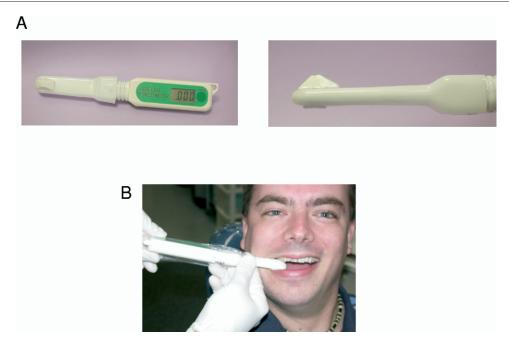


Figure 1. (A) Images of the digital bite force transducer demonstrating the acrylic cone used for testing. (B) Clinical application of the testing device.

Niguel, CA), which acted as an occlusal guide (Fig. 1A). The head of the Tooth Slooth that measured  $18\times8\times5$  mm, was attached on to the bite fork using an adhesive. The instrument was first tested using an Instron universal testing machine (Instron, Norwood, MA). Forces ranging from 0 to 800 Newtons were applied on the bite fork using the Instron machine and forces recorded by the bite fork were noted.

The clinical study consisted of three sessions. On the first session the bite fork was placed between the subject's maxillary and mandibular first molars (i.e. teeth #3 and 30 or teeth #14 and 19) in such a way that the acrylic cone of the bite fork was positioned on the mesiopalatal cusp of the maxillary first molar (Fig. 1B). All subjects were then given the following standardized set of instructions: "I am going to place this bite fork between your upper and lower teeth to measure how hard you are able to bite. I will place the bite fork against your upper tooth and then I would like you to close and gently rest your teeth together on the bite fork. When I signal you, increase biting pressure slowly until you are exerting as much force as possible and release immediately when you feel discomfort or pain. Other patients have described the feeling they have on maximal biting as a pinch, tingle, or strong pressure feeling. The bite force measurement from the time I signal you to start until you open should take approximately five seconds."

The same process was then repeated on the contralateral teeth. This process was repeated 4 more times at 1-minute intervals. Maximal bite force readings were then collected by the other two examiners using the method described above. A total of 10 readings were collected by each examiner at the first session. The maximal bite force was recorded again by the initial examiner at two subsequent sessions. The time period between the sessions was 2 to 4 weeks. Similar to session one, the process was repeated five times at 1-minute intervals. The subjects were kept blinded to the results of the bite force measurements.

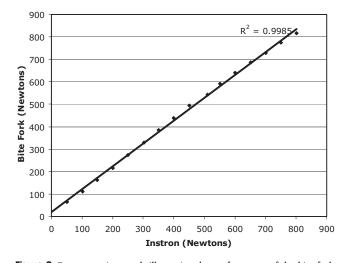
The peak biting force was measured by the digital bite fork in units of Newtons of force. The digital bite fork records force up to 1,000 N. A cut-off value of 775 N was imposed to prevent tooth injury as previous studies have shown that this force produced maximal voluntary contraction without pain in normal teeth (5, 6). The intraclass correlation coefficient was interpreted as a measure of the degree of instrument

reliability using the Landis and Koch scale: slight (0.0-0.2), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80), and almost perfect (0.81-1.00) (7).

#### Results

The results of the in vitro study demonstrate that the bite fork measured the applied force in an accurate manner ( $r^2 = 9.9985$ ) over a range of 0 to 800 Newtons (Fig. 2). The mean slope was 1.005.

Forty-four subjects were recruited to the study. Four subjects did not complete the study, one because of voluntary withdrawal and three because of inability to reappoint within the required 2-week sampling session. The study sample consisted of 22 males and 18 females with an average age of 29.3 years (ranging from 22-64 years). Fifty-five percent of the subjects were Caucasian, 28% were Asian, and 6% were Hispanic. The overall maximal bite force readings were  $507.9 \pm 30.7 \,\mathrm{N}$  (mean  $\pm$ 



**Figure 2.** Representative graph illustrating the performance of the bite fork. Forces ranging from 0 to 800 N were exerted on the bite fork using an Instron machine.

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