Evaluation of instrumentation systems for periodontal mechanical treatment

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Title:

Evaluation of instrumentation systems for periodontal mechanical treatment

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INTRODUCTION

1. Introduction

Periodontology is “the scientific study of the periodontium in health and disease” (1). The periodontium constitutes teeth support tissues and includes the gingiva, alveolar bone, periodontal ligament and root cementum. The anatomy, histology and physiology of the normal periodontium have been described in great detail elsewhere (1).

Periodontal disease involves a number of conditions of the periodontal tissues, which leads to attachment loss and destruction of alveolar bone as a consequence. The natural history of periodontal disease may result in tooth loss (2-6).

Gingivitis is the most frequently occurring periodontal disease, involving inflammation of the gingiva caused by bacteria present in dental biofilm. Clinical signs include changes in tissue colour, volume, temperature, crevicular exudate and bleeding upon gentle provocation with a probe (6,7). These clinical signs of illness reverse once proper oral hygiene is established and effectively maintained (8). However, untreated gingivitis progresses in most individuals to periodontitis, which involves clinical changes that include periodontal pockets, attachment loss, bleeding upon probing, and radiographic bone loss (6,9,10).

The bacterial origin of periodontal diseases is considered the main aetiological factor involved. In contrast to an accumulation of individual bacteria, the oral biofilm is a complex, three-dimensional arrangement of matrix-enclosed bacterial communities (11).

Periodontal disease originates when a group of predominantly Gram-negative bacteria form a bacterial biofilm on the tooth surface. These periodontal pathogens and their

toxins, trigger a response from the host immune system that actuates chronic inflammation and destruction of the periodontium (12-14). The evolution of these pathologies can be influenced by a series of local and systemic modifying factors, such as diabetes mellitus, atherosclerosis, osteoporosis, genetic factors of the host, stress, a removable prosthesis, an overhanging restoration margin, and behavioural and environmental factors such as tobacco smoking (15). An ever-increasing body of scientific evidence supports an association between periodontal infection and certain systemic conditions, and several potential mechanisms have been suggested. Periodontal disease and a number of systemic diseases may share common risk factors (smoking, stress and genetic factors) and an aetiological pathway (16). Systemic diseases can also be influenced by the inflammatory burden caused by periodontal disease, highlighting the relative importance of periodontal and systemic diseases and how they are interrelated (17).

Further investigations have clearly identified periodontal disease as being a risk factor that contributes to the development of various systemic conditions such as cardiovascular disease (CVD), adverse pregnancy outcomes, osteoporosis and diabetes mellitus (18). The diabetes i.e., has a bilateral effect: with an active periodontal infection the metabolic control is more difficult and, at the same time, the diabetes amplifies the periodontal destruction due to the periodontal pathogens. (1,18).

1.1. Classification of periodontal disease

As periodontal disease encompasses a wide range of diseases, not only periodontitis, recognition of these pathologies is required for correct diagnosis (10). Recognizing the various signs and symptoms in the periodontal tissues that lead to the clinical diagnosis of periodontal disease can reveal a diminishing state of health.

The systems of classification of periodontal disease published by the American Academy of Periodontology (AAP) are the most widely endorsed (6,19).

Figure 1: Classification of periodontal diseases and conditions. The 1999 American Academy of Periodontology Classification (6).

I. Gingival Diseases
  A. Dental plaque-induced gingival diseases
    1. Gingivitis associated with dental plaque only
      a. without other local contributing factors
      b. with local contributing factors
    2. Gingival diseases modified by systemic factors
      a. associated with the endocrine system
        (1) puberty-associated gingivitis
        (2) menstrual cycle-associated gingivitis
        (3) pregnancy-associated
          (a) gingivitis
          (b) pyogenic granuloma
      b. associated with blood dyscrasias
        (1) leukemia-associated gingivitis
        (2) other
    3. Gingival diseases modified by medications
      a. drug-influenced gingival diseases
        (1) drug-influenced gingival enlargements
        (2) drug-influenced gingivitis
          (a) oral contraceptive-associated gingivitis
          (b) other
    4. Gingival diseases modified by malnutrition
      a. ascorbic acid-deficiency gingivitis
      b. other
  B. Non-plaque-induced gingival lesions
    1. Gingival diseases of specific bacterial origin
      a. Neisseria gonorrhea-associated lesions
      b. Treponema pallidum-associated lesions
      c. streptococcal species-associated lesions
      d. other
    2. Gingival diseases of viral origin
      a. herpesvirus infections
        (1) primary herpetic gingivostomatitis
        (2) recurrent oral herpes
        (3) varicella-zoster infections
      b. other
    3. Gingival diseases of fungal origin
      a. Candida-species infections
        (1) generalized gingival candidosis
      b. linear gingival erythema
      c. histoplasmosis
      d. other
    4. Gingival lesions of genetic origin
      a. hereditary gingival fibromatosis
      b. other
    5. Gingival manifestations of systemic conditions
      a. mucocutaneous disorders
        (1) lichen planus
        (2) pemphigoid
        (3) pemphigus vulgaris
        (4) erythema multiforme
        (5) lupus erythematosus
        (6) drug-induced
        (7) other
      b. allergic reactions
        (1) dental restorative materials
          (a) mercury
          (b) nickel
          (c) acrylic
          (d) other
        (2) reactions attributable to
          (a) toothpastes/dentifrices
          (b) mouthrinses/mouthwashes
          (c) chewing gum additives
          (d) foods and additives
        (3) other
    6. Traumatic lesions (factitious, iatrogenic, accidental)
      a. chemical injury
      b. physical injury
      c. thermal injury
    7. Foreign body reactions
    8. Not otherwise specified (NOS)

II. Chronic Periodontitis†
  A. Localized
  B. Generalized
III. Aggressive Periodontitis†
  A. Localized
  B. Generalized
IV. Periodontitis as a Manifestation of Systemic Diseases
  A. Associated with hematological disorders
    1. Acquired neutropenia
    2. Leukemias
    3. Other
  B. Associated with genetic disorders
    1. Familial and cyclic neutropenia
    2. Down syndrome
    3. Leukocyte adhesion deficiency syndromes
    4. Papillon-Lefèvre syndrome
    5. Chediak-Higashi syndrome
    6. Histiocytosis syndromes
    7. Glycogen storage disease
    8. Infantile genetic agranulocytosis
    9. Cohen syndrome
    10. Ehlers-Danlos syndrome (Types IV and VIII)
    11. Hypophosphatasia
    12. Other
  C. Not otherwise specified (NOS)
V. Necrotizing Periodontal Diseases
  A. Necrotizing ulcerative gingivitis (NUG)
  B. Necrotizing ulcerative periodontitis (NUP)
VI. Abscesses of the Periodontium
  A. Gingival abscess
  B. Periodontal abscess
  C. Pericoronal abscess
VII. Periodontitis Associated With Endodontic Lesions
  A. Combined periodontic-endodontic lesions
VIII. Developmental or Acquired Deformities and Conditions
  A. Localized tooth-related factors that modify or predispose to plaque-induced gingival diseases/periodontitis
    1. Tooth anatomic factors
    2. Dental restorations/appliances
    3. Root fractures
    4. Cervical root resorption and cemental tears
  B. Mucogingival deformities and conditions around teeth
    1. Gingival/soft tissue recession
      a. facial or lingual surfaces
      b. interproximal (papillary)
    2. Lack of keratinized gingiva
    3. Decreased vestibular depth
    4. Aberrant frenum/muscle position
    5. Gingival excess
      a. pseudopocket
      b. inconsistent gingival margin
      c. excessive gingival display
      d. gingival enlargement (See I.A.3. and I.B.4.)
    6. Abnormal color
  C. Mucogingival deformities and conditions on edentulous ridges
    1. Vertical and/or horizontal ridge deficiency
    2. Lack of gingiva/keratinized tissue
    3. Gingival/soft tissue enlargement
    4. Aberrant frenum/muscle position
    5. Decreased vestibular depth
    6. Abnormal color
  D. Occlusal trauma
    1. Primary occlusal trauma
    2. Secondary occlusal trauma

1.2. Treatment of periodontal diseases

A treatment strategy that includes the elimination of an opportunistic infection must be well defined and followed for every patient that has been diagnosed with periodontitis. In addition, clinical outcome therapy goals must also be defined. Such clinical parameters include (1):

- Reduction or resolution of gingivitis (bleeding on probing; BoP). A patient full mouth mean BoP ≤25% should be reached.
- Reduction in probing pocket depth (PPD). No residual pockets with PPD >5 mm should be present.
- Elimination of (through-and-through) open furcations in multi-rooted teeth. Initial furcation involvement should not exceed 3 mm.
- Absence of pain.
- Individually satisfactory aesthetics and function.

Considering this, it is essential to highlight that risk factors for periodontitis that can be controlled must also be addressed. The three main risk factors for chronic periodontitis are (1) improper plaque control, (2) cigarette smoking, and (3) uncontrolled diabetes mellitus (1,20).

1.2.1. Phases of periodontal treatment

The treatment of patients affected by caries and periodontal disease who display symptoms of associated pathologic conditions such as pulpitis, periapical periodontitis, marginal abscesses, and tooth migration, may, from a didactic point of view, be divided into four distinct phases:

1. Systemic phase of therapy including smoking counselling.
2. Initial (or hygiene) phase of periodontal therapy, i.e., cause-related therapy.
3. Corrective phase of therapy, i.e., additional measures such as periodontal surgery, implant surgery, restorative, orthodontic and/or prosthetic treatment.
4. Maintenance phase (care), i.e., supportive periodontal therapy (SPT).

1.2.1.1. Systemic phase

During the systemic phase, the main objective is to eliminate or reduce the severity of systemic conditions that can negatively influence the outcomes of therapy while taking appropriate preventive measures to protect both the patient and the dental care providers from infectious risks. When necessary, this can be accomplished through contact with a physician or specialist.

Aspects such as infection control must be addressed in the dental office, as they play a central role and are considered to be the principal goals of the systemic phase of periodontal therapy. In order to protect the patient against presumptive complications, such as infection – especially bacterial endocarditis, bleeding, cardiovascular incidences, and allergies – an in-depth knowledge of the patient's medical history and an oral examination are necessary.

Patients with systemic diseases such as diabetes mellitus or cardiovascular diseases are commonly treated with a variety of medications that may interact with drugs prescribed during periodontal therapy. It is therefore highly recommended to take appropriate precautions, and it is suggested to consult the patient's physician prior to commencing systemic periodontal therapy (1). Periodontal treatment can also have a beneficial effect on the systemic health of the patient. In addition, glycaemic control may be facilitated in diabetics if correct periodontal therapy is followed.

Finally, as cigarette smoking is the second highest risk factor for periodontitis after inadequate oral hygiene, smoking counselling has become part of modern periodontal

treatment. Efforts must be made to encourage a smoker to join a smoking cessation program (1).

1.2.1.2. Initial (hygiene) phase

This phase focuses on cause-related therapy. The principal objective of this phase is the realization of clean and infection-free conditions in the oral cavity. This can be achieved through the complete removal of all soft and hard deposits and their retentive factors. Encouraging the patient to perform optimal plaque control also forms an important objective of this phase (1).

It is generally accepted that the goal of initial periodontal treatment is to restore the biological compatibility of periodontally diseased root surfaces, thus arresting the process of the disease. The aim of non-surgical therapy is to reduce both the living bacteria in the microbial biofilm and the calcified biofilm microorganisms from the tooth surface and adjacent soft tissues. The complete elimination of such pathogenic microorganisms is regarded as overly ambitious (21-24). Nevertheless, a reduction in inflammation of the periodontium caused by the lesser bacterial load leads to beneficial clinical changes.

A description of the numerous methods employed to perform non-surgical therapy can be found in the literature. Some examples, described later in detail, are hand instrumentation, ultrasonic and sonic scalers, and ablative laser therapy.

Re-evaluation after initial phase

The conclusion of the initial phase of therapy can be reached by carrying out a thorough analysis of the results obtained in relation to the elimination or degree of control of the dental infection. Therefore, a re-evaluation of the patient's periodontal conditions and

caries activity must be made. The results of this re-evaluation define the selection and, if necessary, additional corrective measures that need to be executed during the phase of definitive treatment (i.e., the corrective phase). Re-evaluation of the initial clinical response to non-surgical therapy while considering modifiable risk factors also permits the clinician to formulate a customized ongoing treatment plan for each individual patient. Re-evaluation should be performed no earlier than 6-8 weeks following the last session of instrumentation to ensure that the tissues have sufficient time to heal (1).

1.2.1.3. Corrective phase (additional therapeutic measures)

This phase concerns the consequences resulting from opportunistic infections. It involves therapeutic measures, such as periodontal and implant surgery, and prosthetic treatment (1).

The amount of corrective therapy required and the selection of the appropriate type of restorative and prosthetic therapy can be determined only after the degree of success of the cause-related therapy is accurately ascertained. The type of corrective treatment required must be determined in relation to the patient's willingness and ability to cooperate in the overall therapy. As incompliance in therapy may occur, initiating treatment procedures may not be worthwhile; this in turn implies that permanent improvement of oral health, function and aesthetics will not be achieved. The validity of this statement is supported by the results of studies aimed at assessing the relative value of different types of surgical methods in the treatment of periodontal disease (25-28).

1.2.1.4. Maintenance phase (supportive periodontal therapy)

The prevention of reinfection and disease recurrence is the key aim of this treatment. A recall system must be tailor-made for each individual patient and include (1) assessment of deepened sites with bleeding on probing, (2) instrumentation of such sites, and (3) fluoride application for the prevention of dental caries. Moreover, this treatment involves the regular control of prosthetic restorations incorporated during the corrective phase of the therapy. As loss of vitality is a frequently encountered complication, tooth sensitivity testing should be performed for abutment teeth. Based on individual caries activity, bitewing radiographs should be included in SPT at regular intervals (29-31).

1.2.2. Non-surgical treatment: Phase I

It is of vital importance that the clinician achieves a controlled surface free of calculus and that the patient achieves optimal oral hygiene control (32-34). Non-surgical treatment consists of the elimination of supra-gingival and sub-gingival plaque, dental calculus, using various types of instruments, and the prevention of the recolonization of periodontal pockets by pathogenic bacteria (21-24). It is equally important for the clinician to achieve a decontaminated surface and patient optimal oral hygiene control (32-34). The beneficial effects of scaling and root planing regarding both clinical and microbiological aspects have also been reported (24,35-38).

1.2.2.1 Types of non-surgical treatment

The most commonly adopted instrumentation techniques in SRP treatment are manual instrumentation with curettes, sonic and ultrasonic instrumentation, and rotating instrumentation with specific burs (37,39-41).

1.2.2.1.1 Manual instrumentation with curettes

Root instrumentation with manual curettes is used to remove dental plaque, calculus and contaminated root cementum (37,39,42). The use of manual curettes is considered technically more difficult than other techniques, more time-consuming, and causes more fatigue to the clinician (40).

The working tips of the curettes are fashioned in a variety of shapes and sizes; however, share a common feature of being rounded at the tip, as this reduces gingival trauma during subgingival cleansing. In contrast, periodontal scalers feature a sharp tip, to access supra-gingival calculus in tight embrasure spaces. This feature clearly makes the curette the primary choice of instrument for treating subgingival areas of calculus accumulation. Curettes are most appropriately used when the terminal shank is held parallel to the long axis of the tooth. Instruments often come with angled terminal shanks to facilitate proper usage.

Historically, two groups of curettes are recognized. A universal curette has a blade that is perpendicular to its terminal shank. This orientation allows the blade to be used

against either the mesial or distal surface of a tooth. The Gracey curette has a laterally-offset blade, offset by 70° relative to the shank. Consequently, a Gracey curette has a lower cutting edge and an upper non-cutting edge. As only one side of each blade can cut, Gracey curettes are site-specific, and a posterior instrument used to clean mesial surfaces of teeth will not work on distal surfaces, and vice versa.

Gracey curettes 1/2, 3/4, and 5/6 are used on the anterior sextants of teeth. The 7/8 and 9/10 are used on the buccal and lingual portions of posterior teeth. The 11/12 and 15/16 are used on the mesial portions of posterior teeth, and the 13/14 and 17/18 are used on the distal portions of posterior teeth.

1.2.2.1.2 Sonic and ultrasonic instrumentation

Sonic instruments are also effective for root debridement. Ultrasonic units in dentistry are currently available in two basic types: magnetostrictive and piezoelectric. The mechanism of action for these types varies. Magnetostrictive units operate between 18 and 45 kHz using flat metal strips in a stack or a metal rod attached to a scaling tip. Here, tip movement is elliptical. Piezoelectric units operate in the 25-50 kHz range and are reactivated by dimensional modifications in the crystals housed within the hand-piece as electricity passes over the surface of the crystals; tip movement is primarily linear in direction. Particular concerns arise during periodontal therapy regarding tooth surface alterations produced by using hand-held or ultrasonic instruments. Varying results have been demonstrated regarding the aggressiveness of magnetostrictive and piezoelectric ultrasonic scaling devices on tooth substances. Flemmig (43) suggested that a magnetostrictive unit is more aggressive than a piezoelectric device for root substance removal. In contrast, Busslinger et al. (44) reported that a piezoelectric device resulted in a rougher surface than a magnetostrictive device after instrumentation.

Vercellotti recently designed Piezosurgery® (Mectron®, Italy), which is a system for osteotomy and osteoplasty with ultrasonic microvibrations. When Mectron® introduced PIEZOSURGERY® in 2001, the technology was seen as being revolutionary for bone surgery. It involved a device that provided precision, safety, ergonomics and high quality to surgeons. The special ultrasonic microvibrations of the original PIEZOSURGERY® technique cut bone and nothing else. Soft tissue is not damaged and, as a result, the clinician is able to work with a precision that facilitates not only the surgery itself, but

also reduces patient postoperative discomfort. This instrument also boasts programs and inserts for root debridement as its technological features, similar to piezoelectric devices.

Ultrasonic scalers are able to remove dental plaque and calculus primarily via the mechanical chipping action of the scaler tip. The removal of such deposits from the tooth surface can be facilitated with the aid of two additional mechanisms. The first mechanism, high-energy shockwaves, produces a phenomenon called cavitation when placed under a cooling water supply (defined as the oscillation of air bubbles and the subsequent implosion in a liquid medium). In the second mechanism, acoustic microstreaming patterns are formed near the surface of the scaler tip. Nevertheless, cavitation and acoustic microstreaming have only been observed to contribute to the removal of dental plaque and calculus *in vitro* (42,45-51).

As mentioned previously, ultrasound can be produced either by magnetostriction or piezoelectricity. Direct comparison of these types of devices (*in vitro*) regarding calculus removal and tooth surface roughness following instrumentation reveals that the piezoelectric system provides more efficient removal of calculus; however, it does leave the instrumented tooth with a rougher surface topography (44). Piezoelectric devices are effective; no consensus exists regarding residual roughness. Indeed, other studies have reported that root surfaces subjected to the piezoelectric device are smoother following instrumentation than surfaces subjected to the magnetostrictive device (52).

A limited number of studies (44,53) have analysed the use of piezoelectric devices in non-surgical periodontal therapy. The piezoelectric device produces superior results in

terms of tissue healing and less damage to the root surface when compared with conventional ultrasound, as shown by Cross-Poline et al. (52) and Flemming (43,54).

1.2.2.1.3 Rotatory instrumentation

Rotary instruments can be utilised to clean and polish the root surface. The Perio Set® system (Intensiv, Swiss Dental Products) includes 12 burs with tapered and flame heads, ISO sizes 012, 014 and 016, in grits 75, 40 and 15 µm, with either a short or long neck for each unit. These supplement the mechanical instrumental treatment of periodontitis. The coarse, 75-µm burs are used exclusively in odontoplasty for furcation enlargement and narrow root concavities. The fine grit, 40-µm burs are used for the depuration of root surfaces. The two shapes enable root cleaning even in morphologically difficult areas. The 15-µm burs are used for the final planing and operate at rotation speeds of 6,000 rpm, with reduced pressure application. According to the manufacturer, these burs are useful to remove supra-gingival and subgingival concrements and for root surface planing.

Although rotatory instrumentation reduces working time and improves access and efficiency during the debridement procedure, it has been associated with an increase in wear and abrasion (55). A SEM study (56) showed that conventional curettes using the Perio Set® after scaling and root planing resulted in a biologically-acceptable root surface, free of bacterial contamination and endotoxin. This study also determined that the Perio Set® is an excellent supplement to curettes in root debridement.

1.2.2.1.4. Ultrasonic devices and manual curettes

From a clinical study of 12 patients with moderate, chronic periodontitis, Alvis (2005) (34) showed that scaling with Gracey curettes or ultrasonic causes identical trauma to the root surface and a loss of attachment of 0.75 mm. These results confirmed those by Khosravi (2004) (57). Previous studies have highlighted that ultrasonic instrumentation is as effective as hand scaling for plaque and calculus removal and the successful healing of diseased periodontal tissues (44,48,56,58-60).

RESEARCH RATIONAL

2. Research rationale

Only a limited number of studies have compared different instruments for scaling and root planing in humans. An *in vivo* study performed by Kawashima (2007) compared root surface instrumentation using two piezoelectric ultrasonic scalers and a hand scaler (53). The conclusion suggested that ultrasonic scalers are reasonable choices for periodontal debridement, as they leave a smoother root surface after treatment when compared to manual instrumentation, with similar clinical results (53).

A further study performed by Beuchat (2001) (61) described the comparison of sonic instruments and curettes for periodontal debridement. Here, 11 patients with adult periodontitis were evaluated. After oral hygiene instructions, two randomly-assigned quadrants per patient were scaled and root planed with curettes (control side), and the remaining two quadrants were scaled and root planed with an ultrasound device. At the two-month follow up, no difference was identified between the two sides. This clinical study demonstrated that ultrasound instruments are relatively as effective as curettes from a clinical standpoint regarding probing pocket depth reduction (61).

In conclusion, although numerous instruments exist for periodontal debridement, controversy remains in the literature regarding the best non-surgical instrumentation method. Furthermore, there is no study in the literature comparing burs and the Piezosurgery Mectron® for non-surgical debridment. The present study aims to provide new and relevant data on scaling and root planing methods in order to evaluate the clinical effectiveness (changes in plaque index, probing pocket depth, attachment level,

and bleeding on probing), the post-treatment morbidity, and the chairside time of different instrumentation systems (sensitivity and pain).

In conclusion, it can be considered that despite the existence of a large number of instruments and techniques for non-surgical instrumentation, there is controversy in which of them may be the one that offers the best results. However, there is no study in the literature comparing the use of rotary instruments with specific burs and the Piezosurgery Mectron®, in scaling and root planing. With the development of this work, it seeks to provide results and information relevant to non-surgical debridement in order to evaluate the clinical effectiveness (changes in plaque index, probing pocket depth, attachment level, and bleeding on probing), the post-treatment morbidity, and the chairside time of different instrumentation systems (sensitivity and pain).

HYPOTHESES

3. Hypotheses

- H_0: No clinical differences exist regarding effectiveness, in terms of clinical parameters, between any of the analysed instruments.

- H_1: Clinical differences exist regarding effectiveness, in terms of clinical parameters, between any of the analysed instruments.

- H_0: No clinical differences exist regarding chair-side time between any of the analysed instruments.

- H_1: Clinical differences exist regarding chair-side time between any of the analysed instruments.

- H_0: No differences exist regarding patient morbidity between any of the analysed instruments.

- H_1: Differences exist regarding patient morbidity between any of the analysed instruments.

OBJECTIVES

4. Objectives

1. To evaluate the effectiveness, in terms of clinical attachment level, of scaling and root planing after using Gracey curettes (Hu-Friedy®), ultrasound (P-5 Booster Suprasson Satelec®), 40-µm diamond burs (Intensiv Perio Set®) and ultrasound piezosurgery (Mectron®) using a split-mouth design.

2. To evaluate the chair-side time after scaling and root planing for each therapy.

3. To evaluate the morbidity after scaling and root planing for each therapy.

MATERIAL AND METHODS

5. Material and Methods

This study was conducted at the dental clinic (CUO) of the Universitat International de Catalunya (UIC), Barcelona, Spain. Patients were enrolled from the Department of Periodontology within the same university. This study was approved by both the local scientific committee and the local ethical committee (clinical study registration number: PER-ECL-2011-11-NF). Each patient agreed to participate and provided informed consent. No patient was admitted to the study until the informed consent form had been signed.

5.1. Study design

A randomized, split-mouth clinical trial was performed to compare the clinical effects, chairside time and post-treatment morbidity of four different instrumentation systems used for periodontal debridement: Curettes (Standard Gracey curette - Hu-Friedy), piezoelectric ultrasound (Suprasson Satelec®), 40-µm diamond burs (Intensiv Perio Set®), and piezosurgery ultrasound (Mectron®).

The study was conducted in three phases:

1) Initial screening (one visit),

2) Patient treatment (two visits), and

3) Re-evaluation and data collection.

One operator performed the initial screening and treatment for each patient. Furthermore, a blinded examiner, an expert periodontist, collected all clinical data.

5.2. Patient selection

Patients were approached at their first visit to the Department of Periodontology at the CUO of the UIC.

Patient inclusion criteria were as follows:

- Patients with generalized moderate to severe chronic periodontitis
    - PPD: At least two sites with a probing depth of ≥4 mm per multi-rooted tooth, and at least three sites with a probing depth of ≥4 mm for all remaining teeth, per quadrant (similar to other studies) (62).
- Systemically healthy.

Patient exclusion criteria were as follows:

- Patients who had undergone antibiotic therapy during the previous two months or who underwent antibiotic therapy during the study.
- Remaining dentition of <20 teeth.
- Recent periodontal treatment.
- Allergy to local anaesthetics.
- Current smoker.
- Physically handicapped subject and/or mental disorders that did not allow proper plaque control.
- Aggressive periodontitis.
- Acute periodontal or endodontic infection.

- Systemic disease:
    - Cardiovascular disease: Uncontrolled hypertension, stable and unstable angina pectoris, recent myocardial infarction (<1 month), myocardial infarction (>1 month without current symptoms), arrhythmia, and cardiac failure.
    - Lung disease: Chronic obstructive pulmonary disease, tuberculosis.
    - Diabetes mellitus.
    - Immune disease: HIV infection and related conditions, connective tissue disorders (lupus erythematosus, pemphigus vulgaris, pemphigoid, Sjogren's syndrome), organ transplant (heart, liver, kidney, pancreas, bone marrow).
    - Haematological disorders: Anaemia, agranulocytosis, cyclic neutropenia, leukaemia, multiple myeloma, lymphoma, thrombocytopenia, haemophilia, von Willebrand disease, disseminated intravascular coagulation, thrombocytopenia, primary fibrinogenolysis.
    - Oncological disease: Patients undergoing radiotherapy or chemotherapy.
    - Psychiatric illness, behavioural disorder, neurological disease: Untreated epilepsy, Parkinson's disease, anxiety, eating disorder, delirium, schizophrenia, depression and bipolar disorder.

5.3. Initial screening

On the first visit, patients underwent a comprehensive periodontal examination. The operator performed an initial examination of the patient and completed a questionnaire collecting the patient's general information. A periodontal examination was performed using a periodontal probe (HU-Friedy® - Chicago.IL.USA - COD: PCPUNC15 30 - CP15) and the periodontal chart used in the university dental clinic (Appendix 1).

The following parameters were examined:

- Plaque index (PI) (63),
- Calculus (subgingival calculus),
- Gingival index (64,65),
- Probing pocket depth (PPD),
- Clinical attachment level (CAL),
- Bleeding on probing (BOP) (65),
- Gingival recession (REC): Measurement between the cementum-enamel junction and the free gingival marginal,
- Mobility (MOB) (Miller 1950),
- Furcation involvement (FI) (Hamp *et al*. 1975), and
- Sensitivity (tested by the operator).

After completion of initial screening, each patient (who met the inclusion criteria) was informed about his/her periodontal status and the clinical study. Patients who agreed to participate signed a consent form.

At the screening visit, patients completed a questionnaire regarding their medical history to ensure that they were medically qualified for participation in the study. The clinician (R.P.) reviewed the study information and completed the medical history forms with the patient. Patients underwent an oral pathology examination by the same clinician. After completion of the oral pathology exam, patients underwent a full mouth manual probing (using a UNC-15 probe) to determine their periodontal status. A diagnosis followed by a prognosis was made using these data. A treatment plan was determined under the supervision of an expert periodontist (A.S.), after which each patient was informed of the treatment plan.

5.4. Patient treatment

After data collection, all study participants received oral hygiene instructions consisting of brushing for 2.5 minutes twice per day using the Bass technique (66) and interdental brushing once daily. A prophylaxis and teeth polishing was also performed for each participant. After an interval of one week, participants were recalled to undergo scaling and root planing from the most posterior to the most anterior tooth, with local anaesthesia (Articaine solutions - 1: 200,000) (67). Two quadrants were treated at each visit; therefore, two visits were necessary to treat all quadrants.

Patient randomization was performed using a software function, as mentioned below. Each quadrant was randomly assigned to the following groups:

- Group A: Curettes (Standard Gracey Hu-Friedy®),
- Group B: Conventional ultrasound (Satelec®),
- Group C: 40-µm diamond burs (Intensiv Perio Set®), and
- Group D: Ultrasound Piezosurgery Mectron®.

The sequence of treatment involved scaling and root planing to the first and fourth quadrants, then the second and the third one-week later. All groups were first provided with local anaesthesia.

- Group A: Curettes (Hu-Friedy®).

The progression of scaling and root planing was performed from distal to mesial (the most posterior tooth first and the most anterior last). Vertical scaling movements were made from the most apical point of the pocket to the cemento-enamel junction. Fifteen strokes were made for each root surface. Short scaling horizontal movements were made in the marginal areas, where it is easier to perform a horizontal movement instead of a vertical movement. After the treatment of two teeth, the curette was sharpened with a ceramic stone to obtain improved control and more efficacy in calculus removal.

Specific curettes were used in accordance with this schema:

Standard Gracey curettes 5/6	---	Anterior teeth
Standard Gracey curettes 11/12	---	Mesial surface of premolars and molars
Standard Gracey curettes 13/14	---	Distal surface of premolars and molars.

- Group B: Conventional ultrasound (Satelec®)

The progression of scaling and root planing was performed from distal to mesial (as mentioned above for Group A). Conventional ultrasound (Suprasson P-5 Booster, Satelec®) with a power of between 11 and 12 and irrigation was applied with combined movements (horizontal and vertical movements), for approximately 15-30 seconds for each tooth surface. Satelec® provides an easy-to-use guide concerning tip wear. When the tip has worn down to the last line on the picture shown in the guide, it is no longer effective and must be changed.

- Group C: 40 µm diamond-burs (Intensiv Perio Set®)

The progression of scaling and root planing was performed from distal to mesial (as mentioned above for the other groups). Movements with termination (40 µm) diamond burs (Intensiv Perio Set®) including irrigation lasted 15 seconds at 3,000 rpm per tooth surface. Movements were made parallel to the axis of the tooth and around each tooth. Intensive® does not describe the number of applications of the burs in terms of recommended use and wear. Therefore, the operator must realise when the bur has worn out and another one is necessary.

- Group D: Ultrasound Piezosurgery Mectron®

The progression of scaling and root planing was performed from distal to mesial (as mentioned for the other groups). Ultrasound Piezosurgery Mectron® was applied in On/Mode Periodontics (ROOT) mode with the PP1 insert at a power between 2 and 3 for 15 seconds for each tooth surface. Combined movements (horizontal and vertical) were used. The tip was parallel to the tooth axis and strokes were made to remove calculus with the tip surface. Unlike the Satelec® device, the Mectron® does not provide a wear guide. Therefore, the operator must himself realise when the bur has worn out and another one is necessary.

5.5. Outcomes

Primary Outcome

The CAL was considered the primary outcome.

Secondary Outcome

PPD, REC, morbidity, chair side time were considered as secondary outcomes.

A questionnaire was used to determine treatment morbidity, by means of hipersensitivity. A numeric, arbitrary scale (0-10, with 0 being absence and 10 being the maximum value) was used. Unlike the visual analogue scale (VAS), this scale allows objective numeric values. Dentin hypersensitivity was assessed by means of air stimulus. The clinician directed an air-blast derived from a dental syringe onto the root surface for 1 second. The syringe tip was placed perpendicular to the tooth, 2-3 mm from the facial root surface. After this stimulation, the patient scored his/her pain using the modified VAS, as explained above. Additionally, dental sensitivity to contact was evaluated in terms of presence or absence, expressed as “yes” or “no”, respectively.

5.6. Re-evaluation and data collection

The operator and the examiner evaluated the reliability of the measurement of the clinical variables (probing pocket depth, probing attachment level, bleeding on probing and gingival recession). This analysis (calibration) was made prior to study commencement. The operator (R.P.) and the examiner (A.S.) had to repeat the acquisition of various complete periodontal charting (filling all the clinical variables) of some random patients attending the periodontal department at the *Universitat International de Catalunya*. Results of the repeated measurements were assessed by means of percent of agreement and weighted Kappa statistics, following the values proposed by Landis and Koch (68): ≤0.00 showed poor agreement, 0.01-0.20 revealed slight agreement, 0.21-0.40 fair agreement, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, and 0.81-1.00 represented almost perfect agreement.

An example of the chart used for the collection of these data is shown in Appendix 1. This chart describes the measurement reliability (frequency) of clinical attachment level (CAL). The operators performed identical measurements; the diagonal boxes (in grey) show the number of similar results. Analysis determined significance (p-value) and the Cohen's kappa coefficient.

The first control after intrumentation was performed one week after quadrant treatment (at one week for quadrants 1 and 4 and at two weeks for quadrants 2 and 3). At eight weeks, data collection was performed by an expert periodontist (A.S.) who was blinded to the study groups. All clinical parameters for this study were recorded (section 5.2).

5.7. Number of patients

A power calculation performed prior to the initiation of this study revealed that a sample size of 17 patients was necessary to detect a difference of 1 mm of CAL gain, assuming a maximal mean and standard deviation of 1 mm using a paired test with 80% power at a 0.05 level of significance (61,62). Therefore, 20 patients were recruited into this study to allow the required statistical significance of the data analysis to be obtained. The analysis was performed using the statistical software package Stratigraphics for Windows.

5.8. Randomization

The treatment modality was randomly assigned by computer software using an electronic function that paired each quadrant with a specific modality treatment. This randomization was performed for all patients and for all groups/quadrants prior to commencement of the study; therefore, each patient received a random allocation of each quadrant. This random allocation was written on the patient's evaluation sheets (Appendix 1) only after the treatment; before treatment the allocation was hidden from the operator.

An expert periodontist performed the randomization and allocation. Doctor R.P. performed the initial screening and treatment for each patient.

Another expert periodontist (A.S.), a blinded examiner during all the duration of the study, collected all clinical data.

5.9. Statistical analysis

As reported in other studies (61,69), intra- and inter-group analyses were performed for each clinical parameter (plaque index, calculus, gingival index, probing pocket depth, probing attachment level, bleeding on probing, gingival recession, mobility, furcation involvement and sensitivity). The pooled data before and two months after instrumentation were then analysed. Each clinical parameter was analysed for each group and was compared between the groups. The statistical analysis was firstly performed at patient level, being the patient the statistical unit, and then for those clinical variables measured site by site, a statistical analysis at site level was also performed. The Student's t-test was used to test the significance (95%) of differences between the groups for PPD, CAL, BOP, REC and PI, as well as to test improvement between baseline and re-evaluation. The normal distribution of data was tested using a Shapiro-Wilks test and the homogeneity of variances was evaluated. The multiple tests were performed with Bonferroni corrections.

RESULTS

6. Results

6.1. Experimental population

Seventeen of the 20 participants completed the study. At baseline, 2586 sites were evaluated. One tooth of Group D on patient n. 3 required extraction during treatment, leading to 2580 sites for study analysis. Sites were used to measure treatment efficacy of the parameters PPD, REC, CAL, PI and BOP; CAL, PPD and REC were also studied at patient level. At baseline, 431 teeth were evaluated, and 430 teeth at the eight-week re-evaluation. Table 1, 2, and 3 present the baseline demographic characteristics and Figure 2 shows the study flow chart.

Table 1. Patient demographic characteristics

Age	**53 ± 7.43 years**	**Number of patients**
Sex	M	12
	F	5
Race	Caucasian	17
Smoking	No Smokers	17

M=Male; F=Female.

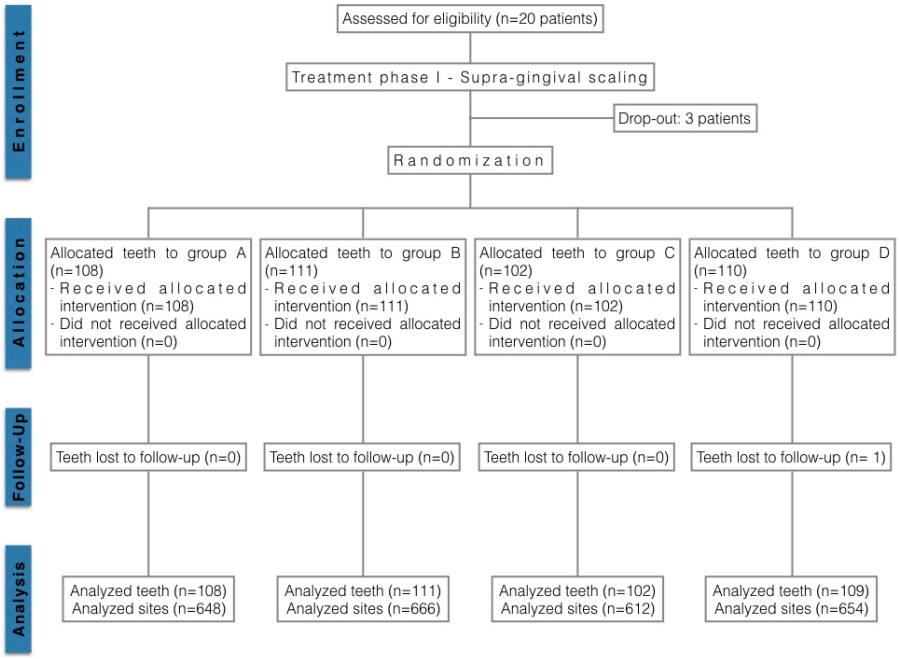


Figure 2. The CONSORT flow chart

Table 2. Baseline Measurements – Site Level.

GROUP / TREATMENT	***PPD***		***REC***		***CAL***		***SENSITIVITY***		***PLAQUE INDEX***	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A	3.30	0.07	1.11	1.34	4.41	1.84	3.08	3.06	1.40	0.50
B	3.28	0.06	1.35*	1.47	4.63	2.01	2.96	2.20	1.35	0.56
C	3.56*	0.07	1.05	1.25	4.59	2.47	2.57	2.44	1.46	0.54
D	3,36	0.07	1.18	1.46	4.54	2.13	3.27	2.25	1.21	0.46
Overall	3.37	1.63	1.18	1.39	4.54	2.12	2.99	2.49	1.35	0.52

*PPD, probing pocket depth; REC, recession; CAL, probing attachment level; SD, Standard Deviation; * =p<0.05; **=p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

Table 3. Baseline Measurements – Patient Level.

GROUP / TREATMENT	**Nº of Patients**	**CAL**		**PPD**		**REC**	
		Mean	SD	Mean	SD	Mean	SD
A	17	4,54	1,09	3,38	0,78	1,16	0,72
B	17	4,62	1,42	3,28	0,78	1,33	0,79
C	17	4,74	0,86	3,59	0,47	1,15	0,81
D	17	4,79	1,47	3,49	0,72	1,30	0,99
Overall	68	4,67	1,21	3,44	0,69	1,23	0,82

*PPD, probing pocket depth; REC, recession; CAL, probing attachment level; SD, Standard Deviation; * =p<0.05; **=p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

6.2. Clinical attachment level

Site-level analysis

At baseline (Tables 2 and 4), the mean CAL showed no significant difference ($p > 0.05$) between the groups. Groups were then compared based on the re-evaluation point: At re-evaluation, differences were observed between Group A and Group D ($p < 0.05$), between Group B and Group D ($p < 0.05$), and between Group C and Groups B and D ($p < 0.05$ and $p < 0.05$, respectively).

At the eight-week re-evaluation point, no significant differences were found between Group A and Groups B and D ($p < 0.05$ and $p < 0.05$, respectively). Superior results were obtained with the ultrasonic piezoelectric Mectron® device (4.04 ± 1.86 mm).

For the initial PPD groups (1-3 mm, 4-6 mm, ≥7 mm): The group with initial PPD of 1-3 mm showed significant differences when group D was compared with other groups at the re-evaluation point ($p < 0.05$) favouring Group D (ultrasonic piezoelectric Mectron® device).

The group with initial PPD of 4-6 mm showed no differences between the groups ($p > 0.05$). The group with initial PPD of ≥7 mm at baseline showed no differences between groups ($p > 0.05$); at the re-evaluation point, differences were observed when Group A was compared with Group C ($p < 0.001$) with superior results for the use of curettes.

The overall analysis of CAL gain was also done for subgroups based on the baseline PPD: 1-3 mm, 4-6 mm, ≥7 mm. All subgroups showed significant gains in CAL at the eight-week revaluation point (Table 5).

Table 4. Comparison of measurements at baseline and at 8-weeks after instrumentation.

(95% confidence interval)

	PPD					REC					CAL				
GROUP	Baseline		8 weeks			Baseline		8 weeks			Baseline		8 weeks		
	Mean	SD	Mean	SD	p-value	Mean	SD	Mean	SD	p-value	Mean	SD	Mean	SD	p-value
A	3.30	0.07	2.81	0.04	**	1.11	1.34	1.35	1.33	*	4.41	1.84	4.16	1.71	*
B	3.28	0.06	2.81	0.04	**	1.35	1.47	1.45	1.47	-	4.63	2.01	4.26	1.72	-
C	3.56*	0.07	2.84	0.05	**	1.05	1.25	1.63	1.23	**	4.59	2.47	4.41	1.78	-
D	3.36	0.07	2.82	0.04	**	1.18	1.46	1.23	1.45	-	4.54	2.13	4.04	1.86	-
Total	3.37	1.63	2.82	1.09	**	1.18	1.39	1.41	1.38	**	4.54	2.12	4.22	1.77	-

*PPD, probing pocket depth; REC, recession; CAL, probing attachment level; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

Table 5. CAL gain at eight-weeks after instrumentation by subgroup PPD: 1-3 mm, 4-6 mm, ≥7 mm (95% confidence interval)

Baseline PPD	**Number of sites**	**CAL gain at 8 weeks**	**SD**
1-3 mm	1522	-0.09*	1.07
4-6 mm	972	0.95*	1.40
≥7 mm	86	2.19*	2.11

*PPD: Probing pocket depth; CAL: Clinical attachment level; SD: Standard deviation; * = p < 0.001*

Patient-level analysis

At baseline (Tables 6), the CAL mean showed no significant difference ($p > 0.05$) between the groups. The same was shown at re-evaluation time, there is no statistical difference between the groups.

Table 6. Comparison of CAL mean measurements at baseline and at 8-weeks after instrumentation. (95% confidence interval).

GROUP	***Nº of Patients***	***CAL mean T0***	***SD***	***CAL mean T8***	***SD***	***p-Value***
A	17	4,54	1,09	4,18	0,84	-
B	17	4,62	1,42	4,25	1,15	-
C	17	4,74	0,86	4,47	1,02	-
D	17	4,79	1,47	4,21	1,13	-
		-		-		
Overall	68	4,67	1,21	4,28	1,02	-

*CAL, probing attachment level; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

Figure 3 shows distribution of CAL for each group at different evaluation time. Also if at 8-weeks re-evaluation CAL mean is less for every group compared with baseline this improvement is not statistical significant (p>0.05).

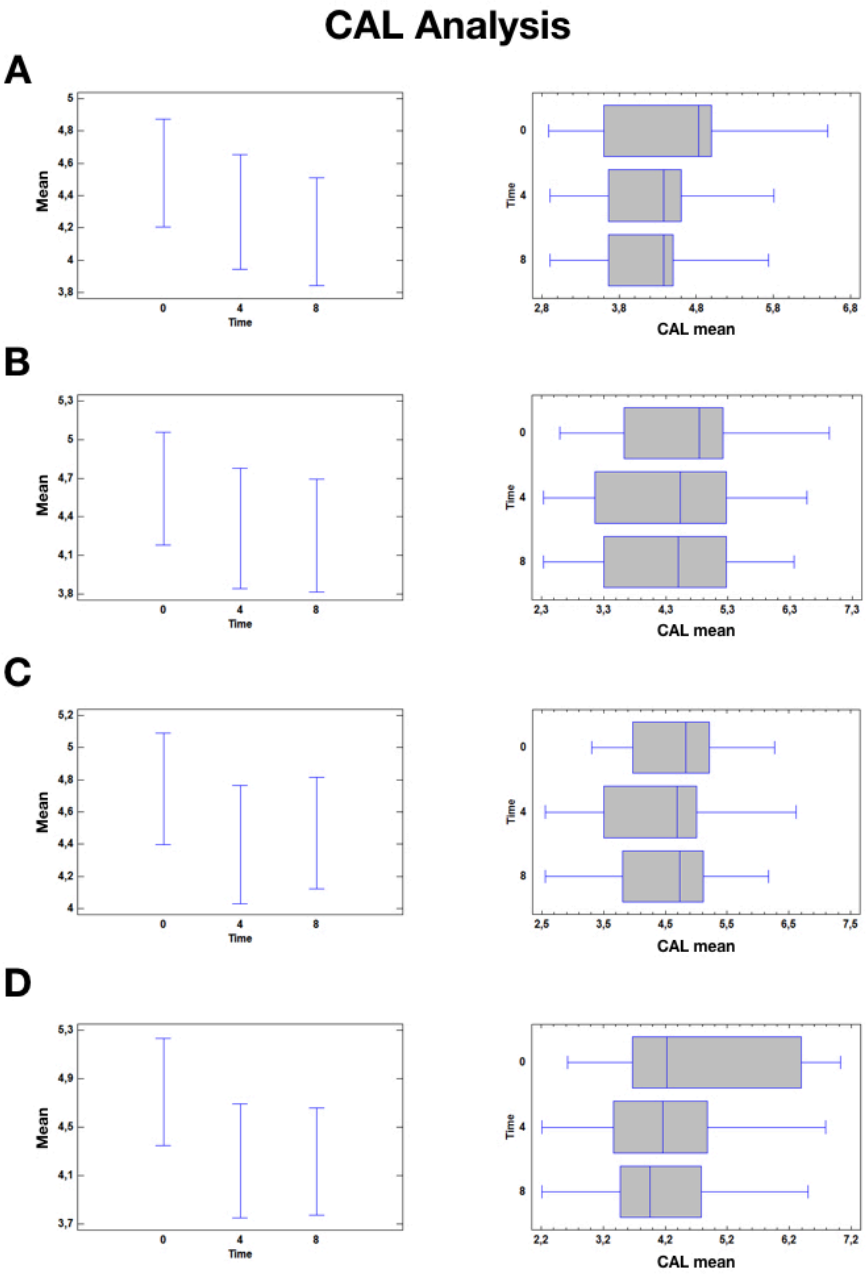


Figure 3. The CAL mean, studied at patient level, showing the change during time for each group. *CAL, probing attachment level; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

6.3. Probing pocket depth

Site-level analysis

At baseline (Tables 2 and 4), the mean PPD of Group C was different to those of the other groups ($p = 0.0126$). No differences were observed between the groups eight weeks after treatment.

The data were then subdivided into three groups according to initial PPD: 1-3 mm, 4-6 mm, and ≥7mm. At the eight-week re-evaluation, the analysis of groups with initial PPD of 1-3 mm showed a significant difference in the reduction of PPD between Group A and Group C ($p = 0.0175$), with residual deeper pockets in Group C, and no differences among the other comparisons.

Analyses of sites with an initial PPD of 4-6 mm or ≥7 mm showed no significant difference in PPD between groups either at baseline and at the eight-week re-evaluation ($p > 0.05$).

Patient-level analysis

At baseline (Tables 7), the PPD mean showed no significant difference ($p > 0.05$) between the groups. The same was shown at re-evaluation, there is no differences between the groups.

This analysis shows a statistical significant reduction for every group. The 8-week re-evaluation of groups A, C, and D showed a significant reduction of PPD mean with p-value < 0.001. The 8-week re-evaluation of group B showed a significant reduction of PPD mean with p-value < 0.05. Figure 4 shows the distribution of PPD mean.

Table 7. Comparison of PPD mean measurements at baseline and at 8-weeks after instrumentation. (95% confidence interval).

GROUP	***Nº of Patients***	***PPD mean T0***	***SD***	***PPD mean T8***	***SD***	***p-Value***
A	17	3,38	0,78	2,80	0,35	**
B	17	3,28	0,78	2,82	0,39	*
C	17	3,59	0,47	2,84	0,25	**
D	17	3,49	0,72	2,84	0,29	**
		-		-		
Overall	68	3,44	0,69	2,82	0,32	**

The PPD mean, studied at patient level, showing the change during time for each group. *PPD, probing pocket depth; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

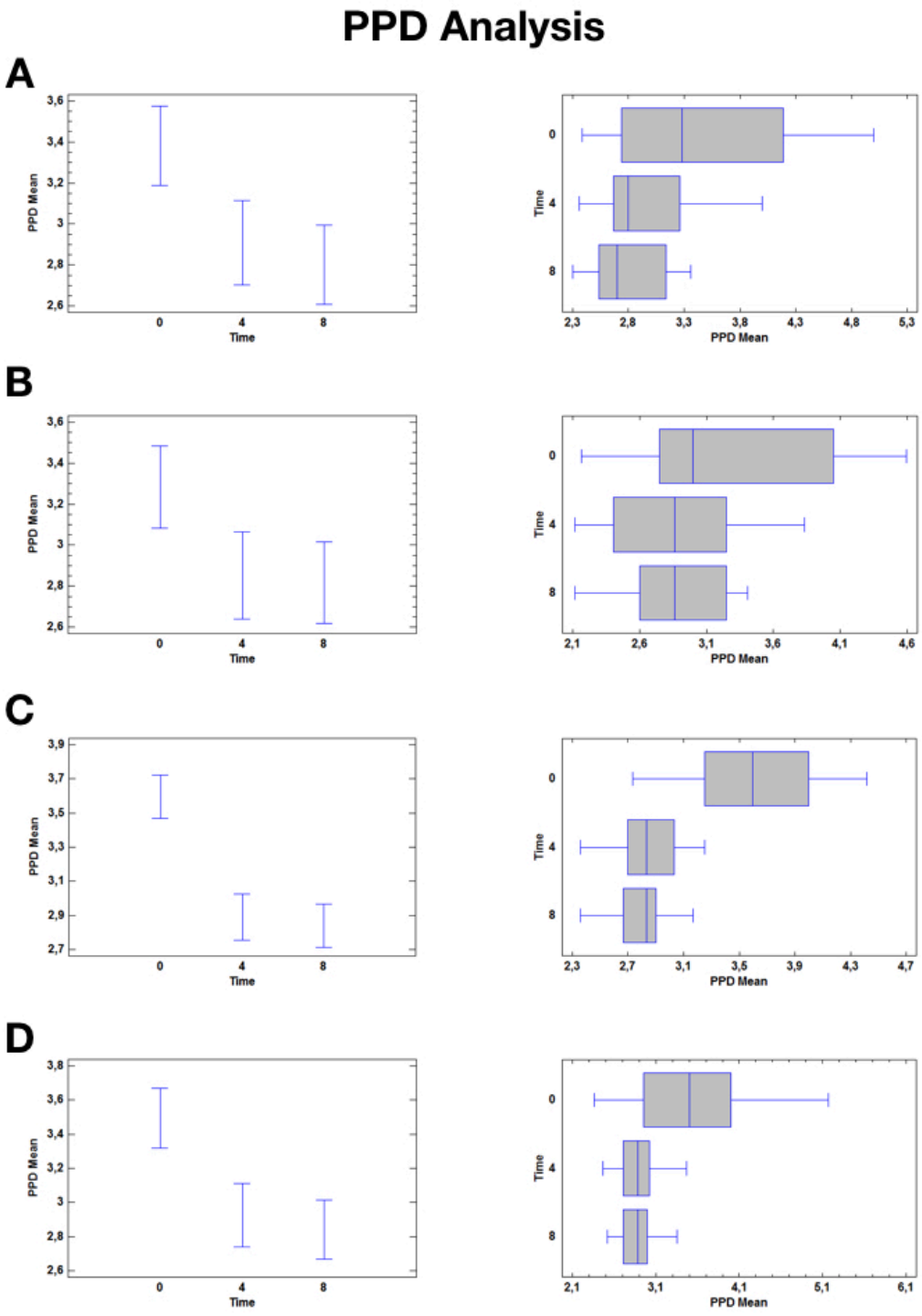


Figure 4. The PPD mean, studied at patient level, showing the change during time for each group. *PPD, probing pocket depth; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

6.4. Recession

Site-level analysis

At baseline (Tables 2 and 4), the mean REC of Group B was significantly difference than that observed for the other groups ($p < 0.05$), with greater recessions in Group B.

At the eight-week re-evaluation, comparisons of Group D with Group B and Group C showed significant differences ($p < 0.001$), revealing fewer recessions with the use of the ultrasonic piezoelectric Mectron® device. Comparison of Group C with Groups A and B showed significant differences ($p < 0.001$), with greater recessions with the use of diamond burs. Comparisons of Group A with Groups B and D showed no differences ($p > 0.05$). Comparison between baseline and re-evaluation is shown in Table 4. Group A and Group C showed significant differences between time intervals ($p < 0.05$ and $p < 0.001$, respectively).

Regarding the initial PPD groups (1-3 mm, 4-6 mm, ≥7 mm): At baseline the group with an initial PPD of 1-3 mm showed significant differences between the Group D and Group C and between Group B and Group D devices at baseline ($p = 0.0175$) with greater recessions in the group using the conventional ultrasonic device (Satelec®). At the eight-week re-evaluation, the use of the ultrasonic piezoelectric Mectron® device showed shallower recessions than those observed in the other groups.

The group with an initial PPD of 4-6 mm showed significant differences between Group A and Group B, between Group A and Group D, between Group C and Group B and

between Group C and Group D at baseline ($p < 0.001$). At the re-evaluation point, comparison between Group A and Group C showed differences favouring Group A.

For the group with initial PPD of ≥7 mm, no statistical significant differences were found among groups at baseline ($p > 0.05$). At the re-evaluation point, the use of curettes and the ultrasonic piezoelectric Mectron® device showed shallower recessions compared with the use of the conventional ultrasonic device (Satelec®) and the use of diamond burs; the use of diamond burs showed deeper recession when compared to other groups ($p < 0.001$).

Patient-level analysis

At baseline (Tables 8), the REC mean showed no significant difference ($p > 0.05$) between the groups. The same was shown at re-evaluation time, there is no statistical difference between the groups.

Table 8. Comparison of REC mean measurements at baseline and at 8-weeks after instrumentation. (95% confidence interval).

GROUP	***Nº of Patients***	***PPD mean T0***	***SD***	***PPD mean T8***	***SD***	***p-Value***
A	17	1,16	0,72	1,38	0,71	-
B	17	1,33	0,79	1,44	0,80	-
C	17	1,15	0,81	1,66	0,83	-
D	17	1,30	0,99	1,37	0,98	-
		-		-		
Overall	68	1,23	0,82	1,46	0,83	-

*REC, recession; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

Figure 5 shows distribution of REC for each group at different evaluation time. Also if at 8-weeks re-evaluation REC mean is deeper for every group compared with baseline this improvement is not statistical significant (p>0.05).

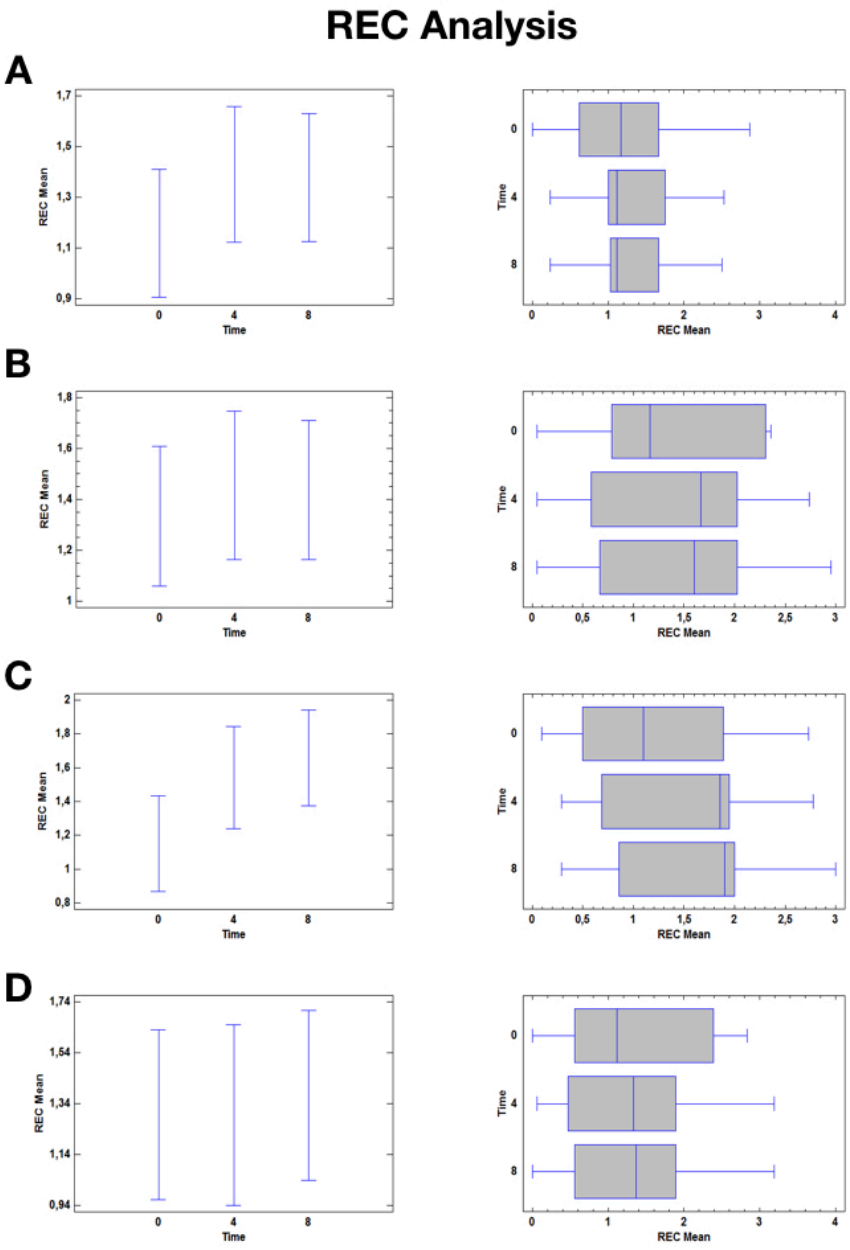


Figure 5. The REC mean, studied at patient level, showing the change during time for each group. *REC, recession; SD, Standard Deviation; * =p<0.05; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

6.5. Dental hypersensitivity

At baseline, the mean value was 2.99 ± 2.49. One week after treatment, the mean hypersensitivity was 4.24 ± 2.91, and at the four-week re-evaluation it was 4.14 ± 3.07. Eight weeks after treatment, the mean hypersensitivity was 3.21 ± 2.98 (Tables 2 and 9). Comparisons between baseline and eight-week re-evaluation showed no differences between the time intervals ($p > 0.05$). Differences were observed between baseline and weeks 1 and 4, and between weeks 1 and 8, and between weeks 4 and 8, when pooled results were evaluated.

Superior results at the eight-week re-evaluation point were obtained for the use of the conventional ultrasonic device (3.04 ± 2.39); however, these results were not significant ($p > 0.05$).

Table 9. Comparison of sensitivity and plaque index. Measurements at baseline and at 8-weeks after instrumentation. (95% confidence interval)

		Sensitivity					**Plaque Index**				
GROUP		Baseline		8 weeks			Baseline		8 weeks		
		Mean	SD	Mean	SD	p-value	Mean	SD	Mean	SD	p-value
A		3.08	3.06	3.68	3.56	-	1.40	0.50	0.48	0.58	**
B		2.96	2.20	3.04	2.39	-	1.35	0.56	0.56	0.54	**
C		2.57	2.44	3.05	3.31	-	1.46	0.54	0.52	0.55	**
D		3.27	2.25	3.04	2.73	-	1.21	0.46	0.69	0.73	**
Total		2.99	2.49	3.21	2.98	-	1.35	0.52	0.57	0.61	**

*PPD, probing pocket depth; REC, recession; CAL, probing attachment level; SD, Standard Deviation; ** =p<0.001; - =p>0.05; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®*

6.6. Plaque scores

For this variable only patient level analysis was performed. At baseline (Tables 2) the mean PI was 1.35 ± 0.52, and no differences were shown between the groups ($p > 0.05$). This value was significantly reduced at the four-week follow-up point, and the analysis of each group between the different time points showed differences between the time intervals ($p < 0.001$). At the eight-week re-evaluation point, the best PI was obtained for Group A (0.48 ± 0.58). Figures 6 and 7 describe the change of the PI for each group, and the relationship of the variation to time, respectively.

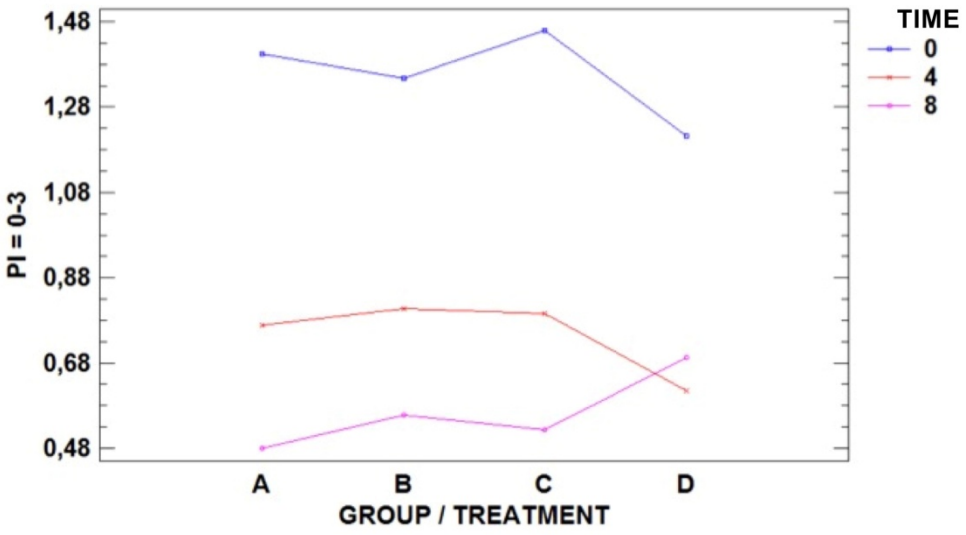
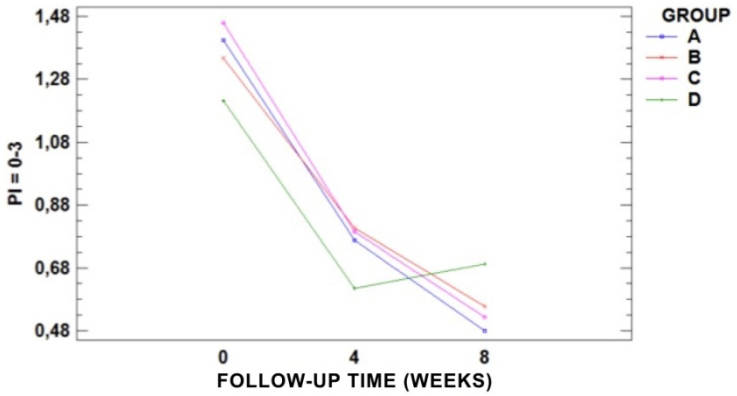


Figure 6. Plaque index for each group (95% confidence interval); Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®

Figure 7. Plaque index in relation to time variation (95% confidence interval); Group A: Curettes (Standard



Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®

6.7. Bleeding on probing

For this variable only patient level analysis was performed. At baseline, the mean BOP score was 48.57%. At the eight-week re-evaluation point, this value was significantly reduced to 26.54% ($p < 0.05$). The use of the ultrasonic piezoelectric Mectron® device showed differences to the other groups at the various re-evaluation times ($p < 0.05$). The results in Figure 8 show the decrease of the percentage of bleeding on probing after treatment.

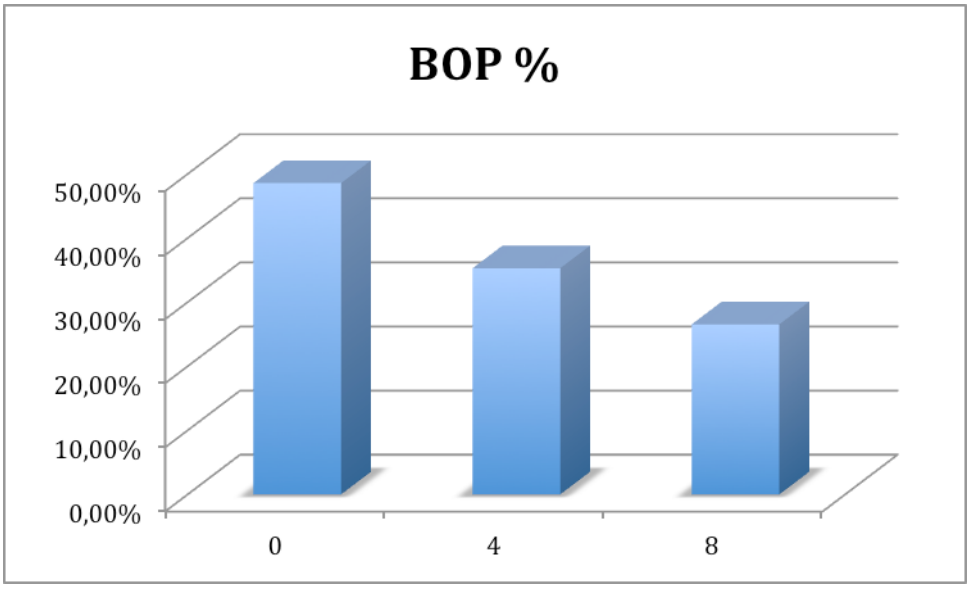


Figure 8. Percentage of bleeding on probing at baseline and at the four and eight-week re-evaluation points

6.8. Chairside time

The mean chairside time for the four groups was Group A: 356 ± 44", Group B: 291 ± 45", Group C: 429 ± 68", and Group D: 291 ± 20". Figure 9 shows the differences between the groups. Differences were observed between all groups ($p < 0.005$) except between Groups B and D ($p > 0.05$).

For the chairside time parameter (expressed in seconds), no differences were observed when comparing Groups B and D ($p > 0.05$). However, differences were observed when Group B was compared to Groups A and C. Differences were also observed when Group B was compared with Group A and Group C, and also when Group D was compared with Groups A and C ($p < 0.05$, Figure 9).

Chairside time was also evaluated individually according to the dental groups, for molars, premolars and anterior teeth (Figure 10). In the molar group, the use of the ultrasonic piezoelectric Mectron® device obtained the best results: 289 ± 23". Comparison between all groups showed significant differences ($p < 0.001$). For the premolars group, the use of the ultrasonic piezoelectric Mectron® device obtained the best results: 285 ± 25". No differences were obtained between Groups A and D ($p > 0.05$), or between Groups B and D ($p > 0.05$). Differences were observed ($p < 0.001$) when Group C was compared with the other groups. For anterior teeth, the use of the piezoelectric ultrasonic device obtained the best results: 268 ± 35". No statistical differences were observed when comparing Groups B and D ($p > 0.05$). Statistical

differences were observed in the other comparisons ($p < 0.001$) when Groups B and D were compared with Groups A and C.

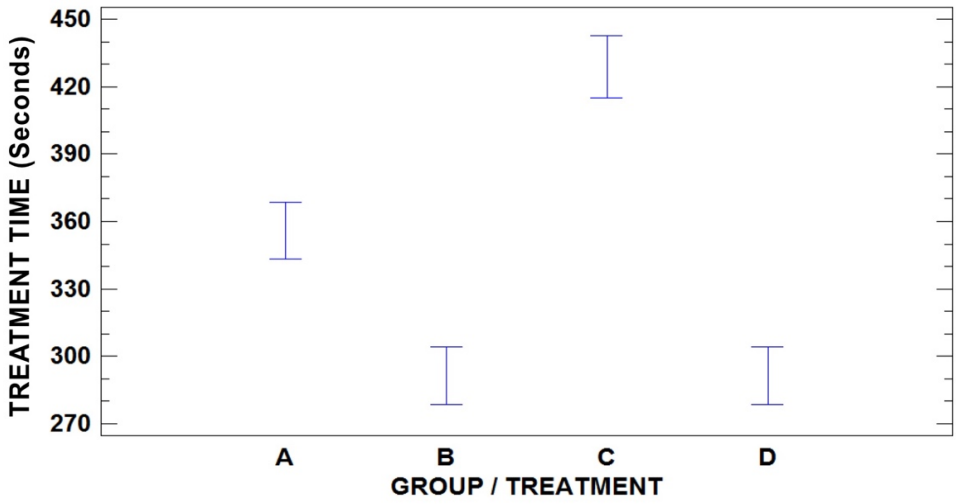


Figure 9. Chairside time (expressed in seconds) related to the four instrumentation systems; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®

Figure 10 shows the chairside time related to the type of tooth that was instrumented with the four types of root instrumentation. It was observed that more time was required with all instrumentation types to scale the molars, except for the piezoelectric device (Mectron®) group, in which no differences between the four types of instrumentation were found.

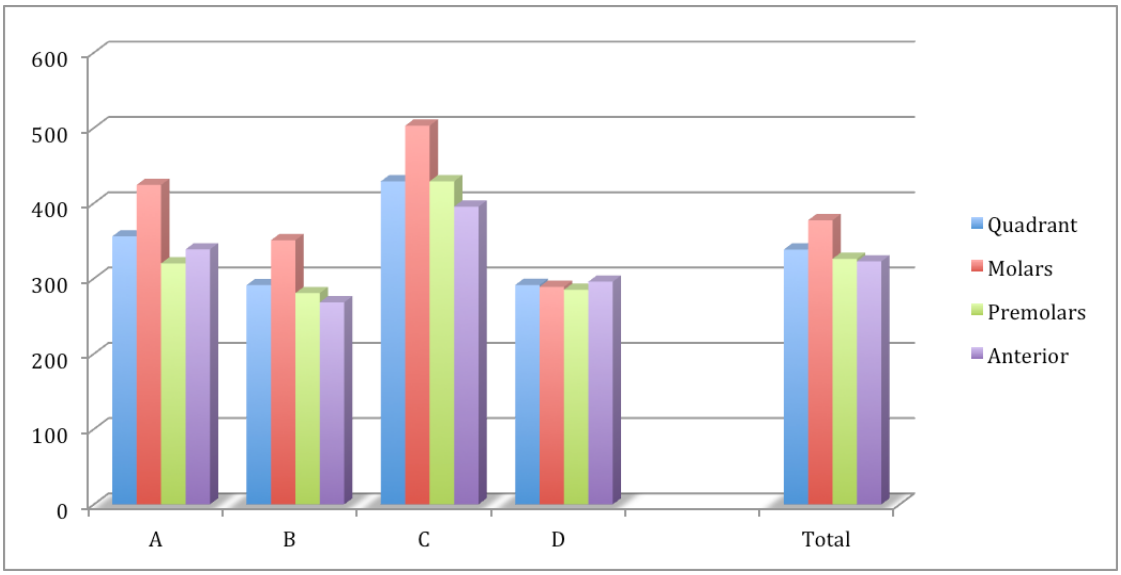


Figure 10. Chairside time related to tooth type for the four instrumentation systems; Group A: Curettes (Standard Gracey Hu-Friedy®), Group B: Conventional ultrasound (Satelec®), Group C: 40-µm diamond burs (Intensiv Perio Set®), and Group D: Ultrasound Piezosurgery Mectron®

DISCUSSION

7. Discussion

The aim of this randomized clinical study was to individually evaluate and compare the effectiveness, chairside time and post-treatment morbidity of four types of instrumentation systems for scaling and root planing. As curettes, ultrasonic, piezo ultrasonic and diamond burs are four periodontal instrumentation systems frequently used for scaling and root planing, these were utilized in each patient quadrant and compared primarily regarding CAL outcomes. The methodology used in this study was previously validated by Badersten and Obeid (62,70).

The comparative efficiency of manual versus sonic and/or ultrasonic instrumentation has been the subject of various studies. In reference to chairside time, these studies have indicated that the time needed to achieve the same clinical end-points is generally longer when using manual instrumentation than when using sonic and/or ultrasonic scaling instruments (22,24,70-74). Indeed, when comparing sonic and/or ultrasonic instruments with manual instrumentation, a number of studies have apprised that the time needed for periodontal debridement procedures can be reduced by 20-50% when sonic and/or ultrasonic instruments are used (22,58,74-76). This outcome in previous reports was confirmed by the results of the current study, as it is here demonstrate that the adoption of ultrasound devices can lead to a time saving of up to 30% when compared with manual instrumentation or with rotatory instrumentation.

In our study the statistics was done at patient level and then at site level. The results regarding patient level analysis show statistical significant difference only for the PPD; CAL and REC does not show statistical significant differences. With this kind of analysis there is no difference between groups at baseline and at 8-week re-evaluation. Also if there is a tendency in the reduction of CAL after treatment for all the groups this is just a tendency because there is no statistical significant difference. Improving the sample probably we could obtain statistical significant results. However the reduction of PPD after treatment show statistical significant differences for all groups.

The results regarding CAL obtained in our study showed a mean loss of attachment of -0.09 mm for sulci of 1-3 mm, a gain of attachment of 0.95 mm for initial pockets of 4-6 mm, and a mean gain of attachment of 2.19 mm for initial pockets >7 mm. A similitude can be noted between these data and previous literature (74). The results obtained from a study carried out by Cobb et al. (2002) (74) showed a mean loss of attachment of 0.34 mm in sulci with an initial depth of 1-3 mm, a mean gain of attachment of 0.55 mm for initial pockets of 4-6 mm, and a mean gain of attachment of 1.19 mm for pockets >7 mm. In like manner, Obeid (62) demonstrated marked improvements in attachment level ($p > 0.01$), and no significant inter-group differences were identified when comparing baseline with the post-treatment time point for manual instrumentation alone, ultrasonic insert followed by the Periopolisher system, the Periopolisher system alone, and the ultrasonic insert alone. The mean CAL gain for these instrumentation types was 1.5, 1.2, 1.5 and 1.6 mm, respectively.

To date, no studies have compared these four types of instrumentation in humans. Piezosurgery has been identified as the best performer in terms of clinical attachment. In contrast, diamond burs have been rated as being the worst performer, as they resulted in an increase in the CAL value. A previous study by our group (Solis et al., 2012) (77) evaluated *in vitro* surface roughness after applying the four instrumentations methods examined in the present study. The piezoelectric instrument (Mectron®) demonstrated a greater reduction in surface roughness when compared with the piezo-ceramic ultrasonic scaler and curettes, while termination diamond burs showed an increase in roughness after treatment.

Although controversy remains in the literature concerning the clinical relevance of roughness after instrumentation, the preliminary results of the current clinical study suggest that the use of systems that lead to a smoother surface have the best clinical results. The ultrasonic piezoelectric Mectron® device is an example. Other studies (44,53) have evaluated the use of piezoelectric devices in non-surgical periodontal therapy. The piezoelectric device appears to produce superior results in terms of clinical parameters and less damage to the root surface than other types of ultrasounds, as shown by Cross-Poline et al. (1995) (52) and Flemming (1998) (43,54).

Regarding post-treatment recession, a slight increase was seen in recession after the four types of instrumentation. The greatest increase was observed in both the rotatory and the curette groups. No differences were seen between the piezoelectric ultrasonic device (Suprasson Satelec®) and the piezosurgery Mectron® device groups between

baseline and the eight-week re-evaluation point. In support of these findings, Beuchat at al. (2001) observed an increased gingival recession in the curettes group ($p < 0.01$) two months after treatment when compared with ultrasonic instrumentation (61). This increase was different to that seen for the rotatory instruments, which damage the free gingiva and soft tissue.

The results obtained here for plaque scores confirmed those from previous studies (70,71,74,78-81). A decrease in plaque index was obtained after the four instrumentation systems; no differences were observed between the groups.

At eight-week post-treatment a reduction of about 22% in bleeding on probing (from 48.57% to 26.54%) was shown when compared to baseline ($p < 0.05$), and an unmistakeable reduction of gingival inflammation was also observed. Moreover, the results obtained with the ultrasonic piezoelectric device were significantly different when compared with other groups at the various re-evaluation times ($p < 0.05$). The literature indicates that mechanical non-surgical periodontal therapy predictably reduces inflammation levels (74). It also appears that the initial reductions in bleeding on probing either remain relatively stable or improve with increasing time post-therapy.

Additional studies related to non-surgical periodontal therapy (44,53) evaluated the use of piezoelectric devices. Superior results both in terms of clinical parameters and decrease in damage to the root surface appear to be produced by piezoelectric devices

when compared to all other types of ultrasound, as shown by Cross-Poline et al. (1995) (52) and Flemming (1998) (43,54). Although the current study did not evaluate the root surface, the clinical results did show that the piezosurgery Mectron® device is equally as effective in the evaluated parameters as the conventional ultrasound and the manual instrumentation that are commonly used in non-surgical periodontal therapy.

Ultrasonic devices are identified by their narrow diameter tips and flexibility that, in some cases, contribute to easily penetrate pocket depths and reduced gingival trauma. Curettes, in contrast, have a wider tip than the ultrasonic devices and, as a result, do not permit easy insertion into deep pockets. The obtained data showed similar results, and no differences were seen in terms of clinical parameters between ultrasonic instrumentation and manual instrumentation with curettes.

Lavespere, observed a reduction in working time and an improvement in terms of access and efficiency when using rotatory instrumentation during the debridement procedure (55). A SEM study (56) documented that conventional curettes with the Perio Set® after scaling and root planing result in a biologically acceptable root surface, free of bacterial contamination and endotoxin. This suggests that the Perio Set® is an excellent supplement to curettes in root debridement. Nevertheless, rotatory instrumentation has been associated with increased wear and abrasion (56). The results of the current study show that rotatory instrumentation is as effective as the other groups in terms of pocket probing reduction and clinical attachment change. However, when rotatory

instruments are compared with other groups, these results show deeper recession. This may occur due to the use of rotatory instruments in the pocket, which may well damage the free gingiva and soft tissue. To our knowledge, no study has yet evaluated diamond burs alone for periodontal debridement.

The treatment of periodontal disease may cause patient discomfort specially derived from dental hypersensitivity, as this can be one of the side effects of root instrumentation (82). During our study, dental hypersensitivity was observed and assessed among groups using a numeric arbitrary scale at specific time points after instrumentation. There was a slight rise in dental hypersensitivity after root instrumentation with the four instrumentation systems; however, this fell to baseline levels after four weeks. No differences were observed between the four instrumentation systems used regarding post-treatment hypersensitivity (73,83).

Advancement in new instrumentation methods has been made by intending to achieve the best possible outcomes in the shortest period of time. It is therefore of foremost priority to optimize and reduce working times, as these are essential in order to reduce operator fatigue. Generally, fatigue is reduced through the use of non-manual devices such as ultrasound and diamond burs at the expense of a loss of sensitive touch (22,24,73,74). The comparative efficiency between manual instrumentation and sonic and/or ultrasonic instrumentation has been reported in a number of studies. In relation to chairside time, these studies have indicated that the same clinical end-points require

longer to achieve with manual instrumentation in respect to sonic and/or ultrasonic scaling instruments (22,24,70-74). In support of this, various studies have illustrated that when sonic and/or ultrasonic instruments are used for periodontal debridement procedures, a 20-50% reduction in time spent can be achieved when measured against manual instrumentation (22,58,74-76). The results of the current study confirm these reports, as they demonstrated that the use of ultrasound devices saves >30% in terms of time spent when compared with manual instrumentation or with rotatory instrumentation.

Non-surgical therapy is documented at length in the literature, and its efficacy has undoubtedly been proven. This randomized trial is the first of its kind to compare these four instrumentation systems. The number of patients treated in this clinical trial was similar to the sample sizes analysed in the majority of the articles evaluated by Cobb in his systematic review. The statistical analysis performed was also done at a site level, following the majority of the articles on this topic (22,24,61,62,70-74,74).

In light of the results obtained in this study, it can be asserted that through the analysis of clinical effectiveness and post-treatment morbidity of these four different instrumentation systems, new data on scaling and root planing methods have now been provided. The objective of this study was to analyse each instrument individually and to compare both the effectiveness and the post-treatment morbidity between the instruments. In a number of clinical variables (CAL and chairside time), piezosurgery

shows comparable results when compared with the other instrumentation systems. Although it cannot be claimed that one method is superior to another, it was determined that an ultrasound piezosurgery system is as effective as the more commonly-used procedures, and, as such, represents a satisfactory alternative means of non-surgical root debridement.

CONCLUSIONS

8. Conclusions

1. There is no clinical differences, in terms of clinical parameters, between any of the analysed instruments.

2. The chairside time analysis showed the ultrasound device (P-5 Booster Suprasson Satelec®) and the ultrasound piezosurgery (Mectron®) to be more time saving compared with curettes (Hu-Friedy®) and 40-µm diamond burs (Intensiv Perio Set®).

3. No differences were observed in post-treatment morbidity after scaling and root planing for all the analysed instrumentation systems.

FUTURE EXPECTATIONS

9. Future expectations

9.1. Study strengths and limitations

This study is the first clinical trial analysing these four instruments. One limitation of this trial concerned the limited number of patients enrolled in the study. Nonetheless, statistically significant results were obtained, and the number of patients treated was similar to the sample size of the majority of the articles evaluated by Cobb (74) in his systematic review. By increasing the number of the sample we could have obtained statistical significant results also in the patient level analysis.

An additional limitation concerned the lack of histological data and residual calculus analysis. Had the treatment been performed on hopeless teeth that required extraction after treatment, this may have been possible.

A comparison between the efficacies of each instrumentation technique with groups associating them was impossible, due to the fact that, neither a negative control group nor a combined group examining the most commonly used techniques (ultrasound + curettes) was included.

9.2. Future trends

In this study, the standard tips of the ultrasound devices were tested. It may be possible to compare these instruments with the most common daily techniques used (ultrasound + curettes) or with other combinations.

It may also be possible to treat hopeless teeth by performing calculus removal assessment by analysing their root surface after extraction.

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APPENDIX

11. Appendix

An example of the patient's evaluation sheets

Approval letter from scientific committee

Approval letter from ethics committee

Informed consensus form

Declaration regarding the informed consensus form

Approval letter from the Doctoral Academic Committee

Articles published during the PhD program

11.1. An example of the patient's evaluation sheets

Randomized Clinical Trial to compare the Effectiveness and Morbidity of four Instruments for Periodontal Debridement after two months of the intervention.

PACIENT: _____ AGE: _____ CH: _____

Address: _____

Telephone number: _____

Date of Birth: _____ Sex: ___ Race: ____

Randomized Sequence: Quadrant 1: ___

Quadrant 2: ___

Quadrant 3: ___

Quadrant 4: ___

- Group A: curettes (Hu-Friedy®)
- Group B: conventional ultrasound (Satelec®)
- Group C: diamond burs 40 µm (Intensiv Perio Set®)
- Group D: ultrasound Piezosurgery Mectron®

Date of first visit and initial date collection: _____

Date Scaling and rooth planing, quadrant 1 and 4: _____

Date Scaling and rooth planing, quadrant 2 and 3: _____

Date reevaluation at 4 weeks: _____

Date reevaluation at 8 weeks: _____

Date reevaluation at 12 months: _____

Inclusion/exclusion criteria

INCLUSIÓN *(All have to be marked)* 🌎	**EXCLUSIÓN** *(Nothing have to be marked)* ☐
☐ Patients with generalized moderate to severe chronic periodontitis.	☐ Systemic deseases: • Cardiovascular disease • Lung disease • Gastrointestinal disease • Genitourinary disease • Endocrine and metabolic disease • Immune disease • Hematological disorders • Oncological disease • Psychiatric illness, disease of the behavior, neurological disease
☐ PPD : at least two sites with probing depth ≥4mm per multi-rooted teeth, and at least three sites with probing depth ≥4mm for all remaining teeth, per quadrant. (like in other studies).	☐ Antibiotic therapy in the last 2 month ☐ Patient less of 18 years old ☐ Pregnant woman ☐ Smokers
	☐ Remaining dentition of less than 20 teeth
	☐ Recent periodontal treatment
	☐ Allergies to local anesthetics
	☐ Physically handicapped subject and/or with mental disorders, who cannot assume proper plaque control
	☐ Aggressive periodontitis
	☐ Acute periodontal or endodontic infection

Paciente:

Historia Clínica:

	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28	ph	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38	fecha
PPD V																																		
PPD L																	B																	
PPD V																	I																	
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Vetibular Aderenth gingiva																	B																	
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Sensitivity																	B																	
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Initia screening
reevaluation 4w
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- Group A: curettes (Hu-Friedy®).

Fifteen (15) vertical strokes will be made for each root surface. The progression of scaling and root planing will be performed from distal to mesial.

Short scaling horizontal movement will be made in the marginal areas.

After treatment of two teeth the curette will be **sharpened.**

- Group B: conventional ultrasound (Satelec®)

With a power of between 11 and 12 combined movements (horizontal and vertical movements). Approximately 15 seconds for each tooth surface.

The progression of scaling and root planing will be performed from distal to mesial.

- Group C: diamond burs 40 µm (Intensiv Perio Set®)

Movements parallel to the axis of the tooth and around each tooth with termination (40 µm) diamond burs (Intensiv Perio Set®) with irrigation will last 15 seconds at 3,000 rpm per tooth surface.

The progression of scaling and root planing will be performed from distal to mesial (as we mentioned in Group A).

- Group D: ultrasound Piezosurgery Mectron®

Ultrasound Piezosurgery Mectron® will be applied in On/Mode Periodontics (ROOT) mode with the insert PP1 at a power between 2 and 3 for 15 seconds for each tooth surface. Combined movements (horizontal and vertical movements).

The progression of scaling and root planing will be performed from distal to mesial.

11.2. Approval letter from the scientific committee

Universitat Internacional de Catalunya

FACULTAD DE ODONTOLOGÍA
Comisión Científica

La Comisión Científica de la Facultad de Odontología de la Universitat Internacional de Catalunya, CERTIFICA, que

El presente protocolo de investigación titulado: "**Randomized clinical trial to compare the effectiveness and morbidity of four instruments for periodontal debridement at two months** ", cuyo investigador principal es el Dr. Antonio Santos y cuyo investigador secundario es el alumno **Rosario Puglisi ,** y cuyo tutor es Javier Sanz.

ha sido evaluado satisfactoriamente y es apto para ser presentado e iniciar su investigación.

Firmado en Sant Cugat del Vallès, a 16 de Diciembre del 2011.

Universitat Internacional de Catalunya
Facultat d'Odontologia

Dra. Montserrat Mercadé i Bellido
Directora de la Comisión Científica de Odontología

Título:	**Randomized clinical trial to compare the effectiveness and morbidity of four instruments for periodontal debridement at two months**
Investigador secundario:	**Rosario Puglisi**
Director de la investigación:	**Dr. Antonio Santos**
Tutor:	**Javier Sanz**
Número de estudio:	**PER-ECL-2011-11-NF**

11.3. Approval letter from the ethical committee

CEIC Comitè Ètic d'Investigació Clínica

CUO Clínica Universitària d'Odontologia | Universitat Internacional de Catalunya

CARTA APROVACIÓ ESTUDI PEL CEIC

Número de l'estudi: PER-ECL-2011-11-NF
Versió del protocol:1.0
Data de la versió:05/03/2012
Títol:"Randomized clinical trial to compare the effectiveness and morbidity of four instruments for periodontal debridement after two months of the intervention"

Sant Cugat del Vallès, 20 de març de 2012

Dr.Antonio Santos

Referència:"Randomized clinical trial to compare the effectiveness and morbidity of four instruments for periodontal debridement after two months of the intervention"

Benvolgut Doctor,

Els membres del CEIC de la Clínica Universitària d'Odontologia, els hi agraeixen l'aportació científica en el camp de la investigació i la presentació del Protocol en aquest Comité per a la seva avaluació.

Valorades les noves aportacions realitzades a l'estudi, sol.licitades pel nostre CEIC, el passat dia 05 de març de 2012, li comuniquem que el dictamen final ha sigut FAVORABLE.

Li recordem que, segons la Normativa del Real Decret 223/2004 art. 27, s'haurà de presentar al Comitè d'Ètica d'investigacions clíniques de la CUO, i a través de la Comissió Científica, un informe preliminar mensual del seguiment de l'estudi i un informe final un cop finalitzat aquest.

1

CEIC Comitè Ètic d'Investigació Clínica

CUO Clínica Universitària d'Odontologia | Universitat Internacional de Catalunya

Quedem a la seva disposició per a qualsevol dubte o aclaració al respecte.

Atentament,

Sra. Imma Puga
Presidenta CEIC

2

11.4. Informed consensus form

CEIC Comitè Ètic d'Investigació Clínica

7a. CONSENTIMIENTO INFORMADO

Número del estudio: PER-ECL-2011-11-NF
Versión del protocolo: 1.0
Fecha de la versión: 5/03/12
Fecha de presentación: 5/03/12
Título: **Randomized Clinical Trial to compare the Effectiveness and Morbidity of four Instruments for Periodontal Debridement *after two months of the intervention***

Investigador/a Principal: Dr. Antonio Santos
Investigador/a Secundario/a (alumno/a): Rosario Puglisi
Tutor/a / Monitor/a: Dr. Antonio Santos Alemany/Javier Sanz
Departamento: Periodoncia
Línea de investigación: Agentes Quimicos y Biomateriales en Periodoncia
Título de la investigación: **Randomized Clinical Trial to compare the Effectiveness and Morbidity of four Instruments for Periodontal Debridement *after two months of the intervention***

Yo, Sr./Sra.: ……..

- He recibido información verbal acerca del estudio y he leído la información escrita que se adjunta, de la que he recibido una copia.
- He comprendido lo que se me ha explicado.
- He podido comentar el estudio y realizar preguntas al profesional responsable.
- Doy mi consentimiento para tomar parte en el estudio y asumo que mi participación es totalmente voluntaria.
- Entiendo que podré retirarme en cualquier momento sin que ello afecte a mi futura asistencia médica.

Mediante la firma de este formulario de consentimiento informado, doy mi consentimiento para que mis datos personales se puedan utilizar como se ha descrito en este formulario de consentimiento, que se ajusta a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

Entiendo que recibiré una copia de este formulario de consentimiento informado.

_____ _____

Firma del paciente o la paciente — Fecha de la firma
N.º de DNI

Página 1 de 2

11.5. Declaration regarding the informed consensus form

CEIC Comitè Ètic d'Investigació Clínica

DECLARACIÓN DEL INVESTIGADOR O LA INVESTIGADORA

El paciente o la paciente que firma esta hoja de consentimiento ha recibo, por parte del profesional, información detallada de forma oral y escrita del proceso y naturaleza de este estudio de investigación, y ha tenido la oportunidad de preguntar cualquier duda en cuanto a la naturaleza, los riesgos y las ventajas de su participación en este estudio.

_____ _____

Firma del investigador o investigadora Fecha de la firma

Nombre:

Página 2 de 2

11.6. Approval letter from the Doctoral Academic Committee

Universitat Internacional de Catalunya

Barcelona, 10 de enero de 2013

Sra. Rosario Puglisi
Corso Vittorio Emanuele N. 700
96014, Florida (SR) - Italy

Estimado Sra.

Por la presente, le comunico que la Comisión Académica del Doctorado en Ciencias de la Salud, en la su sesión del 21 de diciembre de 2012, y una vez estudiada su solicitud ha acordado:

Se acuerda admitir a la Sra. Rosario Puglisi al Periodo de Investigación del Doctorado en Odontología.

Se acuerda aprobar el Proyecto de Tesis titulado "New data on scaling and root planing methods", nombrar al Dr. Jose Nart Molina como Director de la Tesis, a los Doctores Stefano Parma Benfenati y Marco Ferrari como Tutores y se le recomienda eliminar a Antonio Santos Alemany como Tutor por tener ya al Director en la UIC.

Adicionalmente, se le informa que la normativa de la UIC establece que debe obtener una evaluación favorable del Comité de Ética en la Investigación, antes de la puesta en marcha de la investigación. Deberá aportar este informe cuando lo obtenga.

Aprovecho la oportunidad para saludarlo cordialmente,

Jaime Oliver Serrano
Secretario Comisión Académica
Doctorado en Ciencias de la Salud

Universitat Internacional de Catalunya

REGISTRE GENERAL

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11.7. Articles published during the PhD program

TITLE:

In vitro evaluation of the effect of chemical and thermal stress of the mechanical properties of periodontal curettes under simulated conditions of sharpening wear

Authors:
Daniel De Pedro [1], Rosario Puglisi [2], Paul Levi, Jr. [3], Andrés Pascual [4], José Nart [5]

1- Research Resident, Department of Periodontics, Universitat Internacional de Catalunya, Barcelona, Spain. Contribution to the paper: performed the experiments.
2- Master Resident, Department of Periodontics, Universitat Internacional de Catalunya, Barcelona, Spain. Contribution to the paper: wrote the manuscript.
3- Associate Professor, Department of Periodontics, Tuft University, Boston, MA. Contribution to the paper: proofread the manuscript.
4- Associate Professor, Department of Periodontics, Universitat Internacional de Catalunya, Barcelona, Spain. Contribution to the paper: experimental protocol design and contributed to the manuscript.
5- Chairman, Department of Periodontics, Universitat Internacional de Catalunya, Barcelona, Spain. Contribution to the paper: contributed to the manuscript.

Short Title: Chemical and thermal stress in periodontal curettes

Corresponding Author details (essential):
Andres Pascual La Rocca,
Department de Periodoncia, Universidad Internacional de Catalunya, Josep Trueta, s/n 08195 Sant Cugat del Vallés, Barcelona 08195, Spain, Phone: +34-935-042-000, E-mail: pascuallarocca@hotmail.com

KEYWORDS:
Periodontal curettes, non-surgical periodontal therapy, scaling and root planning, sharpening, fracture strength.

CLINICAL RELEVANCE:
It has been suggested sterilization might affect properties of the instruments. The use and maintenance of curettes weakens them, becoming a possible risk of fracture, which could lead to complications during clinical treatments and injury for the patient.
It seems clear the need to establish a relationship between the loss of fracture toughness and its relationship to the continuous processing of the instrument and the number of sterilization cycles.

PRINCIPAL FINDINGS:
Sterilization seems to cause more wear to the instruments increasing the risk of fracture related to the mechanical wear caused by use and sharpening.

PRACTICAL IMPLICATIONS:
Sterilization is a factor to consider when evaluating the longevity of a periodontal curette regarding the loss of fracture toughness and possible clinical complications.

ABSTRACT:
PURPOSE: The aim of this research is to determine if chemical, thermal stress and sharpening are aspects that must be considered to determine when a curette has become too weak to be used safely without the concern of breakage.
MATERIALS & METHODS: A total sample of 35 curette blades was divided in 2 principal groups. The test group included 16 Gracey curette blades that were subject to various degrees of progressive wear and different numbers of sterilization cycles in 3 subgroups. The control group was divided into 3 colours coded groups of 19 similar curette blades and was only subjected to progressive sharpening wear. Using a universal testing machine, all blades were tested for strength until they fractured.
RESULTS: No evidence was found to support that the simple presence or absence of sterilization cycles produces a statistically significant difference between the two studied groups (sterilized and not sterilized). However, when comparing the six subgroups that underwent different numbers of sterilization cycles (subgroups 1 to 3, which not sterilized; subgroup 4 had 5 sterilization cycles; subgroup 5 had 30 cycles and subgroup 6 had 55 cycles), the analysis showed that the more sterilization cycles a curette underwent, the more likely the curette was to fracture. (p-value 0.047).
CONCLUSION: Sterilization by itself does not produce a significant change in the fracture strength, whereas the intensity (number of sterilization cycles) of the sterilization clearly weakens the instrument. Sterilization is a factor to control when evaluating the life of a periodontal curette for the patients' and professionals' safety.

INTRODUCTION:

Normally when evaluating the life and suitability for use of periodontal curettes, visual inspection of the remaining width of the blade is the most common procedure. It is generally accepted that a curette should be replaced when the blade appears thin to visual inspection, as a fractured blade in use can lead to the patient's aspiration or ingestion of the blade, loss of the blade in a deep periodontal pocket or the loss of control by the operator and possible injury to the surrounding soft tissues[21, 24].

Periodontal curettes are frequently used hand instruments during scaling and root planning procedures. It has been suggested that chemical and thermal stress produced during instrument cleaning and sterilization might affect properties of the instruments[16, 19]. These instruments do not present with an expiration date, and there are no regulations that require manufacturers to include package inserts with information related to use and life of a curette[6] since both are considered "obvious" for professionals. The use and maintenance of curettes weakens them[16], becoming a potential risk of injury[9, 21, 24].

Studies have consistently shown the improved outcome of periodontal disease after root debridement using a sharp curette. As a consequence, this method is still the gold standard of therapy when compared to other alternatives. Instrument use and study goes back many decades, and the emphasis and interest in understanding the conditions related to instruments are still valid, due to the fact that hand instrumentation is one of the foundations in periodontal therapy[30].

Some authors have associated the SRP curettes with longer chair time and potential damage to the root surface.[8, 13, 25, 31] Nevertheless, manual instrumentation of diseased root surfaces still plays a key role in the treatment of periodontal disease. Whether it is manual or power assisted, root debridement is the most effective way to remove bacterial plaque and calculus and to smooth rough root surfaces. Thus, root planning is essential in the treatment of subgingivally diseased root surfaces and must be performed by using sharp instruments[18].

Regardless of whether a curette is sharpened or not, wear of that instrument is expected due to its constant contact with calcified tissues. The metal experiences deformation, fatigue and metal particles are lost off of the blade.[22,23] The inevitable consequence of use and sharpening is the progressive diminution of the curette blade, which results in significant thinning of its initial volume, and the loss of the original shape.[9,31] According to studies, the remaining volume of metal in the blade of periodontal curette is directly proportional to its fracture strength.[16]

In addition to sharpening, all instruments must be cleaned, disinfected and sterilized before each use. Today no one questions the importance and necessity of sterilization, and recommendations are reviewed periodically. The generally accepted instrument processing methods[5] were used as guidance in this study.

While some authors have not found negative effects on the cutting edge of the curette after instrument processing[9], others have suggested repeated sterilization has a possible negative influence on the cutting edge of a curette[23], and others have shown that this effect is evident in the reduced effectiveness of curettes, starting from five cleaning and sterilization cycles.[19] Although there is controversy regarding the effect of

sterilization on the wear of the curette, there appears to be no studies addressing the fracture strength after sterilization cycling.
It is reasonable to assume that the decrease in volume of a curette blade is a valid guide in determining the life of a curette. However, should there be a relationship between the loss of fracture strength and continuous instrument processing, then it will also be reasonable to say that determination of the life of a curette should be established not only by the decrease in the remaining volume but also on other considerations such as the number of sterilization cycles to which the curette has been subjected. Wear and sterilization are not necessarily proportional during the life of instruments.
The aim of this study is to determine whether or not sterilization must be considered in deciding when to replace a periodontal curette for the benefit of the patient and the clinician.

MATERIALS AND METHODOLOGY:

Thirty-five Gracey 13/14 curettes blades with sharp retention technology made of cryogenically treated stainless steel alloy (EverEdge®, Hu-Friedy Mfg. Co. LLC, Chicago, Illinois) were analysed. The 35 curettes were divided and colour-coded into an experimental group and a control group (Table 1). Both groups were divided into 3 subgroups, with different degrees of wear, for a total of 6 subgroups with 5 to 6 curette blades in each group (3 experimental and 3 controls). The same operator (D-D) performed all the measurement and fracture strength tests and then the data analysis. A pilot test with 4 curettes was performed to test the reliability of the methodology and to calibrate the operator.

Following a previews method presented by Murray[16], the wear of the curette blade was created by sharpening. A total of 6 groups of Gracey curettes 13/14 (EverEdge, Hu-Friedy Mfg. Co. LLC, Chicago Illinois) were prepared with different degrees of wear (2 groups 0%, 2 groups 25% and 2 groups 50%) by grinding on the lateral surface of the instrument blade. To improve the consistency of the process and maintaining the original contours of the instruments a sharpening device was used specifically for this purpose (3000 PerioStar Kerr Sybron Dental Specialties, Orange, California). Care was used to ensure that the original angle of the lateral surface of the instrument blade was maintained.

The amount of wearing required in each group of specimens was verified using a digital calliper (CD 150 mm, Ratio, Ehlis, SA, Barcelona, Spain) as shown in Figure 1, and next recorded in the results database.

Figure 1

Samples identified as the experimental group (red cassette) underwent progressive sterilization cycles (5 cycles for orange/red subgroup, 30 cycles for violet/red subgroup and 55 cycles for blue/red subgroup), while the control group (yellow cassette) did not undergo sterilization. Each cycle comprised an ultrasonic immersion in a disinfectant solution for 15 minutes (BioSonic UC125®, Coltčne / Whaledent Inc. Ohio, USA; Dento-Viractics 59®, Hygitech, Paris, France) and 58 minutes in the autoclave at 134°C and 3.1 bar (Matachana S100, Barcelona, Spain).

The 6 subgroups were submitted to a fracture strength test and the results (measured in newton: N) were recorded in the database for statistical analysis, with a tractional method used at 5 mm/min speed in the Universal Testing Machine® (Quasar Galdabini, Italy – Located in the laboratory of the Universitat Internacional de Catalunia, Barcelona, Spain). The samples were located and fixed as shown in Figure 2, all with the same inclination allowing the flat base of the tip was parallel to the ground and all with the same direction of the working blade.

All curettes were photographed with magnification (40 X) before and after each step with an optical microscope with built-in digital camera (Olympus Z40, Olympus Corporation, Tokyo, Japan). The pictures were later color coded and organized for comparison and evaluation, looking for signs of tarnish or pitting corrosion on the instruments, the absence of pitting corrosion was useful in order to control the standardized processing was performed under same conditions for all groups of

samples. The findings were not included since quality of the findings revealed a wrong selection of the magnification device.

Figure 2

The statistical analysis was performed using the t-test, two-way ANOVA and linear regression analysis on the computer program "R statistical package version 3.0.1". The student T-test was used to test the significance (95%) of difference between the groups. The ANOVA test was performed considering 6 groups and the level of fracture strength was considered as the principle variable. Regression analysis was performed to verify both: the effect of the sterilization cycling on the fracture strength values, and to verify the effect of the width of the curette blade on the fracture strength values.

RESULTS:
Results obtained in the fracture strength test are shown in table 1 (measured in newton: N).
It was observed that the sterilisation-processed group exhibits slightly higher median fracture strength than the not processed one (Table 1).

Table 1

A statistical model was applied to the data in order to evaluate whether the differences observed in the sample might be generalized to the universe under study (all curettes of the same size and material).
The first level of analysis concerns the statistical difference between the fracture strengths of the two respective samples, which were compared by means of the T-test as shown in Table 2.

Table 2

The sample mean of the fracture strength in the not processed group is 44.74813, whereas the one of sterilisation processed is 40.68615. In accordance with the results of the t-test shown in Table 2 the observed difference is not significant (p-value=0.413).
When the association between fracture strength and the number of sterilization cycles is considered, differences are observed. The higher fracture strength mean value is obtained in subgroups 0 and 4 corresponding to the thicker blades and minimally repeated sterilizations (0 and 5 cycles).
The results of the ANOVA test in Table 2 showed a p-value of 0.047, suggesting that the groups are significantly different with respect to the level of fracture strength.
When comparing the association between the fracture strength and the number of sterilization cycles within the subgroups, important differences were observed. The ANOVA analysis showed (Table 2) that the six subgroups are significantly different with respect to fracture strength when analysing not just the presence of chemical and thermal stress (sterilization processed and not processed samples) but also the number of cleaning cycles, disinfection and sterilization.
A linear regression of the sterilization cycles on the fracture strength was also considered. The level of the response variable is model as a linear function of the number of sterilization cycles. As shown in Table 2, the results obtained confirm the supposed negative association.
Regression analysis was performed to verify the effect of the width of the curette blade and Table 2 shows a remarkably low p-value of 0.00458.

DISCUSSION:

For this study, optimal sharpening of the curettes was done. Care was taken to achieve a clear and precise junction between the two sides of the cutting edge (the face and the lateral surface).[3,15,17,20] Several techniques are proposed to maintain the integrity of the instrument[2], minimize work time, stress and fatigue.[11,17,23,27] These considerations helped us in making the decision to choose the technique for grinding the lateral surface of the curette blade using a motorized device that standardizes several parameters (e.g. force and grinding stone angulations). However, it was difficult to maintain the original contours of the blade during the process of sharpening the curettes.[19]

The sterilization processing chosen was the disinfection in ultrasound bath to complement autoclaving, considering that infection control must be performed cyclically and standardized[14], and chemical disinfection is not effective unless combined with the use of ultrasound equipment.[12,26,28]

According to the results in Table 2, the present study did not find a statistical support to say that the sterilization alone produced the differences found among the experimental and control groups, It is possible to allege that the reduced sample size and the large within-group variance represent the main reasons of this result. Thus, it seems that the fracture strengths were apparently affected by the number of sterilization cycles.

When comparing the groups, the results showed higher fracture strength in the instruments with thicker blades and minimum sterilization cycles. It was also observed that fracture strength was apparently affected by the number of sterilization cycles, with statistical significance. Similar to previous studies[16], six instrument tips bent rather than broke under the force of testing. This suggests that factors like production variables might be involved other than the volume and cycles of sterilization of an instrument.[16]

When analysing chemical and thermal stress and the number of cycles of cleaning, disinfection and sterilization, the fracture strength was significantly affected by the number of sterilization cycles, like suggested in previous studies.[16]

In this study Gracey curette 13/14 were chosen, as it is one of the most used, and has a blade with a width of 0.86 mm similar to the width of other standard instruments (range: 0,86-1mm). According to the manufacturer's information, the life expectancy of an instrument is 720 uses over 18 months. However, in a study, Gorokhovsky et al. using coated curettes showed that the instruments maintained their clinical usefulness for as long as 11 months, depending on the rate of use.[9] The authors of this present study are unaware of other studies where the fracture strength of curettes with this type of alloy was tested and where it was also related to sterilization.

Some authors have claim that the use of blunt curettes can be as effective as a sharpen instrument when "Time factor" is not taken in consideration[10], also Ewen & Gwinnett[7] concluded that the use of blunt curettes can minimize soft tissue harming. These results are not in concordance with the results and recommendations found by most authors supporting the importance and need of sharpening curettes [1-4,9,18,23,29,30]

If a curette is not sharpened and is only sterilized, then it is impossible to relate the wear of the curette with a certain number of sterilizations.

A further study including a large sample, longer aging, cyclic loadings, and a sample holding device to better simulate clinical conditions, would probably help manufacturers

and regulatory bodies to set secure limits in both blade width and sterilizations cycle; and providing guidelines of methods to keep track of these two variables.
A comprehensive interpretation of these results might consider the fact that a single sterilization cycle in and of itself does not produce a significant change in the mechanical properties of periodontal curettes, whereas the number of sterilization cycles does. In the light of these results, as many sterilization cycles, the higher degradation of the instruments, so sterilization is a factor to consider when evaluating the longevity of a periodontal curette in the best interest of the patient's and the clinician's safety.

ACKNOWLEGEMENTS:

To Dr. Juan Ricardo Mayoral for the expert guidance in laboratory procedures
To the personnel working in the sterilization room at Universitat Internacional de Catalunya for the professionalism demonstrated
To Mr. Stefano Nasini from the Universitat Politecnica de Catalunya, for the competent statistical analyses of the data.
To Mr. Jose Luis Manzaneque from Kerr Spain, for providing the sharpening machine and guidance in its use.

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Standard journal article

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TABLES:

Group	Chemical and termal cycling	# of Cycles	Sharpening wear	Approximate Reduction of original size	Remaining Width in mm (Mean for the group)	Fracture strength in Ncm (Mean for the group)
1	No	0	No	0%	0,86	49,88
2	No	0	Yes	25%	0,61	45,15
3	No	0	Yes	50%	0,46	38,19
4	Yes	5	No	0%	0,86	49,07
5	Yes	30	Yes	25%	0,6	49,06
6	Yes	55	Yes	50%	0,45	30,91
Descriptive Analysis of Fracture Strength						
Group	**Mean (N)**	**Median (N)**	**Standard Deviation**		**Range**	
1, 2, 3	44,75	44,21	12,71		22,19 – 67,66	
4, 5, 6	40,69	46,98	13,56		18,99 - 63,29	

Table 1. *Database with results of the* fracture strength *test for statistical analysis, color-coded, the groups were prepared and divided for the experimental samples (groups 4, 5, 6) and control samples (groups 1, 2, 3). Fracture strength test with results measured in newton: N. Statistical Descriptive analysis.*

Two Sample t-test: ***Fracture strength on the sterilized and not sterilized samples***					
t		**Df**	**p value**	**95% confidence interval**	
0.825		25.034	0.4172	-6.077565 / 14.201508	
ANOVA: ***Sterilization Cycles on the Fracture Strength***					
	Df	**Sum Sq**	**Mean Sq**	**F value**	**p value**
Data	1	656	656.05	4.332	0.047 *
Residuals	27	4091	151.5		
REGRESSION: ***Sterilization Cycles on the Fracture Strength***					
	Estimate	**Std. Error**	**t value**		**p value**
Intercept	51.819	4.845	10.696		0.047 *
Data	-2.631	1.264	-2.081		
REGRESSION: ***Width of the Blade on the Fracture Strength***					
	Estimate	**Std. Error**	**t value**		**p value**
Intercept	511.510	33.988	15.050		0.00458 **
Data	-0.3103	0.1004	-3.092		

Table 2. *Statistical differences between the fracture strengths of the two groups compared by means of the T-test, ANOVA test and Regression analysis.*
**=P<0.05; **=P<0.01; t = distribution of probability in the t of student test; Df = degrees of freedom used in the ANOVA to calculate the p-value; Sum Sq = Sum of squares used in the ANOVA to calculate the F-value; F value= f of Fisher also the name for the distribution of probability used in the ANOVA to calculate the p-value.*

FIGURE:

Figure 1.*Digital Caliper measuring a brand new Gracey curette 13/14.*

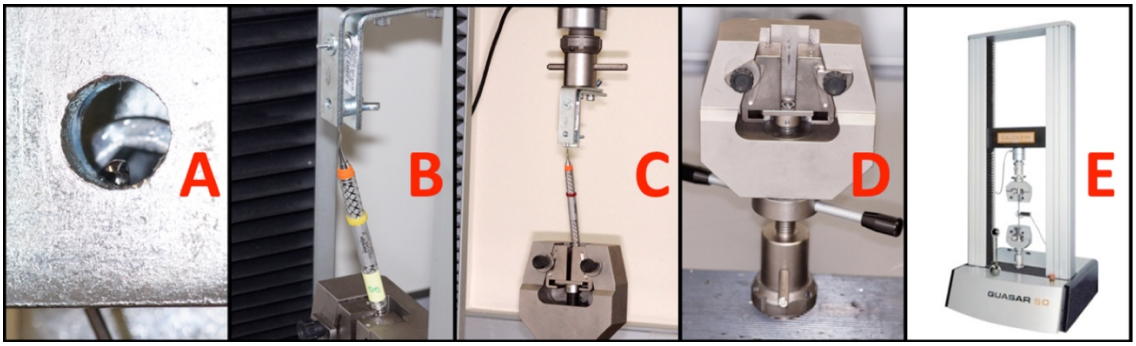

Figure 2. *A) Detail of the holding device for the blades, B) curette in position; C) at a different angle; D) lower support of samples; D) Universal Testing Machine (Quasar Galdabini, Italy).*