TITLE OF THE STUDY: Surgical extrusion for the clinical crown lengthening: a 12-months prospective clinical study

RESEARCH ETHICAL COMMITTEE APROVAL DATE: 15 March 2018

PROTOCOL

1. Scientific background:

Long-term survival rates of restorations after endodontic treatment range between 81% and 100%. Outcome predictors for the restored tooth with a prosthetic crown mainly include cavity wall integrity and the presence of 1.5 to 2 mm of ferrule (360 degrees sound dentin collar). In some clinical situations, the aforementioned requirements cannot be achieved, especially in deep carious lesions, cervical perforations, crown-root fractures, and failed crowns with preexisting subgingival margins. In such cases, ferrule should not be provided at the expense of the remaining tooth structure since it may provoke a biologic width invasion and, consequently, a chronic gingival inflammation and a loss soft tissue and bone.

Three treatment options aim to obtain adequate ferrule while respecting the biologic width: surgical crown lengthening, rapid orthodontic extrusion and surgical extrusion. Surgical crown lengthening involves the removal of hard and soft tissue for the exposure of sufficient supragingival tooth structure. Rapid orthodontic extrusion, which is a less invasive treatment, allows the preservation of periodontal tissues. However, it is necessary to consider the patient's willingness to wear orthodontic appliances, which increases the cost and time of the therapy. Surgical extrusion consists in atraumatic luxation of the tooth to enable its coronal reposition. Several authors have reported survival rates higher than 95% on surgical extrusiosion. However, little prospective studies are available in relation to the periodontal changes after SE.

2. Objectives:

2.1. Main objectives

- Evaluate the success rate after at least 12 months of the surgical extrusion.
- Evaluate the soft tissue rebound (STR) after at least 12 months of the surgical extrusion.

2.1. Secondary objectives

Evaluate the following periodontal and radiographic parameters:

- Gingival papillae shape and height (Jemt index).
- Bleeding on probing (mm).
- Plaque index (Turesky index).
- Gingival index (Silness & Löe index).
- Clinical attachment level (mm).
- Tooth mobility (Miller classification).
- Crown-root ratio (mm).
- Periapical healing (Rud score).
- Root resorption.
- Marginal bone loss.
- Patient satisfaction.

3. Hypotheses

Null hypothesis (H0):

H_o1: Surgical extrusion is not a predictable treatment for the restoration of single rooted teeth.

H_o2: Surgical extrusion of single rooted teeth results in an unfavorable aesthetic outcome.

Alternative hypothesis (H1):

$H_1$1: Surgical extrusion is a predictable treatment for the restoration of single rooted teeth.

$H_1$2: Surgical extrusion of single rooted teeth results in a favorable aesthetic outcome.

4. Study design

This is an interventional, monocentric, single-group, prospective clinical study.

5. Methods

5.1 Study population

This prospective study comprises 14 consecutive patients in whom 15 single-rooted teeth were surgically extruded at the Department of Endodontics at International University of Catalonia, St Cugat del Vallès, Barcelona, Spain. The sample was recruited according to the following inclusion and exclusion criteria:

Inclusion criteria:

- Systemically and periodontally healthy, non-smoking patients.
- Single-rooted, straight teeth with insufficient ferrule, which require restorative treatment.
- Teeth with a favorable crown-root ratio.

Exclusion Criteria:

- Severe systemic disease patients (American Society of Anesthesiologists classification 1 or 2).
- Multi-rooted, curved and/or short teeth.
- Teeth with an uncontrolled periodontal pathology.
- Pregnant women.
- Teeth with types II or III mobility.

All included patients signed an informed consent, and the study was approved by the Ethics Committee of Investigation of the Universitat Internacional de Catalunya (END - ECL – 2017 - 02).

5.2 Treatment plan

5.2.1 Pre-surgical assessment (Visit 1)

On the first appointment, patient's medical and dental history was reviewed. Patients age, sex and tooth number were recorded. A pre-operative cast model of each extruded tooth was taken and digitally scanned to assess the STR. Also, patient's biotype (De Rouck) was registered based on the transparency of the periodontal probe through the gingival margin while probing the buccal sulcus, as follows:

- 0: Both upper central incisors have thin biotype.
- 1: One of the two upper central incisors has a thin biotype.
- 2: Both upper central incisors have thick biotype.

A) Clinical parameters

- Percussion: assessed with a mirror handle in a vertical direction.
- Palpation: assessed by a gentle finger pressure on both buccal and palatal soft tissue around the transplant.
- Periodontal variables, using an standardized manual periodontal probe PCP-UNC 15 (Hu-Friedy®, Rockwell St, Chicago, IL):
    - Periodontal probing depths (PPD): measured at 6 sites per tooth. Defined as the distance, in millimeters, from the gingival margin to the bottom of the probable pocket.
    - Gingival recession: measured at 6 sites per tooth. Defined as the distance, in millimeters, from the cementoenamel junction (CEJ) to the gingival margin.
    - Clinical attachment level (CAL): calculated indirectly as the sum of the previously recorded PPD and gingival recession, representing the distance between the CEJ and the bottom of the pocket on all present teeth.
    - Bleeding on probing (BoP): recorded dichotomously, at six sites, as present or absent within 15 seconds after the direct assessment of PPD, at six aspects of each tooth.

- Tooth mobility (Miller classification): measured using two dental mirror handles.

    - Grade 0: Normal (physiologic) movement when force is applied.
    - Grade 1: Mobility greater than physiologic.
    - Grade 2: Tooth can be moved up to 1mm or more in a lateral direction (buccolingual or mesiodistal). Inability to move the tooth in a vertical direction (apicocoronally).

- Grade 3: Tooth can be moved 1mm or more in a lateral direction (buccolingually or mesiodistally). Ability to move the tooth in a vertical direction.

- Gingival papillae shape and height (Jemt index): based on the distance from the highest curvature of the marginal buccal gingiva to the contact point of the transplanted tooth with the following index scores:

  - 0 No papilla is present.
  - 1 Less than half of the height of the papilla is present.
  - 2 Half or more of the height of the papilla is present but does not extend all the way up to the contact point between the teeth.
  - 3 The papilla fills up the entire proximal space and is in good harmony with the adjacent papillae. There is optimal soft tissue contour.
  - The papilla is hyperplastic and covers too much of the transplanted or adjacent tooth. The soft tissue contour is more or less irregular.

- Bleeding on probing (mm): recorded dichotomously as present or absent within 15 seconds after the assessment of PPD, at six aspects of each transplant.

- Plaque index (Turesky index): visually measured as follows:
  - 0: No plaque present
  - 1: Separate flecks of plaque at the cervical margin.
  - 2: A thin continuous back of plaque (up to 1 mm) at the cervical margin.
  - 3: A band of plaque wider than 1 mm but covering less than one-third of the surface.
  - 4: Plaque covering at least one-third but less than two-thirds of the surface.
  - 5: Plaque covering more than two-thirds of the surface.

- Gingival index (Silness & Löe index): the scores of the four areas of the tooth can be summed and divided by four to give the GI for the tooth.
    - Score 0 = Normal gingiva.
    - Score 1 = Mild inflammation - slight change in color, slight edema. No bleeding on probing.
    - Score 2 = Moderate inflammation - redness, edema, glazing. Bleeding on probing.

      Score 3 = Severe inflammation - marked redness and edema, ulceration. Tendency toward spontaneous bleeding.

B) 2D radiographic parameters

Standardized digital bitewings and periapical radiographs with paralleling technique (Kodak RVG 6100; Carestream Health, Rochester, NY) and a selective CBCT scan (CS 9300; Carestream Health, set at 8.0 mA and 84 kV, with a 12-second exposure time and the smallest possible field of view (5 x 5 cm) were taken to assess root anatomy as well as the following radiographic parameters:

- Preoperative periapical lesion, recorded dichotomously as present or absent from the periapical radiography.

- Crown-root ratio (mm): measured on the periapical radiograph, and scored as follows:
    - Good: crown-root ratio < 1.
    - Just: crown-root ratio = 1.
    - Unfavorable: crown-root ratio > 1.

- Marginal bone loss: based on the bone crest aspect on the bitewing radiograph, as follows:
    - Initial: < 25% of marginal bone loss.
    - Moderate: between 25% - 50% of marginal bone loss.
    - Severe: > 50% of marginal bone loss.

5.2.2 Surgical extrusion (Visit 2)

The principal investigator performed all the procedures following the modified technique described by Kahnberg. Under local anesthesia and after having removed the caries lesion, each tooth was gently luxated with thin elevators, which were placed no more than 1mm within the gingival margin to avoid damaging the cervical PDL cells. Subsequently, teeth were coronally positioned using thin forceps to expose sufficient supracrestal tooth structure and splinted for 4 weeks with a retainer. Post surgery, the patients were prescribed analgesics and antibiotics for 1 week, and instructed to rinse daily with 0.12% clorhexidine and follow a soft diet for 2 weeks.

5.2.3 Endodontic therapy (Visit 3)

All the root canal treatment and retreatments were completed one month after the surgery.

5.2.4 Restorative treatment (Visit 4)

The biologic width of each tooth was left to reestablish itself for 2 months, after which the same operator (ML) restored the teeth with a composite build-up and a fiber glass-reinforced epoxy post (Exacto, Angelus, Londria, PR, Brazil) (if required) and in the same appointment all the teeth were prepared for single crowns with horizontal preparations.

5.2.5 Post-surgical assessment (Visit 5)

Patients were recalled at 12 months post-surgery, when a cast model was taken for the post-operative digital scanning, and the following clinical and radiographic parameters were recorded:

A) Clinical parameters

- Percussion.
- Palpation.
- Periodontal probing depths.
- Gingival recession.

- Clinical attachment level.
- Bleeding on probing.
- Tooth mobility.
- Gingival papillae shape and height.
- Bleeding on probing.
- Plaque index.
- Gingival index.
- Soft tissue rebound (STR): measured in mm by superposing both pre-operative and post-operative scanned models of each patient using surgical planning software (Blue Sky Plan, Blue Sky Bio, Libertyville, IL, USA). Soft tissue rebound was measured by calculating the difference between the lowest point of the gingival margin of the pre-operative model and the lowest point of the gingival margin of the post-operative model.

B) Radiographic parameters

- Periapical healing (Rud score): based on any radiolucency surrounding the apical third of the root, as follows:

    - Complete: Reestablishment of the periodontal space and the hard lamina around the apex.
    - Incomplete (scar tissue): Decrease or alteration of the apical lesion with at least one of the following characteristics: the periphery of the radiolucency is irregular and may be demarcated by a compact bony margin; the radiolucency is located asymmetrically around the apex.
    - Uncertain: Radiolucency greater than twice the width of the periodontal space and surrounded by tissue resembling a hard lamina. Lesion with circular or semicircular periphery and located symmetrically around the apex.
    - Unsatisfactory: Increase or maintenance of the size of the lesion.

- Root resorption: based on the aspect of the transplant periodontal ligament, as follows:

    - Absence of root resorption: complete PDL healing with normal width of the PDL space around the whole root.
    - Inflammatory root resorption: radiolucency is observed all along the external root surface of the dentin.
    - Replacement resorption: resorption lacunae are filled with bone and the PDL space is missing.

- Crown-root ratio (mm).
- Marginal bone loss.

C) Patient's satisfaction

Each patient filled in a questionnaire based on a 10-cm visual analogue scale to assess their degree of satisfaction regarding the surgical procedure and the esthetic outcome; 0 indicated a complete satisfaction while 10 was entirely unsatisfactory.

5.2 Success assessment

The following criteria were evaluated to establish the success of the treatment:

- Normal function of the extruded tooth with physiologic mobility without pain or discomfort.
- Healthy periodontal tissue surrounding the extruded tooth with periodontal pockets < 4 mm.
- Normal appearance of the PDL around the extruded tooth with no signs of any progressive root resorption or marginal bone loss > 25%.

STATISTIC ANALYSIS PLAN (SAP)

The sample size was calculated based on the STR variation, using as a reference the study of Arora et al., in which the mean STR reported at 6 months was 0.77 ± 0.58 mm after the crown lengthening. This measure corresponds to a large effect size (d=1.3). In the present study the sample size was calculated using one sample t-test, considering a relevant STR of 0.5 mm at 12 months and a dropout of 15%. Thus, the final sample consisted in 15 patients, for a power of 80%, and considering an effect size of d = 0.85.

The data contained in the follow-ups were entered into a database (Excel, Microsoft Corporation) for data analysis and preparation for the final report. All the variables were analyzed using a descriptive method (mean, %). Besides, Chi^2 test was used to find a statistical relation between pre-operative and post-operative marginal bone loss of the extruded teeth.

INFORMED CONSENT FORM (ICF)

This study aims to evaluate the clinic and radiographic outcomes of the surgical extrusion at one year. This procedure involves the extrusion (separation) of the tooth with respect to the bone in a vertical direction, in order to expose sufficient tooth structure to restore the tooth. Subsequently, the tooth is stabilized with a wire attached to the adjacent teeth for 2 – 4 weeks. Then, the root canal treatment / retreatment is performed, after which the tooth is restored with a prosthetic crown.

We have requested your participation in a research study. Before deciding whether to agree to participate, it is important that you understand the reasons for the research, how your information will be used, what the study will consist of, and the possible benefits, risks, and discomforts that may result.

VOLUNTARY PARTICIPATION

Participation in a trial is a voluntary and personal decision. In the case of not wanting to participate or wanting to leave the study, the quality of the care you will receive will not be affected and the usual protocols will be followed. If you choose to participate, the Patient Information Sheet and the Informed Consent will be given to you to sign all sheets of both documents.

If the Principal Investigator considers that the study may harm your health, he or she will invite you to abandon it, and will give you the pertinent explanations.

Finally, once your participation has ended, you must follow the procedures indicated by the doctor to guarantee your safety.

The immediate benefit of participating in the study is your contribution to scientific knowledge and development, without being able to guarantee an immediate benefit for you.

Me, Mr./Mrs.:……..

I have received verbal information about the study and have read the attached written information, of which I have received a copy. I have understood what has been explained to me.
I have been able to comment on the study and ask questions of the responsible professional.
I give my consent to take part in the study and I assume that my participation is completely voluntary.
I understand that I can withdraw at any time without affecting my future medical care.

By signing this informed consent form, I give my consent so that my personal data can be used as described in this consent form, which complies with the provisions of Organic Law 15/1999, of December 13, Protection of Personal Data.

_____ _____

Signature of the patient Date of the signature
DNI

STATEMENT OF THE INVESTIGATOR OR INVESTIGATOR

The patient who signs this consent form has received, from the professional, detailed information in oral and written form of the process and nature of this research study, and has had the opportunity to ask any questions regarding the nature, the risks and benefits of participating in this study.

_____ _____

Signature of the investigator Date of the signature
Name: