
Tesis doctoral

Surgical extrusion for the clinical crown lengthening: a 12-months clinical study.

Marc Llaquet Pujol



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Surgical extrusion for the clinical crown lengthening: a 12-months clinical study

Department of Endodontics, Faculty of Dentistry

Doctorate in Health Sciences

Universitat Internacional de Catalunya

DOCTORAL THESIS
MARC LLAQUET PUJOL

Director: Francesc Abella Sans

Co-director: Andrés Pascual La Rocca

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Dedicated to my wife Georgina and my daughter Bruna,
to my parents Antonio and Carina,
and to my sister Marta

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ABBREVIATIONS

Abbreviations

ETT	Endodontically treated tooth
STR	Soft tissue rebound
GI	Gingival index
BOP	Bleeding on probing
PPD	Periodontal probing depth
PDL	Periodontal ligament
VAS	Visual analogue scale

INTRODUCTION

1. Introduction

1.1. The endodontically treated tooth

The biological goals (success) of endodontic treatment are the prevention and/or healing of pulpal and periapical pathologies for the re-establishment of periapical tissues (1, 2), achieved between the 68 – 98 % of the cases (3-6). Besides, mechanical goals (survival) lie in the retention of the symptomless tooth and the re-establishment of the functions of mastication, phonetics, and aesthetics (7, 8), accomplished in the 86 – 97 % of the times (6, 9, 10).

Endodontically treated teeth (ETT) are more vulnerable to loss than teeth with vital pulps as a result of the following biomechanical changes:

1. Substantial loss of tooth structure due to caries, restorative, and endodontic procedures (11, 12).
2. A significant weakening of dentine caused by endodontic solutions such as calcium hydroxide, sodium hypochlorite (NaOCl), and ethylenediaminetetraacetic acid (EDTA) (13-16).
3. A reduced toughness and fracture resistance provoked by dentine dehydration due to loss of unbound water from the root canal space and dentinal tubules (17).

1.1.1. Outcome of endodontically treated tooth restoration

The reasons for extraction of ETT have long been the subject of research as described in the literature on this topic. A part from endodontic failures and vertical root fractures (18), some authors observed a direct effect of the periodontal status of the ETT at the time of the root canal treatment (19). After 9 years, the survival rate of the ETT was 90%, 71% and 59% for teeth showing healthy, mild, and moderate periodontium, respectively. A statistically significant difference was observed between groups.

Specifically, teeth with mild periodontitis were two times more likely to be lost compared with those with a normal periodontium. This risk increased up to 3.1 for teeth showing moderate periodontitis. Additionally, those authors demonstrated that smoking status is a significant predictor of tooth extraction, since ETT in active smokers were observed to be 2 times more likely to be lost compared with none/former smokers.

By means of a systematic review, Ng et al. concluded that the time between the root canal treatment and the tooth filling had no influence on tooth survival, on those teeth restored with a crown (9). However, some authors could demonstrate that the time of crown placement after the root canal treatment was significantly correlated with the survival of ETT (20-22). Aquilino et al. stated that “time from obturation to foundation placement was significantly associated with tooth survival” (21). Pratt et al. showed that after 8 years, the survival rates of ETT that received crown within 4 months of the endodontic treatment were 85%, and after 4 months were 68%. They also found that ETT protected with temporary restorations are 4 times more likely to get lost compared with those that received permanent crowns (20). The same study revealed that there was no significant difference on ETT survival regarding the dental arch, type of opposing dentition, gender, age, and type of tooth, which was also found by Olcay et al. (22). In the same line, Dammaschke et al. and Tan et al. found that the location and type of tooth had no significant effect on survival of ETT (23, 24). To this contrary, Lee et al. demonstrated that tooth type was a significant factor affecting tooth survival, showing that anterior teeth and premolars had a statistically higher survival rate than that of molars. Also, the authors observed that ETT opposing a fixed prosthesis showed a significant greater longevity than opposing natural teeth (25). Similarly, Matsumoto et al. found a lower survival rate of ETT opposing natural teeth, compared to those opposing any tooth or a fixed prosthesis. The authors related this fact to the adverse effects during occlusal function, which could increase the risk of tooth fracture (26).

It has been demonstrated widely that the most common reasons for extraction are prosthetic and restorative considerations, mainly caused by subgingival caries (22, 27-31). For this reason, coronal restoration plays a decisive role in the survival of the ETT. The main described restoration techniques for the ETT are direct filling with composite, indirect inlay, onlay and overlay, and complete crown. However, there is no clear consensus on the ideal material and approach for restoring the ETT. In addition, different success and survival rates have been reported depending on the type of restoration, the presence and characteristics of a post, the core and used material, as well as the period of observation (32-35).

Preservation of a sound tooth structure is considered a critical aspect of the survival rate of ETT, given the possible structural compromise that occurs as a result of restorative and endodontic procedures, caries lesions, aging, or trauma (33).

For its part, direct composite restoration provides a less invasive preparation than crowns do, thus conserving more of the tooth structure (34). A good prognosis was shown in a prospective study of 192 direct composite restorations for ETT, in which 167 were judged successful (86.95%) and 180 teeth (93.7%) survived for up to 10 years, with an annual failure rate of 2.4% (32).

On the other hand, there is evidence to support the notion that full cuspal coverage with single crowns prevents root fracture in endodontically treated posterior teeth, showing better results than direct composite restorations (36, 37). Stavropoulou et al. analysed the relationship between complete crown placement and the long-term survival rate of ETT. They demonstrated statistically significant differences between teeth restored with full-coverage crowns (81.12%) and direct composite filling (63.15%) after 10 years (38). Similarly, Suksaphar et al. found that the survival rate of endodontically treated premolars was 95.1% when restored with full-coverage crowns and 77% when restored with resin composite (39). Comparable survival rates were found by De Backer et al. for 1312 single crowns on ETT (95.2%, 84.7% and 79.4%) after 6, 12 and 18 years (40, 41) and by Leempoel et al. in which the survival rate of crowned ETT after 12 years ranged from 78% to 94% (42). Along the same lines, comparing different core restorations in 307 single crowns of ETT, Fokkinga et al. showed survival rates of 71–94% after a 17-year follow-up period. They concluded that preservation of the remaining tooth structure seems to be key to the long-term survival of the crowned ETT (43).

Today, there still is not enough clear evidence on whether to provide a restoration with or without the use of a post. In a randomized clinical trial, Ferrari et al. stated that post placement is indicated when less than 2 walls are present in anterior teeth and premolars (44). Moreover, they showed that fibre posts significantly decreased the risk of failure in endodontically treated premolars, given their protective role against root fracture (45). Similarly, Guldener et al., showed that ETT restored with a fibre post presented a statistically significant higher survival rate (94.3%) than ETT restored with a composite filling without a post (76.3%) (46).

However, a number of studies failed to show any positive effect of post placement on the survival of ETT (47). By means of a systematic review and meta-analysis after 6 years, Ploumaki et al. reported a 94% success rate in single crowns on ETT without a post, whereas in cases when posts were placed, the success rate dropped slightly to 92%, but

the difference was not statistically significant (48). In an *in vitro* study, Magne et al. demonstrated that fibre posts do not increase the load-bearing strength or survival of anterior teeth restored with all-ceramic crowns. They concluded that there is still a lack of evidence in relation to the ideal treatment in the absence of ferrule (49).

In the same line, in a systematic review, Meyenberg concluded that given currently available adhesive procedures, the rationale for using a post is no longer to increase the core build-up retention, but to increase the adhesion surface for the build-up restoration. Additionally, he recommended the use of a post when less than 50% of the coronal structure remains in anterior teeth and premolars (34). Unlike molars, premolars present generally less tooth structure and smaller pulp chambers to support build-up restoration after endodontic treatment. In molars, a post is no longer required, other than in cases of total loss of tooth structure and insufficient pulp chamber surface (50).

Over an observation period of 1 to 25 years in 1273 ETT, Sorensen et al. found that the use of a post had no significant impact on the success rate for anterior and posterior teeth (51-53). Accordingly, in a 5-year clinical study, Salvi et al. reported no statistically significant differences in survival rates for teeth restored with (93.5%) and without (95%) a post, for titanium posts (92.5%), cast posts and cores (97.1%), and teeth without post restorations (94.3%) (54).

The post design, and material have been also studied by several authors (55-58). Some authors has demonstrated that ETT restored with post with a lower modulus of elasticity, like fiber posts, have higher resistance to fracture than those restored with cast post (55, 56). Two randomized control trials have compared the survival of ETT restored with glass fiber or with cast metal posts (59, 60). On the one hand, those authors showed that survival rates of both types of posts have similar survival rates (glass fibre posts 97.1%, and cast metal posts 91.9%) after 3 years. On the other hand, they found that cast metal posts (1.2%) presented similar annual failure rates compared with glass fiber posts (1.7%) after 5 years. After 3 and 5 years, both studies demonstrated similar clinical performance in ETT without ferrule(59, 60).

Martino et al. also found no significant differences in survival rates among the following posts types: prefabricated fiber-reinforced composite resin posts (12 years), prefabricated metal posts (10.2 years), or custom-cast metal posts (11.8 years) (61). This retrospective study revealed that glass ionomer cement showed significantly higher risk of failure than zinc phosphate cement. Also, it was demonstrated that posts in posterior ETT had significantly higher survival rates than anterior ETT, and that teeth presenting more than 75% root in bone had a significantly lower risk of failure.

By an *in vitro* study, Schmitter et al. compared the fracture loads of anterior teeth restored with two different lengths of threaded, metal posts: short (3 mm) and long (10 mm) (58). When the posts were pretreated (tribochemically coated and then silanized), fracture loads of teeth restored with long ones were higher than for teeth using short ones (436 N and 285 N, respectively). However, if posts were not pretreated, fracture loads for teeth with short metal posts were significantly higher (248 N versus 133 N). Another *in vitro* study revealed that teeth restored with fiber-reinforced resin posts and cast posts and cores resulted in similar strengths after cyclic fatigue (57). However, the former exhibited a higher rate of supracrestal oblique fracture, while cast posts and cores presented more vertical root fractures.

The effect of the post length on the failure of the restoration has also evaluated. Abdulrazzak et al., evaluated the failure mode of ETT restored with glass fibre posts, composite resin cores and cast metal crowns, with post spaces prepared at 2/3, 1/2 and 1/3 of the root length (62). The authors found that the post length had no significant effect on the fracture resistance of ETT. Also, the 0mm ferrule ETT with short posts exhibited the most unrestorable failure mode.

1.1.2. Effect of permanent restoration on the outcome for the endodontically treated tooth

The impact of definitive restoration on the outcome for ETT has been widely studied (63-65). One of the first and most relevant studies in this area was that of Ray and Trope (63). This retrospective article offers comparisons before and after endo-restorative dentistry. For 1010 examined cases of ETT, the authors found that the odds of absence of apical lesions were 4.32 times greater when good root canal treatment was present, and 11.12 times greater when good restoration was present. They demonstrated that the quality of the permanent restoration is significantly more important than the technical quality of the root canal treatment in ensuring its long-term success (63). In contrast, Tronstad et al. assessed 1001 cases of ETT, noticing that the quality of the endodontic treatment was significantly more important than the quality of the coronal restoration, where the periapical status of the ETT was considered (64). The main limitation of these studies is that the quality of the coronal restoration was evaluated radiographically, rather than clinically. Despite this, coronal leakage of ETT began to receive a great deal of attention as a potential cause of endodontic failure (64). Based on clinical and radiographic examinations, Chugal et al. concluded that coronal restoration contributes only minimally to the outcome of endodontic treatment (65).

Song et al. observed that teeth with adequate root canal treatment and a well-sealed coronal restoration are 3.6 times more likely to heal than teeth treated with inadequate restorations and adequate endodontic filling. However, the authors concluded that both factors were of equal importance and were independent predictors of the outcome of the endodontic treatment (66). A systematic review and meta-analysis revealed no significant differences in the odds of healing when adequate endodontic treatment combined with inadequate coronal restoration versus inadequate endodontic treatment combined with adequate restoration were compared. In this case the authors concluded that the odds of healing increase with both adequate endodontic treatment and adequate coronal restoration (67). These results are in line with Kirkevang et al., who found that the rate of apical periodontitis was 31.2 % in cases of both adequate root canal treatment and coronal restoration, compared with 78.3 % in cases of inadequate endodontic and coronal restoration (68).

1.1.3. Structural tooth integrity: remaining walls and the ferrule effect

The most critical predictor of survival for the restoration of the ETT is the amount of supragingival crown structure, which includes the integrity of the remaining tooth wall and the presence of 1.5 – 2 mm of ferrule (44, 69, 70). Nagasiri et al. reported 5-year survival rates of less than 50% in teeth with moderate (tooth structure of approximately a Class II cavity preparation with no less than 2 walls with at least 2 mm thickness) and minimum remaining coronal structure (less than 2 walls with at least 2 mm thickness). In contrast, a survival rate of 78% was found in teeth with the maximum tooth structure (class I cavity preparation with at least 2 mm of surrounding wall thickness) for the same observation period (71). Salameh et al. found that the resistance to fracture of endodontically treated molars filled with composite restorations is intimately related to the number of residual walls (72). Similar results were demonstrated in premolars, in which the mean fracture strength for teeth with mesio-occluso-distal cavities was 50% less than for unaltered teeth (73).

For its part, the ferrule effect, described as a “360° metal collar of the crown surrounding the parallel walls of the dentine extending coronal to the shoulder of the preparation” (69), is fundamentally important in fracture resistance (62). A systematic review showed that restorations with ferrule survived significantly better (98%) than without ferrule (93%) after 5 years. Even though 1 mm of coronal dentin was found to be enough to increase the fracture strength significantly under exposure to static loading (74), the higher the ferrule length, the greater the fracture resistance of ETT (62). Ferrule of 1.5 - 2 mm significantly reduces the risk of fracture in ETT by strengthening the external

surface of the tooth and distributing the forces that concentrate at the narrowest circumference of the tooth (75, 76). Therefore, the minimum ferrule length for a central incisor should be 1.5 mm (76). Sorensen et al. found that nearly double the failure threshold was observed in teeth with no coronal dentinal extension (mean failure load 36.3 kg), compared with that teeth with 1 mm of residual dentin coronal to the shoulder of the margin preparation (mean failure load 65.3 kg) (74). Another investigation revealed that a 4-mm ferrule height significantly increases the fracture resistance compared with 2-mm and 0-mm, and a 2-mm ferrule provides significantly higher fracture resistance than cases without ferrule (62). Creugers et al. found that restorations with more than 75% ferrule had a 5% higher survival rate than those with less than 75% ferrule (77).

1.2. Supracrestal tissue attachment invasion in restorative dentistry

Supracrestal tissue attachment, formerly known as “biological width” (78), is histologically composed of approximately 1 mm of junctional epithelium and 1 mm of the connective tissue attachment (79, 80). Available human studies demonstrate that infringement within the supracrestal tissue attachment is associated with chronic gingival inflammation and an unpredictable loss of soft tissue and bone (81, 82). Lang et al. described changes in subgingival microflora under overhanging restorations, in which bacteria resembling those of chronic periodontitis (gram-negative anaerobic bacteria) were detected in higher proportions compared to that present in clinically perfect margins. The authors stated that overhanging subgingival margins are potential triggers of periodontal disease (81). In the same vein, Flores-de-Jacoby et al. confirmed that the location at the subgingival margin of a fixed prosthesis favoured an increased bacterial accumulation and a worse composition (higher percentages of motile rods and spirochetes). They also observed higher gingival index scores and probing depths, increasing the risk of periodontal disease (82). These findings are comparable with other studies that revealed that the closer the subgingival crown margin was to the epithelial attachment, the higher the probabilities of a severe gingival inflammation, recession, and bone loss (83-85).

In an attempt to establish a fixed measure of the supracrestal attached tissues, Deas et al. noted that “*surface-to-surface, tooth-to-tooth, and patient-to-patient variability*” may be disregarded (86). Therefore, despite a lack of clear evidence, a distance ranging from 3.5 to 5 mm of supraalveolar tooth structure is recommended for long-term successful tooth reconstruction (1.5 - 2 mm ferrule + 2 - 3 mm of supracrestal tissue attachment) (87).

1.3. Treatment options to obtain ferrule respecting the supracrestal tissue attachment

In some clinical situations, the aforementioned dimensions cannot be achieved, especially in deep carious lesions, cervical perforations, crown-root fractures, and failed crowns with preexisting subgingival margins (88). In such cases, ferrule should not be provided at the expense of the remaining tooth structure since this could result in biological width invasion (82, 89, 90). Instead, the clinician should consider one of three treatment options aimed at obtaining adequate ferrule while respecting the biological width: surgical crown lengthening (91), forced orthodontic extrusion (92), and surgical extrusion (93). The decision on whether to choose one treatment over another should be focused on different clinical, anatomic, and aesthetic factors; tooth crown-to-root ratio, root proximity to other anatomic structures, and restorative, endodontic and periodontal

conditions. Root morphology and furcation involvement limit the choice of both forced orthodontic extrusion and surgical extrusion, since they are not indicated in multirooted teeth. Also, tooth position on arch may determine one option or another, since surgical crown lengthening of 1 anterior tooth is not usually recommended (87, 94-96).

1.3.1. Surgical crown lengthening

Surgical crown lengthening entails the removal of soft and hard coronal tissues in order to expose sufficient sound tooth structure for the placement of the final restoration margins at least 3 mm from the alveolar crest (91). However, there may be some drawbacks to this treatment: from the patient's point of view, there is a delay in treatment due to the required soft tissue healing process, especially critical in terms of aesthetics, before the definitive restoration placement (97, 98). Some authors recommend a wait of at least 3 months to allow gingival tissues to re-establish (88, 97, 99, 100) and even up to 6 months for anterior teeth (98). This healing period may vary depending on intra-surgical factors, such as the extent of the osseous resection (101) or the post-surgical flap position (86, 102), and patient-related factors, such as the patients' phenotype (97). In cases where the distance between the gingival margin and the alveolar bone is ≤ 2 mm, a significant rebound of the soft tissues may be expected after 6 months (98). Pontoriero et al. found a coronal migration of the soft tissues 6 to 12 months after surgical crown lengthening, which was more pronounced in thick-phenotype patients (97).

Moreover, the more apical the relocation of the bone crest, the higher the risk of furcal involvement in posterior teeth, the poorer the crown-root ratio and the higher the mobility in an already weakened tooth (99). In addition, this procedure often calls for the need to sacrifice the supporting bone of the adjacent teeth in order to achieve a positive bone architecture (88). Consequently, in the anterior zone, where aesthetics are of high concern, surgical crown lengthening of 1 tooth can result in disharmonious gingival margins or interproximal papillae loss, leading to an unsuccessful aesthetic outcome (88, 91, 101, 103-105).

1.3.2. Forced orthodontic extrusion

In clinical situations where any of the aforementioned alterations could occur, rapid or forced orthodontic extrusion may be considered (106, 107). This technique was proposed by Heithersay in 1973 for the management of ETT with subgingival coronoradicular fractures (108). It is a less invasive procedure aimed at increasing the exposure of the submarginal tooth structure to facilitate restoration and is indicated particularly in cases of high aesthetic demand (106). This procedure allows the tooth to be moved from

the alveolar bone in an axial direction while periodontal structures remain in the same position (109, 110), as a result of the application of heavy forces without an intermediate tooth stabilization period (106). Gonzalez-Martin et al. stated that combination of severance of periodontal fibers with root planing should be done to avoid simultaneous coronal displacement of surrounding hard and soft tissues. The last two therapies aim to prevent intrusive relapse of those tissues (111). Fiberotomies are recommended to be performed once (before or after initiating the orthodontic movement) or repeated times during the orthodontic treatment every 15 days (106, 112). However, even fiberotomy sessions are performed, clinicians must be aware that some degree of relapse can occur and additional surgical correction may be required after the stabilization period (113-115). Moreover, a minimal periodontal surgery may be required at the end of the orthodontic treatment to correct any discrepancy between adjacent periodontal levels (116).

Predictability of tooth displacement in response to a force direction and magnitude may be influenced by several factors; required extrusion amount, tooth type (number of roots), patient age (the younger the patient, the faster the movement), surrounding alveolar bone mineralization, and PDL health (partial replacement resorption may hamper the extrusive movement) (117). In general terms, Brindis et al. reported that tooth can be orthodontically extruded as fast as 1 mm per week, with no damage to the PDL (118). Those forces may be as high as 50 to 75 g, depending on the case (119).

Regarding the direction of the movement, the indicated vector of movement follows the long axis of the tooth, unless this tooth requires a correction of the position or angulation (106, 118, 119).

The definitive crown design will dictate the orthodontic movements. For this reason, before the wires are placed (recommended along the cervical margin), the tooth should be temporary restored with the final shape of the tooth, in order to apply the forces following the final result (118). Moreover, an adequate surface is needed to apply correct bonding techniques to bond the bracket. In case of a several damaged crown, the temporary crown is widely recommended, since it will provide the sufficient surface for an ideal bonding of the bracket (118).

Frequently, the incisor edge of the tooth needs to be reduced in height during the extrusion process to prevent tooth tipping in consequence to tooth contact as the tooth erupts. This might entail the root canal treatment before the tooth extrusion, which should be considered by the clinician during the treatment plan (118). Even in some cases, the root canal treatment of the tooth to be extruded have been recommended prior

the orthodontic treatment, to prevent sensitivity and exposure of the pulp during the occlusal reduction during the extrusion (120). Moreover, a histologic study demonstrated that rapid extrusion could be traumatic to the pulpal tissue (121) It have been found odontoblastic degeneration after 1 week of activation and pulpal fibrosis after 4 weeks in a tooth undergone forces of 50 g. This could be explained by ischemia secondary to rapid movement (122).

In regards to anchorage, Ziskind et al. stated that sufficient anchorage must be used to control both the amount and direction of the extrusion, and to prevent any adverse compensatory movement of the teeth used as anchors. For this purpose, three or more teeth in both mesial and distal sides of the extruded tooth are recommended to use as anchors (123).

From the best of our knowledge, the evidence including complications or failures with forced orthodontic extrusion is scarce (95, 114, 124). One of the inconveniences of this procedure is the long chair-time associated with the number of required appointments of the patient. Brindis et al. recommend examining the patient the following day of the orthodontic extrusion activation in order to evaluate the patient's response to the extrusion and verify any premature contact. Additionally, patients undergoing this treatment should be recalled closely and in short (every 1 to 2 weeks) to assess their oral hygiene, change the orthodontic appliance, adjust occlusion if necessary, and monitor the amount of extrusion (118). Once the final position of the tooth is achieved, a final stabilization of 6 to 12 weeks is required to allow the bone, the PDL and gingival tissues to re-establish themselves and minimize the risk of relapse (119). Period length depends on the length of tooth erupted and the speed of the tooth extrusion (118). After the final stabilization, a periapical radiograph should be taken to check the formation of apical bone subsequent the tooth extrusion, to verify whether the tooth has been stabilized for sufficient time (106).

Braga et al. reported that "precise control of the technique (fiberotomy and root planing) itself is quite difficult, especially when this approach is to be performed on a limited portion of the root perimeter in teeth affected by angular defects" (114). This could be a drawback and hinder the final outcome if those procedures are carried out by a clinician unexperienced in periodontics.

The risk of root resorption increases when rapid, heavy orthodontic forces are applied, especially when intrusion is performed (115, 125, 126). Although the root resorption is considerate a rare adverse event with extrusion orthodontic movement, Arhun et al.

found the association between orthodontic extrusion and severe root resorption in a case report (106, 127).

The clinician must also consider the patient's willingness to wear orthodontic appliances, which increases the cost and the treatment chair-time. Hence, this treatment is not applicable in all situations.

1.3.3. Surgical extrusion

One possible alternative that can be used to overcome the disadvantages of these two treatments is surgical extrusion, also called intra-alveolar transplantation (128). This straightforward, 1-step treatment allows the restoration of teeth with extensive tooth loss and insufficient ferrule, preserving hard and soft tissues in a way that requires less chair-time and a lower cost compared with orthodontic treatment (129, 130).

1.3.3.1. Original technique (Tegsjö, 1978)

First developed by Tegsjö et al. in 1978 (128), this procedure initially comprised mucoperiosteal flap elevation of both buccal and palatal soft tissues and exposition of the root apex through ostectomy. The removed bone was placed in physiological sodium chloride solution, after which the apex was pushed coronally using a crown remover. Finally, the removed bone was used to graft the apical area of the tooth in order to support it in the coronal position (Figure 1). The authors observed a success rate of 86% after a period ranging from 1 to 12 months, with no progressive resorptions and improved or unchanged periodontal tissues.

1.3.3.2. Modified technique (Kahnberg, 1985)

In 1985, Kahnberg et al. (131) used a marginal approach to modify the technique by gently luxating the tooth using thin carvers as periostomes and elevators, thereby avoiding surgical root exposure and periapical bone grafting. The authors observed no progressive root resorptions or physiological pocket depths in any case. In addition to the improved outcome (121), the modified technique is easier to carry out, and because no flap raising or bone grafting is involved, there are fewer postoperative complications (132).

1.3.3.3. Current status and treatment outcome

The current evidence of surgical extrusion is mainly comprised of case series and case reports (93). The MINORS index (methodological index for non-randomized studies) revealed fair and low quality case series and case reports, respectively (94). Nevertheless, the available evidence shows very good results for surgical extrusion (133). A study in which the original surgical extrusion technique was compared with the modified version

described by Kahnberg et al. showed physiological pocket depths in both groups, but more apical root resorptions were observed in the original technique (121). In a 10-year follow-up study of the modified technique of surgical extrusion, apart from a slight shortening of the roots in 5 teeth (26.3%), no other endodontic or periodontal pathologies were found (132). The reported survival rate was 98.8%, which is consistent with that reported by Elkhadem et al. (95 %) (94), Calışkan (98%) (134), and Pham et al. (100%) (133). In a 6-month study on surgical extrusion in anterior fractured teeth, Pham et al. reported probing depths of ≤ 3 mm, a slightly increased mean gingival index, and no mobility in any teeth (133).

Aside from the aforementioned root resorptions (apical resorption and ankylosis), the technique may involve some complications. This technical-sensitive procedure depends greatly on the surgical skills of the operator; tooth manipulation requires careful, gentle movements with controlled forces to prevent fracture of the weakened tooth. Also, the involved tooth and/or the buccal bone may fracture during the surgical tooth manipulation (135), which might lead to tooth extraction. This is the reason why surgical extrusion is contraindicated in teeth with root anatomy incompatible with atraumatic extraction, such as multi-rooted teeth with divergent roots. Also, this treatment is not indicated to patients with medical contraindications to any surgical therapy (136).

In addition, surgical extrusion might result in an excessively narrow supragingival tooth structure, hampering the prosthetic management of both the tooth emergence profile and the interproximal space of the adjacent teeth (93). To address this problem, some authors (137, 138) have reported the biologically oriented preparation technique (BOPT) to restore surgically extruded teeth, in which the gingival margin can be remodeled by modulating the temporary crown emergence profile, thus thickening the supracrestal soft tissue (139, 140).

The only report of patient satisfaction in relation to the treatment and the aesthetic result of the extruded tooth was that of Pham et al. A 7-question survey revealed an excellent response in relation to the final aesthetic outcome, with no pain or discomfort of the extruded tooth (133).

To date, to our knowledge, there are no prospective clinical studies to assess survival, success, and periodontal changes after at least 1 year of surgical extrusion. The only found prospective clinical study was limited to a 6-month follow-up and included only anterior teeth that suffered a complicated crown-root fracture. The authors evaluated the gingival margin position at 1, 3, and 6 months by means of a periodontal probe. This clinical method is less accurate than digital measurements with an intraoral scan (141). Virtual

image superimposition of the baseline clinical situation and its corresponding follow-up allow a detailed analysis of soft-tissue volumetric changes of a treated tooth (142).

1.4. Aims

In view of the foregoing summary of the existing literature, the aims of the present study are (1) to report the survival and success rates of surgical extrusion in single-rooted teeth; (2) to evaluate soft tissues changes after surgical extrusion by digital means; and (3) to observe the patient's satisfaction of the treatment after a minimum of 1 year-control.

HYPOTHESES

2. Hypotheses

2.1. Work hypotheses

H1: Surgical extrusion of single-rooted teeth has a survival rate of 95% or more after at least 1 year post-treatment.

H2: Surgical extrusion of single-rooted teeth has a success rate of 90% or more after at least 1 year post-treatment.

H3: Surgical extrusion of single-rooted teeth results in stability of the gingival margin after at least 1 year post-treatment.

OBJECTIVES

3. Objectives

3.1. Main objectives

- To evaluate the survival rate of the surgical extrusion of single-rooted teeth after at least 12 months of treatment.
- To evaluate the success rate of the surgical extrusion of single-rooted teeth after at least 12 months of treatment.
- To evaluate the soft tissue rebound (STR) of surgically extruded teeth after at least 12 months of treatment.

3.2. Secondary objectives

3.2.1. To evaluate the following clinical and radiographic parameters after at least 12 months of treatment

- Gingival index (Silness & Løe index).
- Bleeding on probing.
- Probing depths (mm).
- Tooth mobility (Miller classification).
- Gingival papillae shape and height (Jemt index).
- Periapical healing (Molven score).
- Root resorption (Trope classification).
- Crown-root ratio.
- Marginal bone loss (%).

3.2.2. To evaluate patient satisfaction in relation to surgical extrusion, in terms of both the aesthetic result and the functioning of the extruded tooth

METHODOLOGY

4. Methodology

4.1. Study population

This prospective study was approved by the Ethics Committee of Investigation of the Universitat Internacional de Catalunya (END - ECL – 2017 - 02) (Annex 1), in accordance with the principles of Helsinki (version 2008), and the trial was registered on clinicaltrials.gov with ID: NCT03855501.

The sample size was calculated based on the STR variation, using as a reference the study of Arora et al. (102), in which the mean STR reported at 6 months was 0.77 ± 0.58 mm after the crown. This measure corresponds to a large effect size ($d=1.3$). In the present study, the sample size was calculated using a 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 of 13 patients, for a power of 80%, and considering an effect size of $d = 0.85$.

4.2. Patient recruitment

The study was carried out between February 2017 and June 2020. Any patient referred to the Department of Endodontics at the Clinica Universitaria de Odontología - Universitat Internacional de Catalunya (St. Cugat del Vallès, Barcelona, Spain) with at least one non-restorable single-rooted permanent tooth, was recruited according to the following inclusion and exclusion criteria.

4.2.1. Inclusion criteria

- Systemically and periodontally healthy, non-smoking patients.
- Single-rooted, straight teeth ($< 10^\circ$ of curvature (143)) with insufficient ferrule, requiring a restorative treatment without invading the supracrestal tissue attachment.

- Ferrule is considered a 360°-circumferential supragingival dentine collar at least 2 mm in height (44).
- Supracrestal tissue attachment is composed of the gingival sulcus (0.69 mm), junctional epithelium (0.97 mm) and supracrestal connective tissue attachment (1.07 mm), which measures approximately 3 mm (78, 79).
- Teeth with enough crown-root structure for a favourable crown-root ratio at the final restoration.

4.2.2. Exclusion Criteria

- Patients with severe systemic disease (American Society of Anesthesiologists classification 3 or 4).
- Multi-rooted teeth.
- Single-rooted curved ($\geq 10^\circ$ of curvature) teeth (143).
- Single-rooted teeth with an insufficient root length for a predictably favourable crown-root ratio after the extrusion.
- Teeth with an uncontrolled periodontal pathology.
- Pregnant women.
- Teeth with type II or III mobility.

Any possible case for surgical extrusion was evaluated by the principal researcher (F.A.). All patients were informed about the benefits and drawbacks of the following treatment options: surgical crown lengthening, orthodontic forced eruption, surgical extrusion, tooth extraction, and dental implant. They were also informed about the present study and about the timing of all the phases included in the surgical extrusion: surgery, endodontic treatment, tooth restoration, provisionalization, and controls. All included patients were required to sign an informed consent (Annex 2).

4.3. Treatment plan

4.3.1. Pre-surgical assessment

On the first appointment, the patient's medical and dental history was reviewed by the secondary researcher (ML). The patient's age, gender, and tooth number were recorded.

A pre-operative cast model (Super Rock Ex, Kuraray-Noritake Dental, Tokyo, Japan) of each extruded tooth was obtained for digitally scanned using a laboratory optical scanner

(Trios, 3Shape, Copenhagen, Denmark). One-step double-mix impression technique (144) was carried out in all cases, in which the low-viscosity polyvinyl siloxane material (Aquasil XLV; Dentsply, Konstanz, Germany) was injected all over the tooth and its surrounding tissues (145). This material was used since it offers a high dimensional stability (146, 147) with a minimal gingival displacement of the teeth to be extruded (to avoid any alteration of the soft tissue dimensions) (148). Retraction cords were not employed in order to prevent any gingival displacement during the impression. Then, a tray loaded with a medium-body viscosity polyvinyl siloxane (Aquasil Ultra+ Medium, Dentsply Sirona, PA, USA) was inserted on the patient mouth. Dental impressions were poured immediately in order to optimize the dimensional accuracy and stability of the material (149).

A. Clinical parameters

- Patient's phenotype (De Rouck index (150)): based on the transparency of the periodontal probe through the gingival margin while probing the buccal sulcus, as follows:
 - 0 (thin): Both upper central incisors have a thin phenotype.
 - 1 (intermediate): One of the two upper central incisors have a thin phenotype.
 - 2 (thick): Both upper central incisors have a thick phenotype.
- Percussion: assessed using a mirror handle in a vertical direction.
- Palpation: assessed by gentle finger pressure on both buccal and palatal soft tissue around the tooth.
- Periodontal variables, using a 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.
 - Bleeding on probing (BOP): recorded dichotomously, at 6 sites, as present or absent within 15 seconds after direct assessment of PPD, for six aspects of each tooth.
- Tooth mobility (Miller classification (151)): measured using two dental mirror handles.
 - Grade 0: Normal (physiological) movement when force is applied.
 - Grade 1: Mobility greater than physiological.

- Grade 2: Tooth can be moved up to 1 mm 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 1 mm 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 (152)): based on the distance from the highest curvature of the marginal buccal gingiva to the contact point of the extruded 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 it 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 an optimal soft tissue contour.
 - 4 The papilla is hyperplastic and covers too much of the extruded or adjacent tooth. The soft tissue contour is more or less irregular.
- Gingival index (Silness & Loe index, (153)): the scores of the 4 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 colour, 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 to 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 (Planmeca ProMax 3D Classic, Helsinki, Finland) set at 8.0 mA and 84 kV, with a 12-second exposure time and the smallest possible field of view (8 x 8 cm) were taken to assess root anatomy as well as the following radiographic parameters:

- Pre-operative periapical lesion, recorded dichotomously as present or absent, judged from the periapical radiography.
- Crown-root ratio: measured on the periapical radiograph, and scored as follows:
 - Good: crown-root ratio < 1.
 - Just: crown-root ratio = 1.
 - Unfavourable: 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.

During the same appointment, each patient received hygiene treatment using an ultrasonic scaler (Satelec, P5 Newtron, Acteon, France).

4.3.2. Surgical extrusion

The secondary investigator (ML) performed all 13 surgical extrusions (2 maxillary incisors, 2 maxillary canines, 3 maxillary premolars, and 6 mandibular premolars). In all cases, the surgery followed the modified technique described by Kahnberg in 1996 (132), as follows: under local anesthesia and after having removed the caries lesion, each tooth was carefully luxated with thin elevators (L2S and L31C, Directa, Sweden), placed no more than 1 mm within the gingival margin to avoid damaging the cervical periodontal ligament (PDL) cells. Subsequently, teeth were positioned coronally using thin forceps (ASH No. 1, 13, 113, and 137, Dentsply Sirona, Ballaigues, Switzerland) with gentle movements to obtain a minimum of 4 mm of supracrestal tooth structure. A periapical radiograph (Kodak RVG 6100; Carestream Health, Rochester, NY) was taken to ensure the final position of the tooth, prior to fixing. Based on the immediate stabilization, 10 teeth were splinted for 4 and 3 teeth for 6 weeks with a semi-rigid retainer (Ortho Flex Tech, Reliance Orthodontic Products, Itasca, Illinois) attached to both adjacent teeth, as follows: teeth were etched using 37% phosphoric acid (Total etch, Ivoclar Vivadent; Schaan, Liechtenstein) for 30 seconds and rinsed with water. Adhesive was applied to the conditioned surface of the 3 teeth according to the manufacturer's instructions (Adhese Universal, Ivoclar Vivadent, Schaan, Liechtenstein) and photopolymerized for 40 seconds for each tooth. Finally, flowable composite (SDR, Dentsply Caulk, Milford, DE)

was applied and photopolymerized for 40 seconds for each tooth. Post-surgery, the patients were prescribed analgesics (600 mg Ibuprofen every 8 hours for 3 days) and antibiotics (500 mg Amoxicillin every 8 hours for 1 week) (154), and instructed to rinse daily with 0.12% chlorhexidine (Perio Aid Tratamiento[®], Dentaïd, Cerdanyola del Vallés, Spain) and follow a soft diet for 2 weeks.

4.3.3. Endodontic therapy

Root canal treatments/retreatments were completed in a single visit by students of the European Master of Endodontics (UIC). Following the same protocol, these treatments were performed 1 month after the surgery in order to have enough exposed coronal structure to allow proper isolation with a rubber dam. However, in two cases, the root canal retreatment was performed before the extrusion due to the risk of fracture during the surgery as result of a shortage of remaining tooth structure. Before beginning, the number and location of the root canals were checked in the CBCT. Under local anesthesia and rubber dam isolation, access cavities were prepared with turbine diamond round burs (801 010-012, Komet, Brasseler, Germany) and/or contra-angle tungsten carbide round burs (H1 010-016, Komet, Brasseler, Germany). In those 3 teeth in which the retainer was maintained during 6 weeks, the clamp was placed over the stabilized tooth for the proper placement of the rubber dam, in order to avoid removing the wire. Once the pulp chambers had been debrided and the root canals located, working lengths were estimated using an apex locator (Root Z, Morita, Irvine, CA, USA). A glide path was created in all teeth with a 15 K-file (Dentsply-Maillefer; Ballaigues, Switzerland), and rotary files (Reciproc Blue, VDW GmbH, Munich, Germany) were used in a reciprocating movement following the recommendations of the manufacturer. In case of root canal retreatments, the same file system was used to remove the gutta-percha of the previous canal treatment. Recapitulation with a 10 K-file followed by irrigation with 5% NaOCl (Dentaflux, Madrid, Spain) was repeated until the rotary file reached the working length. The final irrigation was completed with 5 mL of 17% EDTA (Dentaflux, Madrid, Spain) for 1 minute, followed by 5 mL of 5% NaOCl (Dentaflux). After apical gauging with rotary files (Profile, Dentsply-Maillefer; Ballaigues, Switzerland), the canals were dried using paper points (VDW GmbH, Munich, Germany) and filled using the vertical technique of warm gutta-percha (Autofit, SybronEndo, Glendora, CA, USA) and resin-based sealer (AhPlus, Dentsply, DeTrey, Konstanz, Germany).

4.3.4. Restorative treatment

In accordance with Meyenberg (34) and Ferrari et al. (45), fibre glass-reinforced epoxy posts (Exacto, Angelus, Londrina, PR, Brazil) were placed in all teeth, since there were less than 2 walls or 50% of the coronal structure, following the same adhesion protocol: a length equal to 3/4 of the root canal length or at least equal to the length of the crown was calculated (155) by checking the post-operative periapical radiograph. The post was selected using the post template (Exacto 0.5 - 3), based on the root canal dimensions. The post space was created using the corresponding drill (Drill 0.5 – 3, Londrina, PR, Brazil) of the previously selected post. According to the manufacturer, a periapical radiograph was taken to check the post fitting before its conditioning. Each post was cleaned with alcohol, dried with air, and silane (Silano Angelus, Londrina, PR, Brazil) was applied and allowed to dry for 1 minute. Meanwhile, each root canal was conditioned using 37% phosphoric acid (Total etch, Ivoclar Vivadent; Schaan, Liechtenstein) for 15 seconds, washed with copious water and dried with paper points. Primer (Fusion-Duralink, Angelus, Londrina, PR, Brazil) was applied into the root canal, and 1 minute later adhesive (Fusion-Duralink Catalyst, Angelus, Londrina, PR, Brazil) was applied to both root canal and post. The post was embedded with a resin-based cement (Variolink, Ivoclar Vivadent, Schaan, Liechtenstein), introduced into the root canal, and light-cured. Finally, a composite build-up (SDR, Dentsply Caulk, Milford, DE) was reconstructed over the extruded tooth.

4.3.5. Temporary phase

Once reconstructed, the supracrestal tissue attachment of each tooth was left to mature and re-establish itself for 2 months (101, 156). During this period, each tooth was restored with a temporary prosthesis by the residents of the Master's Degree in Aesthetic Restorative Dentistry (MORE, UIC), fabricated from either a diagnostic wax-up or the previous crown of the patient, and designed with a supragingival margin (at least 1 mm from the gingival margin) to respect the healing of the periodontal tissues (101). All provisionals were made of bis-acryl resin (Integrity; Dentsply Sirona, Ballaigues, Switzerland) and cemented with a temporary cement (Temp-Bond™; Kerr, Orange, CA, USA) applied with a micro brush.

4.3.6. Permanent restoration

Three months after the surgical extrusion, the residents of the Master's Degree in Aesthetic Restorative Dentistry (MORE, UIC) prepared 12 teeth for single crowns with turbine diamond cylinder/tapered burs (6836KR, 8847KR, Komet, Brasseler, Germany).

One tooth was used as a bridge abutment made of the same material (IPS e.max CAD, Ivoclar Vivadent) and prepared with the same burs (Komet, Brasseler, Germany). In all teeth, a horizontal supragingival margin was prepared. However, in some cases the prepared margin was very near to the gingival sulcus, especially in interproximal areas. For this reason, before taking the impressions, the gingival sulcus was displaced using the two-cord retraction technique (Sizes 000 - 1, KnitTrax Cord Pascal International).

Subsequently, the double-mix impression technique with light- and heavy-body polyvinyl siloxane silicones (Extrude, Kerr Dental, Orange, CA) was used in all cases. Impressions of the opposite arch were taken with alginate (Alginoplast, Heraeus Kulzer, Hanau, Germany), and a self-polymerizing A-silicone (Occlufast, Zhermack, BadiaPolesine, Italy) was used for the interocclusal record. A plaster cast model (Super Rock Ex, Kuraray-Noritake Dental, Tokyo, Japan) of each impression was obtained according to the manufacturer's recommendations and subsequently digitized with a laboratory optical scanner (Trios, 3Shape, Copenhagen, Denmark). All the digital impressions were sent to the laboratory for computer-aided design / computer-assisted manufacture (CAD/CAM) fabrication of all the restorations using lithium disilicate blocks (IPS emax CAD, Ivoclar Vivadent, Schaan, Liechtenstein).

Under rubber dam isolation, each restoration was checked for fitting and cemented following the same adhesion protocol: composite build-ups were sandblasted with 30 µm silica-coated Al₂O₃ powder (Rocatec Soft, 3M ESPE, St. Paul, MN). Even teeth were extruded, some of them still presented enamel remains, especially over the buccal and/or palatal surfaces, as a result of the supragingival preparation. In those teeth, 37% phosphoric acid (Total etch, Ivoclar Vivadent; Schaan, Liechtenstein) was applied along the remnants of enamel for 15 seconds, followed by 15 seconds on the dentin. The tooth surface was washed copiously with water, gently airdried without desiccation, and silanized (Monobond Plus, Ivoclar Vivadent; Schaan, Liechtenstein) with a microbrush. Meanwhile, the inner part of each restoration was conditioned with 5 % hydrofluoric acid (49) for 20 seconds, and washed copiously with distilled water. Silane (Monobond Plus, Ivoclar Vivadent; Schaan, Liechtenstein) was applied for 20 seconds and then dried, and adhesive (Heliobond, Ivoclar Vivadent, Schaan, Liechtenstein) was applied to both restorations and tooth surfaces without photopolymerization. Resin cement (Multilink Automix System, Ivoclar Vivadent, Schaan, Liechtenstein) was used for the definitive cementation, followed by 1 second-photopolymerization of both the buccal and lingual/palatal aspect of the tooth. After removing the excesses of cement with an exploratory probe (Hu-Friedy, Chicago, IL, USA) and dental floss (Colgate-Palmolive Company, NewYork, NY), glycerin (Reverse, Nissin Dental Products Incorporated,

Kyoto, Japan) was applied/coated along the restoration margins for the final photopolymerization of 40 seconds per tooth aspect. Where needed, interfaces for tooth – restoration were polished with fine grit diamond burs (ZR8850, Komet, Brasseler, Germany) and repolished using a polishing kit for ceramic (Dialite Polishing Kit, Komet, Brasseler, Germany). Finally, the occlusion was checked with a 40- μ m articulating paper (Bausch Articulating Papers, Nashua, NH) in all cases and adjusted if needed.

4.3.7. Post-surgical assessment

Patients were recalled at 3- and 6-months post-surgery for a radiographic control, in which periapical radiographs and bitewings were taken. Also, a clinical examination was performed by the secondary researcher (ML), which included percussion, palpation and mobility test in each extruded tooth. Due to restrictions related to Covid-19 throughout Catalonia (Spain), 4 and 8 cases could not be examined at 3- and 6-months follow-up, respectively. At 12 months post-surgery, a second cast model was taken in all patients for the post-operative digital scanning, following the same procedures as for the pre-operative model. Additionally, a satisfaction questionnaire was given to each patient, and the following clinical and radiographic parameters were recorded:

A. Clinical parameters

- Percussion.
- Palpation.
- Gingival index.
- Bleeding on probing.
- Periodontal probing depths.
- Tooth mobility.
- Gingival papillae shape and height.
- Soft tissue rebound: measured in mm by superposing both pre-operative and post-operative scanned models of each patient using surgical planning software.

B. Radiographic parameters

- Periapical healing (Molven classification (157)): based on any radiolucency surrounding the apical third of the root, as follows:
 - Complete: Re-establishment 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 was irregular and might be demarcated by a compact bony margin; the radiolucency was 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 (failure): Increase or maintenance of the size of the lesion.
- Root resorption (158): based on the aspect of the 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 observed all along the external root surface of the dentin.
 - Replacement resorption: resorption lacunae filled with bone and the PDL space was missing.
- Crown-root ratio.
- Marginal bone loss.

C. Patient-related outcome

Each patient filled in a questionnaire based on a 10-cm VAS (visual analogue scale) to assess their degree of satisfaction regarding the surgical procedure, the tooth function, and the aesthetic outcome of both crown and gum of the extruded tooth; a score of 0 indicated complete satisfaction while 10 was entirely unsatisfactory.

Sobre el tratamiento / *About the treatment:*

1. ¿Te acuerdas de la cirugía?
- Do you remember the surgery?*

Muy bien / *Very well*Para nada / *No at all*

2. ¿Notó dolorosa la cirugía?
- Did you feel pain or discomfort during the surgery?*

Si / *Yes*Para nada / *No at all*

3. ¿La decisión de realizar la extrusión fue fácil o difícil para usted?

*Was the decision to undergo surgery easy or difficult for you?*Difícil / *Difficult*Fácil / *Easy*Sobre el resultado / *About the result*

1. ¿Podría decirme cuál es el diente extruido?
- Do you know today which is the extruded tooth?*

Lo sé perfectamente / *Know for sure*No lo sé / *Do not know*

2. ¿Cómo percibe el diente extruido en comparación al resto de dientes?

*How do you perceive the extruded tooth in comparison with your other teeth?*Completamente diferente /
*Completely different*Igual que el resto /
The same as the others

3. ¿Le supone un esfuerzo extra mantener el diente extruido en comparación al resto?

*What effort does it take to maintain the extruded tooth in comparison with your other teeth?*Un esfuerzo extra /
*Takes an extra effort*Igual que el resto /
The same as the others

4. ¿Está satisfecho/a con el resultado estético?
- Are you satisfied with the aesthetic result?*

Insatisfecho / *Dissatisfied*Muy satisfecho / *Very satisfied*

Figure 1. Questionnaire filled in by each patient

4.4. Digital scan processing and digital analysis

Digital analysis was based on an optical three-dimensional (3D) measurement technique adapted from Rebele et al. (142). To this end, a laboratory optical scanner (Trios, 3Shape, Copenhagen, Denmark) was used to digitize the plaster study models of the pre-operative and post-operative surgically treated sites.

The acquired data were exported in surface tessellation language (STL) file format and imported into digital imaging and computer-aided design software (Exocad; exocad GmbH, Darmstadt, Germany). Baseline and corresponding follow-up scans of each clinical case were aligned and superimposed using a best-fit algorithm based on stable reference areas.

STR was measured in a cross section at the central buccal site, taking baseline and follow-up gingival margin position as landmarks. Direct measurements were discarded to avoid biased data, since significant changes also occurred horizontally due to restorative profile modifications. Therefore, a prior manoeuvre was executed consisting of the projection of the most coronal point of the gingival margin, either preoperative or postoperative, over the alternative scan mesh. Projection was performed following a perpendicular vector to the tooth longitudinal axis. This in turn resulted in a newly created horizontally unbiased vertical measurement landmark.

STR was recorded to the nearest 0.01 mm. Positive values indicate gingival margin coronal migration, negative values denote an increase of gingival recession.

4.5. Assessment of success

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 $> 25\%$.

4.6. Statistical analysis

Statistical analysis consists of a general *descriptive analysis* for ordinal and categorical variables by means of absolute and relative frequencies. All the variables were analysed

using a descriptive method (mean, %). Quantitative variables were described using mean, standard deviation, range and median.

The *inferential analysis* included (SPSS 15.0. Chicago, IL):

- *95% confidence interval of median*, in order to conclude about the presence of rebound.
- *Wilcoxon's test*, to assess if there were changes of clinical parameters from T0 to T1. This test checks the homogeneity of distributions of variables, at least ordinal, in dependent samples (T0 vs. T1).
- *Mann-Whitney's test*, to study if STR values depend on some independent two-level factors. For more than 2 levels, the generalization to *Kruskal-Wallis's test* was used.
- Estimation of *Spearman's non-linear correlation coefficient*, to assess the degree of association between STR and variables measured at continuous-ordinal scale.
- Binomial test was used to assess if the incidence rate of any clinical alteration at T1 could be considered 50%.

The reference *level of significance* was set up to 5% ($\alpha=0.05$).

The Wilcoxon's test, under 95% confidence level and assuming an effect size $d=0.8$ (large), provides power at 73% for within-subjects contrast (changes over time).

A one-side test about the nullity of the Spearman's correlation reached power 57% to detect $r=0.5$ (moderate) as significant.

The data contained in the follow-ups were entered into a database (Excel, Microsoft Corporation) for analysis and preparation of the final result.

Radiographic assessment of marginal bone loss, apical healing, and the final crown-root ratio was performed by three calibrated specialists in endodontics (examiner 1), periodontics (examiner 2), and prosthodontics (examiner 3). The Kappa index was calculated to assess inter- and intra-examiner reliability, with the corresponding 95% confidence interval based on the jackknife method. Its interpretation was based on the Landis-Koch's criteria. For variables measured at ordinal-scale with more than two possible categories, a linearly weighted Kappa's index was computed. Any disagreement between assessors was resolved by discussion until agreement was reached.

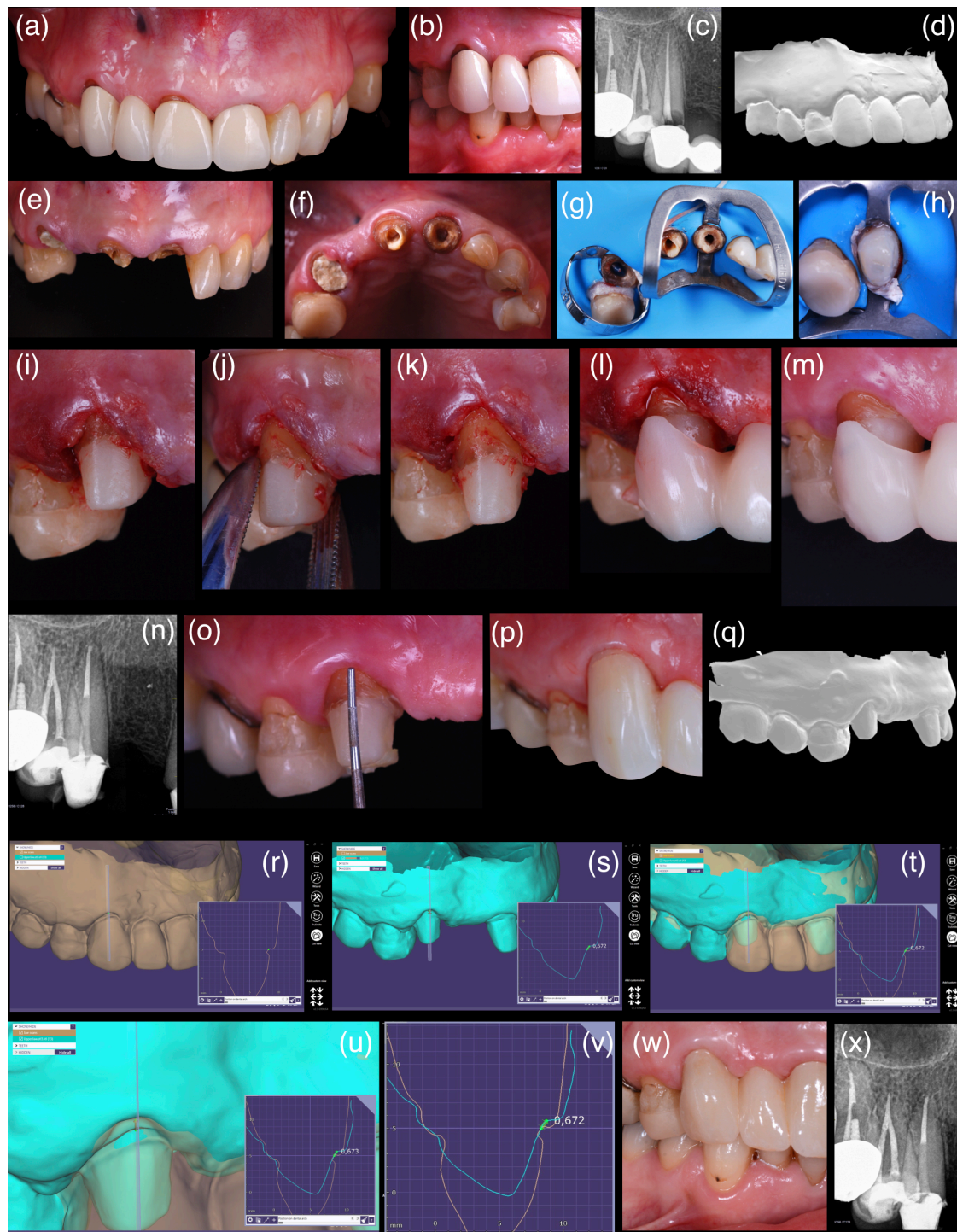


Figure 2. Treatment sequence of surgical extrusion, restoration and digital analysis of STR of an upper right canine: Treatment sequence of surgical extrusion, restoration and digital analysis of STR of an upper right canine: (a, b) Initial clinical situation. (b) Pre-operative periapical radiograph showing the extension of the caries under the bridge. (d) STL of the upper arch obtained from the pre-operative digital scan. (e, f) Frontal and occlusal views of the bridge abutments. (g, h) Non-surgical retreatment, post placement and build-up restoration of the abutments. (i - k) Surgical extrusion of the canine due to the absence of ferrule. (l) Provisionalization of the extruded tooth, ensuring an ability to clean the cervical soft tissues. (m - o) Clinical and radiographic 1-month control showing 2 mm additional ferrule compared with the pre-operative situation. (p) 1-year control showing the soft tissue stability of the provisionalised tooth. (q) STL of the upper arch from the post-operative digital scan. (r - v) Digital analysis by superimposition of both pre- and post-operative STLs for the STR assessment. (w, x) 14-month clinical and radiographic control of the extruded tooth restored with the definitive bridge.

RESULTS

5. Results

5.1. Results of demographic characteristics of patients

A summary of the participants' gender, age, extruded tooth, gingival phenotype, and follow-up is presented in Table 1. The sample consisted of 13 patients (11 female and 2 male, average age at the time of extrusion 23 –51 years, median age 39.7 ± 7.8 years). Two patients (15.38%) presented a thin phenotype, 6 (46.15%) presented an intermediate phenotype, while 5 (38.46%) presented a thick phenotype. From a total of 13 extruded teeth, 2 were maxillary incisors, 2 were maxillary canines, 3 were maxillary premolars, and 6 were mandibular premolars. The mean follow-up period was 18.8 months, with a range of 12 - 24 months (Table 1).

Table 1. Demographic characteristics of patients

	Age (years)	Gender	Extruded tooth	Gingival phenotype	Follow-up (months)
1	34	Female	15	Intermediate	14
2	42	Female	35	Thick	17
3	23	Female	23	Intermediate	21
4	39	Female	45	Thin	24
5	42	Female	11	Thin	18
6	49	Female	45	Intermediate	21
7	37	Female	35	Intermediate	12
8	30	Female	25	Thick	17
9	51	Female	15	Thick	21
10	36	Male	13	Intermediate	23
11	47	Female	45	Thick	24
12	43	Male	35	Intermediate	18
13	43	Female	22	Thick	15

5.2. Overall survival and success rate

The survival rate was 100%, because no teeth were extracted during the follow-up. Twelve surgically extruded teeth fulfilled the success criteria, for a 92.3 % success rate after one year.

5.3. Soft tissue rebound

Results from pre- and post-operative model scan superposition revealed a mean STR of -0.46 ± 0.69 mm (maximum value = 0.79 mm, minimum value = - 1.53 mm, median = - 0.56 mm) (Table 2). Figure 3 shows the complete distribution of STR values, showing that 76.9 % of cases (n = 10 cases) presented a gingival recession, while 23.1 % (n= 3) presented a gingival rebound. However, a statistically significant STR from the baseline situation was not found.

Table 2. STR values (mm)

STR	mm
N	13
Mean	-.46
Standard Deviation	.69
Minimum	-1.53
Maximum	.79
Median	-.56

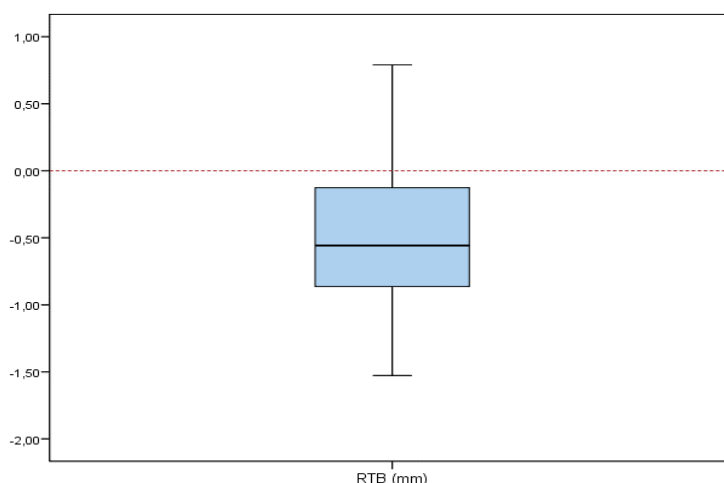


Figure 3. Distribution of STR values

A Mann-Whitney (MW) test and a nonlinear Spearman correlation coefficient r test were employed to find the statistical association between STR and the other independent variables (Table 3). No variables were found to influence STR.

Table 3. Statistic association between STR and other independent variables

	r	p-value
Follow-up	0.36	0.257
Age	0.20	0.529
Gender		0.182 (MW)
Phenotype	0.36	0.254
Arch		0.876 (MW)
Previous apical lesion		0.368 (MW)
BOP T0	0.23	0.468
PPD T0	0.32	0.315
IG T0	0.36	0.252
JEMPT mesial T0	0.12	0.711
JEMPT distal T0	-0.24	0.453

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

5.4. Results of clinical variables

5.4.1. Gingival index

Mean pre- (T0) and post-operative (T1) GI scores were distributed as follows (Table 4 and Figure 4): score 0: 15.4 %, score 1: 30.8 %, and score 2: 53.8 %. After 1 year, mean post-operative (T1) GI scores were: score 0: 38.5 %, mean score 1: 53.8 %, and mean

score 2: 7.7 %. A statistically significant reduction ($p = 0.014$) of GI was observed between pre- and post-operative situations.

Table 4. Distribution of mean pre- (T0) and post-operative (T1) GI scores

GI		N	%
GI T0	Total	13	100.0
	0	2	15.4
	1	4	30.8
	2	7	53.8
GI T1	Total	13	100.0
	0	5	38.5
	1	7	53.8
	2	1	7.7

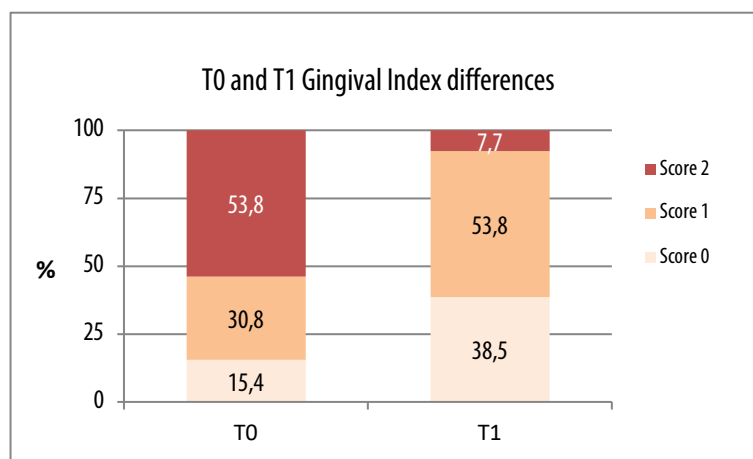


Figure 4. Distribution of mean pre- (T0) and post-operative (T1) GI scores

5.4.2. Bleeding on probing

Table 5 and Figure 5 summarize the results of bleeding on probing (BOP) at 6 sites of each extruded teeth before (T0) and 1 year after the extrusion (T1), respectively. In 4 sites of the teeth the BOP was reduced to 0 %, and in the other 2 sites a substantial BOP reduction is observed (from 30.8 % to 15.4 % and from 15.4 % to 7.7 %). Mean BOP was significantly reduced from the pre-operative situation (T0 = 19 %), compared with 1 year after the surgery (T1 = 4 %) ($p=0.016$).

Table 5. Differences between pre- (T0) and post-operative (T1) BOP values

N	13
Mean	-.15
Standard Deviation	.20
Minimum	-.67
Maximum	.00
Median	-.17

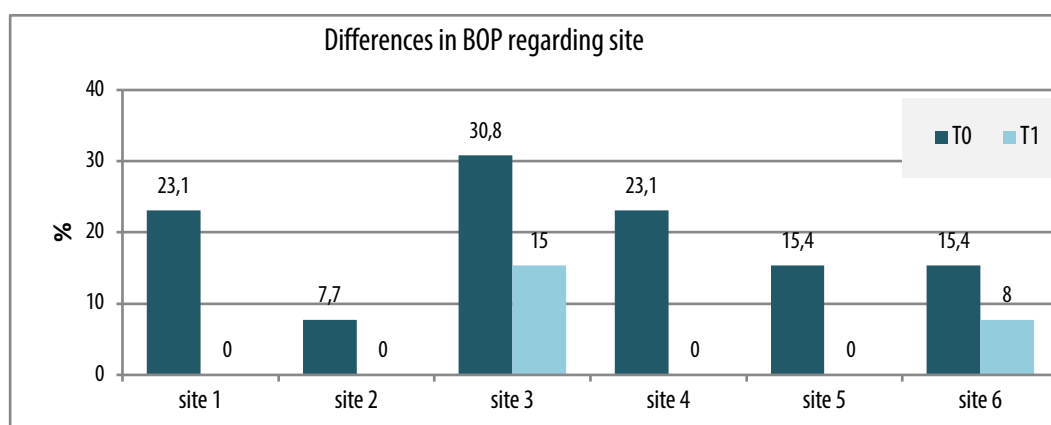


Figure 5. Differences between pre- (T0) and post-operative (T1) BOP values regarding site

5.4.3. Periodontal probing depths

Tables 6 and 7 show mean, standard deviation, minimum, maximum, and median pre- (T0) and post-operative (T1) values of PPD. Pre-operative mean PPD values range from 2.23 – 3 mm, while post-operative mean PPD range from 2.23 – 2.85 mm. PPD was slightly shallower 1 year after the extrusion, but statistical differences were not observed (Fig. 4).

Table 6. Pre-operative (T0) PPD (mm) values

PPDs T0	N	Mean	Standard Deviation	Minimum	Maximum	Median
PPD1 T0	13	3.00	.91	2.00	5.00	3.00
PPD2 T0	13	2.08	.76	1.00	4.00	2.00
PPD3 T0	13	2.77	1.30	1.00	5.00	3.00
PPD4 T0	13	2.69	.85	1.00	4.00	3.00
PPD5 T0	13	2.23	1.24	1.00	4.00	2.00
PPD6 T0	13	2.85	.99	2.00	5.00	3.00
PPD T0	13	2.60	.60	2.00	3.83	2.33

Table 7. Post-operative (T1) PPD (mm) values

PDs T1	N	Mean	Standard Deviation	Minimum	Maximum	Median
PPD1 T1	13	2.85	.80	2.00	4.00	3.00
PPD2 T1	13	2.23	.73	1.00	3.00	2.00
PPD3 T1	13	2.69	1.25	1.00	5.00	3.00
PPD4 T1	13	2.69	.75	1.00	4.00	3.00
PPD5 T1	13	2.54	.66	1.00	3.00	3.00
PPD6 T1	13	2.77	.83	2.00	4.00	3.00
PPD T1	13	2.63	.40	2.00	3.33	2.67

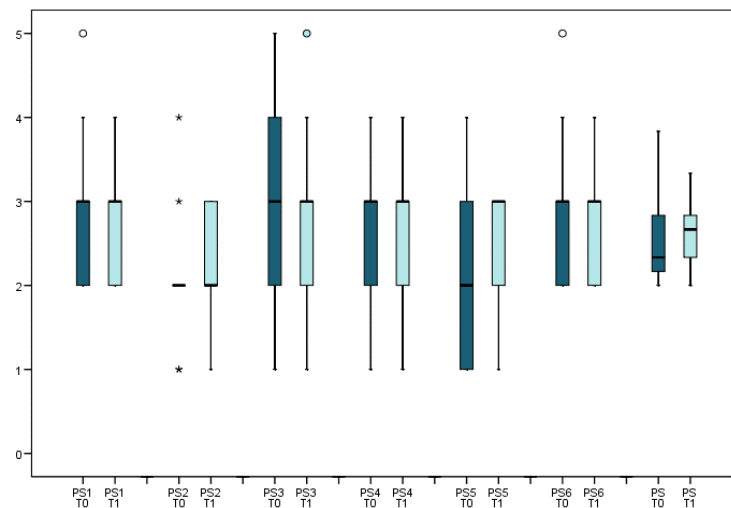


Figure 6. Distribution of pre-operative (T0) and post-operative (T1) PPD (mm) values for different sites

Table 8. Pre- (T0) and post-operative (T1) PPD (mm) value differences grouped by site

DIF. PDs T0-T1	N	Mean	Standard Deviation	Minimum	Maximum	Median
PPD1	13	-.15	.55	-1.00	1.00	,00
PPD2	13	.15	.69	-1.00	1.00	,00
PPD3	13	-.08	.86	-2.00	1.00	,00
PPD4	13	.00	.41	-1.00	1.00	,00
PPD5	13	.31	1.44	-2.00	2.00	,00
PPD6	13	-.08	.86	-1.00	2.00	,00
OVERALL PPD	13	.03	.37	-.67	.50	,17

5.4.4. Mobility

All teeth presented mobility < 1 before the surgical extrusion (T0). After 1 year (T1), no teeth presented mobility > 1 except for 1 case, which presented a type 2.

5.4.5. Jemt index

Tables 9 and 10 show respectively the pre- (T0) and post-operative (T1) distribution (%) of the mesial and distal interproximal papillae values according to the Jemt score. A general interproximal papillae height loss was observed. Only 1 mesial and 1 distal papilla showed increased scores (from 2 to 3 and from 1 to 2, respectively), while 46.15 % (6/13) of the mesial papillae remained stable in height, and 46.15 % (6/13) decreased in score. In relation to distal papillae, 5 out of 13 papillae lost height (38.46 %) and 8 cases retained height (61.53 %), as shown in Figure 7.

Table 9. Pre-operative (T0) distribution (%) of the mesial and distal Jemt scores

JEMPT		N	%
JEMT MESIAL T0	Total	13	100.0
	1	3	23.1
	2	6	46.2
	3	4	30.8
JEMT DISTAL T0	Total	13	100.0
	1	6	46.2
	2	6	46.2
	3	1	7.7

Table 10. Post-operative (T1) distribution (%) of the mesial and distal Jemt scores

		N	%
JEMT MESIAL T1	Total	13	100.0
	1	5	38.5
	2	7	53.8
	3	1	7.7
JEMT DISTAL T1	Total	13	100.0
	1	8	61.5
	2	5	38.5

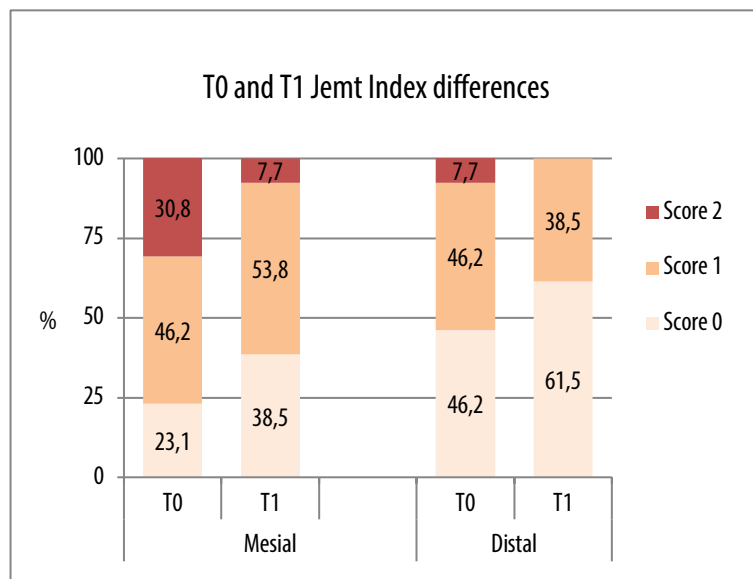


Figure 7. Differences between pre-operative (T0) and post-operative (T1) Jemt scores in mesial and distal papillae

5.5. Results of radiographic variables

Cohen kappa analysis of inter-observer reliability showed values of 0.67 (good), 0.58 (moderate), 1 (perfect), and 0.68 (moderate) for the evaluation of crown-root ratio, periapical healing, root resorption, and marginal bone loss, respectively, revealing a moderate-to-good reliability among the 3 examiners.

Table 11. Inter-observer reliability

	Kappa	IC95 %	Reliability
Crown-root ratio	0.67	0.36 – 0.98	Good
Periapical healing	0.58	0.23 – 0.94	Moderate
Root resorption	1.00	1.00 – 1.00	Perfect
Marginal bone loss	0.48	-0.30 – 1.24	Moderate

*p<0.05; **p<0.01; ***p<0.001

For examiner 1, Cohen kappa analysis of intra-observer reliability showed values of perfect for the evaluation of crown-root ratio, periapical healing, root resorption, and marginal bone loss.

Table 12. Intra-examiner concordance of examiner 1: level of agreement (%), Kappa's index, 95% confidence interval and qualitative interpretation

	%	Kappa	IC95%	Reliability
Crown-root ratio	100	1.00	1.00 – 1.00	Perfect
Periapical healing	100	1.00	1.00 – 1.00	Perfect
Root resorption	100	1.00	1.00 – 1.00	Perfect
Marginal bone loss	100	1.00	1.00 – 1.00	Perfect

*p<0,05; **p<0,01; ***p<0,001

For examiner 2, Cohen kappa analysis of intra-observer reliability showed values of good (0.65), perfect (1.00), good (0.79), and good (0.60) for the evaluation of crown-root ratio, periapical healing, root resorption, and marginal bone loss, respectively.

Table 13. Intra-examiner concordance of examiner 2: level of agreement (%), Kappa's index, 95% confidence interval and qualitative interpretation

	%	Kappa	IC95%	Interpretación
Crown-root ratio	76.9	0.65	0.31 – 1.00	Good
Periapical healing	100	1.00	1.00 – 1.00	Perfect
Root resorption	84.6	0.79	0.51 – 1.00	Good
Marginal bone loss	76.9	0.60	0.25 – 0.95	Good

*p<0,05; **p<0,01; ***p<0,001

For examiner 3, Cohen kappa analysis of intra-observer reliability showed values of good (0.68), perfect (1.00), good (0.60), and moderate (0.58) for the evaluation of crown-root ratio, periapical healing, root resorption, and marginal bone loss, respectively.

Table 14. Intra-examiner concordance of examiner 3: level of agreement (%), Kappa's index, 95% confidence interval and qualitative interpretation

	%	Kappa	IC95%	Interpretación
Crown-root ratio	76.9	0.68	0.33 – 1.00	Good
Periapical healing	100	1.00	1.00 – 1.00	Perfect
Root resorption	76.9	0.60	0.25 – 0.95	Good
Marginal bone loss	84.6	0.58	0.10 – 1.00	Moderate

*p<0,05; **p<0,01; ***p<0,001

5.5.1. Periapical lesion healing

Pre-operative radiographic examination revealed apical lesion in 4 cases, which appeared as completely healed in the periapical radiographs obtained in the last follow-up.

5.5.2. Root resorption

No root resorptions were observed in any tooth in the last follow-up.

5.5.3. Crown-root ratio

Tooth crown-root ratio was favourable (< 1) in all cases before the extrusion, while in 3 cases (15.4 %) it became just ($1 = 1$) in the last follow-up.

5.5.4. Marginal bone loss

Out of 13 cases, only 1 case presented > 25 % of marginal bone loss during the follow-up period, which was considered a failure.

5.6. Results of patient satisfaction

Figure 8 shows the questionnaire on the pain perception, and functional and aesthetic outcome, filled in by each patient during the last follow-up, using the 10-cm VAS. Table 12 shows the answer values for each question given by each patient. Figure 9 shows the distribution of the answer values (0 to 10) from the VAS, grouped by questions (Q). With regard to intra-surgical pain or discomfort, all patients recalled the surgery (Q1), but 3 remembered it as a painful experience with scores 1.3/10, 2.4/10, and 3.5/10 (Q2). Only 2 patients had doubts about whether to undergo the procedure, considering the option of the dental implant (Q3). All but 2 patients could exactly recognize the extruded tooth (Q4). Twelve patients (92.3 %) perceived the extruded tooth identically to the others (Q5) and only 3 patients (23 %) had to take special hygienic care of the extruded tooth (Q6). Twelve patients exhibited satisfaction with the final aesthetic result of the extruded tooth (Q7).

Table 15. Results of answer values of the questionnaires filled in by each patient

Patient	Questions						
	About the treatment			About the result			
	1	2	3	4	5	6	7
1	0	1.3	10	0	10	10	9.8
2	0.5	2.4	6.5	0	10	9.8	7.8
3	0	7.7	7.1	0	10	9.9	9.5
4	0	4.7	9	3.2	10	10	9.3
5	0	7.8	7.6	0	9.9	10	8.1
6	0	8.7	0	0	10	4.1	10
7	0.8	7.6	7	0	10	2.9	10
8	0	10	10	0	10	10	9.9
9	0	3.5	4.4	4.4	10	10	5
10	0	9	8.7	0	10	9.7	8.6
11	0.4	10	8.1	0	6.8	2.2	10
12	0	9.8	10	0	10	10	10
13	0	10	0.2	0	10	10	10

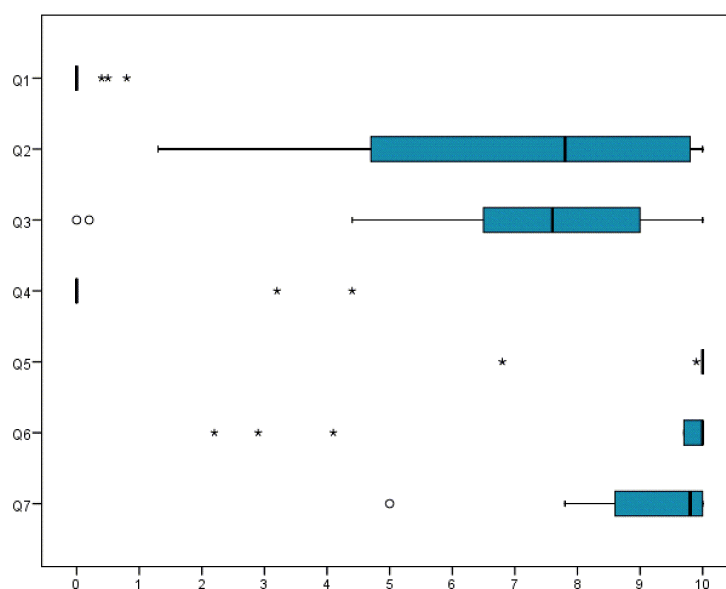


Figure 8. Distribution of answer values (0 to 10) from the VAS, grouped by questions (Q)

DISCUSSION

6. Discussion

Surgical extrusion allows the restoration of structurally compromised teeth by obtaining an adequate supracrestal tooth structure in a single step (135). In contrast to Tegsjö's original technique (128), Kahnberg's modified technique entails the gentle luxation and repositioning of the tooth into a new coronal position using thin carvers and elevators (121). This simpler and less invasive approach minimizes post-operative complications related to both relieving incisions and bone exposure. For this reason, in this study we employed Kahnberg's modified technique, which has been demonstrated to be more highly predictable with fewer resorptions than the traditional approach (121, 131, 132).

During the first appointment, all patients received detailed information about the different treatment options for their teeth: surgical crown lengthening, orthodontic forced eruption, surgical extrusion, tooth extraction, and dental implant. Surgical crown lengthening was rejected by the patients in 4 cases, since the teeth were anterior. As stated by many authors, surgical crown lengthening for restorative purposes of a single anterior tooth can provoke disharmonious gingival margins or loss of interproximal papillae, and the subsequent result is unaesthetic (88, 103, 104). In contrast, surgical extrusion permits coronal tooth structure to be obtained in one tooth of the aesthetic zone, as shown by Krug et al. (159). Orthodontic forced eruption was also considered a viable treatment option for the remaining teeth (91, 95). However, none of the included patients was willing to wear orthodontics due to the longer treatment period and higher cost, compared with surgical extrusion. Recently, Casaponsa et al. (160) described the technique of orthodontic magnetic extrusion for the treatment of a severely compromised premolar. The treatment mainly involves the placement of one cylindrical silane-coated neodymium-iron-boron magnet on the affected tooth, and another on a resin-bonded fixed partial restoration of the same tooth. After 3 weeks, 4.5 mm of extrusions were provided, and after an additional stabilization period of 12 weeks with both magnets in contact, the tooth was restored. While this non-invasive approach overcomes the limitations of orthodontic appliances, it has some drawbacks: on the one hand, fiberotomy of supracrestal periodontal fibers and root planing must be performed

regularly, because coronal regrowth of soft tissues may be expected (111). Second, a period of 15 weeks (3 weeks of active extrusion and 12 of stabilization) is needed to extrude the tooth. In general, evidence in support of this technique is scarce (161-163).

The main objectives of the present investigation were to evaluate survival and success rates, and the STR of surgically extruded teeth after at least 1 year following treatment. To the best of our knowledge, this is the first prospective clinical study to assess outcome, periodontal healing, and volumetric changes of surgically extruded teeth at 12 months post-surgery.

Since Kahnberg first proposed the flapless, modified technique of surgical extrusion in the 1980s, rates of survival for this technique have been shown to be consistently high following several long-term follow-up studies (121, 131, 132, 164). In a retrospective 10-year follow-up study of surgical extrusion, Kahnberg showed that in only 1 out of 21 teeth had to be extracted (8 years later), due to an invasive cervical resorption, resulting in a 98.8 % survival rate (132). Similar results were shown by the same author in a 2-year follow-up study, in which surgical extrusion was performed in 23 crown-root fractured teeth and no tooth was extracted during the follow-up period (131). The aforementioned survival rates are consistent with those reported by several authors. A clinical review of this technique by Calışkan et al. showed 1 extraction out of 20 cases (95 % survival rate), coinciding with Elkhadem et al., who found a tooth loss rate of 5 % (94). Pham et al. observed a 100 % survival rate after 6 months of surgical extrusion in anterior teeth (133), which is the same as that obtained in the present investigation (100 %).

The second main objective of this study was success rate. While survival rates of surgical extrusion have been widely and consistently reported (tooth retained or tooth loss), success rate has been scarcely and unclearly defined in the literature (128, 165). No studies have reported accurate success rates (%) of surgical extrusion. One possible reason could be a lack of evidence to define a precise success criterion for surgical extrusion. In the present study, success was defined based on the following clinical and radiographic parameters: asymptomatic, functional tooth with physiological mobility and a crown-root ratio < 1 , periodontal pockets ≤ 4 mm, and with no signs of apical lesion, root resorption or marginal bone loss > 25 %. These success criteria were adapted from both Lucas-Taulé et al. (166) and Czochrowska et al., in which survival and success rates of autotransplanted teeth were evaluated 17-41 years post-treatment (167). In this article, the success criteria included: “(1) the absence of progressive root resorption, (2) normal hard and soft periodontal tissues adjacent to the transplanted tooth, and (3) a crown-to-root ratio less than 1 (i.e., the suprabony part shorter than the intrabony part)” (167). In

the present investigation, a 92.3 % success rate was found, due to one tooth that presented a marginal bone loss > 25 % at the follow-up visit.

The third main objective of this investigation was to evaluate the STR of the single-rooted tooth at least 1 year after surgical extrusion. Various methods have been described in the literature to measure STR (86, 97-100, 102, 142). Pontoriero et al. calculated it by measuring the distance between a fixed reference point and the gingival margin using a periodontal probe. The authors prepared round notches or vertical grooves over the teeth or roots to standardize the probe position (97). Other authors fabricated customized probing stents from the patients' study cast models, in which vertical grooves were marked to ensure a fixed reference point for the periodontal probe (86, 88, 98, 100, 102, 168).

CAD/CAM technology has been introduced progressively into periodontics to improve treatment planning, diagnosis, and treatment (169-172). By means of an *in vitro* study, Windisch et al. compared the volume differences between specimens, imitating a pre-operative ridge defect and a corresponding surgically treated post-operative situation, assessed by software on a Cerec 3 (Sirona Dental Systems GmbH, 64625 Bensheim, Germany) machine. Differences between the test measurements and the control values did not exceed 1.5 %, revealing the high accuracy of this digital method for measuring volume differences. Moreover, very good reproducibility was demonstrated, with coefficients of variation from 0.05 – 0.5 % (173). Strebel et al. compared volumes of a thin composite resin layer applied on 9 dental interproximal papillae *in vivo*, in an effort to provide a reliable protocol to assess change in soft tissue under clinical conditions. Results from a CAD / CAM device were compared to micro computed tomography (μ -CT) analysis and a volume calculation using weight measurements with high-precision scales (control methods), and the results differed by only 7.5 % and 5.8 %, respectively. A high accuracy was shown both inter- and intra-examiners, allowing the clinical validity of the method to be confirmed (174).

Schneider et al. compared clinically the accuracy of 2 digital methods and 2 conventional ones for the measurement of gingival recession and papilla height. For digital methods, the authors used 3D optical scans to measure both intraoral virtual models and the patients' cast models, and for conventional methods they used a periodontal probe intraorally and on the patients' cast models. The conventional methods produced results with less agreement, while digital methods revealed the highest agreement (175). Similarly, Fageeh et al. compared the reproducibility of 4 different measurement methods for gingival recessions: conventional method with periodontal probe, conventional method on cast model using calliper, digital measurements of intraoral scans, and digital

measurements of digitized cast models. They observed a higher inter-examiner variability when conventional measurements were used, concluding that variations in measurements between examiners can be reduced using digital methods (141).

Lehmann et al. were the first to demonstrate *in vitro* highly reproducible measurements of volumetric changes in gingival recession by superimposing procedures with 3D optical scanning. This method showed small standard deviations and interclass correlation coefficients between 0.997 – 0.999 (176). Gonzalez-Martín et al. put this superposition method into practice through a randomized controlled trial, to compare the vertical position of the gingival margin of one- versus two-stage crown lengthening. Dental casts of each patient were fabricated and subsequently 3D-scanned at baseline and 6- and 12-months post-surgery. An STL file of each digital model was generated and superimposed to assess the STR between baseline and the follow-ups (177).

In the present investigation, a digital analysis of STR was used to assess the volumetric gingival changes of the extruded tooth, by superimposing both baseline and follow-up scanned models of each patient using surgical planning software. To the best of our knowledge, the present investigation is the first to analyse digitally the STR of the extruded tooth. The employed technique was adapted from Rebele et al., who evaluated volumetric changes in soft tissue between the baseline and the post-operative situation after surgical root coverage. Digital measurements were performed using an optical scan on study cast models of the surgically treated sites at both baseline and follow-up. The acquired data were saved as STL files for virtual superposition with digital imaging software. This process allowed the measurement of healing dynamics at 6 and 12 months (142). However, in the present study, 6-month healing could not be assessed in 7 patients, because they could not attend the follow-up visit due to problems related to Covid-19 restrictions throughout Catalonia (Spain).

Digital analysis showed apical soft tissue migration in 76.9 % of the teeth, which means that 10 teeth suffered gingival recession, while 3 presented gingival rebound. Despite this high recession rate, the overall mean STR was -0.46 ± 0.69 mm, revealing no significant changes one year post-surgery.

These data coincide with those reported by Pham et al. (133), who showed no significant gingival changes between baseline and 1, 3, or 6 months after the surgical extrusion. Compared to surgical crown lengthening, Dominguez et al. observed a significant STR 42, 90, and 180 days post-treatment, but only when the distance between the gingival margin and the alveolar bone at the time of suturing was ≤ 2 mm. Furthermore, Arora et al. (102) observed a mean STR of 0.77 ± 0.58 mm 6 months after treatment, revealing

a significant gingival regrowth. The authors also showed a significant increase in STR in patients who presented a thick-flat phenotype compared with those with a thin-scalloped phenotype. In the same vein, Pontoriero et al. found a significant STR (2.9 ± 0.6 mm) after 1 year of the surgical crown lengthening, which was more pronounced in patients with a thick phenotype (97). In the present study, a Mann-Whitney test revealed no significant correlation between STR and any other analysed variable, including the patient's phenotype, possibly due to the limited sample.

In contrast, Bragger et al. (88), Lanning et al. (100), and Gonzalez-Martín et al. (177), found no significant STR after 6 months, from 3 to 6 months, and from 6 to 12 months after surgical crown lengthening, respectively.

Among the different adverse healing events reported after surgical extrusion, root resorptions are the most common, mainly classified as: inflammatory root resorption, surface root resorption, replacement resorption (ankylosis), internal resorption, and invasive cervical resorption. Any root resorption begins after the damage of cementum or dentin as a result of odontoclastic action (158, 178, 179). If cementoblasts are able to repopulate the damaged surface, spontaneous healing will occur, giving rise to surface (transient) resorption (180). In the case of inflammatory root resorption, an inflammatory response is initiated over the PDL surface, leading to resorption of the root with a periodontal infiltrate of granulation tissue (181). If the previously damaged protective surface is the pre-dentin, internal resorption will occur (182). Furthermore, if the inflammatory resorption occurs immediately below the epithelial attachment of the tooth due to cementum loss at that level, an invasive cervical resorption will begin (183, 184). Otherwise, if osteoblasts are able to repopulate the uncovered external surface of the root, direct contact with bone will occur, resulting in a replacement resorption (158, 180).

In a systematic review of 243 teeth, Elkhadem et al. (94) showed that the most common adverse finding after surgical extrusion was surface (non-progressive) root resorption, accounting for 30 % of cases. In respect of inflammatory (progressive) root resorption, the authors found this in just 3.3 % of cases (94), while Ebeleseder et al. (185) and Kahnberg et al. (121), recorded rates of 73 % and 29.3 %, respectively. It should be noted that these studies involved surgical extrusion in teeth that had previously suffered traumatic injury. Any dental injury can provoke direct damage to both the PDL and the cementum layer, which varies according to the severity of the tooth luxation, as described by Trope (178). As mentioned previously, loss or alteration of this protective layer will trigger an inflammatory response that results in bone and root resorption (158). This could explain the high incidence of external root resorptions reported in these studies. Moreover, intrusive injuries make up a high proportion of cases in these studies, and

present the highest probability of unfavourable healing, since the entire root is pushed against the bone, causing damage to the whole root surface (178).

In the present investigation, no type of root resorption was observed, which can be explained by the following factors. On the one hand, in contrast to the aforementioned studies, no cases of dental trauma were included, and the indication for surgical extrusion included insufficient ferrule for proper tooth restoration, due to subgingival caries or failed crowns and bridges with pre-existing subgingival margins. On the other hand, the mean follow-up period in the present study was 18.8 months, which is less than in the studies of Tegsjö et al. (165) and Kahnberg et al. (121), which were 4 and 5.5 years, respectively. Although those authors did not specify when root resorptions were found, delayed root resorptions have been reported in studies of tooth autotransplantation (167).

Another possible reason for the absence of root resorptions is that all the surgeries were carried out by a single operator experienced in surgical extrusion. Despite the existence of clear data in studies of surgical extrusion, the authors strongly believe that this treatment is highly conditioned by the surgical skills and experience of the clinician of this technique. As stated before, any PDL damage has a direct impact on the appearance of root resorptions. Therefore, in order to prevent damage to the PDL of the coronal third of the root (which will become the cervical part of the tooth once it has been extruded), the forces applied to the tooth should be gentle and controlled. For this reason, it is recommended to avoid introducing both forceps and elevators beyond the cemento-enamel junction.

In this study, endodontic therapy of 2 teeth was performed before the surgical extrusion, and in 11 teeth it was performed 2 weeks after the surgery, which could also explain the absence of further root resorptions. After replantation (or surgical extrusion) of mature teeth, pulp regeneration cannot be expected, and ischemically necrosed pulp becomes infected after about 3 weeks (179). This infection stimulates an inflammatory response and further inflammatory root resorption (186, 187). Thus, in our study complete apical healing with no types of root resorption was found during the control period. Our results are in line with those of Pham et al. (133) and Lee & Yoon (188), who also found no root resorptions at follow-up.

Another factor to consider with regard to the prognosis of the extruded tooth is tooth splinting. Andreasen et al. (180) observed a higher risk of ankylosis when stabilization periods exceeded 6 weeks. Therefore, in the present study, teeth splinting was accomplished by a semi-rigid wire attached to the neighbouring teeth for no more than 1 month, which could explain the absence of ankylosed teeth. By comparison, Pham et

al. (133) and Elkhadem et al. (94), who both observed the occurrence of ankylosis, reported splinting periods ranging from 7 to 21 days.

The European Society of Endodontology recommends requesting a selective CBCT scan for pre-surgical assessment prior to complex peri-radicular surgery (189). Thus, following this recommendation, a pre-operative CBCT scan with a limited field of view was taken in each case to evaluate any possible radicular curvature in a buccal-lingual/palatal direction, or apical root thickening in the same direction. These anatomic limitations cannot be appreciated from periapical radiographs (190) and could hamper surgical extrusion.

The secondary objectives of this study included the evaluation of the healing of the soft tissues. To the best of our knowledge, this study is the first to assess GI, BOP, PPD, Jemt index, tooth mobility, C-R ratio and marginal bone loss after at least 12 months of surgical extrusion.

The present study revealed general improvement of the clinical periodontal indices at 1-year post-surgery (GI, BOP, and PPDs). Compared with the baseline, the authors observed a significant decrease of both mean GI and BOP. Moreover, PPDs were non-significantly shallower 1 year after extrusion, and no PPDs > 4 were found at the last follow-up. There are a number of possible explanations for this gingival healing. Firstly, at the first periodontal evaluation, all teeth presented subgingival caries or subgingival pre-existing prosthetic margins, provoking local gingival inflammation and bleeding on probing (81, 83, 191). This initial situation explains both the high rate of pre-operative GI score 2 (mean score 0: 15.4 %, mean score 1: 30.8 %, and mean score 2: 53.8 %) and BOP (19 %). In contrast, during the last periodontal evaluation, teeth were properly restored with supragingival adapted restorations, which promoted gingival healing, as shown by many authors (82, 192, 193). Moreover, the patients were given regular oral hygiene instructions including brushing and interdental floss at all appointments. This final situation could explain the favourable post-operative periodontal results, with a significant increase in the rate of post-operative GI score 1 (mean scores were 0: 38.5 %, 1: 53.8 %, and 2: 7.7 %). Our results corroborate those obtained in the systematic review of Das and Muthu, in which normal probing depths and no bleeding on probing were observed at the follow-ups (194). Similar results were found by Pham et al., who found a significant decrease in GI from 1 to 3 months, and from 3 to 6 months post-surgery. A non-significant difference was found between pre- and post-surgery BOP at 1 month, and between 3 and 6 months. However, they did find a significant decrease from 1 to 3 months post-surgery. Additionally, PPD values decreased significantly at 1, 3 and 6 months in comparison with the post-operative PPD values (133).

In general terms, the interproximal papilla was maintained or decreased in height, coinciding with the apical migration of the gingival margin. In 42.3 % of cases, the Jemt index score decreased, while 53.8 % of the teeth maintained the same papilla score at the post-operative assessment. Loss of interproximal papilla height might lead to an unaesthetic gingival result. In addition to this problem, as the root diameter decreases in the apical direction, a reduced cervical diameter of the tooth is expected, as result of the coronal position of the extruded tooth (129). The final narrow supragingival structure may hinder the prosthetic management of both the tooth emergence profile and the interproximal space of the adjacent teeth (129). To address this problem, Kahnberg (121) rotated the roots in order to gain additional cervical width during the surgical extrusion. Other authors (137, 138) have reported the biologically oriented preparation technique (BOPT) to restore surgically extruded teeth. As described by Loi et al., the BOPT technique can be used to remodel the gingival margin by modulating the temporary crown emergence profile, thus thickening the soft tissue (139). Despite a lack of well designed studies in support of the use of the BOPT technique in surgically extruded teeth, the authors believe that the use of this restoration technique could overcome both recession and interproximal papilla loss after surgical extrusion.

It has been widely demonstrated that para- and sub-gingival preparations are more likely to promote localized gingivitis and gingival recession than supragingival preparations, as result of plaque retention and the discrepancy between tooth margin and restoration (195, 196). However, supragingival preparations provide better gingival healing, since they allow better access for cleaner, more accurate preparation, and more precise verification of the prosthetic restoration (140, 197). In other words, supragingival preparations lead to fewer dimensional alterations of the gingival tissues than either para- or sub-gingival preparations (82, 192, 193).

Regarding the marginal design feature, Paniz et al. demonstrated that vertical crown preparations (feather edge finishing lines) caused significantly more BOP than horizontal preparations (chamfer). The authors justify these findings in terms of problems related to the design and fabrication of the restoration, including an unsuitable emergence profile of the provisional crowns, discrepancies of the position of the crown margin and finishing lines, or overcountouring of definitive crowns (140). Therefore, in order to avoid affecting the soft tissue stability of the extruded tooth, in the present study all teeth were prepared with horizontal supragingival margins.

All teeth showed physiological mobility beyond 3 months after surgical extrusion, except for 1 lower premolar, which presented type 2 mobility after 15 months. One possible reason was its final crown-root ratio of 1:1, as a result of the amount of tooth extruded

during the surgery. In cases of this type, tooth extraction can be considered, given the amount of coronal structure needed to restore the tooth in relation to the short root, which provoked this final crown-root ratio. The authors highlight the importance of a proper digital treatment plan and root measurement with CBCT, in order to avoid future unwanted drawbacks.

Marginal bone loss is an adverse event found at low rates by many authors after surgical extrusion (94, 134). According to Khayat et al. (198), this phenomenon could occur as a consequence of the pressure applied with the elevators and forceps in the cervical area of the tooth during the extrusion. Kahnberg et al. (164) found marginal bone loss in 11 out of 15 teeth, which were arrested in all cases except one. In a clinical study published 14 years later, the same author noticed marginal bone loss around all the extruded teeth, as a result of the discrepancy between the socket and the dimensions of the extruded tooth (132). However, no clinical or radiographical signs of pathological conditions were evident in any case after 10 years. It should be made clear that all the cases included in Kahnberg's studies involved traumatic injuries. Thus, the marginal bone loss could be initiated as a consequence of the trauma, as demonstrated by Andreassen (199). Conversely, in a systematic review involving 243 teeth, Elkhadem et al. (94) found marginal bone loss in only 3.7 % of the cases, which is similar to that observed by other authors (134, 188, 194). All teeth in the present study had less than 25 % marginal bone loss, except for one tooth presenting a distal marginal bone loss ranging from 25 to 50 %, which was considered a failure.

Clinical trials in dentistry tend to focus on research on the success and/or survival of a treatment, based on objective clinical and radiological parameters (200). However, patient-centred outcomes (patient's feedback) have generally been ignored in clinical research for many years and is still rare in the current literature (201, 202). Patient-reported outcome measures (PROMs) register any aspect of the impact of an intervention on a patient's health status directly from the patient, without interpretation by the clinician (203, 204).

Of the different possible types of response options used in clinical trials (205) (categorized VAS, Likert scale, rating scale, pictorial scale, and checklist), a 10-cm VAS was selected for the present investigation. This method consists of a fixed-length line orientated from the left (worst) to the right (best), with words defining each extreme of the scale (e.g., *very well* and *not at all*), but without any words along the line. Patients are asked to draw a mark at any point on the line, depending on their view (206). After the VAS has been completed, a ruler is used to measure the distance of the mark in order to determine a score.

As a refinement of the VAS, a categorized VAS includes one or more marks along the line with reference terms (e.g., *much better*, *somewhat better*, *no change*, *worse*) to assist the patient in recognizing locations between the two extremes of the scale. In the case of the Likert scale, patients are requested to choose among an ordered set of simple terms (e.g., *strongly agree*, *agree*, *neutral*, *disagree*, and *strongly disagree*). Alternatively, the rating scale uses numerical categories, a pictorial scale, a set of pictures, or a check list to provide a set of simple options among a limited range of choices (e.g., *yes*, *no*, and *don't know*).

The scientific literature on patients' satisfaction with surgical extrusion is somewhat limited (133). Pham et al. first reported patient feedback in relation to pain or sensitivity, mobility, and aesthetic result (definitive porcelain crown, gingival margin position and smile) of the extruded tooth. For this purpose, 6 months after the surgery, the authors offered a 7-question survey to each patient, with a checklist containing the following 3 options: "Yes", "No", and "No comment". All patients gave an excellent response in relation to the final aesthetic outcome, with no pain or discomfort of the extruded tooth (133).

In our study, the first 3 questions (Q1, Q2, and Q3) were directed towards the surgery, while the last 4 (Q4, Q5, Q6 and Q7) were related to the functional and aesthetic outcomes of the treatment. This VAS was adapted from the one used by Czochrowska et al. on patients who had undergone tooth autotransplantation, to examine their own assessment in relation to both treatment surgery and outcome (167). In our investigation, all patients clearly remembered the surgery (Q1), while 3 patients perceived pain, and 1 discomfort (Q2). Two patients responded as "*Difficult*" the decision of whether to undergo surgical extrusion or another treatment option (Q3). Initially, they considered the dental implant to be a shorter and simpler option. However, after describing the advantages and disadvantages of the two treatments (highlighting the importance of maintaining their own teeth) both patients opted for surgical extrusion. Eleven patients could recognize the extruded teeth exactly (scores 0), while 2 responded with scores 3.2/10 and 4.4/10 on whether they knew the extruded tooth. These patients expressed some uncertainty between the extruded and the neighbouring teeth (Q4). All but 1 patient (92.3 %) perceived the extruded tooth identically to the others (Q5). This patient described the feeling as "*somewhat mobility*", since the tooth presented a type-2 mobility. Three patients had to use an interproximal brush on the extruded tooth, due to interproximal black triangles created between the extruded tooth and the neighbouring teeth, as result of interproximal papillae loss (Q6). With a score 5, only 1 patient was not completely satisfied with the aesthetics, claiming that interproximal papilla did not entirely cover the space between the teeth. Despite this inconvenience, 12 patients were

highly satisfied with the final aesthetic result (Q7). Therefore, based on the results of the VAS, patients were generally satisfied with the surgery and the functional and aesthetic result, which is comparable to the levels of satisfaction observed by Pham et al. (133).

Although the approaches of surgical extrusion and surgical crown lengthening are completely different, both treatments aim to obtain sufficient ferrule to enable the tooth to be restored. No split-mouth randomized controlled trials compare these treatments, and certainly not in terms of patient satisfaction. However, using a 10-cm VAS, Ribeiro et al. reported high levels of satisfaction in relation to aesthetics after 6 months of aesthetic crown lengthening in patients with excessive gingival display (207). Further split-mouth controlled trials comparing surgical extrusion and surgical crown lengthening on single-rooted teeth are needed for proper comparison of patient-related outcomes for the two treatments.

The results of the present doctoral thesis show that all the alternative hypotheses can be accepted: (1) Surgical extrusion of single-rooted teeth has a success rate of more than 90 %. (2) Surgical extrusion of single-rooted teeth has a survival rate of more than 95 %. (3) Surgical extrusion of single-rooted teeth results in stability of the gingival margin.

Study limitations:

To the knowledge of the authors, this prospective clinical study is the first to analyse soft tissue rebound digitally after at least 1 year of surgical extrusion. However, the following limitations apply:

1. Due to restrictions related to Covid-19 throughout Catalonia (Spain), neither clinical or radiographic variables, nor scanned models could be registered at 3- and 6-months follow-up in some cases. Therefore, dynamic healing assessment of the soft tissues could not be achieved.
2. Even Cohen kappa analysis of inter-observer accuracy revealed a moderate-to-good reliability among the 3 examiners, they were not previously calibrated.
3. In contrast to other studies (132-134), the extent of the extruded tooth was not measured in the present study. This parameter might provide additional information in relation to the post-operative mobility or marginal bone loss.

Future perspectives:

Despite having achieved the sample objective of a minimum of 12 patients, use of a larger sample size could help to find a statistical association between STR and other variables.

Likewise, a longer follow-up period could reveal delayed failures due to root resorptions, as demonstrated in long-term studies of tooth autotransplantation (167).

Moreover, prospective randomized clinical studies should be performed to compare these results with those after surgical crown lengthening and forced orthodontic extrusion.

Since some authors (137, 138) have shown successful aesthetic results for the soft tissues after the BOPT technique in surgically extruded teeth. Such findings shed some light on where to focus future prospective studies of the BOPT technique in surgically extruded teeth.

CONCLUSIONS

7. Conclusions

1. The results of the present study showed that surgical extrusion is a predictable technique for the treatment of single-rooted tooth without ferrule, with a 100 % survival rate.
2. Surgical extrusion was demonstrated to present a 92.3 % of success rate.
3. The extruded teeth did not show significant soft tissue rebound 1 year post-surgery and no factors were demonstrated to influence the outcome of the treatment.
4. A significant improvement of the gingival index of the extruded teeth 1 year post-surgery.
5. A significant improvement of the bleeding on probing of the extruded teeth 1 year post-surgery.
6. Probing depths of the teeth were non-significantly shallower after the last follow-up.
7. Tooth mobility > 1 was a rare adverse event found after 1 year of the surgical extrusion.
8. The extruded teeth did not show significant interdental papilla loss 1 year post-surgery.
9. Surgical extrusion was not associated with occurrence of apical lesion 1 year post-surgery.
10. Surgical extrusion was not associated with occurrence of root resorptions 1 year post-surgery.
11. Changes in crown-root ratio were not significant 1 year after the surgical extrusion.

12. Changes in marginal bone loss were not significant 1 year after the surgical extrusion.
13. Surgical extrusion was an acceptable treatment to patients, who were highly satisfied with the functional and aesthetic result. Furthermore, surgically extruded teeth were generally possible to maintain in the same way as others.

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ANNEXE

Annexe I. Approval letter of Ethics Committee of Investigation of The Universitat Internacional de Catalunya



Comitè Ètic
d'Investigació
Clínica



Clínica
Universitària
d'Odontologia

Universitat
Internacional
de Catalunya

APROVACIÓ ESTUDI PEL CEIC / APROBACIÓN ESTUDIO POR EL CEIC / RESEARCH ETHICAL COMMITTEE APPROVAL STUDY

Codi de l'estudi / Código del estudio / Study Code: END-ECL-2017-02
Versió del protocol/ Versión del protocolo / Study version: 1.1
Data de la versió/ Fecha de la versión/ Version date: 01/03/2018
Títol/ Título / Title: Extrusión quirúrgica para el alargamiento de corona: estudio clínico a 12 meses.
Investigador Principal / Main researcher: Dr. Francesc Abella Sans
Investigador Secundari/ Second researcher: Marc Llaquet Pujol
Tutor/Monitor: Andrés Pascual La Rocca

Sant Cugat del Vallès, 15 de març de 2018

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 Comitè per a la seva avaluació.

Valorades les noves aportacions realitzades a l'estudi, sol·licitades pel nostre CEIC, el dia 1 de març de 2018, li comuniquem que el dictamen final ha sigut FAVORABLE.

Li informem que 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.

El Comitè, tant en la seva composició, com en els PNT, compleix amb les normes de BPC (CPMP/ICH/135/95) i amb el Real Decreto 1090/2015, i la seva composició actual és la següent:

- o Dr. J.Manuel Ribera Uribe (Presidente, Médico-estomatólogo)
- o Dr. Pau Ferrer Salvans (Vicepresidente, Farmacólogo clínico)
- o Sra. Noelia Nogales (Secretaría técnica, Bióloga)
- o Dr. Joan Janáriz Roldán (Miembro, Médico especialista en medicina interna i oncología)
- o Dr. Andreu Hernando Chaure (Miembro, Jurista)
- o Sra. Patricia Dominguez Tordera (Miembro, Farmacéutica Hospitalaria)
- o Sra. Klaudia Obolończyk (Miembro, Farmacéutica de Atención Primaria)
- o Dr. Christian Villavicencio-Chávez (Miembro, Médico gerontólogo)
- o Sra. Laia Wennberg Capellades (Miembro, Enfermera)
- o Sr. Antonio Alcáraz Gibert (Miembro lego, Persona ajena a la profesión sanitaria)

Que en aquesta reunió del Comitè Ètic d'Investigació Clínica es va complir amb el quorum preceptiu legalment.

Atentament,

Apreciados Doctores,

Los miembros del CEIC de la Clínica Universitària d'Odontologia, les agradecen su aportación científica en el campo de la investigación y la presentación del Protocolo a este Comité para su evaluación.

Valoradas las nuevas aportaciones realizadas al estudio, solicitadas por nuestro CEIC, el 1 de marzo de 2018, le comunicamos que el dictamen final ha sido FAVORABLE.

Le recordamos que deberá presentar al Comitè d'Ètica d'Investigacions Clíniques de la CUO, y a través de la Comisión Científica, un informe preliminar mensual del seguimiento del estudio i un informe final una vez finalizado el mismo.

Annexe II. Informed consent

CONSENTIMIENTO INFORMADO

Código del estudio: **END-ECL-2017-02**

Versión del protocolo: **1.1**

Fecha de la versión: **01/03/18**

Fecha de la presentación: **15/02/18**

Título del Proyecto: **Extrusión quirúrgica para el alargamiento de corona: estudio clínico a 12 meses.**

Director/a del Proyecto: Dr. Francesc Abella Sans

Investigador/a: Marc Llaquet Pujol

Departamento: Endodoncia

Yo, el Sr./la Sra:

- He recibido información verbal sobre el estudio y he leído la información escrita que se adjunta, la cual me ha sido facilitada una copia.
- He comprendido lo que se me ha explicado y los posibles riesgos y beneficios de participar en el estudio.
- He podido comentar el estudio y hacer preguntas al profesional responsable.
- Doy mi consentimiento para tomar parte en el estudio y asumo que mi participación es totalmente voluntaria.
- Entiendo que me podré retirar en cualquier momento.

Mediante la firma de este formulario de consentimiento informado, doy mi para que mis datos personales se puedan usar como se ha descrito en este formulario de consentimiento, que se ajusta a lo que dispone 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 Participante
Núm. de DNI

Fecha de la firma

Firma del Investigador/a
Nombre:

Fecha de la firma

DOCUMENTO DE INFORMACIÓN AL SUJETO PARTICIPANTE DEL ESTUDIO DE INVESTIGACIÓN

Código del estudio: **END-ECL-2017-02**

Versión del protocolo: **1.1**

Fecha de la versión: **01/03/18**

Fecha de la presentación: **15/02/18**

Título del Proyecto: **Extrusión quirúrgica para el alargamiento de corona: estudio clínico a 12 meses.**

Director/a del Proyecto: Dr. Francesc Abella

Investigador/a: Marc Llaquet Pujol

Departamento: Endodoncia

Hemos solicitado su participación en un estudio de investigación. Antes de decidir si aceptan participar, es importante que comprendan los motivos por los cuales se lleva a cabo la investigación: como se usará su información, en qué consistirá el estudio y los posibles beneficios, riesgos y molestias que pueda comportar.

En caso que participen en algún otro estudio, lo tendrán que comunicar al responsable para valorar si pueden participar en este.

¿CUÁLES SON LOS ANTECEDENTES Y EL OBJETIVO DE ESTE ESTUDIO?

La técnica de la extrusión quirúrgica está descrita desde hace más de 40 años. Lo que se quiere evaluar con el presente estudio son los cambios de los tejidos blandos del diente y la satisfacción del paciente después de 12 meses del tratamiento.

¿TENGO LA OBLIGACIÓN DE PARTICIPAR?

La decisión sobre participar o no en la investigación corresponde a ustedes. En el caso en que no quieran participar o bien quieran abandonar, la calidad de la asistencia que reciban no se verá afectada. Si deciden participar, les pasaremos un formulario de consentimiento informado para que lo firmen.

¿CUÁLES SON LOS POSIBLES EFECTOS SECUNDARIOS, RIESGOS Y MOLESTIAS ASOCIADOS A LA PARTICIPACIÓN?

Los posibles efectos secundarios del tratamiento son posibles molestias post-operatorias durante 5-7 días, así como incomodidad al masticar durante 1 semana.

¿CUÁLES SON LOS POSIBLES BENEFICIOS DE PARTICIPAR?

El beneficio inmediato de participar en el estudio es la contribución en el desarrollo científico.

¿CÓMO SE UTILIZARÁN MIS DATOS EN EL ESTUDIO?

El trato, la comunicación y la cesión de los datos de carácter personal de los sujetos participantes en el ensayo se ajustan a lo que dispone la Ley orgánica 15/1999, del 13 de diciembre, de protección de datos de carácter personal.

Estos datos, no incluyen ni su nombre ni su dirección, sino que se le asignará un número de código. Únicamente el equipo investigador, tendrá acceso a la clave del código que permite asociar los datos del estudio con ustedes. No obstante, las autoridades reguladoras, el comité

de ética independiente u otras entidades de supervisión podrán revisar sus datos personales. El objetivo de dichas revisiones es garantizar la dirección adecuada del estudio o la cualidad de los datos del estudio.

Si retiran del consentimiento informado de usar sus datos para el estudio, no podrán continuar participando en la investigación. Han de tener en cuenta que los resultados del estudio pueden aparecer publicados en la bibliografía, si bien, su identidad no será revelada.

¿CÓMO PUEDO ESTABLECER CONTACTO SI NECESITO OBTENER MÁS INFORMACIÓN O AYUDA?

Mediante la firma de este formulario, asienten que han sido informados de las características del estudio, han entendido la información i se les ha clarificado todas sus dudas.

En caso de padecer un daño relacionado con el estudio o para obtener respuesta a cualquier pregunta que pueda surgir durante la investigación contacte con:

Dra./Dr. Francesc Abella
Universitat Internacional de Catalunya
Dirección: C/ Josep Trueta, s/n, 08195, Sant Cugat del Vallès
Nº de teléfono: 93 504 20 00