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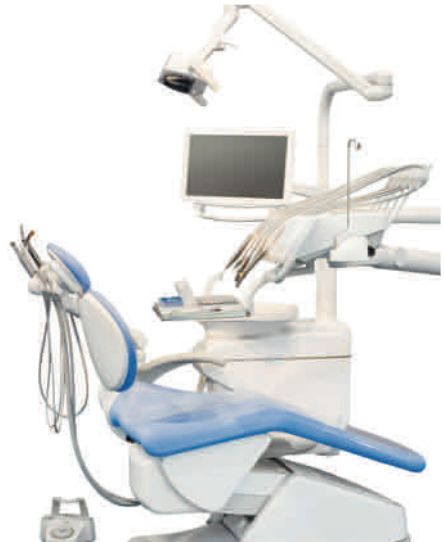

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contents

editorial

Dr. Jesús Calatayud Sierra
Editor of *Científica Dental*.

As our readers know *Científica Dental* every year awards three prizes in three categories (best scientific article, best case study and best first scientific work by a new author) to the articles published in the journal; hence in this special edition we present the award-winning articles and the other finalists, six fine scientific works which readers may consult in open access on our website www.cientificadental.es.

In this edition we present a review by González Fernández-Tresguerres *et al* of the new oral anticoagulants. This is a newsworthy piece as it provides information for practical dentistry at a time in which an increasing number of patients are being treated with these medicaments and we lack information applied to our needs.

We also have three unusual case studies. The work of Sergio García *et al* on the surgical treatment of large post-extraction oroantral fistulas with the use of the buccal fat pad, an option not normally considered in general clinical practice. The case study of Pilar Muñoz *et al* on a difficult mandibular second molar which requires endodontic retreatment, with a broken file, a third root with a new canal and deficient prior canal treatment requiring considerable effort to overcome the obstacles to correct sealing. And the case study of Mónica Serrano *et al* on the surgical extraction of impacted third and fourth molars which is extremely helpful on how these complex cases should be dealt with.

There are two experiment-based articles. A clinical study by Anitua on the use of growth factor-rich platelets (Endoret®) to help bone regeneration in alveoli post-extraction; and the in vitro study of Bruno Baracco *et al* on the adhesive force of various bonding adhesives.

As always I would like to thank all those who have made this edition of *Científica Dental* possible, particularly the authors for their unselfish efforts, and the readers for whom all of this work is ultimately intended.

Best regards to you all.

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Bibliographic review

New oral anticoagulants: implications in odontology

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ABSTRACT

The number of patients with cardiovascular problems who come in for dental consultation has increased in the recent years. The most prevalent cardiovascular pathologies are: hypertension, ischemic heart disease and arrhythmias, with atrial fibrillation (AF) being the most common. One of the fundamental pillars of care for patients with AF is prevention of thromboembolic stroke because of its severity and the potential for prevention with the use of anticoagulant drugs.

Vitamin-K antagonists have been the most widely used anticoagulants over the past 50 years. However, the advent of new oral anticoagulants (NOACs), supported by clinical trials in more than 50,000 patients, has led to a revolution in cardiovascular therapy that is changing the recommendations of international clinical practice guidelines for the treatment of AF. As a result, anticoagulant treatment with NOACs is a therapeutic challenge for dentists and we should be familiar with its treatment protocol, since despite being safer drugs, they can complicate an hemorrhagic event, for there is no antidote (except in the case of Dabigatran).

The purpose of this review is to provide an update on the new oral anticoagulants and their implications on dental treatment.

Dabigatran, Rivaroxaban and Apixaban are reviewed, along with their pharmacological properties, indications and contraindications, as well as the protocol to be followed in the event of an intervention that results in bleeding in the oral cavity

KEYWORDS

New oral anticoagulants; Thrombotic risk; Hemorrhagic risk; Oral surgery; Dabigatran; Rivaroxaban; Apixaban.

ABBREVIATIONS

OAC: oral anticoagulant; NOAC: new oral anticoagulant; VKA: vitamin K antagonist; LMWH: low molecular weight heparin; HBP: high blood pressure; INR: international normalized ratio; AF: atrial fibrillation; VTE: venous thromboembolism; TIA: transient ischemic attack; PE: pulmonary embolism; AMI: acute myocardial infarction; CHF: congestive heart failure; DVT: deep vein thrombosis; P-gp: P-glycoprotein; PT: prothrombin time; aPTT: activated partial thromboplastin time; DTT: diluted thrombin time; TT: thrombin time; ECT: ecarin clotting time; FFP: fresh frozen plasma; PCC: prothrombin complex concentrate.

INTRODUCTION

The number of patients with cardiovascular problems who come in for dental consultation has increased in recent years. Because they have a good quality of life, they are candidates for any type of dental treatment including surgery. The majority of these patients have suffered from angina, infarctions or strokes, or they have chronic diseases such as high blood pressure (HBP) or atrial fibrillation (AF) and they take antihypertensive, anti-platelet or anticoagulant (OAC) medications on a daily basis.

Acenocoumarol (Sintrom®) is a drug that belongs to the vitamin K antagonists (AVK) group and has been used for more than 50 years to prevent brain embolism in patients with atrial fibrillation. However, it has a delayed onset of action and a narrow therapeutic range given that low dosages do not prevent thrombosis and large dosages may lead to hemorrhage. Therefore, strict monthly monitoring is required to adjust the dosage. In addition, there are many interactions: dietary (green vegetables...), pharmacological (antibiotic, anti-fungal) and even viral diseases (cold, flu...). More than 700,000 people take Sintrom® in Spain and the majority are over 70 years of age. This results in high costs for the healthcare system, not because of acenocoumarol itself, which is cheap, but because of the necessary monthly monitoring.

New oral anticoagulants (NOACs) have been developed in the recent years and they are progressively replacing Sintrom® because they do not have variations, have few interactions and do not require laboratory monitoring. Their efficacy is backed by clinical trials carried out with the collaboration of more than 50,000 individuals. As new clinical trials are published, the indications for these new drugs increase, given that they are as effective as acenocoumarol for the prevention of thrombosis but they are safer when considering the risk of bleeding, which is the primary problem with anticoagulant drugs. The incidence of hemorrhage, especially intracranial hemorrhage, is indicative of the drug's safety, which is lower in NOACs.[1]

ATRIAL FIBRILLATION (AF)

Atrial fibrillation is the most common arrhythmia. More than a million individuals (1-2%) have AF in Spain with an estimated prevalence of 8% of the Spanish population over 60 years of age. An important consequence of AF is that it results in a fivefold increase in the risk of stroke, meaning 1 out of every 5 strokes is due to this arrhythmia.[1] In addition, stroke caused by AF is thromboembolic and more severe than an ischemic stroke. It can have fatal consequences in both sexes, from minor to severe disability or even death. In addition, half of strokes are usually recurrent, meaning that a previous stroke predisposes to a subsequent event. In other words, it is a risk factor. To address this, many Spanish hospitals have what is called a "stroke code", which consists of activating an emergency specialized treatment protocol within the first minutes in order to prevent the fatal consequences derived from a stroke.

However, the risk of stroke is no longer unpredictable. Currently, there are tools to predict the risk of stroke in patients with AF.[1] Since 2001, the CHADS2 risk stratification criteria (Table 1) has served to

Table 1. Stratification of stroke risk ($CHADS_2$ scale)

$CHADS_2$	Criteria	Points
C (Congestive heart failure)	Recent history of CHF	1
H (Hypertension)	HBP	1
A (Age)	Age > 75 years	1
D (Diabetes)	History of diabetes mellitus	1
S_2 (Stroke)	History of stroke/TIA (double points)	2
Maximum score		6

0: Low Risk No treatment or treatment with anti-platelet agents
1. Medium risk. Treatment with anti-platelet agents or oral anticoagulants
≥2: High risk. Treatment with oral anticoagulants

grossly classify the entire population. The risk factors on this scoring scale are the following: congestive heart failure (CHF), High Blood Pressure (HBP), age over 75 years, diabetes mellitus, and history of stroke or transient ischemic attach (TIA). On this scale, 0 is low risk, 1 is moderate risk and more than 1 is high risk. Low risk may or may not be treated with anti-platelet medications, moderate risk requires anti-platelet or anticoagulant treatment and high risk always requires oral anticoagulant treatment.[1] The CHADS2 criteria have been recently modified in order to discriminate between low and moderate risk populations (CHADS2 0 or 1). New criteria were presented in 2010 named CHA2DS2-VASc (Table 2) which added three additional factors: female sex, age 65 to 74 years and vascular events [Acute Myocardial Infarction (AMI) or peripheral arterial disease] each scoring 1 point. Age over 74 is 2 points with a maximum score of 9. On this scale, 0 is low risk, 1 is intermediate risk and ≥ 2 is high risk. Anticoagulant treatment is used when the risk is ≥ 1.[1]

Table 2. Stratification of stroke risk (CHA_2DS_2-VAS_c scale)

CHA_2DS_2-VASc	Criteria	Points
C (Congestive heart failure)	CHF	1
H (Hypertension)	Hypertension	1
A_2 (Age)	Age ≥ 75 years	2
D (Diabetes)	Diabetes mellitus	1
S_2 (Stroke)	History of stroke/TIA (double points)	2
V (Vascular disease)	Vascular disease (AMI or peripheral)	1
A (Age)	Age 41-60 years	1
Sc (Sex category)	Female sex	1
Maximum score		9

0: Low Risk No treatment or treatment with anti-platelet agents
1. Medium risk. Treatment with anti-platelet agents or oral anticoagulants
≥2: High risk. Treatment with oral anticoagulants

Another important criteria to keep in mind is the risk of bleeding in patients with AF who are on anticoagulants, which is measured using the HAS-BLED scale (Table 3). Risk factors for bleeding include uncontrolled HBP, altered renal and/or liver function, history of stroke, history of bleeding, labile INR, age greater than or equal to 65 years and use of medications or alcohol. On this scale, 0 is considered low risk, 1-2 is medium risk and ≥ 3 is high risk. A score ≥ 3 indicates a high risk of bleeding, meaning the patient must be closely monitored under any treatment (antithrombotic or anticoagulant).[1]

NOACs

The new oral anticoagulants have become substitutes for vitamin K antagonists because they have a greater therapeutic index, have few interactions and do not require monthly monitoring for dosage adjustment, as they are administered at fixed dosages. The mechanism of action for NOACs is different than that of acenocoumarol (Sintrom®) or warfarin (Aldocumar®), which are anti-vitamin K drugs (AVK) that inhibit the synthesis of coagulation factors II, VII, IX and X in the liver. NOACs are direct thrombin inhibitors (Dabigatran) or factor Xa inhibitors (Rivaroxaban and Apixaban).[2-4] Several clinical trials have demonstrated their efficacy.

The Re-LY study[5], a randomized multicentric study carried out with 18,000 participants with non-valvular AF, compared dabigatran (110 mg q12 h and 150 mg q12h) versus warfarin (dosage adjusted for an INR between 2 and 3) for 2 years. The occurrence of thromboembolic stroke was recorded as the efficacy endpoint variable and the occurrence of severe hemorrhage was the safety endpoint variable. The study concluded that dabigatran 150 mg was associated with a lower rate of stroke than warfarin. Severe hemorrhages were significantly lower with dabigatran 110 mg. However, the percentage of treatment abandonment was greater with dabigatran due to dyspepsia.

Table 3. Bleeding risk stratification table HAS-BLED scale

Risk factor	Description	Score
H ("Hypertension")	Uncontrolled hypertension (systolic blood pressure ≥ 160 mmHg)	1
A ("Abnormal kidney and/or liver function")	Renal or hepatic insufficiency	1 per pathology (1 or 2)
S ("Stroke")	Previous history of stroke	1
B ("Bleeding")	History of bleeding, anemia or predisposition towards bleeding	1
L ("Labile INR")	Unstable/high INR (less than 60% of the therapeutic range)	1
E ("Elderly")	Age ≥ 65 years	1
D ("Drugs and/or alcohol")	Medications that affect hemostasis (e.g.: Acetylsalicylic Acid (ASA), clopidogrel) and/or intake of ≥ 8 alcoholic drinks per week	1 for each (1 or 2)
Maximum score		9

0: Low risk
1-2: Medium risk
3: High risk.
A score ≥ 3 indicates a high risk of bleeding, meaning the patient must be closely monitored with any treatment (anti-platelet or anticoagulant)

The ROCKET AF study[6], carried out with more than 14,000 patients with non-valvular AF, studied rivaroxaban (20 mg daily) versus warfarin. The study concluded that rivaroxaban was not inferior to warfarin in the prevention of stroke or embolism, and the risk of bleeding was not different.

The ARISTOTLE study[7], carried out with the collaboration of more than 18,000 patients with non-valvular AF, compared apixaban (5 mg q12h) versus warfarin (at a dosage to keep INR between 2 and 3). The results revealed that apixaban was superior to warfarin in the prevention of thromboembolic stroke, caused less bleeding and annual mortality was lower.

Based on these evidences, NOACs are gradually replacing Sintrom®.

According to the Spanish Agency for Medications and Health Products, the current indications for NOACs are:

- Primary prevention of Venous Thromboembolic Events (VTE) in adult patients undergoing total hip or knee replacement surgery.
- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation, with one or more risk factors.
- Treatment of deep vein thrombosis and pulmonary embolism (except dabigatran).

In general, the contraindications for NOACs[1] are:

- Patients with prosthetic heart valves (in whom the use of AVKs is better).
- Patients with AF who also have a stent (treated with acenocoumarol and double anti-platelet therapy with acetylsalicylic acid-Adiro® and clopidogrel-Plavix®).
- Patients with severe renal insufficiency (with a creatinine clearance <15 ml/min).
- Patients with severe liver disease (associated with coagulopathies).
- Pregnancy and lactation.
- Patients with high bleeding-risk diseases (gastrointestinal ulcers, aneurysms, neoplasms, etc.).

Dabigatran (Pradaxa®) is a direct thrombin inhibitor (factor IIa). It is ingested as a prodrug (dabigatran etexilate), which is transformed by plasma and liver esterases into dabigatran. It is a competitive and reversible thrombin inhibitor that blocks the conversion of fibrinogen to fibrin, thereby inhibiting clot formation. It has been shown to inhibit free thrombin, thrombin bound to fibrin and thrombin-induced platelet aggregation.[3] It is absorbed orally, though its bioavailability is around 5-6%. Its onset of action takes 1-1.5 hours and its half-life is 12-18 hours (Table 4).[4] Eighty percent is excreted unchanged in urine, so patients with very severe renal insufficiency, with a creatinine clearance less than 15 ml/min, it should not be used.[8] It is not metabolized in the liver nor is it a cytochrome P450 substrate. it is a P glycoprotein (P-gp) substrate, so P-gp inhibitors such as amiodarone may increase its effect. Only 30% binds to plasma proteins, so in the event of overdose or hemorrhage, hemodialysis may help remove it as it has a 70% free fraction.[3,9].

Prothrombin time (PT) and INR are not valid for evaluating the risk of hemorrhage. Activated partial thromboplastin time (aPTT) provides a qualitative but not a quantitative measure, although it may be useful to determine excess anticoagulant activity. An aPTT greater than 80 seconds is associated with an increased risk of bleeding. An aPTT less than 30 seconds indicates an absence of anticoagulant activity. Du et al.[10] carried out a study to compare the efficacy of different methods for measuring plasma concentrations of dabigatran and concluded that the most specific tests are the Hemoclot and ecarin time (ET) tests. Hemoclot is a variant of the diluted thrombin time (dTT) that is specifically calibrated for dabigatran. This test identifies patients with higher risk of hemorrhage in a more precise, sensitive and specific way. If the time is greater than 60 seconds, it is associated with an increased risk of bleeding. It is not routinely performed, but rather only in case of severe bleeding or emergency surgery. Ecarin time (ET) transforms prothrombin into meizothrombin, a labile thrombin precursor. Both compounds are inhibited by dabigatran, resulting in prolonged coagulation time. There is a linear correlation between prolonged ET and dabigatran concentrations. It is not influenced by heparin, which is probably the most accurate test, but it is costly and not available in many laboratories.[10]

In July 2015, an antidote for dabigatran named Idarucizumab was developed.[11] It is the only NOAC with an antidote. The rest are being tested in phase II clinical trials.[11]

We should also be aware of drug interactions. P-gp inhibitors (amiodarone, verapamil, quinidine, ketoconazole, dronedarone, clarithromycin) increase plasma dabigatran concentration, P-gp inducers (rifampicin, carbamazepine or phenytoin) lower it. Other drugs that affect P-gp (ritonavir, protease inhibitors) and other anticoagulants or anti-platelet agents (acenocoumarol, heparin, ASA, clopidogrel) also interfere.[5,12]

The most common side effect of dabigatran is dyspepsia.

Rivaroxaban (Xarelto®) is a direct and reversible factor Xa inhibitor that interrupts the intrinsic and extrinsic coagulation pathways. Its onset of action ranges between 30 and 180 minutes and its half-life is 7 to 9 hours (11 in the elderly).[3] Ninety-five percent binds to protein so hemodialysis does not contribute to its elimination (Table 4). Fifty percent of the drug is metabolized in the liver via cytochrome P450 and the remainder is eliminated unchanged by urine, so in patients with severe renal insufficiency, and a creatinine clearance less than 15 ml/min, should not be used. It has been available in Spain since 2012.

The usual dosage is 20 mg daily in a single dose, taken with food to avoid dyspepsia, 10 mg daily in the prevention of venous thromboembolism in knee and hip replacement surgery.[14]

INR is not useful for measuring the anticoagulant activity of rivaroxaban. However, prothrombin time (PT) and activated partial thromboplastin time (aPTT) can be used. Specific calibration curves are re-

Table 4. Characteristics of NOAC$_S$

	Dabigatran	Rivaroxaban	Apixaban
Brand name	Pradaxa®	Xarelto®	Eliquis®
Peak plasma concentration (hours)	1-1.5	2-4	3-4
Time to reach maximum concentration (hours)	2	3	3
Plasma half life (hours)	12-18	7- 9 (11 in the elderly)	8-15
Protein binding	30-35%	90-95%	87-90%
Excretion	Renal (80%)	Renal (66%)	Renal (25-30%)
Bioavailability	6%	80%	60%
Elimination by dialysis	Yes	No	No
CYP metabolism	No	30% CYP3A4, CYP2J2	15%CYP3A4
GP-P transport	Yes	Yes	Yes
Inhibited coagulation factors	IIa (inhibits free thrombin, thrombin bound to fibrin and thrombin-induced platelet aggregation)	Xa	Xa
Dosage	110 mg/ 12h or 150 mg/ 12h	20 mg/ daily	2.5 mg/ 12h
Indications	· Prevention of VTE in adult patients undergoing hip or knee replacement surgery. · Prevention of stroke and systemic embolism in adult patients with non-valvular AF	· Prevention of VTE in adult patients undergoing hip or knee replacement surgery. · Prevention of stroke and systemic embolism in adult patients with non-valvular AF · Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrences.	· Prevention of VTE in adult patients undergoing hip or knee replacement surgery. · Prevention of stroke and systemic embolism in adult patients with non-valvular AF · Treatment of deep vein thrombosis and pulmonary embolism and prevention of recurrences.
Drug interactions	· Contraindicated Dronedarone, ketoconazole, itraconazole, cyclosporine, tacrolimus. · Caution with: rifampicin, phenytoin, carbamazepine and St. John's Wort.	· Contraindicated: azole antifungals, HIV protease inhibitors. · Caution with: rifampicin, phenobarbital, phenytoin, carbamazepine and St. John's Wort.	· Contraindicated: azole antifungals, HIV protease inhibitors. · Caution with: rifampicin, phenobarbital, phenytoin, carbamazepine and St. John's Wort.

quired. ET and thrombin time (TT) are not useful because thrombin is not affected. A new test called the Heptest, which measures anti-Xa activity, is available. It is an adequate but costly method. Chromogenic methods for measuring anti-Xa activity may be useful in emergency surgery situations.[15]

Its drug interactions are: drugs that interact with cytochrome P450 (azole antifungals such as Ketoconazole and HIV protease inhibitors such as Ritonavir). Rivaroxaban also interacts with other anticoagulants and anti-platelet agents. Cytochrome P450 and P-gp inhibitors (azole antifungals, protease inhibitors) increase its blood concentration and cytochrome P450 inducers (Rifampin) reduce its concentration.[6]

The most common side effect of this drug is nausea and, in rare cases, arthralgia, edema, rash, pruritus, dizziness, generalized malaise or asthenia, all of which are mild. Episodes of bleeding of the mucosae and anemia are the most common adverse reactions. Episodes of bleeding correspond mostly to epistaxis, bleeding of the gums, gastrointestinal bleeding and genitourinary bleeding.[16]

Apixaban (Eliquis®) is a direct and reversible factor Xa inhibitor. Oral bioavailability is 66%, its effect takes between 30 and 120 minutes and its half life is 8 to 15 hours. It binds extensively to plasma proteins so it is not dialyzable. Thirty percent is metabolized in the liver via cytochrome P450 and 70% is eliminated via the fecal route with the remaining 30% eliminated renally[17], but it is also contraindicated in patients with severe renal insufficiency (Table 4).

The normal dosage is 2.5 mg q12h but it may be increased in some cases such as treatment for deep vein thrombosis and PE, in which the initial dosage is 20 mg daily for the first 7 days and then reduced to 10 mg.[7,14]

Its main drug interaction is with other medications that affect hemostasis such as anticoagulants, antiplatelet agents and NSAIDs. However, it also interacts with cytochrome P450 and P-gp inhibitors (azole antifungals and protease inhibitors), which increase plasma concentration of apixaban. Cytochrome P450 and P-gp inducers (phenytoin, carbamazepine, phenobarbital) reduce plasma concentrations.[17]

IMPLICATIONS ON DENTAL TREATMENT. TREATMENT PROTOCOLS

There has been a lot of controversy in recent years regarding patients who were taking acenocoumarol who need dental treatment that involves bleeding. Initially, Sintrom was discontinued and substituted by Low Weight Molecular Heparin (LWMH), keeping INR between 2-3 and performing surgery using only local hemostasis measures.

With the arrival of NOACs, dentists need to know how to avoid bleeding in these patients without provoking a thromboembolic accident. The management of patients who take NOACs requires the dentist to make decisions, so professionals must be familiar with the indications and contraindications of these anticoagulants in order to avoid bleeding (that is usually not significant) and the onset of a thromboembolic accident caused by discontinuing anticoagulant treatment (which has greater repercussions on the patient's quality of life).[18]

As there is no standardized method to evaluate the risk of bleeding in these patients nor an antagonist in the event of hemorrhage, except in the case of dabigatran, management of these patients can be a challenge for the dentist.

In cases of high thromboembolic risk, the dental treatment should be planned in consensus with the patient's cardiologist. Before carrying out any treatment in the dental clinic, a thorough medical history including underlying diseases, personal and family history, medications and allergies, etc. should be taken.

Three aspects should be considered when planning treatment in these patients[18]:

- Type of dental treatment and estimation of the amount of possible bleeding involved. In a healthy

patient, the risk of bleeding is only related to the complexity of treatment.

- Medical history (risk of bleeding versus risk of thromboembolism)
- Availability of local and systemic hemostatic measures[19]

In general, hospital physicians consider surgical interventions in the oral cavity to be of low risk. Examples of procedures that involve bleeding include extractions, radicular filing and polishing, biopsy sampling (especially in inflamed or vascular areas), periodontal graft, implant placement techniques or regenerative techniques. One should also take into account factors such as the number of teeth affected, the number of implants placed, soft tissue trauma, the level of invasion, severity of local inflammation, etc. All of these factors should be part of a general evaluation of the risk of hemorrhage.[20]

When the dental procedure carries a low risk of hemorrhage, the NOAC regimen does not have to be modified. Simple dental surgical acts are extractions of up to 3 teeth, radicular filing and polishing and surgery for placement of 3 or fewer implants. Complex surgical acts are those that involve more than 3 extractions or placement of more than 3 implants, bone and connective tissue grafts, nasal sinus and fossae elevations, as well as other bone regeneration techniques (split crest, bone distraction, Khoury, etc.). Prior to surgery, elimination of inflammation and irritation of oral cavity tissues is recommended in order to avoid a greater tendency towards bleeding (radicular filing and polishing, oral hygiene techniques, recommend antiseptic mouthwash on days prior to surgery, etc.). [21,22]

Evaluation of the medical history should focus on factors that increase the risk of hemorrhage (renal insufficiency, liver damage or use of drugs that increase bleeding such as anti-platelet agents and corticosteroids) or increase the risk of thromboembolism. Both factors can be measured using the HAS-BLED and CHA2DS2-VAS_c scales, respectively. If the patient has a high risk of suffering thromboembolism, anticoagulant therapy cannot be interrupted. In such cases, it may be necessary to postpone the procedure and reschedule it or carry out treatment without discontinuing the NOAC[21] (Table 5).

Table 5. Treatment protocol in oral surgery based on the risk of Thromboembolism (CHA_2-DS_2-VAS_c) and bleeding (HAS-BLED)

Hemorrhagic risk (HAS-BLED)

Thromboembolism risk (CHA_2-DS_2-VAS_c)	HIGH (≥3)		MEDIUM (1-2)		LOW (0)	
	Complex surgery	Simple surgery	Complex surgery	Simple surgery	Complex surgery	Simple surgery
HIGH (≥2)	Postpone surgery	Postpone surgery	Perform the surgery as late as possible after the last dose	Maintain NOAC	Maintain NOAC	Maintain NOAC
MEDIUM (1)	Discontinue 1 dose of NOAC	Discontinue 1 dose of NOAC	Discontinue 1 dose of NOAC	Postpone the daily dose or perform the surgery as late as possible after the last dose	Postpone the daily dose or perform the surgery as late as possible after the last dose	Maintain NOAC
LOW (0)	Discontinue 24-48h	Discontinue 24-48h	Discontinue 24-48h	Discontinue 1 dose of NOAC	Discontinue 1 dose of NOAC	Maintain NOAC

In summary, there are three options when confronting a patient who is taking NOACs who will undergo dental treatment[21] (Figure):

1- Treat the patient while continuing anticoagulant therapy.

2- Postpone the daily dose until the procedure is done or skip one dose (especially in those who require two daily doses). Another valid approach would be to perform the dental treatment as late as possible after the last NOAC dose.

3- Temporarily discontinue the NOAC, the day of surgery or the day before (24-48h).

The last two options reduce blood NOAC levels although not completely, so there still is a risk of bleeding. Despite the fact that discontinuing NOACs for a longer period (generally three days prior to the day of surgery) is recommended for hospital surgical procedures, it is believed that the majority of dental treatments can be carried out safely with a minimal interruption in NOAC treatment. In general, the tendency should be to change the regimen and dosage as little as possible and, in the opinion of many authors, this second option is the one that best meets this objective. However, decisions should be made on an individual basis according to each patient's characteristics.[21]

Special considerations in these patients should include the availability of local hemostatic measures (tranexamic acid, hemostatic sponges, oxidized cellulose, antifibrinolytic rinses, etc.) so that they can be applied when necessary. Chitosan (Hem-Con®) has also become available in recent years. It is a polysaccharide that produces local red blood cell aggregation without intervening in coagulation and is very useful for stopping hemorrhages in emergency situations. In addition, attempts should be made to make the procedures as atraumatic as possible. Good primary closure should be performed and we must keep the patient under observation for 45-60' postoperatively until adequate hemostasis is achieved. If the anticoagulant has been discontinued, you must ensure that no delayed bleeding occurs when restarting anticoagulant therapy. This usually occurs the first day after surgery.[17]

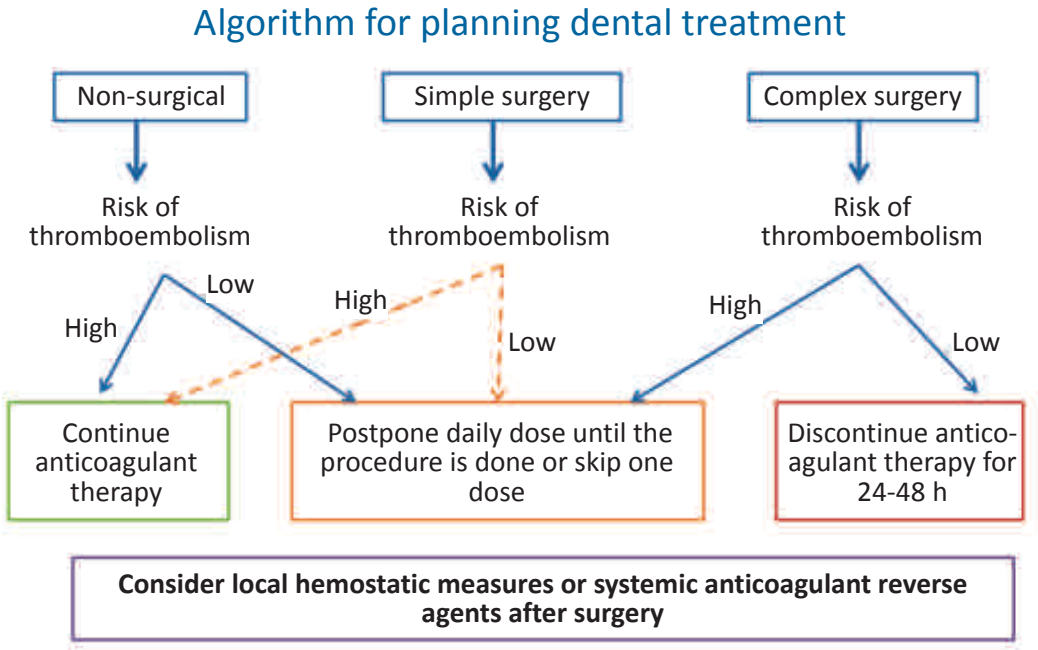

Figure. Algorithm for planning dental treatment. Modified from Elad et al, 2016[21]

The patient will be instructed to perform tranexamic acid rinses for 2 to 7 days and scheduled for a follow-up visit on the days after surgery in order to ensure adequate monitoring. Postoperative indications are of great importance in these patients, and clear written information is recommended.[20]

Before performing any procedure, we must consider systemic measures for the treatment of uncontrolled hemorrhage; these measures depend on the type of NOAC. In the case of dabigatran, a protocol for emergency hemodialysis should be followed since this is the treatment of choice in cases of plasma overdose, in order to reduce the drug's blood concentration . It may also be necessary if the patient has renal dysfunction. Transfusions of concentrated coagulation factors can be done in the hospital for other NOACs.[21]

More clinical studies are needed to establish clear directives on the dental treatment of patients who take NOACs, as well as a specific test to stratify these patients based on their risk of bleeding.

REVERTING THE ANTICOAGULANT EFFECT

The new oral anticoagulants are not exempt from hemorrhagic complications and because there is no specific antidote, there may be problems in managing hemorrhages.

An antidote for dabigatran, idarucizumab (Praxbind®), was introduced in Europe in 2015. This is the first agent for reverting a non-vitamin K antagonist anticoagulant to obtain approval in the European Union, which makes dabigatran the first and only NOAC to have a reverting agent.[11]

NOACs have a short half-life, so in the majority of cases of hemorrhage caused by these drugs, the response is to simply discontinue therapy, keep the patient under observation and provide support treatment when necessary. The use of systemic reversing agents will only be necessary in more severe situations that may represent a risk to the patient's life.[23]

An example of a systemic reversing agent is activated charcoal, which absorbs drugs and toxins on its surface as it passes through the gastrointestinal tract, thereby avoiding or reducing their absorption systemically. When the last NOAC dose has been recently administered, within 2 hours, oral administration of activated charcoal can decrease its absorption.

It has been shown that administration of fresh frozen plasma (FFP) can reduce hemorrhage volume in patients who take high-dose dabigatran, but it is less effective in patients who take low dosages. Recombinant factor VIIa has also been shown to effectively revert the anticoagulant effect of dabigatran. We have already mentioned that hemodialysis has been shown to be an effective measure in cases of plasma overdose of dabigatran due to its low level of plasma protein binding. It has also been postulated that blood infusion of activated charcoal may be a useful method for eliminating dabigatran, although this requires further study.[24]

Conversely, hemodialysis does not work for eliminating rivaroxaban and apixaban due to the high level of plasma protein binding.

Regarding rivaroxaban, current recommendations are controversial given that they are based on animal models and few clinical experiences. These studies indicate that administration of recombinant factor VIIa has a moderate effect on stopping bleeding caused by rivaroxaban.[25] Prothrombin complex concentrate (PCC) was studied in a clinical trial with 12 healthy volunteers in which it was capable of immediately and completely reverting the anticoagulant effect of rivaroxaban. However, more studies are needed to measure its effect.[24] The use of perioperative tranexamic acid has been shown to significantly reduce postoperative blood loss in patients treated with rivaroxaban. Neither vitamin K, protamine or plasma transfusion modifies the anticoagulant effect of rivaroxaban.

No specific antidote is known for apixaban. However, phase II trials are underway testing two synthetic molecules, Andexanet alpha and Aripazine, and the preliminary results are promising[11,25].

CONCLUSIONS

1. NOACs should not be discontinued in patients who are at high thromboembolic risk.
2. When the dental procedure carries a low risk of hemorrhage, the NOAC regimen does not need to be modified.
3. Before performing a dental procedure that involves a risk of bleeding, consensus must be reached with the cardiologist on the best possible regimen for each patient based on the thromboembolic risk and the risk of bleeding. The options are:

- Do not discontinue the drug.
- Postpone the daily dose until after the procedure.
- Discontinue the drug 24-48 hours prior to surgery and restore it the next day.

The authors state they have no conflicts of interest.

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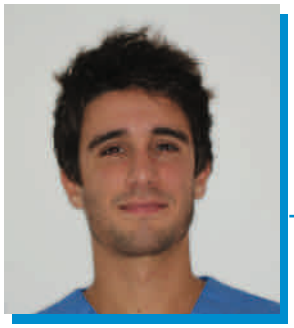

Clinical case

Surgical treatment of oroantral post-extraction fistulas. Case presentation and review of the literature

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ABSTRACT

Introduction: Oroantral fistulae are communications between the oral cavity and the maxillary sinus, primarily caused by tooth extractions. The majority of these communications close spontaneously due to their small size, but others form fistulae, perpetuating this pathological situation until proper treatment is provided, causing both local and general pathology.

Case report: We present the case of a 49-year-old male without previous medical history who was referred to the Oral Surgery Department at Hospital Virgen de La Paloma presenting with a three-week history of oroantral fistula with acute sinusitis of the left maxillary sinus. After evaluation of the various therapeutic options, Bichat's buccal fat pad pedicle flap was performed along with a vestibular advancement flap, in a double-layer closure technique.

Conclusions: There are multiple techniques described in the literature for correcting this pathological entity, each with their own advantages and disadvantages. It is necessary to know the details of each of them in order to establish the ideal treatment for each situation.

KEYWORDS

Oroantral fistula; Oroantral communication; Surgical treatment.

INTRODUCTION

An oroantral communication (OAC) is a pathological condition characterized by the presence of a continuity between the oral cavity and the maxillary sinus that affects both the sinus, the oral mucosae and the maxillary bone between them. The most common cause of OAC is simple or surgical tooth extraction of antral teeth; Franco et al.[1] state that this is the cause in 92.63% of cases of OAC. It can also be found in the field of implantology, either immediately at the time of surgery, or following the placement of implants. Other less frequent etiologies include the presence of cysts or tumors in the maxillary sinus (4.47%), trauma (1.3%), peridontal infections (0.93%), radiation to the head and neck, syphilis, tuberculosis and bisphosphonate-induced osteonecrosis[2-6].

The clinical presentation of OAC is highly variable. It can be asymptomatic or present notable signs and symptoms such as functional changes in swallowing, respiration or phonation, pain around the cheek, infraorbital area and tissues surrounding the OAC, supuration from the communication itself or the ipsilateral nasal fossa, swelling of the area, generalized malaise or fever.

Treatment of this pathology is primarily surgical, with multiple techniques described for this purpose. The most commonly used techniques are trapezoidal vestibular advancement flap (TVAF), rotational palatal flap (RPF) and Bichat's buccal fat pad (BBFP).

TVAF is usually performed in small OACs since there is a risk of recurrence in larger communications. RPF is a full-thickness mucoperiostic flap of the palatine fibromucosa that is rotated to cover the area of the OAC defect, leaving an exposed area of bone that heals secondarily in a period of 3-4 weeks. Bichat's buccal fat pad (BBFP) consists of traction of the flap through a 0.5 to 3 cm horizontal incision in the periosteum at the level of the zygomatic arch, suturing it to the palatine mucosa and replacing the vestibular flap over it; the exposed fat tissue will epithelialize within approximately 3 weeks; this flap provides a large amount of vitalized tissue that is highly vascularized by the maxillary, superficial temporal and facial arteries, which allows to close large OACs with a low percentage of complications and a high rate of success.

CASE REPORT

We present the case of a 49-year-old male without previous medical history who was referred by his dentist to the Oral Surgery Department at Hospital Virgen de La Paloma in Madrid. The patient presented with swelling and intense pain in the cheek with suppuration in the oral cavity and left nasal fossa three weeks after having undergone extractions in the left posterior maxillary sector. In addition to local symptoms, the patient referred malaise and high fever.

After clinical and radiological examination, it was concluded that the patient had post-extraction OAC, located approximately where the molar was removed. Acute sinusitis was also present (Figure 1).

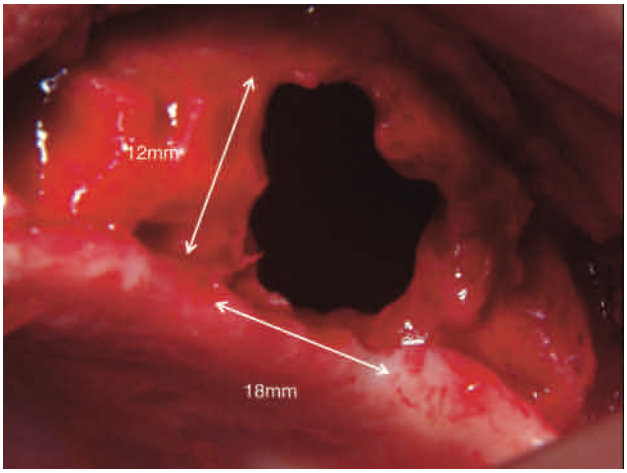

Figure 1. Dimensions of the underlying bone defect.

Given the patient's pathology, pharmacological treatment was initially administered (amoxicillin/clavulanic acid 875/125 mg every 8 hours for 1 week).

After this period, surgical closure of the OAC was performed via a BBFP. First, a supracrestal incision was made with mesial and distal openings to expose the bone defect (Figure 2), through which we proceeded

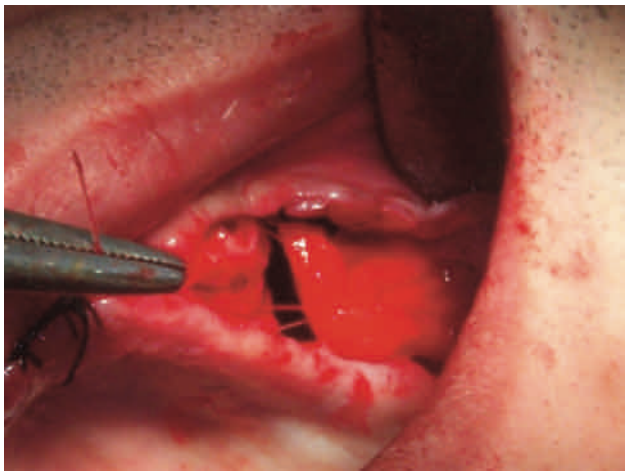

Figure 2. Traction of the Bichat's pad of fat.

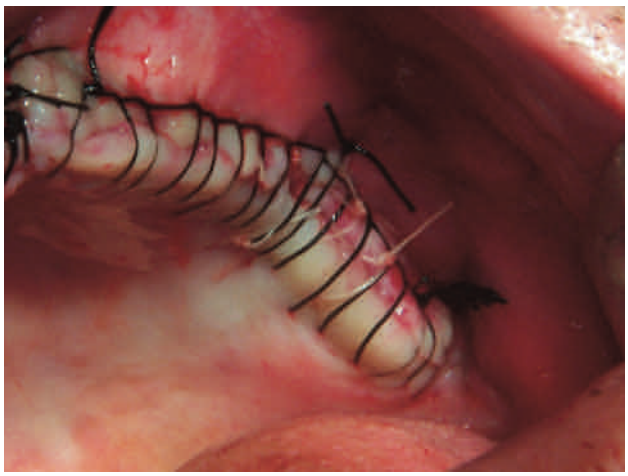

Figure 3. Suturing of the surgical wound.

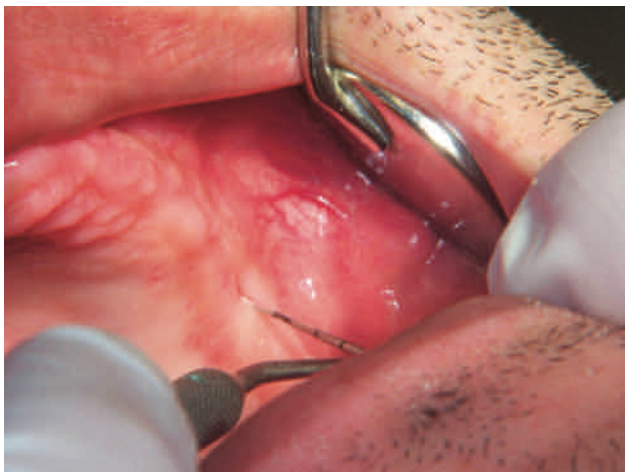

Figure 4. Appearance at 6 weeks.

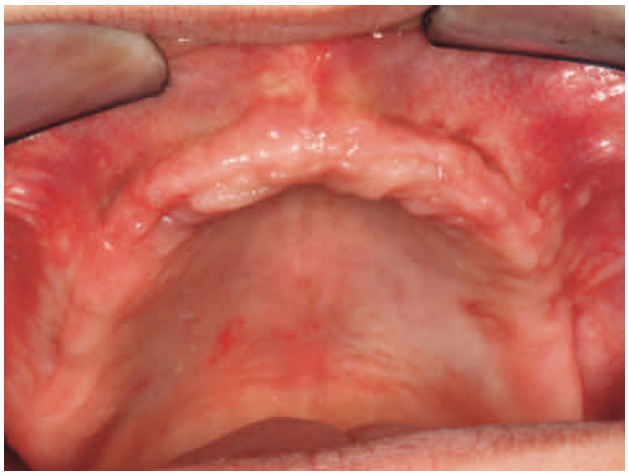

Figure 5. Appearance at one year.

to clean the sinus using 0.12% chlorhexidine lavages and careful curettage. Once clean, a horizontal incision was made in the periosteum at the level of the vestibular fundus of the second and third molar in order to access Bichat's buccal fat pad. Once exposed, it is dissected and progressively pulled until the entire bone defect is covered with no tension on the flap (Figure 3) and the palatine mucosa is sutured. In this case, given the large bone defect, the adipose tissue was covered with a TVAF in order to provide more stability and to avoid possible complications derived from scarring of the adipose tissue that was directly exposed in the oral cavity.

The patient was followed and evaluated at days 3rd, 7th, at the 3rd and 6th weeks (Figure 4) and at one year (Figure 5) postoperatively. No complications occurred and complete resolution of the sinus pathology and the oroantral fistula was achieved.

DISCUSSION

There are multiple surgical techniques and protocols for the treatment of OAC with no clearly established and unanimously accepted action criteria.

The majority of authors state that small OACs close spontaneously without the need for surgical treatment within a period of 2 days to 2 weeks in the absence of

sinus pathology[7]. Some authors claim that the maximum width for spontaneous closure be 2 mm[7,8] or up to 5 mm as referred by others[9,10].

Prior to surgical closure of the communication, evaluation of the state of the maxillary sinuses is required; if they are involved or there was sinus pathology prior to tooth extraction, intraoral treatment of the sinuses using a Cadwell-Luc approach or endoscopic treatment via the nasal fossae would be required[7,11].

There is a high level of variability on the usage criteria, limitations, complications, etc. among the most commonly used techniques.

According to most authors, TVAF is the technique presenting the fewest postoperative complications, but it has the greatest risk of recurrence of the oroantral fistula. Some authors found recurrence only in patients treated with TVAF but not with other techniques[7,9]. However, Franco et al.[1] reported a failure rate of 10.39%, which is even lower than RPF, with a failure rate of 11.68%, although this is due to the fact that their meta-analysis included authors who used RPF to treat OACs caused by extraction of superior third molars, a technique not indicated for this type of defect unless the anterior palatine orifice is extended[12]. Batra et al.[7] consider this technique to be contraindicated when there are large bone defects, sinus involvement, reinterventions or when the OAC is very posterior or very palatinized, given that in these cases, the tension on the flap is much greater, which increases the risk of failure. They also consider it contraindicated when the patient is going to receive rehabilitation with any type of removeable prosthesis due to the decrease in the width of permanent vestibular fundus that is present in 40% of patients[7,9]. TVAF has also been used as a complement to the BBFP technique, as in the case presented, in order to provide greater safety to the intervention and to avoid the risk of healing-related complications associated to this technique such as herniation of the flap, partial necrosis and in particular excessive granulation tissue formation during healing[1]; however, other authors state that it does not provide any significant advantage over the conventional BBFP technique and only recommend its use when the Bichat's pad has been perforated or excessively stretched under traction, a situation that can be solved with the use of lyophilized porcine dermal membranes, without losing vestibular depth[5,7].

Another possible combination described in the TVAF literature is using small-sized RPF that, although it slightly decreases the possible tension on the suture, it adds some loss of the vestibular fundus that results from TVAF to the morbidity of RPF.

RPF has been used to close both small and very extensive OAC. It has been reported to successfully close a 2 x 4 cm OAC[8]. The main disadvantage of this technique reported by the majority of authors is postoperative complications and the high number of complications that can occur (persistence of the passage of air and liquids between the nose and oral cavity below the flap until healing has concluded, flap necrosis, postoperative bleeding, excessive granulation of the scar, etc.)[1,7]. Batra et al.[7] state that the remaining techniques available are less aggressive and equally successful. Therefore, they recommend avoiding its use except in very specific situations, although other authors claim these problems are minimal and they indicate its use for closure of large or long-duration OACs prior to TVAF and BBFP[8,13,14]. However, all authors concur in that OACs in a very posterior or very vestibularized location are best treated with a technique other than RPF.

The majority of authors consider BBFP to have the lowest risk of recurrence. Franco et al.[1] report a 1.30%, much lower other techniques. According to the literature, the use of this technique is indicated in defects up to 7 x 5 cm, but the majority of authors recommend limiting this technique to defects smaller than 5 x 4 cm[15]. The reasons for the high success rate of this technique appear to be related to the large mass of vitalized tissue that is highly vascularized by the maxillary, facial and superficial temporal arteries. This promotes rapid epithelialization once exposed to the oral cavity within 3-4 weeks[15]. In addition to

the high level of success, BBFP is increasingly becoming the technique of choice for post-extraction OACs due to its ease of extraction with minimal dissection, the low rate of complications, low morbidity in the donor zone and because this technique can be performed under local anesthesia in the dental office. Although less frequent than RPF, BBFP is also not exempt from complications, some of which are more significant than those produced by other techniques. These include partial necrosis of the flap, fibrosis, trismus, marked inflammation, excessive formation of granulation tissue and complications derived from deficient surgical technique such as hemorrhage and damage to the facial nerve[8,9].

This technique was used in the case presented in order to achieve maximum predictability in the closure of such a large OAC. RPF was discarded despite a larger vestibular fundus being preferable in light of future prosthetic rehabilitation because it was not a sound reason because of the complications that could arise, such as a worse surgical field for cleaning the sinus or greater postoperative damage, in a patient who had just had all of the maxillary teeth extracted. Although the patient initially lost length of the vestibular fundus, he recovered the original dimensions over time, with complete symmetry at the one-year follow-up visit.

There are also other techniques based on mobilization of the soft tissues such as the lingual flap, the buccal mucosal flap from the genial region or the temporal muscle flap. These are currently used much less frequently due to their high morbidity, and practically abandoned for closure of post-extraction OAC[7].

We can also find techniques that are not only based on mobilization of soft tissues for closure of OAC such as the use of alloplastic materials including gold or polymethacrylate sheets, but these can result in complications such as extrusion, migration or infection[16]; or autologous transplant and subsequent endodontics of the third superior molar to the bed where the defect is located[17].

In patients needing prosthetic rehabilitation with the use of osseointegrated implants, closure of the OAC by surgical techniques that only involve mobilization of different soft tissues, the sinus mucosa and the oral mucosa will be in contact without a barrier between them, which significantly difficults future surgery to elevate the sinus for the placement of implants. In order to avoid this problem, en block bone grafts from different donor areas can be used, whether they are intra-oral or extra-oral[18-21], or autologous cartilage implants, be they auricular or from the nasal septum; these types of grafts have the advantage of being more resistant to infection than osseous tissue and they do not require vascularization for integration, which considerably reduces the risk of failure in addition to lower morbidity of the donor zone[22]. Within this field, there are also authors who propose the use of bone morphogenic protein 2 (BMP2), claiming that there is a lower risk of infection compared to conventional bone grafts, when the previous chronic infection of the target area is eliminated[23].

CONCLUSIONS

There is no single solution for the treatment of this pathology, nor are there unanimous criteria on when one technique or another is indicated. For this reason, it is very important to understand the limitations and disadvantages of each technique and to integrate aspects such as location, time of disease progression, size of the OAC and type of prosthetic rehabilitation that the patient will use in the future. The therapeutic approach that best suits the individual patient's situation should be chosen.

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Original article

Use of Endoret® (PRGF®) (Platelet Rich Growth Factor) in the post-extraction socket: a new regenerative approach

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ABSTRACT

Objective. There are numerous techniques on preserving or regenerating the post-extraction socket described in the international literature that employ different materials alone or in combination.

Materials and methods. A randomized double-blind clinical trial was conducted in which post-extraction sockets in mandibular molars were regenerated over a period of 12 weeks. A total of 60 patients were recruited and randomized either to the Endoret® (PRGF®) group (36 patients) or the control group (24 patients).

Results. Dental CT analysis (cone beam computed tomography: CBCT) at 12 weeks after extraction revealed that the group treated with Endoret® (PRGF®) achieved a socket regeneration volume greater than or equal to 75% in 96.67% of cases, while ony 45.45% of the control group, with statistically significant differences (p=0.005). The percentage of newly formed bone measured by histopathologic examination was 63.08% for Endoret® (PRGF®) compared with 35.56% for the control group. Better epithelialization was also observed at 3, 7 and 15 days in the experimental group as well as lesser pain.

Conclusions. The technique evaluated in this clinical trial can be considered safe, no negative adverse effects occurred, and it was more effective in improving different aspects of post-extraction socket regeneration (patient quality of life and post-extraction socket regeneration).

KEYWORDS

Post-extraction socket; Regeneration; Endoret-PRGF®.

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INTRODUCTION

There are numerous techniques on preserving or regenerating the post-extraction socket described in the international literature that employ different materials alone or in combination[1-3]. Endoret® Platelet Rich Growth Factor (PRGF®) and autologous fibrin are 100% autologous products that are simple and inexpensive to obtain. It is also important to highlight that the use of this biological socket regeneration technique does not have side effects or dangerous effects for the patient. It is recommended as a preventive therapy for alveolitis by significantly reducing its incidence as demonstrated in the studies carried out by Mancuso et al., 2003[4] (on 117 patients) y Rutkowski et al., 2007[5] (on 506 patients), in addition to our experience over the years[6-9].

One of the first studies published on the potential of Endoret® (PRGF®) as a regenerator of post-extraction areas for future placement of dental implants was reported in 1999[7]. In this study, epithelialization of 10 patients treated with Endoret® (PRGF®) was excellent. In three patients, split-mouth extractions were carried out with Endoret® (PRGF®) and a control, and in these patients differences in epithelialization could be compared under the same circumstances.

In 2009, an animal model study was published in which the regenerative power of Endoret (PRGF®) was determined[8]. The study was carried out on goats in which 5mm diameter cavities in the tibias were prepared to simulate artificial sockets that were then refilled with Endoret® (PRGF®). Evaluation of the regeneration of the defects was done at 8 weeks after surgery using histological preparations where the newly formed bone was studied and tissue histomorphometric analysis was performed.

Newly formed trabecular bone surrounded by a densely vascularized connective tissue could be histologically identified in the Endoret® (PRGF®) group. The pathologic specimens in the control group consisted of highly cellular connective tissue with some small areas of intramembranous bone tissue.

Finally, in 2010, a new study revealed the regenerative potential of Endoret® (PRGF®) in humans[9]. The study was performed on 14 patients who underwent tooth extractions and were treated using the Endoret® (PRGF®) technology compared to patients in whom teeth were extracted without the use of Endoret® (PRGF®) by conventional treatment (filling the socket with blood clot). After the waiting period for placement of the implants (between 11 and 14 weeks), Cone Beam Computed Tomography (CBCT) was performed to measure the volume of regenerated bone inside the socket as well as the density of the new bone in Hounsfield units in the interior and exterior portion of the future site of the implant and inside the socket defect.

Densitometry of the interior and exterior of the measuring cylinder for the implant on CBTC and the center of the regenerated socket revealed differences between both groups, being statistically significant in the areas corresponding to the implant's measuring cylinder.

The objective of this study is to evaluate the efficacy of Endoret® (PRGF®) as regenerative material for the post-extraction socket in humans via a randomized double-blind clinical trial .

MATERIALS AND METHODS

A randomized double-blind clinical trial was carried out in which post-extraction sockets in mandibular molars were regenerated over a period of 12 weeks. A total of 60 patients were recruited who were then randomized to either the Endoret® (PRGF®) group (36 patients) or the control group (24 patients).

The inclusion criteria were: adult patients of both sexes, with indication for single exodontia of mandibular molars that could be followed during the treatment period.

The exclusion criteria were: included third molars or those with horizontal inclination, severe inflam-

mation prior to the intervention in the areas of exodontia, severe hematological alteration or disease, having received radiation therapy, chemotherapy or immunosuppressant therapy in the previous 30 days, as well as systemic corticosteroids and/or anticoagulants, on regular nonsteroidal anti-inflammatory treatment, history of chronic hepatitis or liver cirrhosis, diabetes mellitus or poor metabolic control (glycosylated hemoglobin greater than 9%), dialysis patients, presence of malignant tumors, hemangiomas or angiomas in the area of the extraction, history of ischemic heart disease in the previous year, pregnancy, metabolic bone disease, and patients on oral or intravenous bisphosphonate treatment.

The main variable studied was the percentage of sockets that achieved 75% of regenerated bone volume at the end of follow-up in each treatment group. Secondary variables were also evaluated: final bone density (measured in Hounsfield units on CBCT, soft tissue epithelialization index (scale 1 to 5), keratinized thickness of the gums, postoperative pain (measured on a visual analogue scale) and inflammation (scale of 0 to 3). Bone and soft tissue biopsies were also performed at the time patients received dental implants, after the follow-up period.

The clinical trial was approved by the Ethics Committee. Patients signed informed consent. The clinical trial reference number was: ClinicalTrials.gov (NCT01465399).

The pain scale from 0 to 10 and the percentage of socket closure, the percentage of newly formed bone and the final bone density of the socket were evaluated as quantitative variables and the means were compared between the control and treatment groups using Student's t test, with a statistically significant p-value of $p \leq 0.05$. To evaluate the soft tissues and degree of inflammation, as well as the type of bone obtained in the regenerated zone, the Mann-Whitney test was used with a statistically significant value of $p \leq 0.05$.

RESULTS

Inspection of the socket after extraction of the lower molars indicated the presence of radicular septum in 54.16% of the control group, while the septum was only preserved in 38.9% of the defects in the treatment group. Because of this difference, the defects in the Endoret® (PRGF®) group were of greater volume than those treated in the control group, as shown in Figure 1.

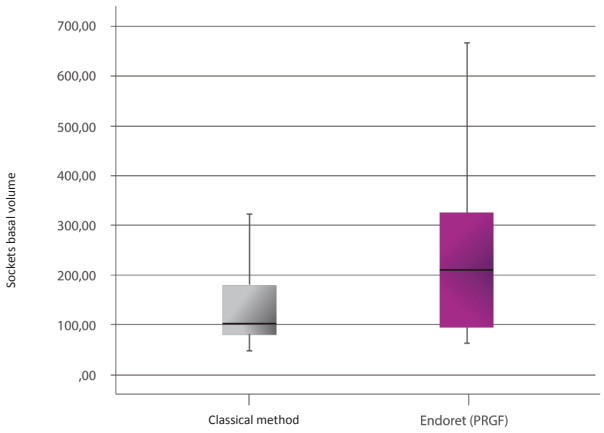

Figure 1. Comparison of defects treated by the classical method (blood clot-control group) and the Endoret® (PRGF®) group.

The group treated with Endoret® (PRGF®) achieved a socket regeneration volume greater than or equal to 75% in 96.67% of cases, while ony 45.45% in the control group, differences being statistically significant (p=0.005) (Figure 2).

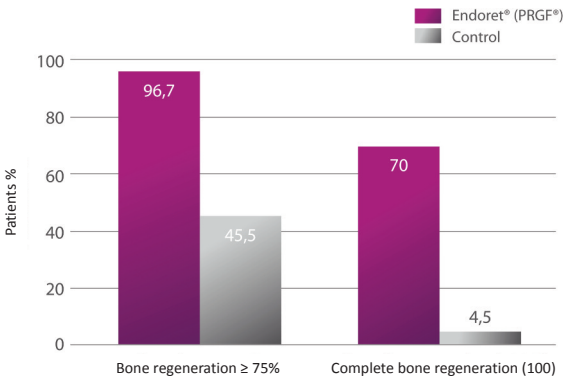

Figure 2. Bone regeneration in the Endoret® (PRGF®) group (purple) compared with the control group (gray) of 75% and 100% of the socket volume.

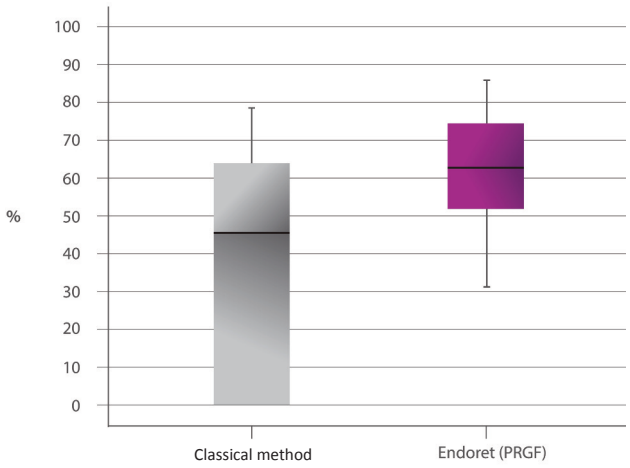

Figure 3. Newly formed bone in the Endoret® (PRGF®) group and the control group.

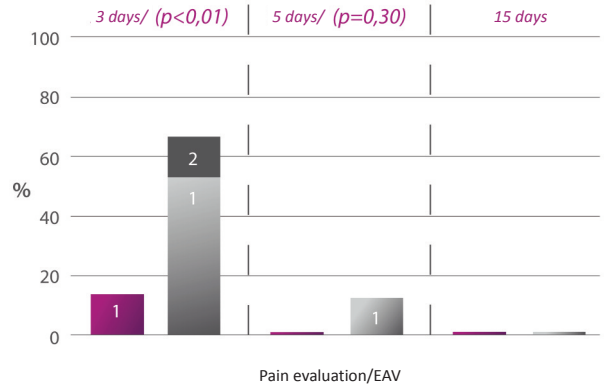

Figure 4. Postoperative pain evaluation at days 3rd, 7th and 15th in both groups.

The percentage of newly formed bone measured by hystopathologic examination was 63.08 for the Endoret® (PRGF®) group compared to 35.56% for the control group, as shown in Figure 3. Bone density of the newly formed bone as measured on CBCT was greater in the treatment group (mean 450 HU) compared to the control group (mean 318 HU), statistically significant (p=0.04).

In this trial, we also evaluated the effect of Endoret® (PRGF®) in extractions on the patient quality of life by evaluating postoperative pain, inflammation and epithelialization, since despite the impression provided by patients treated with Endoret® (PRGF®) following tooth extraction, there were no studies to confirm this.

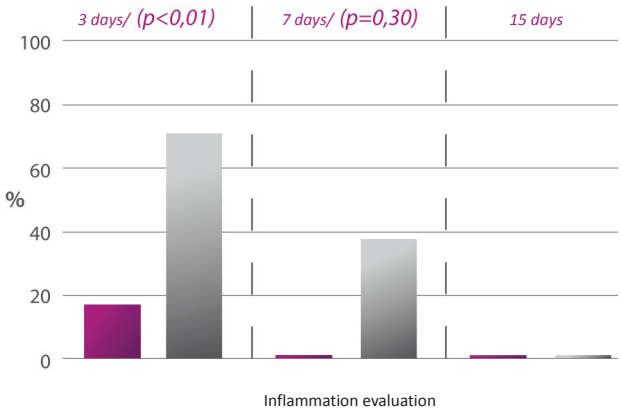

Figure 5. Postoperative inflammation evaluation at days 3rd, 7th and 15th in both groups.

On pain evaluation at day 3rd, there was pain in 18% of patients in the treatment group, while we found pain in 62% of patients in the control group, statistically significant (p=0.003). The pain had disappeared at day 7th in the Endoret® (PRGF®) group while it was still present in 15% of the control group. Pain was absent at day 15th in both groups (Figure 4).

On evaluation of the inflammation index at day 3rd, inflammation was found in 18% of patients in the Endoret® (PRGF®) and 65% of the control group, differences being statistically significant (p=0.03). Inflammation persisted at day 7th in 39% of the control group, while it had disappeared completely in the treatment group, differences statistically significant (p=0.038). The inflammation disappeared in both groups at day 15th (Figure 5). Figure 6 shows one of the cases included in the control group compared to another case included in the Endoret® (PRGF®) group.

DISCUSSION

All of the studies published in the international literature that have tested the potential of Endoret® (PRGF®) as a post-extraction socket regenerator have demonstrated its good performance in obtaining bone and soft tissue regeneration outcomes.[5-9] The results of our study reinforce these data both in hard tissue and

soft tissue, in addition to adding other variables such as pain, inflammation and therefore indirectly evaluating patient quality of life following tooth extraction and its regeneration with Endoret® (PRGF®).

Alisa et al., (2010) reported a decrease in pain within the first three days in the experimental group versus the control group and better primary intention closure, both variables presenting statistically significant differences ($p<0.05$).[10] Other authors like Gürbuzer et al., (2008), Ogundipe et al., (2011) and Celio-Mariano et al., (2012) focused the results of their studies on bone regeneration without evaluating pain or soft tissues.[11-13] They found improvement in the bone volume achieved in the experimental group compared with the control group, as evaluated by different techniques (subjective gray scale, Scintigraphy, dental cone beam tomography), though none of them found statistically significant differences between groups.

CONCLUSIONS

The decrease in pain and inflammation, and the achievement of a faster primary closure observed in this study confirms that the quality of life of patients treated with Endoret® (PRGF®) is superior to the conventional treatment (blood clot).

The technique evaluated in this clinical trial can also be considered safe as there were no negative or adverse effects. In addition, we were able to predict outcomes like:

- Closure of the socket greater than or equal to 75% with better density and better proportion of newly formed bone.
- Better epithelialization at days 3rd, 7th and 15th with statistically significant differences, obtaining a greater thickness of the keratinized gum.
- Significant differences in pain at day 3rd (early postoperative, where there is a greater pain level), as well as in inflammation at days 3rd and 7th.

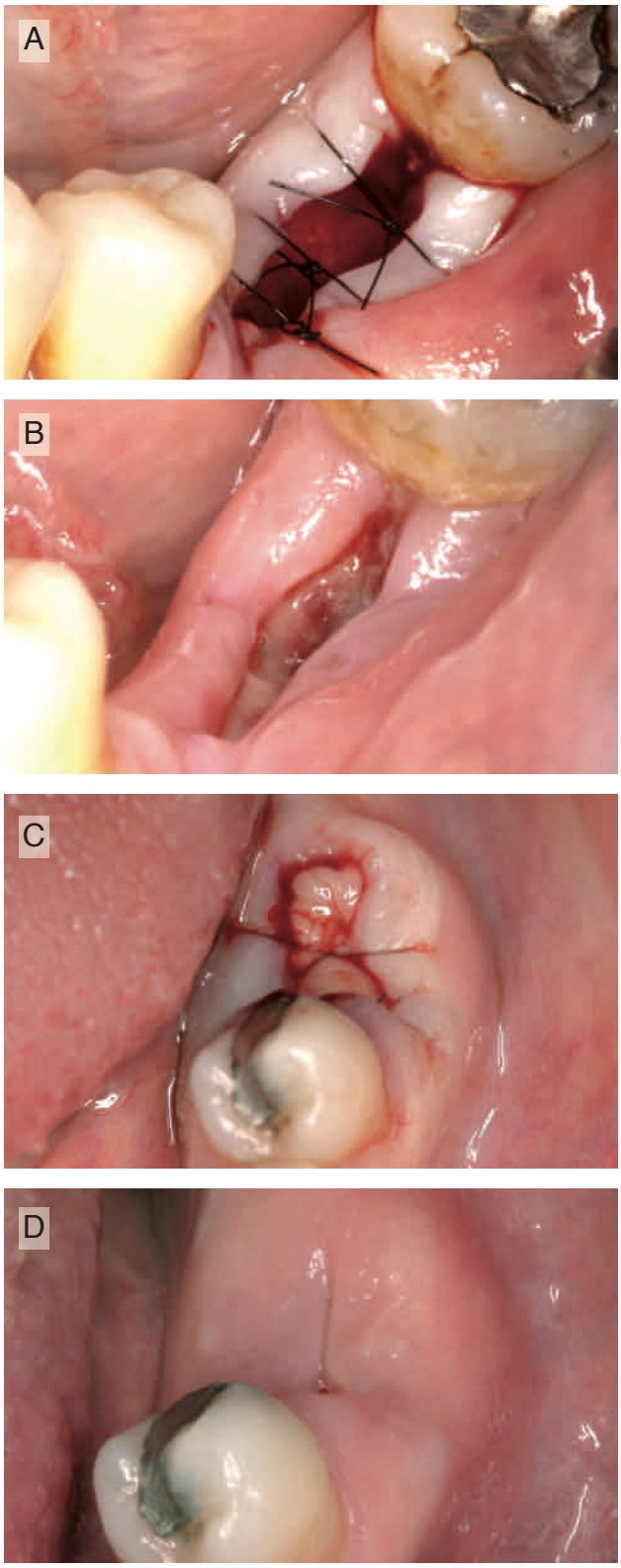

Figure 6. A) Tooth extraction included in the control group. B) Socket regeneration at day 15th. C) Tooth extraction included in the Endoret® (PRGF®) group. D) Socket regeneration at day 15th.

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Original article

The effect of thermocycling and acid pre-etch on bond strength to enamel of different self-etch adhesives

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ABSTRACT

Introduction: Self-etch adhesives are becoming more widely used. Their acidity can vary greatly. This determines the degree of infiltration into hard dental tissues and its adhesive ability.

Objective: To determine the effect of thermocycling and pre-etching with orthophosphoric acid on the adhesive resistance of different self-etching adhesives.

Method: The following adhesives were applied to bovine vestibular enamel: 1) Filtek Silorane (FS), 2) Filtek Silorane with acid pre-etch (AFS), 3) Adper Scotchbond 1XT (XT), 4) Adper Scotchbond SE (SE) and 5) Adper Scotchbond SE with acid pre-etch (ASE). All were applied following the manufacturer's instructions. The restored teeth were stored in water (24h, 37 °C) or thermocycled (5000 and 10000 cycles) before being sectioned and subjected to the microtraction test. Two-way ANOVA and Student-Newman-Keuls tests were used for statistical analysis (α=0.05).

Results: XTZ250 achieved the highest values and FS achieved the lowest after all artificial aging. 10000x thermocycling significantly reduced bond strength in all systems. AFS bond strength was 25.7% greater than FS, while ASE was 3.8% greater than SE.

Conclusions: The material and aging influenced bond strength. The ultra-mild self-etch adhesive obtained the lowest values after all aging treatments. Pre-etching was especially beneficial for FS.

KEYWORDS

Self-etch adhesives; Acid etching; Enamel; Thermocycling; Bond strength.

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Ilustre Colegio Oficial de Odontólogos y Estomatólogos de la Iª Región

INTRODUCTION

Self-etch adhesive systems are those that do not require prior application of an etching acid as they contain acidic monomers that are capable of conditioning and infiltrating dental tissue, meaning the risk of discrepancy between both maneuvers is decreased or nonexistent.[1] They are easier to use, and to apply, so their use has increased in the recent years.[2]

Based on the number of steps required for application, self-etch systems can be two or one-step systems. Two-step systems require application of a self-etch primer and then the adhesive resin. One-step systems, also known as "all in one", are products that simultaneously etch, condition and adhere to the tissue.[1]

The principle by which self-etch adhesives bond to the enamel and dentin depend fundamentally on their pH and their ability to chemically interact with them.[2,3] The acidity is used to classify this heterogeneous family of adhesives. This depends on the level of interaction with the hard dental tissues. They are divided into: ultra-mild (pH>2.5), mild (pH≈2), medium strength (1<pH<2) and strong (pH≤1)[3].

The most acidic systems base their function on hybridization of the hard tissues by establishing a micromechanical coupling similar to acid-etching adhesives but much less extensive than that achieved by them.[1,4] Conversely, mild self-etch adhesives base their mechanism on establishing a chemical bond with the hard tissues which, as long as they remain stable over time, increases the quality and longevity of the adhesion.[4,5]

In vitro studies report that strong self-etch adhesives have acceptable performance when they adhere to the enamel.[2] Mild self-etch adhesives have mediocre adhesive ability when bonding to enamel. Occasionally they show good adherence to the dentin due to their mild demineralization and subsequent interaction with the remnant hydroxyapatite.[6,7] This may be contradictory especially after confirming that the maintenance of hydroxyapatite at the interface predisposes to the establishment of a strong bond to the dentin, given that the enamel contains much more hydroxyapatite. This appears to be the exact cause, since it is necessary to obtain a certain degree of micromechanical coupling in the enamel via an etching agent in order to create a resistant interface.[8-11]

All adhesive systems are susceptible to some degree of hydrolytic degradation, but given that degradation of the resin is due to its ability to absorb water, the adhesives' hydrophilic properties modulate their predisposition to suffer this unfavorable phenomenon.[12,13] For this reason, simplified adhesives that combine hydrophilic and hydrophobic monomers can result in interfases that lack an adequate layer of hydrophobic resin that is isolated and free of solvents, which makes them more susceptible to hydrolytic degradation.[14] The best example of hydrolytic degradation is represented by one-step self-etching adhesives that are very rich in highly hydrophilic monomers.[15] They behave as semipermeable membranes even after polymerization.[16]

Etching with orthophosphoric acid prior to application of self-etching adhesives, especially the mild ones, is a technique recommended to improve their bond to the enamel given that it reduces the appearance of marginal defects in both in vitro[8] and in clinical studies.[10,11] In addition, an increase in adhesive ability of several self-etching systems has been observed when this extra step is included[7,17,18], though few studies include acid-etch adhesives as a control material. In addition, the high level of diversity between different self-etch adhesives can cause the previous etching to have a different effect due to the nature and acidity of the adhesive tested.[2]

The objectives of this in vitro study were to determine 1) the bond strength to microtraction to the enamel of different adhesive systems (two self-etch systems with different acidity and one total acid etching adhesive) after three artificial interface aging treatments and 2) the effect of pre-etching with orthophosphoric acid on the bond strength of the systems analyzed.

MATERIALS AND METHODS

Experimental groups

The adhesives used are detailed in Table 1. The experimental groups were the following:

- Group 1: Filtek Silorane Restorative System (FS). Filtek Silorane Adhesive System and a resin composed of low polymerization contraction, Filtek Silorane Low Shrink Posterior Restorative. Due to the new chemical composition of the resin from both materials, they both need to be applied together.
- Group 2: AFS was also reconstructed with the Filtek Silorane system. However, prior to application of the adhesive, 35% orthophosphoric acid Scotchbond Etchant, 3M ESPE) was applied for 15 seconds and rinsed for 10 seconds.
- Group 3: Adper Scotchbond 1 XT (XT) adhesive system, a total acid etch adhesive, and Filtek Z250 microhybrid resin compound.
- Group 4: Adper Scotchbond SE (SE) two-step self-etch adhesive system and Filtek Z250 microhybrid resin compound.
- Group 5: ASE, meaning reconstruction with Adper Scotchbond SE and Filtek Z250, 35% orthophosphoric acid (Scotchbond Etchant, 3M ESPE) was applied for 15 seconds and rinsed for 10 seconds prior to the application of the adhesive.

All materials belong to 3M ESPE company (Minnesota, USA). The color of the resin compounds was A3 VITA in all cases. The technical characteristics and usage instructions for the adhesives evaluated are shown in Table 1.

Sample preparation

Forty-five permanent bovine incisors were used. After being washed and analyzed with a stereoscopic microscope (Olympus SZX7, Hamburg, Germany) to rule out the presence of cavities or cracks, they were refrigerated (4°C) in a distilled water and thymol salt solution for a period of less than six months from the date of extraction. In order to facilitate handling of the teeth, the root was separated from the crown with diamond burrs and the pulp chamber was filled with composite for dual-healing stumps (ParaCore, Coltène-Whaledent) adhered using XP Bond adhesive (Dentsply), with both materials polymerized with the Elipar S10 LED (3M ESPE) unit.

The vestibular surface of the teeth was then polished with 600 grit silicon carbide discs mounted to the polisher (Buehler) under irrigation. This procedure eliminated the original convexity of the vestibular surface and exposed a flat prismatic enamel surface. With a stereoscopic microscope and injecting air, we confirmed that all of the preparations were limited to the thickness of the enamel.

The teeth were then randomly divided into 5 groups (9 teeth per group) according to the 5 experimental groups described above. The adhesives were applied exclusively to the prepared enamel according to the manufacturer's instructions and resin compound blocks were constructed on them. This was always placed using an incremental technique (three increments of composite, 2 mm in height each). The polymerization unit used was LED Demetron I (Kerr), which has a minimum power density of 550 mW/cm2.

The prepared teeth were then subdivided again. In this way, 3 subgroups of 3 teeth each were created from each of the experimental groups based on the following aging treatments:

- Subgroup A: Storage in distilled water at 37°C for 24h.
- Subgroup B: 5000 cycles of thermocycling between 5 and 55°C with a 30-second immersion time.
- Subgroup C: 10000 cycles of thermocycling between 5 and 55°C with a 30-second immersion time.

Once the different aging treatments were concluded, the teeth were sectioned longitudinally with a low-velocity diamond disc using abundant irrigation with water (IsoMet® 5000 Linear Precision Saw, Buehler). The cuts were made along the x- and y-axes in order

Table 1: Adhesive systems evaluated. Information provided by the manufacturer.

Adhesives	Composition	Instructions for use	Type	pH
Filtek Silorane Adhesive System	Self-etch primer: phosphorylated methacrylates, Vitrebond™ copolymer, Bis-GMA, HEMA, water ethanol. Filler: silica treated with silane, initiators, stabilizers.	Self-etch primer: Shake. Apply for 15" in the cavity. Disperse with air injection. Photopolymerize 10".	Two-step self-etch	2.7 (ultra-mild)
	Adhesive: hydrophobic dimethacrylate, phosphorylated methacrylates, TEGDMA. Filler (same as the primer).	Adhesive: Shake. Apply in the cavity and distribute uniformly with air. Photopolymerize 10".		
Adper Scotchbond 1XT	HEMA, Bis-GMA, dimethacrylate, polyacrylic and polythionic acid-based functional metacrylate copolymer, water and ethanol. Nanofiller and photoinitiator.	Acid etch: Apply 35% orthophosphoric acid (Scotchbond Etchant, 3M ESPE) for 15" and rinse for 10". Remove excess humidity without desiccating.	Two-step total acid-etch	4.7
		Adhesive: Apply two successive layers for 15". Gently dry with air (2-5") to evaporate the solvent. Photopolymerize 10".		
Adper Scotchbond SE	Liquid A (primer): water, HEMA, surfactant, pink coloring.	Liquid A (primer): Apply in the cavity until it is completely stained pink.	Two-step self-etch	1 (strong)
	Liquid B (adhesive): UDMA, TEGDMA, TMPTMA, HEMA, MHP. Nanofiller with zirconium, photoinitiator.	Liquid B (adhesive): Apply actively for 20". As the pink color applied from Liquid A disappears, indicating activation of the acid part of the adhesive and the start of the self-etch process. Dry with air 10". Apply a second layer of the adhesive followed by a smooth current of air. Photopolymerize 10".		

to obtain bar-shaped sections with a quadrangular section and a transverse area, meaning the bonded surface measuring approximately 1 mm^2. An average of 20 specimens were obtained from each tooth that were valid for the subsequent microtraction test.

In order to precisely calculate the bonded surface area of each specimen, their lateral sides were measured using a digital caliper to a 0.001 mm level of precision (Mitutoyo). The samples were then individually submitted to the microtraction test using an Instron 3345 universal trials machine, to which they were glued using cyanoacrylate glue (Loctite Gel) to the machine's clamps. The microtraction values are expressed in megapascals (MPa). All of the specimens that fractured prior to being submitted to the microtraction test were recorded but excluded from the statistical analysis.

Table 2: Mean values (standard deviation) corresponding to the microtraction strength of the enamel (expressed in MPa), number of samples tested (N), types of failure [adhesive (A), cohesive (C), mixed (M)] and number of pre-test failures (%) for each of the experimental groups based on the type of aging treatment applied.

Aging	24 h					5000x					10000x				
Adhesive system	x̄(sd)	n	A/C/M	%	x̄(sd)		N	A/C/M	%		x̄(sd)	n	A/C/M	%	
FS	23.1 (4.2)	63	58/1/4	2	C 1	22.8 (5.2)	61	54/2/5	3	C 1	18.5 (3.5)	60	57/0/3	2.4	D 2
AFS	29 (4.2)	65	51/6/8	0.3	B 1	27.8 (4)	61	52/5/4	0.5	B 1	23.4 (4)	61	57/1/3	2	B 2
XT	34.1 (4.1)	66	50/4/12	1	A 1	33.4 (4.2)	64	51/2/11	0.8	A 1	31.1 (4)	65	55/2/8	1	A 2
SE	29.4 (3.9)	65	53/3/9	2	B 1	27 (3.8)	61	52/1/8	3	B 2	20.8 (3.7)	60	54/0/6	4.3	C 3
ASE	29.8 (3.7)	62	49/6/7	0.2	B 1	27.1 (4.4)	61	53/2/10	1	B 2	22.9 (4.3)	60	55/0/5	1.2	B 3

Similar letters in the same row mean similar microtraction strength values between the restorative systems after each of the aging treatments.
Similar numbers in the same column mean similar microtraction strength values between the aging treatments for each of the restorative treatments.

The fractured surfaces of all of the specimens were subsequently analyzed with a stereoscopic microscope (Olympus SZX7) in order to determine the type of failure that occurred in each: adhesive (between the adhesive and the enamel-dentin and/or between the adhesive and the composite), cohesive (fracture in the sinus of the enamel-dentin or the composite) or mixed (adhesive and cohesive failure occurring simultaneously). This analysis was performed with a magnification up to 50x and always by a single observer.

Statistical analysis

All of the results obtained were statistically analyzed using IBM SPSS 19 (IBM Corporation, Armonk, New York, USA) for Windows. The accepted level of significance was 0.05 in all cases. First, a descriptive analysis was presented using central tendency measures and the arithmetic mean with the standard deviation used as a measure of dispersion. In order to evaluate how the independent variables (adhesive system used and aging treatment) influenced the quantitative outcome variables (bond strength to the enamel), a two-way ANOVA test was applied. Subsequent comparisons were made using the Student-Newman-Keuls test.

RESULTS

The statistical analysis determined that the bond strength to the enamel was influenced by the adhesive system used and the aging treatment applied. The interaction between both factors was also significant. The means and standard deviations corresponding to the microtraction bond strength test for the systems evaluated are detailed in Table 2.

Influence of the adhesive for each aging treatment

The results obtained are shown in Figure 1. Application of the one-way ANOVA test detected statistically significant differences between the mean microtraction values obtained for the different adhesive systems after each aging treatment, so the next comparison was carried out using the Student-Newman-Keuls test ($p<0.05$).

- 24 h: The highest bond strength values were achieved with XT. The second statistical group included three systems with statistically similar values (in descending order: ASE, SE and AFS). The FS system was in the last place.

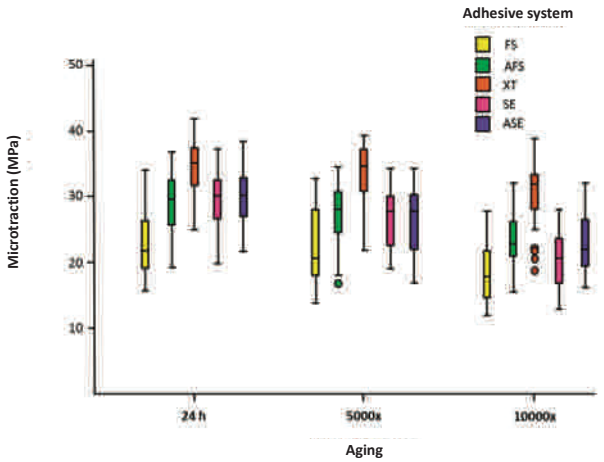

Figure 1. Distribution of the bond strength values after each of the aging treatments obtained for each adhesive system.

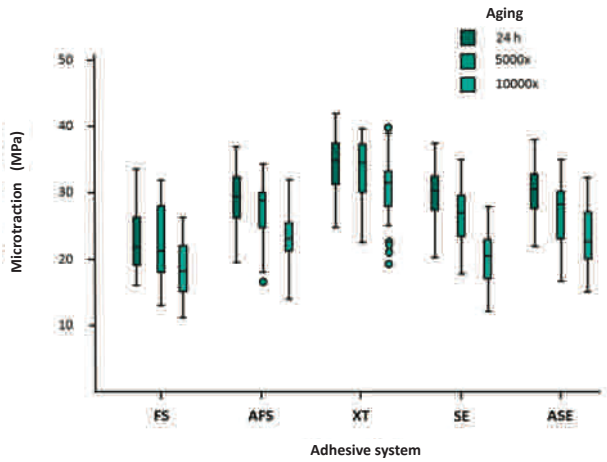

Figure 2. Distribution of the bond strength values obtained for each adhesive system after the different agin treatments.

- 5000 thermocycles: XT was once again in the first place. In the second statistical group, with statistically similar values, were the same three systems as those after 24 hours, though in a different order. In descending order: AFS, ASE and SE. The FS system once again had the lowest strength values.
- 10000 thermocycles: Once again, the bars for the XT system had the highest values. Next, with statistically similar values, were the two groups with self-etch adhesives and reinforcement with acid etching: AFS and ASE. Finally, the values achieved with SE and FS are in third and fourth place, respectively.

Influence of the aging treatment applied for each adhesive

The results obtained are shown in Figure 2 and described below. The one-way ANOVA test detected differences between the microtraction values obtained after the different aging treatments for all of the experimental groups, revealing the following:

- FS, AFS, and XT: the microtraction values obtained were statistically similar after 24h and 5000 thermocycles, being significantly inferior to those registered after 10000x thermocycling.
- SE and ASE: the values decreased statistically with each aging treatment that was applied, meaning the highest values were obtained after 24h of storage, the intermediate values after 5000 thermocycles and the lowest values after 10000 thermocycles.

Observation of the fractured surfaces with a stereoscopic microscope revealed the nature of the failure in each of the samples evaluated. The results are shown in Table 2.

DISCUSSION

The results obtained in this study determined that the bond strength to the enamel is dependent on the restorative system used and the aging treatment applied, as well as the interaction between both variables. Using an intersystem comparison, it is clear that thermal aging reduces the microtraction values achieved by the five experimental groups. However, the intersystem comparison also reveals the important differences in the performance that each of the materials demonstrated.

According to the literature, total acid-etch adhesive systems achieve the best results and are recognized as the gold standard.[1,19] The orthophosphoric acid etching pattern allows the adhesive resin to penetrate between the crystals and into the prisms, as well as allowing for deeper penetration between the interprismatic spaces.

This creates a superficial morphology that is capable of initiating the micromechanical bond that reports the highest levels of adhesion to the enamel[9,19,20], which also makes it easier for the adhesive to achieve greater resistance to the propagation of microfractures.[7,9]

These advantages related to acid etching were also present in our study, given that XT, the only total acid-etch adhesive analyzed, achieved the highest bond strength values after all of the aging treatments. In addition, there was only a significant decrease in its microtraction values after application of more aggressive thermocycling of 10000 cycles (Table 2). The supremacy of the enamel bond of the total acid-etch adhesive over the self-etch systems evaluated is supported by numerous scientific studies.[19-24]

The reduced demineralization capacity of the majority of self-etch adhesives is particularly evident when bonding to the enamel, the dental substrate with the highest inorganic content. Their acidic monomers are limited to acting on the most superficial enamel, which only achieves a mild, flat, uniform etching.[7-25] For this reason and for quite some time, some authors have been promoting the benefits of performing selective etching with orthophosphoric acid, meaning limited to the enamel, prior to applying the self-etch adhesive.[8-11]

In 2009, Erickson et al.[25] analyzed the effect of acid etching once they had the strength values for various self-etch adhesives, including Clearfil SE (Kuraray) and Adper Prompt L-Pop (3M ESPE). As explained below, these two adhesives can be relatively comparable to the two self-etch systems in our study: FS and SE.

On the one hand, Clearfil SE and FS are both mild two-step self-etch systems, given their pH of 2 and 2.7, respectively. Both base their adhesive capacity on the chemical interaction established with the hard dental tissues (via the MDP monomer in the case of Clearfil SE and via the polyalkenoic acid copolymer in FS). To date, their bond strengths to enamel have not been compared directly but their bond to dentin has. Clearfil is considered the gold standard, revealing similar results between them.[26]

On the other hand, SE is a two-step adhesive that nevertheless has very similar performance to a one-step adhesive given that its acidic monomers are not found in its primer, but rather in the adhesive itself, and they are activated only when both liquids are mixed in the oral cavity. This allows it to be assimilated to Adper Prompt L-Pop, a one-step self-etch adhesive that, unlike adhesives from this group, maintains its different components conveniently separated thanks to its characteristic presentation form (mini-lollipop) that are mixed and activated just prior to application. Both adhesive systems base their function on their elevated acidity (they have a pH of 1 and 0.9, respectively), which gives them the ability to etch the enamel in a way that is as similar as possible to orthophosphoric acid.[27]

Erickson et al.[25] found that acid pre-etching improved outcomes for Clearfil SE and Adper Prompt L-Pop by 41 and 27%, respectively. Despite the greater increase in the case of mild self-etch adhesive, the bond values for both were statistically similar to total acid-etch adhesive (control material) after 24h of storage in water (the only aging treatment applied). However, this did not occur in our study given that, despite the fact that the results shown by the acid pre-etch systems were higher than those obtained following their recommended application, they were not statistically comparable to the results obtained with the Adper Scotchbond 1 XT.

The values obtained with AFS were significantly better than those of FS, revealing increases of 28.5, 22.3 and 26.4% (corresponding to the three aging treatments: 24h, 5000 and 10000 thermocycles).

However, the benefit of acid pre-etch was much more discrete in the case of SE, since specimens that had acid applied showed a 10% increase in their microtraction values after 10000 thermocycles and only 1.3 and 0.3% after 24h and 5000 thermocycles, respectively. In fact, this irregular increase in microtraction values for the self-etch systems also had a very variable effect on the distribution of the type of failure that occurred in the specimens. In the case of FS, previous applica-

tion of acid increased non-adhesive failures by 25%. Conversely, there was an inverse tendency in the case of SE given that there were 6% more failures of this kind when orthophosphoric acid was not applied (Table 2).

This remarkable difference in the influence that acid pre-etching had on the outcome of self-etch adhesives was the result of the actual nature and pH of each of the systems. While FS had a clear inability to demineralize the surface due to its low acidity and benefited from the microporosity created by the acid etching, SE, with its low pH, would be capable of blurring the pattern created by the acid.

Leaving aside the effect of acid pre-etching, in order to analyze the results obtained from the recommended application of the self-etch adhesives, it is necessary to point out that SE achieved statistically higher bond strength values than FS after all of the aging treatments, which is consistent with a previous study.[28] This once again confirms the importance of the acidity of adhesive systems and the micromechanical coupling that results from adequate etching of the enamel surface for adhesive quality.[2,6,27,29]

CONCLUSIONS

Total acid-etch adhesive achieved the highest values and FS, the ultra-mild self-etch system achieved the lowest, after all aging treatments. 10000x thermocycling significantly reduced the values of all adhesive systems. Application of orthophosphoric acid was particularly beneficial for FS since its values were superior to those obtained with the recommended application after all aging treatments.

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Clinical case

Retreatment of a lower second molar endodontic presenting with complex anatomy

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ABSTRACT

The purpose of this work is to present the management of a retreatment with complex anatomy, with the presence of broken instrument and filling material difficult to clear.

We present the case of a patient with pain in an endodontically treated 37. The diagnostic tests showed the presence of apical periodontitis because of previous treatment failure due to complex anatomy and sub-obturation of the canals. Upon opening, the presence of an extra root was confirmed, in which a broken file and a material similar to the composite used to fill the distal root was found. Due to the broken files, ledges and filling materials, it took three appointments to reach the working length of the entire root canal system. An irrigation protocol with 4.25% hypochlorite, 17% EDTA and 4.25% hypochlorite activated with Endoactivator was used. It was filled with the B&L®system. Follow-up at 13 months revealed healing of the previous apical periodontitis. Moreover, the tooth presented adequate function and esthetic.

In conclusion, deep understanding of the internal anatomy of the teeth and their possible variations is essential. The broken instruments and alterations in the original anatomy are the primary obstacles to overcome for a successful endodontic retreatment, which should be the first option when confronting a primary treatment failure.

KEYWORDS

Endodontics; Retreatment; Entomolaris, second lower molar.

INTRODUCTION

The purpose of endodontic retreatment is to prevent and, when necessary, cure apical periodontitis. In order to achieve this objective, endodontics is based on biological principles that consist mainly of eradicating microorganisms from the root canal system[1].

A fundamental difference between initial treatment and retreatment is the need to eliminate the filling material that may be present, managing existing obstructions or any other impediments. Only when the entirety of the root canal system is made patent can the deficiencies of the previous treatment be corrected[2].

The main factors related to failure of an endodontic procedure are the extent of the filling material, the quality of the filling, complexity of anatomy, deficient cleaning and conformation and iatrogenic procedural errors[3, 4].

Many of the difficulties encountered during treatment of root canals are due to anatomical variations[5,6]. We must be aware of the internal morphology of[7, 8] permanent teeth, as well as the possible anomalies that can be found. The success of the case depends to a large extent on these factors.

Despite the large number of publications on alterations in root canal morphology, few studies on the anatomy of second lower molars have been carried out[9,10]. These studies generally describe three canals in the interior (two mesial and one distal), but with a considerable amount of variability with regards to the number and location. Based on the race of the study subjects, there can be an increased incidence of the "C" configuration in the root canal system. These facts confirm that an opening conditioned by the occlusal morphology does not guarantee the unveiling of all of the canals[11].

One of the anatomical variants that we can find in lower molars is the presence of an extra root located lingually. First cited in the literature in 1844, it is known as radix entomolaris (RE). In European populations, it has been reported[12] in 3.4% of lower molars[12]. The probability of a third root in second lower molars is less than that of first molars. Some articles

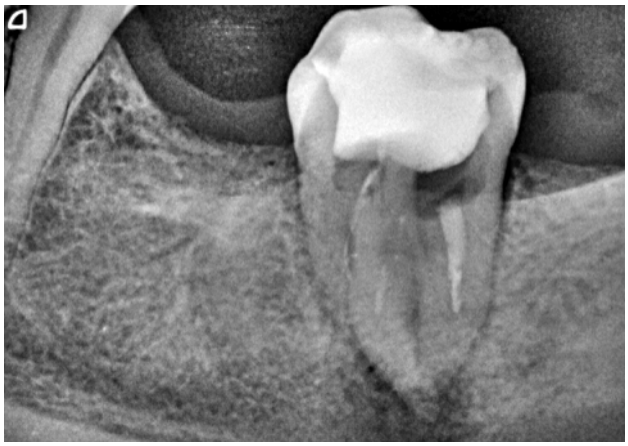


Figure 1. Initial radiograph.

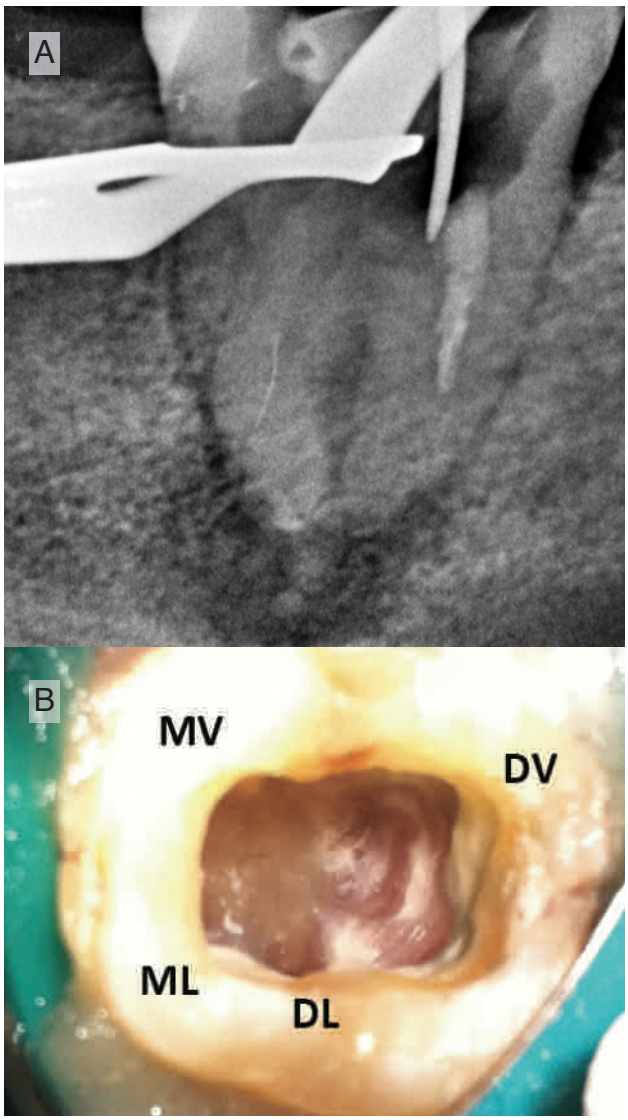


Figure 2. A) Confirmation of the trajectory of the distal root. B) Photo of the filling of the distal root.

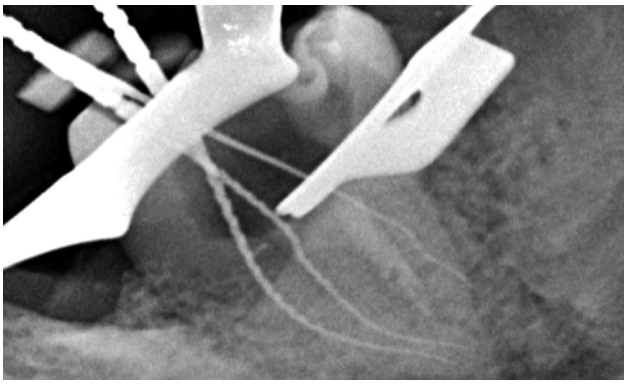


Figure 3. Patency of the mesial canals.

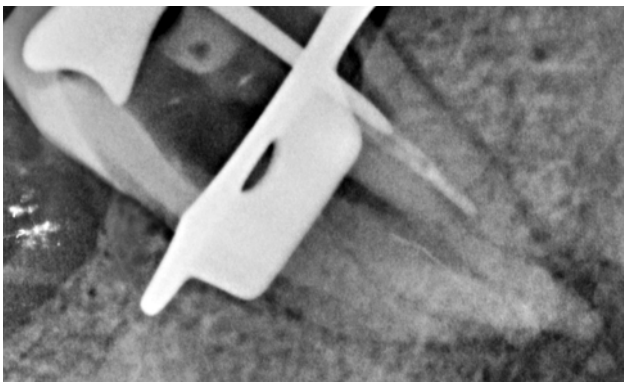


Figure 4. Confirmation of the trajectory of the distal root.

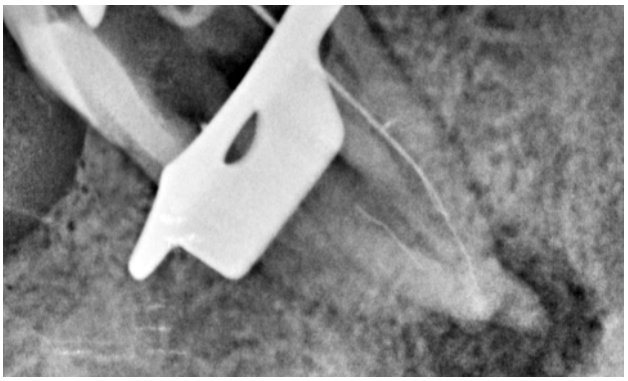


Figure 5. Patency of the distal root.

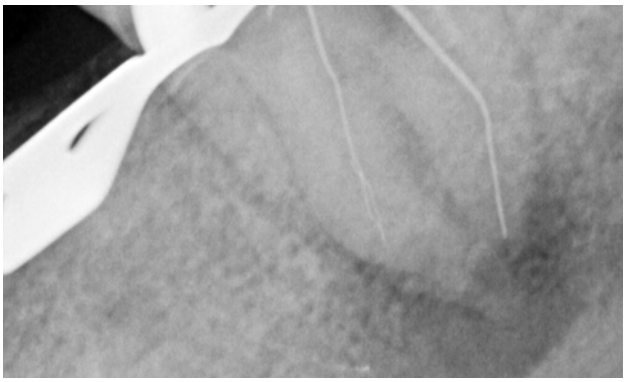


Figure 6. Broken instrument in the extra root (DL).

do not even mention it. In a recent publication by Plotino et al.[13] 161 second lower molars were analyzed using in vivo three-dimensional radiographs, finding only 3 cases of an extra root.

In the case described here, we present the retreatment of a symptomatic second lower molar with ledges, a broken instrument and complex anatomy due to the presence of an extra lingual root that, according to the Carlsen and Alexandersen classification, is classified as the AC type due to the central position between the mesial and distal root components[12].

CLINICAL CASE

We present the case of a patient without previous medical history presenting with pain and inflammation in a left second lower molar treated endodontically one year before (Figure 1). The patient referred that she went to another dentist who attempted to perform retreatment and ended up recommending extraction. Diagnostic tests showed the presence of acute apical periodontitis due to failure of the previous treatment and a complex anatomy and sub-obturation of the canals. The patient was offered the possibility of being retreated. Various objectives were established:

1. Open the mesial root, with alteration of the normal anatomy.
2. Treat the extra root, with a fractured instrument in its interior.
3. Open the distal root, the coronal third of which is filled with a material similar to composite.

The patient gave consent given her desire to preserve the tooth. Each of these objectives was completed at separate visits given the high degree of difficulty.

After opening, the presence of an extra root was confirmed. It was located on the lingual wall, centered between the mesial and distal canals, in which a broken file was found. In addition, a material similar to composite used to fill the distal root was found (Figure 2). At the first visit, after a long session, the

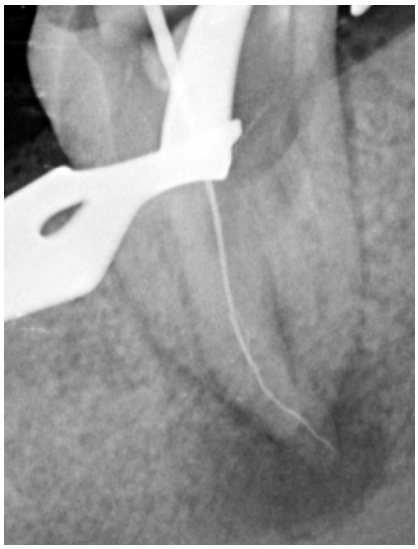


Figure 7. Patency of the distolingual root.

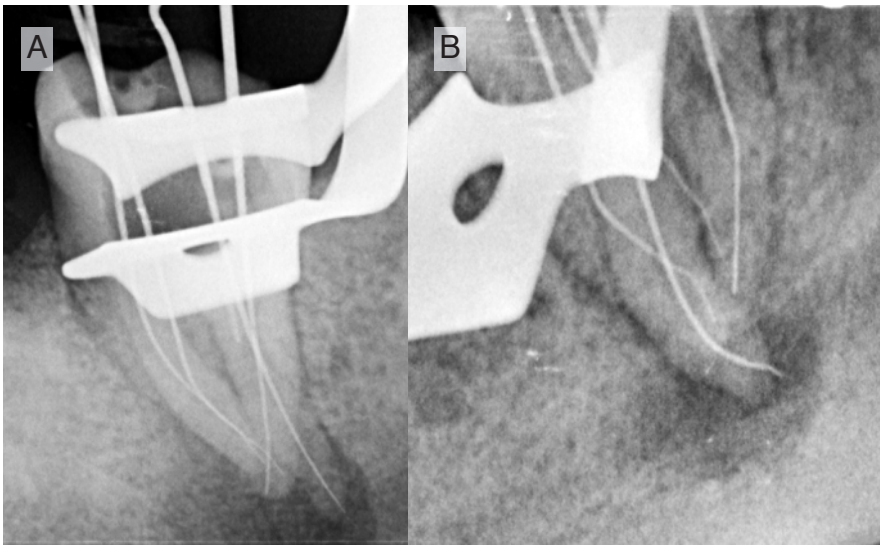


Figure 8. Measurement of the canal: A) Distoradial projection. B) Mesioradial projection

working length of the mesial canal was achieved (Figure 3). Following access rectification, reaching the mesial wall and proper preflaring, precurved number 08 and number 10 K-files® (Dentsply-Maillefer, Ballaigues, Switzerland) were used to open the root. Solvent was not used in this case because removal of the gutta-percha remnants was not difficult. However, it was truly difficult to bypass the deformation in the canal due to previous manipulation and the curvature present in the apical third. It was decided to delay treatment for a second visit.

Then, the distobuccal root was unblocked where a resin material compatible with composite had been introduced up to the radicular middle third. This material was removed slowly with the help of ultrasonics. Radiographs were taken to confirm that the correct axis of the root was being followed at all times (Figure 4). Once all of the composite was removed, we found it difficult to bypass a ledge that was present at this point (Figure 5). Finally, the distobuccal canal was opened with precurved 08 and 10 files that were essential during the entire retreatment. Due to the prolonged time and complexity of the case, it was necessary to continue at a third visit. The patient agreed given that she had been informed about the high difficulty of the case.

The extra root (distolingual) was addressed in this last session in which a broken instrument was found (Figure 6). Given the lack of magnification and the position of the file, located in a curvature within the radicular middle third, the objective was to try and bypass it rather than remove it from the canal. The procedure was similar to that in the mesial root, starting with repositioning of access to the root, proper coronal widening, followed by the use of various fine precurved files until the fragment was bypassed. Once this first objective was achieved, we found again alterations of the original anatomy with ledges located on its external wall. Several thin files, patience, time and a lot of cooperation from the patient was needed until the definitive working length

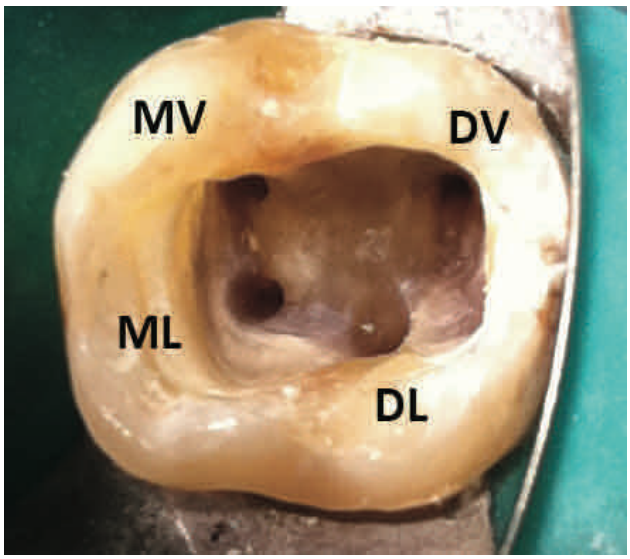


Figure 9. Chamber photo of the unblocked canals.

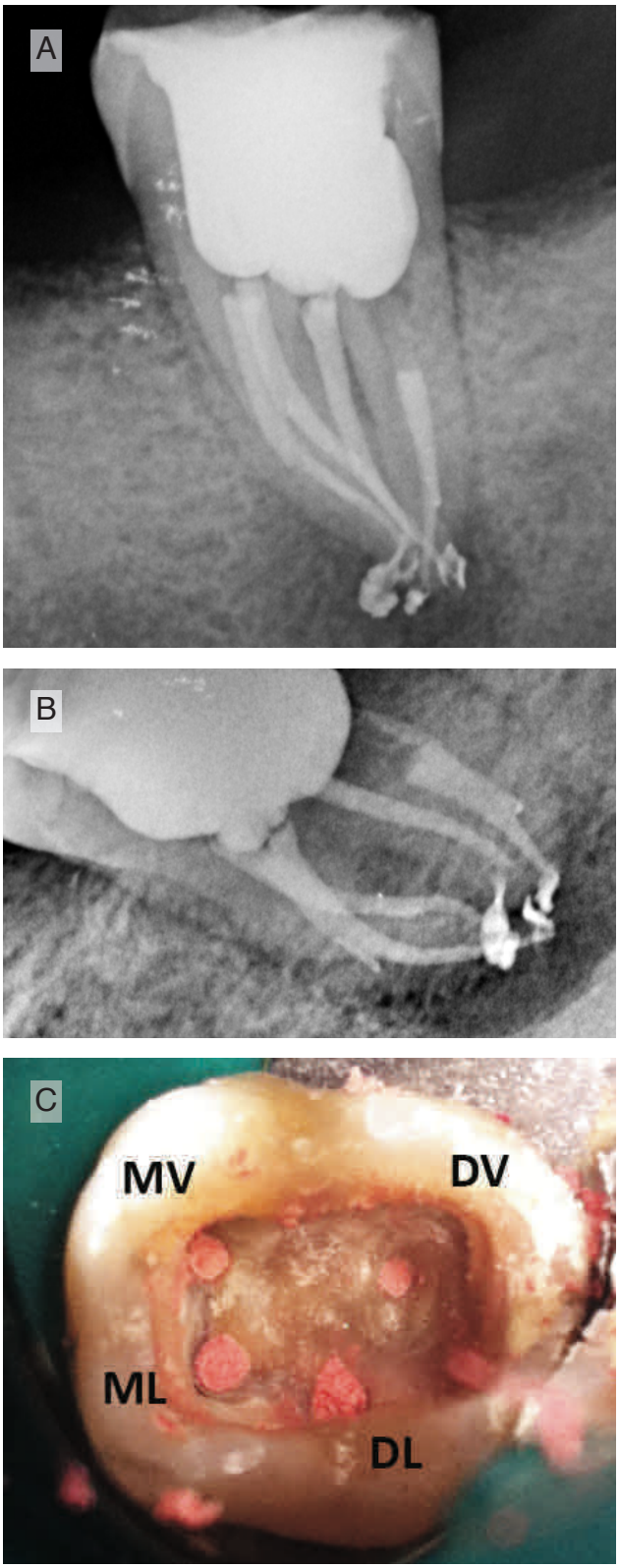


Figure 10. A) Orthoradial projection of condensation. B) Mesioradial projection where ledges can be seen. C) Photo of the entrance to the filled canals.

was achieved (Figure 7).

Once access to the apical foramen was achieved, the working length of all canals was reached with the use of a Raypex 6® apex locator (VDW, Munich, Germany) and once the measurement was radiographically confirmed (Figure 8), mechanical instrumentation was carried out with manual files up to a 20 k file® (Dentsply-Maillefer). The mesial canals were instrumented with Mtwo® (VDW) rotating files up to 30.06. The distal roots were manually worked due to the presence of ledges. Mtwo® rotating files were then introduced manually up to 25.06 in DL (distolingual) and 40.04 in DV (distobuccal).

Cleaning and disinfection of the radicular canals was carried out during the entire treatment with 4.25% sodium hypochlorite and the procedure was finalized with a protocol of 4.25% sodium hypochlorite, 17% EDTA solution and sodium hypochlorite again, all activated with Endoactivator® (Advanced Endodontics, Santa Barbara, CA) in 30-second cycles. Once the root canal system was patent, instrumented and disinfected (Figure 9), thermoplastic filling was carried out. The help of a calibrated cold spray (Sybron Endo, Sybron Dental, Orange, CA) was necessary in order to be able to precurve the Autofit® tips with 4% conicity and allow them to be positioned over the working length because if they had been introduced straight, they would have bended at the anatomical alterations inside the root canal.

Condensation was done with the help of a size A digital spacer (Dentsply-Maillefer) and accessory tips in order to ensure good compaction of the gutta-percha in the interior of the canals. The continuous-wave technique described by Buchanan[14] was then applied using heat with the B&L® Alpha System (B&L Biotech USA, Inc., Bala Cynwyd, PA, USA.) up to 4 mm less than the working length, followed by vertical condensation with a manual plugger. Filling of the coronal 2/3 of the canals was carried out using gutta-percha injection with the B&L® Beta System (Figure 10). The distal radiographic projection clearly shows the existing ledges in the distobuccal, distolingual and mesiobuccal canals, given that the thermoplastic filler has perfectly filled these alterations of the original anatomy.

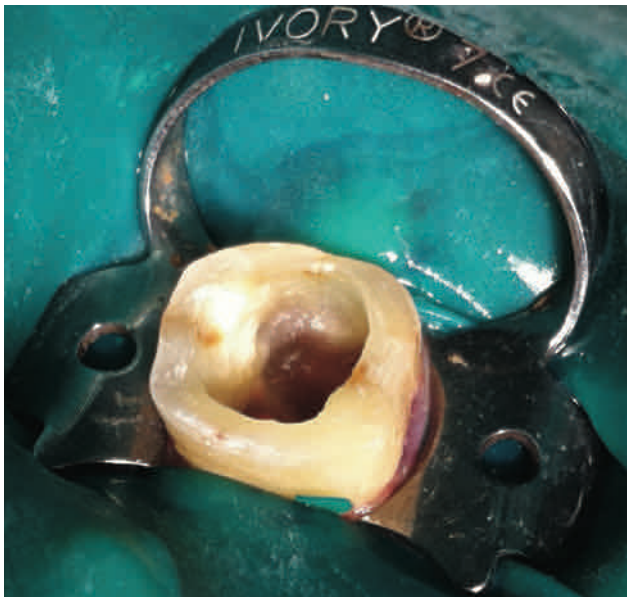


Figure 11. Provisional restoration.

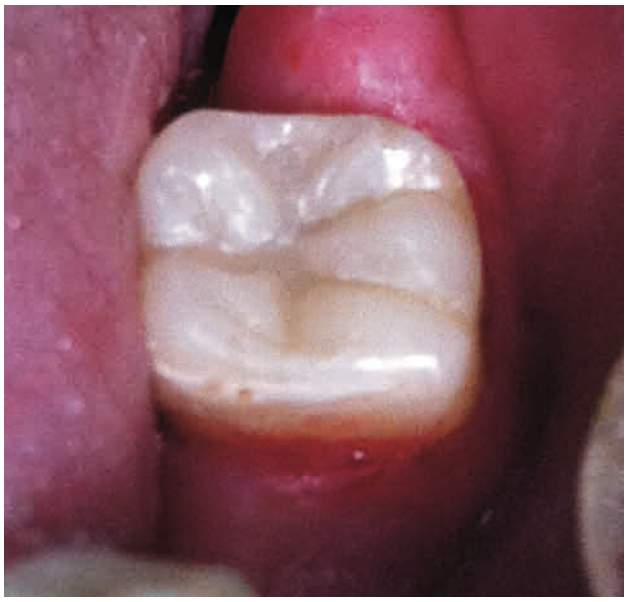


Figure 12. Reconstruction with cuspid cap.

At a fourth visit, the patient was asymptomatic with no inflammation or pain. Reconstruction of the tooth was performed using a cusped cap based on the criteria by Dietschi et al[15]. (Figure 13). Direct composite was performed, allowing the tooth to be protected from a possible fracture at a low cost to the patient while we follow the endodontic retreatment. A final radiograph was taken once the treatment was completed as baseline to compare with future follow-ups (Figure 13). The patient was seen again at 6 and 13 months (Figure 14) where resolution of the previous apical periodontitis and formation of new bone tissue are visible.

DISCUSSION

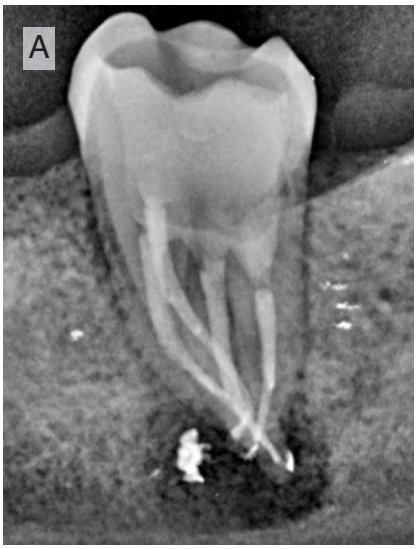
Various publications report an 80% success rate in endodontic treatment[16,17]. With regards to retreatment, one study by Torabinejad et al[18] states that the rate of successful retreatment is 78.8%, over teeth that have lost or notably decreased their radiolucidity.

In order for retreatment to work, the etiological factors must be addressed. To achieve this objective without extracting the affected tooth, treatment guidelines must be established. We must weigh the risks and benefits[19]. In general terms, the benefits "are treatments[20] that in some way lead to the patient's wellbeing, health or both."

The risks to keep in mind when evaluating the case are: crown restoration, the presence or absence of a post, obstacles to the radicular canal, nearby anatomical[21] structures, accessibility[21]...

Once the viability of the tooth and the risks and benefits have been weighted, it is very important to inform the patient in order to make them aware of the difficulty of the case and the prognosis. In this case, the patient wanted to keep her tooth at all costs.

A common controversy in retreatments is whether or not to use solvents to resoften the gutta-percha. Traditionally, chloroform was the solvent of choice[22] because it is the most effective[22]. However, concerns have been raised about its cytotoxicity when it contacts the periapical tissues; it has been classified as a[23,24] carcinogen and it is potentially risky for dental personnel. However, there is [24] limited evidence of its carcinogenicity[24]. For a less toxic alternative, there are other solvents on the market such as eucalyptol, xilene/xilol, trichloroethane, tetrahydrofuran, methylene chloride, halothane and orange[25] oils. In general, all solvents are toxic to some degree and their use should be limited or avoided if they are not nec-



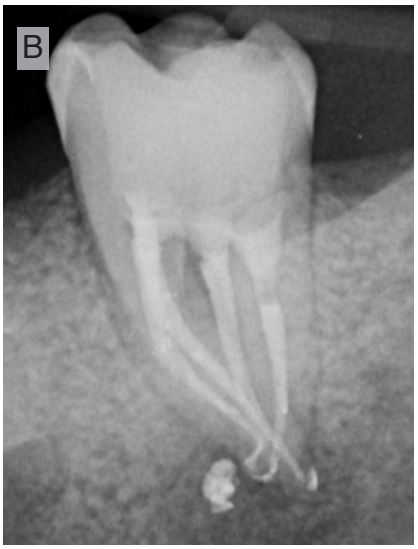


Figure 13. Final radiograph: A) Orthoradial. B) Distoradial.

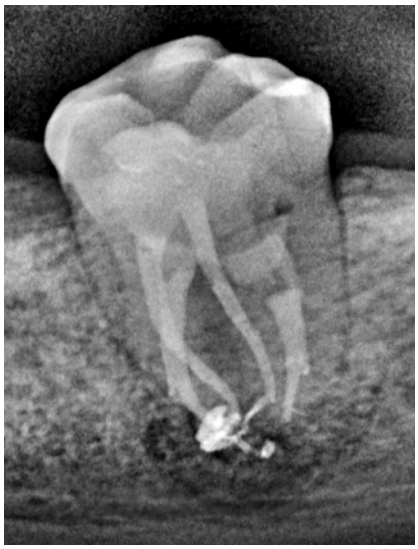


Figure 14. 13-month follow-up.

essary[26]. In the case presented above, the use of solvents was not necessary because the remnant guttapercha in the canals was not difficult to remove. The difficulty derives primarily from the deformation of the canals caused by previous treatments. The most difficult material to remove was the composite located in the distal root, so the use of ultrasonics was employed.

Breakage of instruments in the interior of the root is an unfortunate occurrence that can make cleaning and disinfection procedures in the canal difficult and affect the treatment prognosis[27]. In the case presented, we decided to bypass the file instead of trying to remove it from the root canal system because it was located in an extra root, which is usually narrow and curved, and there was a high probability of damaging the structure when removing the fragment. At this point, the advantages provided by the operative microscope would have made the job easier, but no magnification system was used in this case.

Attempts to remove the broken instruments were influenced by various factors such as the anatomy of the root, the location of the instrument and the operator's skill. Nevertheless, there could be complications that may compromise the viability of the tooth. Bypassing the fragment located in the middle/apical thirds or beyond the curvature of the radicular canal may be the proper treatment option since it meets the treatment objective for the radicular canal: adequate cleaning, conformation of the canal system followed by good filling[28]. Therefore, this practice has been categorized as a successful[29,30] approach.

One source of controversy has been the direct replacement of the tooth with an implant, as had been previously proposed to the patient. If we review the literature, Becker[31] reports that the reasons for extracting a compromised tooth and replacing it with an implant are: an unfavorable crown, insufficient root length, questionable periodontal status and status of the surrounding dentition. In our case, none of these criteria had been met. If we add to this the survival rate cited above for retreatment of single teeth (78.8%)[13], we do not believe that an implant would be the first choice. Using this conservative treatment option, the patient's symptoms could be alleviated and proper aesthetics and function of the second lower molar were achieved at a much lower cost compared to an implant. In addition, the patient was advised to replace the missing first lower molar with a supported crown implant.

CONCLUSIONS

Retreatment should be the first option in cases of endodontics with apical periodontitis whenever restoration of the tooth has a good prognosis.

A deep understanding of the internal anatomy of the teeth and their possible variations is essential in order to successfully carry out endodontic treatment.

The broken instruments and alterations in the original anatomy are the primary obstacles for a successful endodontic retreatment.

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Clinical case

Simultaneous surgical treatment of impacted third and fourth molars: a case report

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ABSTRACT

Introduction: Supernumerary teeth or hyperdontia is an uncommon alteration characterized by an increased number of teeth in an individual, the etiology of which remains controversial. This abnormality is more common in females and the most frequent location is the maxilla, usually on the midline.

Objectives: This paper describes simultaneous surgical treatment of impacted third and fourth molars as well as the diagnostic protocol necessary to perform it.

Clinical case: We present the case of a 48-year-old female who came in to the Orofacial Implantology Surgery Service at Hospital Virgen de La Paloma who was referred by her regular dentist. Radiological study with panoramic radiographs revealed the presence of bilateral impacted lower distomolars next to third molars. Their relationship with the inferior dental nerve was determined by tomography. Once the patient was informed, and after obtaining informed consent, surgical extraction of the four lower molars was carried out.

Conclusions: The treatment of supernumerary molars should be performed as soon as possible to avoid displacement and eruption of permanent teeth.

KEYWORDS

Lower third molars; Distomolars; Surgical treatment.

INTRODUCTION

Supernumerary teeth, or hyperdontia, has been defined as a dental abnormality characterized by an increase in the number of teeth in an individual compared to the normal configuration of temporary and permanent dentition, made up of 20 and 32 teeth, respectively.[1,2]

The appearance of these alterations is not very common, with an incidence of 0.3 to 0.6% in temporary dentition and 0.1 to 3.8% in adult dentition.[3] Prevalence is higher in females by a 2:1 ratio.[4]

They usually appear in greater proportion in the maxilla than in the mandible by a ratio that varies from 5:1 to 10:1.[5] In addition, the most common location is the midline despite being found at any point on the dental arcade. This type represents 80% of supernumerary teeth and is known as mesiodens[6,7] and is followed, in order of frequency, by fourth upper molars, inferior premolars, upper lateral incisors, fourth lower molars and central lower molars, with the rarest being the presence of upper premolars, upper and lower canines and lower lateral incisors.[8]

The etiology of supernumerary teeth is still controversial. However, it has been shown that the type of dentition in humans favors their appearance given that humans have diphyodont (two dentitions) heterodont (distinct morphology for each dental group) dentition, that has undergone numerous variations over their phylogenic evolution.[5]

The diagnosis of supernumerary teeth is the result of incidental findings during routine radiographic examinations.[9] Only one-fourth completely or partially erupt, with the majority remaining included. The presence of hyperdontia can lead to multiple complications including delay in the eruption of permanent teeth or dental malposition (rotation, torsion, version), which in many cases is the first clinical manifestation of a supernumerary tooth.[10,12] In addition, it can lead to rhizolysis and periodontal injury of the adjacent teeth due to compression of the roots, and we can even find radicular cysts associated with these teeth, though it only occurs in 5% of cases.[5,13,14]

Supernumerary teeth are classified according to their morphology, number and location:

Regarding morphology, a distinction is made between "supplemental teeth" that appear to be a normal tooth (eumorphic) and "supplemental teeth" that have atypical morphology (heteromorphic), and those that may appear with distinct forms: conical supplemental teeth that are small in size with a rudimentary crown and root and tubular teeth with crowns with multiple cusps and a single curved root.[5, 15-17]

Regarding the number of supernumerary teeth, we can find cases of single hyperdontia (a single supernumerary tooth), with the mesiodens being the most common as a single finding and the fourth molar being the second in order of frequency.[18] A less common finding is multiple hyperdontia in which multiple supernumerary teeth usually appear both anteriorly and posteriorly. They may be associated with complex syndromes such as cleidocranial dysplasia[19], Gardner's syndrome or cherubism.[5]

Finally, supernumerary teeth are also classified upon their location. Focusing on the molar region, which is the area that we are dealing with primarily in this paper, we can find distomolars or retromolars, which are those located distal to the third molar on the same line of the dental arcade, or we may find those known as paramolars, located in the interdental triangle between the second and third molar or less frequently between the first and second, outside of the line of the arcade on the vestibular, lingual or palatine side.[15,17,20]

For this reason, radiological studies are necessary in order to determine the position of the supernumerary tooth, its size, shape, proximity to adjacent teeth and anatomical structures and the distance that separates it from the occlusal plane.[21]

Extraction of these supernumerary teeth is generally

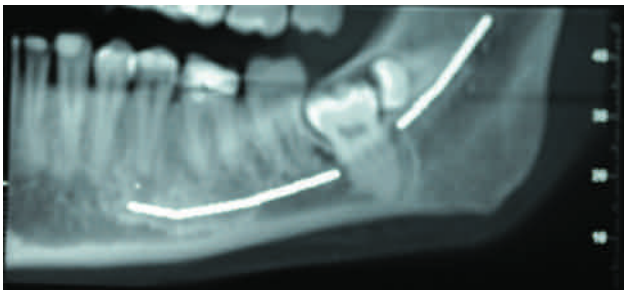

Figure 1. Panoramic slice on CBCT. Note the presence of the left lower distomolar and the third molar in relation to the inferior dental nerve.

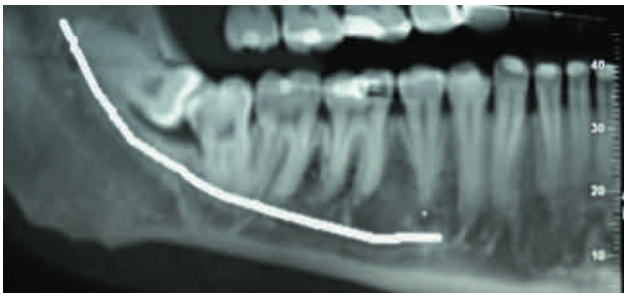

Figure 2. Panoramic slice on CBCT. Note the presence of the fight lower distomolar and the third molar in relation to the inferior dental nerve.

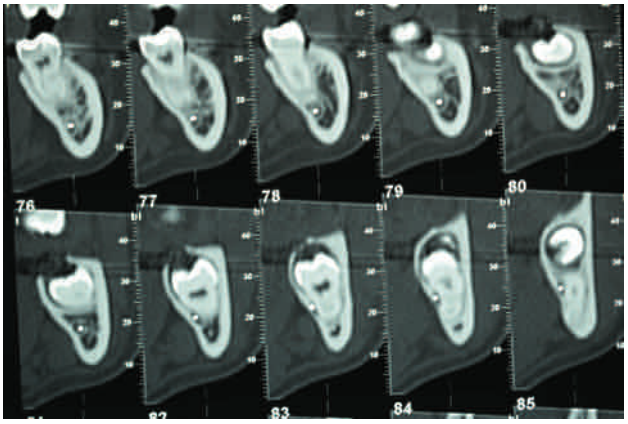

Figure 3. Left transverse slices which reveal the lingual position of the inferior dental nerve.

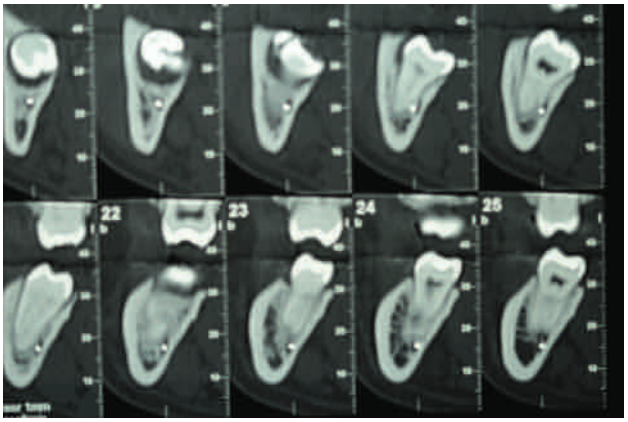

Figure 4. Right transverse slices with lingual position of the inferior dental nerve.

the first treatment option in order to avoid future complications[8], as it is usually done for included third molars.[22]

The purpose of this paper is to present a clinical case of bilateral lower distomolars that, despite their position and close relationship with the inferior dental nerve, did not present any clinical signs.

CLINICAL CASE

A 48-year-old female patient comes in to the Orofacial Surgery and Implantology Department at Hospital Virgen de La Paloma, referred by her regular dentist. The patient had unremarkable previous history. She underwent an exhaustive intraoral and extraoral examination which did not reveal any pathology. Radiological testing with a panoramic radiograph revealed the presence of impacted bilateral inferior distomolars next to third molars. The right lower third molar was in a horizontal position and the contralateral was vertical. The anatomy was eumorphic and its relationship with the inferior dental nerve advised the performance of a tomography (Figures 1-4).

Once both diagnostic tests were obtained, the patient was notified of the benefit of surgical extraction of the four molars, as well as the advantages of performing this procedure under general anesthesia.

Once consent was obtained, a preoperative workup was ordered which included a chest x-ray, electrocardiogram and systemic blood tests.

The surgery was performed following disinfection of the surgical field with povidone iodine, a linear festoon incision was made from the mesial side of the second molar with distal unloading (Figure 5) and mucoperiosteal detachment exposing the bone in order to perform the osteotomy followed by extraction of the left lower distomolar (Figure 6). Following extraction of the distomolar, exodontia of the left lower third molar was performed which required odontosection of the crown (Figure 7). To clean the surgical area and remove the bone remnants, the field was ir-

rigated with normal saline solution prior to closure of the soft tissues with 3-0 suture (Figure 8).

The surgical intervention was finalized by removing the third and fourth molar on the contralateral side, initially by ostectomy and then via odontosection of the distomolar that was finalized with exodontia (Figures 9 and 10). Exodontia of the right lower third molar was then carried out. Odontosection was not necessary at this point.

Postoperatively, the patient received antibiotics (amoxicillin 750 every 8 hours for 7 days), anti-inflammatories (sodium diclofenac 10 mg every 8 hours for 4 days) and rescue analgesia if needed.

After a week, the patient went to the outpatient clinic for follow up. The surgical area was checked and the sutures removed.

DISCUSSION

Supernumerary teeth occur as developmental alterations. They appear infrequently in any area of the dental arch and may be associated with systemic syndromes.

Leco Berrocal *et al*.[23] published a study in 2008 analyzing the surgical activity carried out in the Master's in Oral Surgery program at Universidad Complutense de Madrid, in which 6750 interventions were performed. Only 0.5% of the interventions were due to the presence of supernumerary teeth.

The percentage of fourth molars varies according to the results published by different authors, from 1% according to Menardia *et al*.[24] and Stafne *et al*.[25], 2% for Luten *et al*.[26], up to 1.9% for Backmann *et al*.[27]

They appear more frequently in the maxilla than in the mandible, as described by authors such as Muhammed-Isa Kara *et al*.[9], with 84.4% and 15.8%, respectively, Leco Berrocal *et al*.[28], who found 79.2% in the maxilla and 20.8% in the mandible, or Menardia *et al*.[24], who reported 86.8% of supernumerary molars in the maxilla.

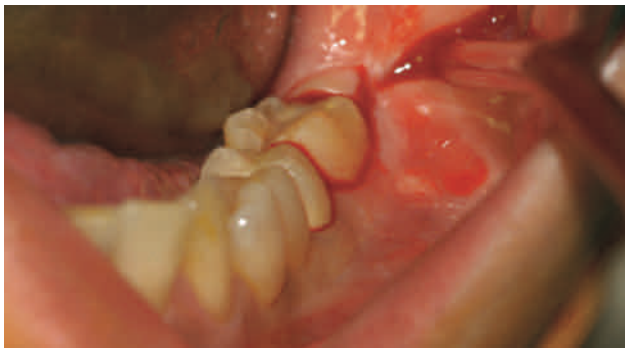

Figure 5. Linear incision with posterior unloading for surgical access.

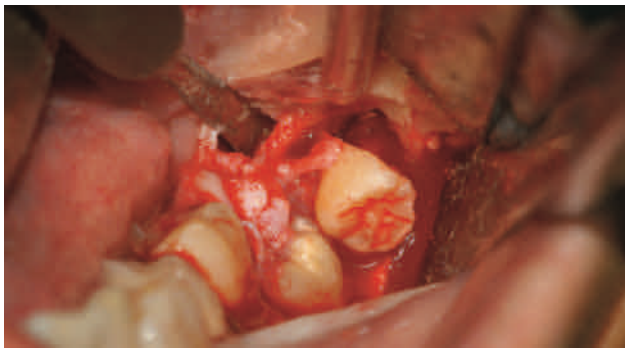

Figure 6. Extraction of left lower distomolar.

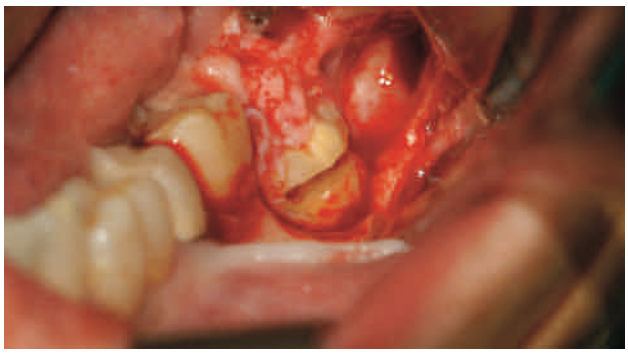

Figure 7. Odontosection of the crown of the left lower third molar.

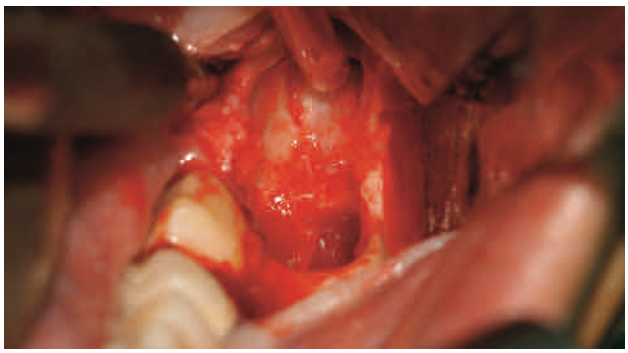

Figure 8. Appearance of the residual cavity after extraction of both retained teeth.

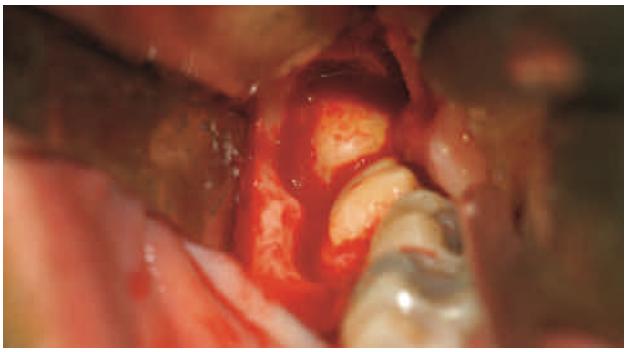

Figure 9. Detail of the ostectomy for extraction of the distomolar and right lower third molar.

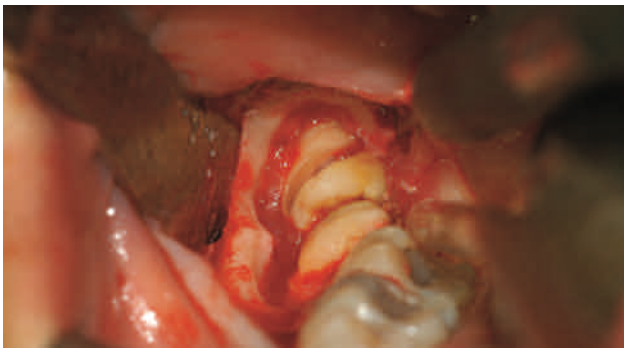

Figure 10. Odontosection performed on the left lower distomolar.

The etiology is still controversial. Three main theories have been proposed to explain polydontia:

The "embryonic epithelium hyperactivity" theory, the most widely accepted theory in the literature, defines epithelial hyperactivity at any time during embryonic development as the cause of new dental formation.[29]

The "dental follicle excision" theory, which states that factors such as trauma or developing disturbances (developing mutations) may provoke division of the follicle in two or more fragments, which would lead to the formation of two teeth from a single germ (dichotomous theory).[5,29]

The "atavism" theory, which explains the formation of supernumerary teeth as a phylogenic reversion, meaning a return to a primitive dental formula, similar to that of in certain vertebrates with a greater number of teeth, such as primates.[5]

The gender association leans towards females, as reported by Shahzad *et al*.[30] in their 2012 study which reported that 65% of those affected were females. Regarding the most common age of onset, Salcido-Garcia *et al*.[31] determined that the presence of supernumerary teeth is greater during the first decades of life.

Regarding the position, it is more common to find supernumerary molars as distomolars, with a smaller number of cases being found in a paramolar position. This was described in the 2012 study by Muhammed-Isa Kara et al.[9], who found that 63% of cases were distomolars and only 37% were paramolars. In addition, Leco Berrocal *et al*.[28] found that out of 2000 patients, 79.2% were in the distomolar position.

These data are surprising given that authors such as Donado *et al*.[32], Gay-Escoda *et al*.[8] or Penarrocha et al.[5] consider paramolars to be third and fourth in frequency among supernumerary teeth.

Unlike our clinical case, the majority of authors describe the presence of bilateral fourth molars frequently in the maxilla, as described in 1992 in the study by Martinez-Gonzalez *et al*.[29]

Regarding the treatment of supernumerary molars, authors such as Donado *et al*.[32] state that treatment should be carried out as soon as possible to avoid displacement and eruption of permanent teeth. This same opinion is reported by Cozza *et al*.[33]. However, authors like Koch *et al*.[34] advise against extraction of these included molars in children under 10 years of age given the need to perform the procedure under general anesthesia in the majority of cases. In addition, Kruger *et al*.[35] suggest delaying exodontia, but in this case they indicate the need for adjacent teeth to have closed apices.

However, all authors agree that, when performing exodontia, it is paramount that surgery should begin with the tooth that is in the most coronal position, performing its odontosection in order to simplify surgery and avoid performing aggressive osteotomies that may worsen the postoperative course. This is the procedure that was utilized in the clinical case presented in this article.

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