INTRODUCTION

Apical periodontitis is a common bacterial disease; its prevalence varies from 27% to 70% worldwide and increases with age (1). It is an inflammatory reaction of the periapical tissues and an immunological response of the host defence system to microbes that have infected the root canal (2, 3).

Some researchers attest that shaping and cleaning are strategically more significant than obturation for eliminating root canal infections and promote apical healing (4, 5). Nevertheless, it has been demonstrated that even meticulous canal treatment, shaping and cleaning rarely lead to a total microbial eradication (6, 7). It is wellknown that organisms colonizing the root canal space survive in well-protected biofilms (8, 9). This biofilm is extremely difficult to eliminate, and now, apical periodontitis is considered a biofilm-induced disease (10, 11).

The obturation of the canal space to the working length has been a critical component of root canal treatment for sealing and isolating the periapical tissues from the biofilm and irritants that remain after shaping and cleaning and for eliminating the possibility of subsequent leakage. Some have shown that the quality of the root filling has an important contribution to the success of primary and secondary root canal treatment (12-16), but more prospective evidence is lacking to show the impact of the apical sealing as the most important key to improve the periapical healing. This study attempts to provide evidence from a clinical viewpoint that the bacteria persisting...
within the root canal system do not have a significant impact on the treatment outcome as long as an adequate apical sealing is performed.

**MATERIALS AND METHODS**

**Study design**
A randomized, two-arms parallel-group, controlled trial.

**Population and clinical evaluation**
From the 42 patients, one mandibular tooth from each patient was consecutively enrolled in the present longitudinal prospective study. The patients were randomly assigned to two groups: 21 patients to the experimental group (only apical third obturation) and 21 to the control group (Fig. 1). They were recruited at the University Dental Clinic of the endodontic specialization program at the Autónoma de Querétaro University School of Medicine.

An informed and voluntary written consent was obtained from patients according to the ethical principles of Helsinki declaration. Prior to oral and systemic health questionnaire and a clinical examination and before explaining the clinical procedures, risks involved and all questions raised by the patients were clarified. It was explained very clearly to each patient that each one would be continuously monitored and that in case of presenting spontaneous pain or swelling, he or she would be excluded immediately from the study and proceed to do whatever was necessary to solve their discomfort.

The study protocol was reviewed and approved by the Investigation Committee of the Dentistry area of the Autónoma de Querétaro University School of Medicine. The diagnosis was performed by an experienced endodontist; clinical examination was performed to evaluate the presence of pain, the presence of swelling, tenderness to percussion and palpations and abnormal tooth mobility. Patients must have a restorable tooth, pulp necrosis and a periapical index (PAI) score (17) of 5 with a no more than 4 mm periapical radiolucency determined in the preoperative radiograph on a light box by measuring the largest diameter with a ruler (Fig. 2). Only single rooted (one canal) teeth and distal roots of molars were included. Exclusion criteria included sinus tract presence, medically compromised patients or patients with allergies to antibiotics.

**Clinical procedures**
All patients were treated in one visit; clinical procedures were performed by the same experienced endodontist according to a standardized regimen, including local anaesthesia and isola
tion of the tooth by rubber dam. Disinfection of the tooth and the rubber dam was done using 2.5% sodium hypochlorite (Na-OCl). Caries and weak tissues were removed, and the endodontic access was prepared with a sterile high-speed N°4 carbide bur. N°3 Gates Glidden drill was used for coronal flaring with copious irrigation of 2.5% NaOCl. The working lengths of the root canals were determined with size 15 stainless steel hand files and a Root ZxII electronic apex locator (J. Morita and Co, Tustin, CA, USA).

All root canals were instrumented using a standardized crown-down technique with ProTaper rotary system (Dentsply Maillefer, Ballaigues, Switzerland), initially S1, S2 and SX files were used in the coronal two-thirds, following the use of each shaping file, copious irrigation with 2.5% NaOCl was done and an apical patency with a size 10 file every time. S1 and S2 files were used in this manner until the depth of the size 15 hand file. Working length was reconfirmed.

The instrumentation was finished using one or more of the ProTaper (Dentsply Maillefer, Ballaigues, Switzerland), finishing files, F1, F2, F3 or F4. The canal was irrigated with saline solution and the patency was confirmed again. The root canals were dried with sterile paper points and irrigated with 17% ethylene diamine tetra-acetic acid during 5 minutes. A final irrigation was done with NaOCl and a confirmation of the working length again. All canals were obturated using gut-ta percha and zinc oxide eugenol sealer by lateral compaction technique after the sealer was spun into the canals with the aid of a lentulo spiral and taking care of compacting as best as possible the apical third. In the experimental cases, another experienced endodontist removed the root canal filling with the F5 file at 4 mm less to the full length confirmed by a radiograph (Fig. 3). This second intervention by another endodontist was performed at the same appointment with the objective of keeping the first endodontist blind to the objectives of the study. The excess cavities of all cases were filled with an intermediate restorative material (Dentsply/Caulk, Milford, DE, USA). All patients were advised to take 400 mg of ibuprofen every 8 hours for 3 days and to attend the university clinic at any time in case of pain, swelling or any discomfort. Everyone agreed to attend the follow-ups, first at one month and then every 3 months during 2 years.

At each appointment, clinical examination was performed to evaluate the presence of pain, the presence of swelling, tenderness to percussion and palpation and abnormal tooth mobility. Also, after the first follow-up, a periapical radiograph was taken every time with a radiographic holder Rinn XCP (Dentsply, Elgin, IL, USA), in order to maximize the reproducibility of the radiographic paralleling technique (Figs. 4-6).

Radiographic analysis
Pre- and postoperative radiographs were compared during each follow-up appointment. Each radiograph was digitized into joint photographic experts group format using a digital camera (Nikon, Tokyo, Japan) at a resolution of 1600’1200 pixels; contrast and brightness were automatically adjusted for all images using Adobe Photoshop 7.0 software (Adobe, San Jose, CA, USA), and the images were then evaluated in a dark room using a 15-inch screen and a 1280´800 pixel resolution.
test or the Fisher exact test (when appropriate) for qualitative values. For all tests, P<0.05 was considered statistically significant.

RESULTS

Seven patients were eliminated from the study because they fail to attend all the follow-ups. The interexaminer consistency was 0.80. Patients’ characteristics data are summarized in Table 1. There was no statistical difference in the distribution of the patients by age or gender. The mean age of the study population was around 45 years; and the gender was slightly predominant female (62.8%). No statistical difference was found in the distribution of tooth included in both groups (Table 2).

There were no significant differences between the groups in terms of preoperative conditions. Only in the one-month postoperative evaluation, there were reports of the presence of pain, swelling, tenderness to palpatations or to percussion and abnormal tooth mobility; however, no significant differences

| TABLE 1. Clinical characteristics of the study patients |
|--------------------------------------------------------|
| Group | Complete obturation n=16 | Only apical obturation n=19 | P |
|-------|--------------------------|-----------------------------|---|
| Age (years)* | 46.7±12.1 (21-62) | 43.3±17.2 (21-80) | 0.3710 |
| Frequency (%) | | | |
| **Male | 8 (50) | 5 (26.3) | 0.1789 |
| Female | 8 (50) | 14 (73.6) | |

| X: Mean, SD: Standard deviation, *Mann-Whitney test, **Fisher exact test |

| TABLE 2. Distribution of the teeth included in both groups |
|----------------------------------------------------------|
| Complete obturation n=16 | Only apical obturation n=19 |
|--------------------------|-----------------------------|
| Molars | 10 (62.5) | 10 (52.6) |
| Premolars | 3 (18.7) | 3 (15.7) |
| Incisors | 3 (18.7) | 6 (31.5) |

P=0.6879, Chi-square test
were observed between groups (Table 3). In none of the other follow-ups were there any signs or symptoms. With respect to the PAI, no patients were scored less than 5 in the first two follow-ups (1 and 3 months), but from the third and sub-sequent (6, 9, 12 and 15 months), lower scores were assigned. Twelve months were enough for 68.1% of the experimental group and 74.9% of the control group to go through the ini-tial PAI-5 score to a PAI≤2 score. At 15 months of follow-up, all missing cases of both groups (100%) were classified with a PAI≤2 score (Table 4) so the trial finished at this point. No sta-tistical difference was observed between the number of cases that ended the study with a PAI-1 or -2 score (Table 5).

In general, all cases presented clinical success, absence of pain, swelling, sinus tract, tenderness to palpation or percussion and presented normal tooth mobility.

TABLE 3. Preoperative and one-month postoperative evaluations of both groups

| Frequency (%) | Preoperative evaluation | Complete obturation n=16 | Only apical obturation n=19 | P* |
|---------------|-------------------------|--------------------------|-----------------------------|----|
| Presence of pain | 11 | 9 | 0.3064 |
| Presence of swelling | 9 | 10 | 1.0000 |
| Tenderness to palpitations | 10 | 13 | 0.7362 |
| Tenderness to percussion | 11 | 15 | 0.7003 |
| Presence of abnormal tooth mobility | 6 | 9 | 0.7338 |

TABLE 4. Six to 15 months’ distribution of PAI scores in both groups

| Frequency (%) | Only apical obturation n=19 | Complete obturation (n=16) | PAI-1 | PAI-2 | PAI-1 | PAI-2 |
|---------------|-----------------------------|-----------------------------|-------|-------|-------|-------|
| 6 months | 0 | 0 | 1 (5.2) | 0 |
| 9 months | 6 (37.5) | 2 (12.5) | 4 (21.0) | 1 (5.2) |
| 12 months | 3 (18.7) | 1 (6.2) | 4 (21.0) | 3 (15.7) |
| 15 months | 3 (18.7) | 1 (6.25) | 4 (21.0) | 2 (10.5) |

TABLE 5. Comparison of both groups ended on a PAI-1 or -2 score

| Frequency (%) | Only apical obturation (n=19) | Complete obturation (n=16) |
|---------------|-------------------------------|--------------------------|
| PAI1 | 12 (75) | 13 (68.4) |
| PAI | 2 (25) | 6 (31.5) |

P=0.7233, Fisher exact test

DISCUSSION

Root canal treatment of teeth with apical periodontitis aims at the complete elimination of microbial invaders; however, endodontic treatment might still fail in some cases because of the incredible persistence and difficulty to eliminate of the microbial biofilm despite mechanical and chemical disinfection (18, 19).

Literature shows that microbial biofilms are difficult to remove from the root canal system, yet the favourable outcome for apical periodontitis is in a range of 75%-80% (13, 20, 21). It has been suggested that this rate of success is due to an appropriate reduction of the microbial bioburden to levels that are compatible with per-irradicular tissue healing (22). This may be true only to some extent, because it is well-known that if any bacteria survive to the mechanical and chemical disinfection and it is exposed to nutrients such as serum in the case of apical third, these organisms can alter their gene expression to accommodate to their new environment (10, 23-25) and will adversely affect the outcome of the root canal treatment (18, 26, 27). This has been shown in earlier clinical cross-sectional studies in humans (19, 28). The high rate of success can only be explained by the fact that microorganisms have been adequately isolated from the periapical tissues by obturation. In this study, the root canal treatment procedures were performed in root canals where a microbial bio-film is well-established and will be impossible to be completely eliminated, despite performing all mechanical and chemical routine procedures. By eliminating the obturation materials of most of the canal, the remaining bacteria would multiply or at least remain present for a while if they do not find a substrate. These bacteria without the apical sealing could maintain or even aggra-vate the periapical disease.

Results of this study are somehow consistent to the outcomes of performing endodontic treatment in one or two appointments using calcium hydroxide (29). We, as many others, believe that it has been the same because in both cases the microbial bio-film is only being isolated from the periapical tissues, and nei-ther one nor several appointments can actually eliminate it.

Complete elimination of microbial irritants is a fundamen-tal objective of endodontic treatment. However, with all the knowledge that currently exists about the biofilm and the complexity of the root canal sys-tem, together with advances in root canal treatment procedures, the complete elimination of micro-organisms and their toxins cannot be achieved.

This study was a longitudinal prospective controlled investiga-tion in similar patients by age and gender and a similar distribu-tion of the treated teeth. All teeth had the same diagnosis, apical periodontitis and periapical radiolucency, so the included teeth would represent a long-standing pathologic process caused by a well-established intraradicular infection. All this makes the comparison between groups suitable. No clinical symptoms were registered after the first follow-up, thus the outcome was classified mainly on the radiographic evaluation.

The PAI scoring method was used to compare differences in periapical status from the beginning of the treatment to 15
months follow-up evaluation. This index has shown to have the potential for detection of healing with good reproducibility because it is based on a histological correlation (17, 30). A PAI-1 or -2 score is defined as healed or minimally inflamed and PAI-3 to-5 scores are defined as diseased. However, it is still a subjective outcome prone to observer variation. To overcome this disadvantage as much as possible, we undertook the task of calibrating observers until we could have a good consistency.

On the other hand, it is well-known that clinical outcome studies take a long time to monitor, demand substantial economic resources and are at risk of losing patients at follow-ups, so it is a common problem with these clinical studies to achieve enough sample size to a statistical significance. The number of patients available in our study as well as most other prospective studies is limited, within the limitations, no significant differences in the healing of periapical radiolucency were observed. Clinical success of teeth filled in the apical was comparable to those teeth filled to the canal orifices despite the small sample size included, these findings may still be clinically relevant. In this study, we had a high success rate in both groups that do not coincide with previous reports. This could be attributed to differences in study parameters and inclusion criteria for patients selection. Studies showed that systemic diseases such as diabetes or a compromised immune system have a significant influence on the success rate of root canal treatment on teeth with apical lesions (31, 32). We excluded cases with presence of sinus tracts or periapical radiolucency was larger than 4 mm. A better prognosis has been reported in teeth with periapical lesions with diameter less than 5 mm compared to larger lesions (33, 34). In addition, as we only included single rooted (one canal) teeth and distal roots of molars, some clear complexity-ties of the treatment of multi-rooted teeth were eliminated. Furthermore, by including only the distal roots, we eliminated the possibility of counting that teeth as a failure, as when some multi-rooted teeth are evaluated as whole units, the risk of observing persistent apical periodontitis after treatment is multiplied. Notably, this study has only included mandibular teeth. It has been reported that a better outcome is usually observed in mandibular than in maxillary teeth (34). We do not promote stopping cleaning and shaping of the root canals or filling routinely only the apical third. Rather, we firmly believe that if an adequate apical seal is performed in every case, the general success rate will not be affected, providing that there is an adequate coronal seal.

Investigations have shown that more than 2 mm short or beyond the apical foramen could result in poor treatment outcomes (12). Studies also showed that 1 mm loss in working length is enough to increase the incidence of treatment failures in teeth with apical periodontitis (12, 35). It has been concluded that a periapical tissue response will not develop unless microbial irritants can have a pathway to the periapical tissues. Three-dimensional filling of the root canals will entomb the remaining micro-organisms inside the root canal walls; however, this procedure is unpredictable, especially in the apex. That is why it is very important to confirm the working length during entire procedure and to ensure the canal patency by passing a size 06, 08 or 10 hand file to the canal length before obturation, with an adequate working length control, the sealer and/or gutta-percha will flow into recesses of the canal (including accessory canals).

There is no enough evidence yet to support the ability to improve clinical performance of many of the recently introduced obturating materials and techniques. This emphasizes the need to translate anecdotal information into clinically relevant research data on new obturating materials and techniques.

**CONCLUSION**

Within the limitations of this study, no significant differences in healing rates after complete obturation or only apical third obturation were observed. An adequate apical sealing can improve periapical healing; thus, intracanal remnant bacteria apparently have no significant impact, at least for the first 15 months of follow-up.

**Disclosures**

**Ethics Committee Approval:** The study protocol was reviewed and approved by the Investigation Committee of the Dentistry area of the Autónoma de Querétaro University School of Medicine.

**Conflict of interest:** No conflict of interest was declared by the authors.

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