



MINIMALLY INVASIVE ANATOMICAL CLEANING

Patent Pending

BY YOUR SIDE

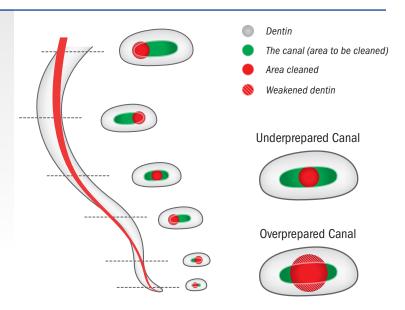


THE CHALLENGE...

NiTi instrumentation has made a significant impact on the field of endodontics. However, despite the benefit of improved efficiency, all traditional NiTi file systems have the same universal disadvantages:

Non-anatomical shaping

The root canal system is highly complex. The majority of canals have an irregular anatomic shape. Despite significant advancements, conventional files can only make round shapes and cannot reach significant parts of the canal during treatment.



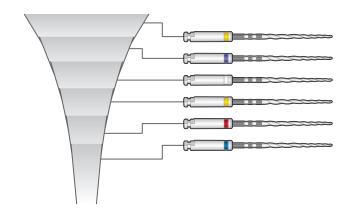
Excessive torque/ fatigue

Traditional NiTi files are prone to file deformation and potential separation, and they apply unwanted stress to the tooth.



► Require the use of multiple NiTi files

In order to reduce cyclic and torsional fatigue, multi-file sequencing techniques are utilized. This adds cost, complexity and chair-time.



Tooth image credit: Incidence of Dentinal Defects after Root Canal Preparation: Reciprocating Versus Rotary Instrumentation. JOE. 2013; 37(4):501-504

THE SOLUTION...



MINIMALLY INVASIVE ANATOMICAL CLEANING

The XP-3D Shaper addresses the shortcomings of traditional NiTi instrumentation and ushers in a new biologic standard of care in endodontic instrumentation.

The patented XP-3D Shaper safely, efficiently and effectively cleans the root canal system three dimensionally while respecting the canal anatomy. As it rotates, the instrument's orbit expands and contracts to abrade the broad and narrow aspects of the canal equally. This intuitive micro mechanical debridement allows the practitioner to utilize a single instrument to safely and efficiently clean and enlarge the canal while respecting the original canal morphology.

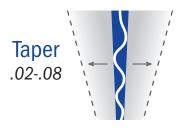
Anatomically Prepared Canal



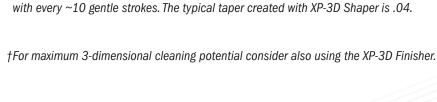
SIZE & EXPANSION CAPACITY

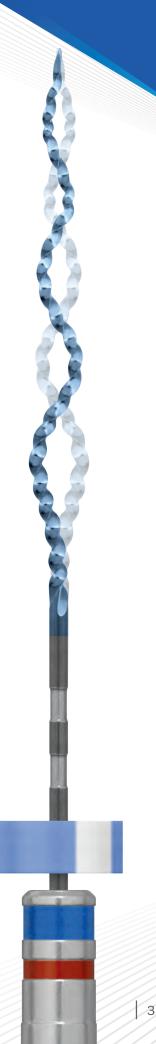
The XP-3D Shaper is an ISO #30 with a 1° taper. Its adaptive core design allows it to adapt to canal morphology ranging from size #30 to size #90 at a .02 to .08 taper.* The flexible core gently pulsates within the root canal as it spins, continually adapting to the canal's natural anatomy.[†]





^{*}For roots above size #30, the natural <u>apical</u> anatomy will be maintained. Taper increases \sim .02 degrees with every \sim 10 gentle strokes. The typical taper created with XP-3D Shaper is .04.





► MAXWIRE®

Featuring Brasseler's exclusive MaxWire® Technology, the XP-3D Shaper adapts to the canal's natural anatomy by expanding once exposed to body temperature.



- · Super elasticity, extreme flexibility and resistance to cyclic fatigue
- •Transformation to a robust, predefined serpentine shape at body temperature 95°F (35°C)
- · Ability to gently expand to the natural anatomy of the root canal

68°F (20°C) M-PHASE Martensitic Phase

At or below room temperature the instrument is very malleable and has a relaxed serpentine shape.



95°F (35°C)

A-PHASE Austenitic Phase

When introduced to warmer temperatures (>95°F), the instrument transitions to a more robust serpentine shape.



► PRODUCT OFFERING (3 PACK)

File/Tip ID	Tip Size	21 mm (Stopper)	25 mm (Stopper)	31 mm (Stopper)
▲ Blue	30	5025846U0	5025845U0	5025847U0

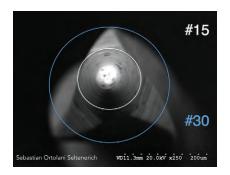
BOOSTER TIP™

The patented Booster Tip design helps guide the serpentine XP-3D Shaper around curvatures and keeps it centered in the canal. The tip of the XP-3D transitions from an ISO# 15 to an ISO# 30 within 1mm from the tip, thereby functioning as both a scouting and finishing file.

- · Six cutting edges for optimal guidance and scouting
- Shaping begins at ISO #15 and transitions to ISO #30
- ·Tip transitions from six to three cutting edges to improve the clearing of debris







► ADAPTIVE CORE™ TECHNOLOGY

The XP-3D Shaper featues unique Adaptive Core Technology which allows the smaller central core of the file to move freely and adapt to the canals natural morphology. This facilitates debris removal, making it more efficient without occluding the dental tubules. Furthermore, the turbulence generated by the XP-3D Shaper enhances the penetration of irrigants into dentinal tubules and improves the overall disinfection of the canal.

Traditional Core Files
Debris Accumulation/Compaction

XP-3D Shaper - Adaptive Core
Free-Floating with Turbulance

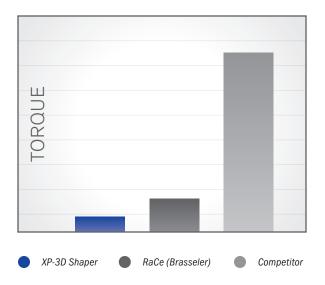
Debris

Stress applied to the canal wall

► GENTLE, LOW-STRESS MECHANICAL DEBRIDEMENT

The XP-3D Shaper's design characteristics drastically limit the amount of torque and stress applied to both the instrument and the canal. This results in reduced instrument separation and dentinal micro-cracks.

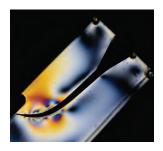
The below graph shows the result of a test performed on plastic blocks demonstrating the average torque generated by three instruments during canal treatment.



On average, the XP-3D Shaper generates 47% less torque than the RaCe instrument and 88% less than the leading competitor's instrument.*

The images below show the result of a photoelasticity test performed on plastic blocks to illustrate the stress applied by instruments during canal treatment. The greater the stress, the higher the risk of microcracks and instrument separation.

Competitor A*



Alternating Movement: Very High Stress

Competitor B*



Rotary Movement: High Stress

XP-3D Shaper^{™*}



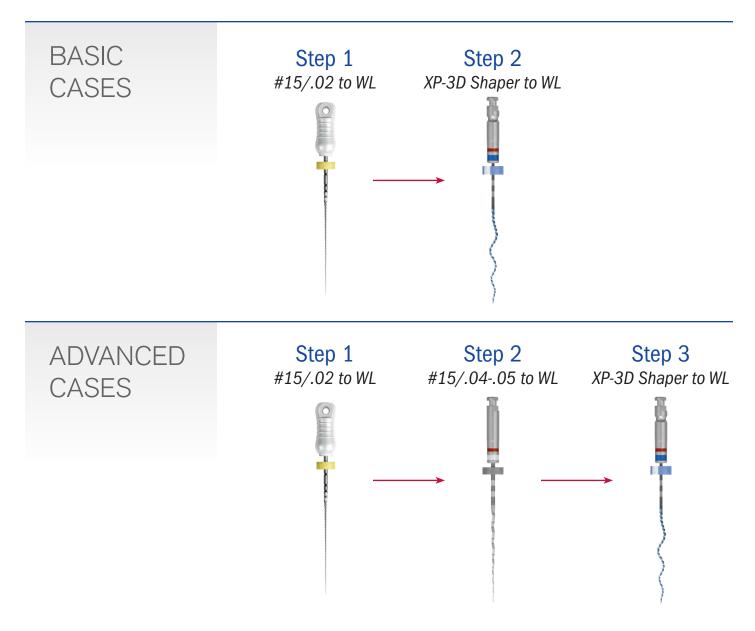
Rotary Movement: Very Low Stress

CLINICAL APPLICATIONS

- · Anatomical debridement of basic and advanced root canal anatomy
- · Retreatment of failed root canals
- · Enhanced irrigation

CLINICAL TIPS

- · Packaged sterile
- · 800-1000 RPMs; Torque: 1Ncm
- · Use long gentle strokes (5-7mm) to progress down to working length (WL). If WL is not reached in three strokes, stop, irrigate and recapitulate.
- · Irrigate frequently



Final Preparation Size:

Once WL is reached, re-irrigate and work the instrument in long strokes to WL for another 5-10 seconds.

- **Tight Canals** (apex is naturally smaller than #30): The minimal preparation is a #30/.02 (~5 strokes). The taper can be increased to .04 (~10 strokes). The tip will not expand beyond #30 unless the apex is naturally larger than #30.
- Larger Canals (apex is naturally larger than #30): The XP-3D Shaper's tip can reach up to size #90 if space permits. When using the instrument for an additional ~10 seconds (after initial WL is reached) the taper is typically .04. Prior to obturation it is recommended to confirm the final apical diameter with an apical verifier, gutta percha point or conventional file.

BIOCERAMIC BONDED OBTURATION

In the era of modern endodontics, shaping is no longer dictated by the limitations of obturation materials. The introduction of non-shrinking bonded obturation (BC Sealer™ and BC Points™) allows practitioners to embrace the XP-3D Shapers adaptive and minimally invasive design. Unlike traditional sealers, BC Sealer does not shrink and therefore it is not necessary to condense gutta percha in an effort to minimize the sealer interface. With BC Sealer the function of gutta percha is simply to take up space, provide a path for retreatment and provide for hydraulics/delivery of the sealer.

BC Sealer/Filler™



► XP-3D[™] OBTURATION TECHNIQUE

- 1. Confirm the apical diameter with an apical verifier, gutta percha point, paper point or file.
- 2. Coat the canal walls with BC Sealer.
- 3. Coat the appropriate gutta percha point with BC Sealer and place to length.
- 4. Sear off gutta percha at the canal orifice and vertically compact with the appropriately sized plugger.

CASE STUDIES

CASE 1

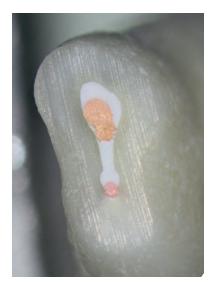
Canal preparation (ex-vivo) of a maxillary right first premolar to size 30/.04 with the XP-3D Shaper then filled with EndoSequence® BC SealerTM and EndoSequence® BC PointsTM. We can see that the original shape of the canal has been perfectly preserved.



Radiograph showing the bucco-lingual aspect of the maxillary first premolar



Cross-section 1 mm from the apex



Cross-section 4 mm from the apex



Cross-section 7 mm from the apex

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CASE 2

A 62 year old woman presenting with symptomatic pulpitis on the upper right first molar. After preparing a glide path to 15/.02, the canals were instrumented with the XP-3D Shaper to 30/.04 following the instructions for use. The canals were then obturated with EndoSequence® BC sealerTM and EndoSequence® BC PointsTM.



Pre-op



Post-op

CASE 3

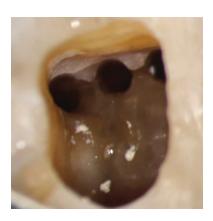
Pulpectomy peformed on lower right first molar. After preparing a glide path, the five canals were instrumented with the XP-3D Shaper. The canals were further cleaned with the XP-3D Finisher and obturated with EndoSequence® BC Sealer™ and EndoSequence® BC Points™.



Pre-op



Post-Op: View of canals after instrumentation with the XP-3D Shaper and bioceramic obturation



Microscopic view (x12) of 3 mesial canals after instrumentation with the XP-3D Shaper, and cleaning with the XP-3D Finisher



Microscopic view (x12) of 3
mesial canals after obturation
with EndoSequence
BC Sealer and
EndoSequence BC Points.

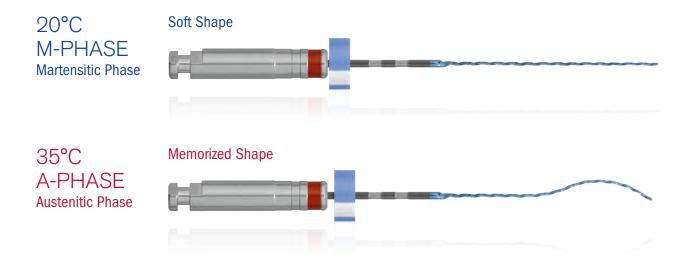


MINIMALLY INVASIVE ANATOMICAL CLEANING



Like the XP-3D Shaper, the XP-3D Finisher utilizes Brasseler's exclusive MaxWire Technology to adapt to the canal's natural anatomy. The XP-3D Finisher has a bowed shape at body temperature and is incredibly flexible. The instrument debrides the root canal system 3-dimensionally and allows for enhanced irrigation. Unlike the XP-3D Shaper, the XP-3D Finisher is intended to clean a prepared canal and will not change the shape once prepared.





► PRODUCT OFFERING (3 PACK)

File/Tip ID	Tip Size	21 mm (Stopper)	25 mm (Stopper)
Red	25	5025842U0	5024933U0
▲ Blue	30	5025844U0	5025843U0

► SIZE & EXPANSION CAPACITY

The XP-3D Finisher is an ISO #25 with a 0° taper. Its capacity to expand improves its reach 100-fold compared to a standard instrument.



Standard Instrument



XP-3D Finisher

CLINICAL APPLICATIONS

- · 3-D debridement
- · Enhanced irrigation
- · Retreatment

CLINICAL TIPS

- · 800-1000 RPMs; Torque: 1Ncm
- · XP-3D Finisher should be used only after canal preparation to at least #25
- · In multirooted teeth, start with the largest canal
- · Work along the entire length of the canal for approximately one (1) minute
- · Place the XP-3D Finisher into the orifice of the canal prior to placing the irrigant and begin rotation

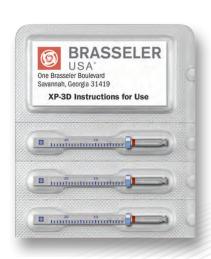
PACKAGING

Three instruments in a sterile blister pack, for single use (each instrument can be used to clean one tooth with up to four canals).



The instruments are stored inside a plastic tube so their straight shape can be maintained or restored and the working length can be defined.





IN VITRO REVIEW

▶ BENCH-TOP CROSS-SECTION REVIEW

Mesial root of an artificial lower molar sectioned at 1, 3, 5 and 7mm from apex:

Group 1
Canal before preparation

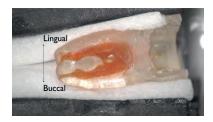
1mm

3mm

7mm

► BENCH-TOP CLEANING & OBTURATION SIMULATION

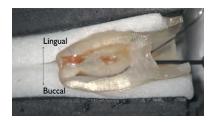
1 Pre-op with pulp.



3 After preparation with XP-3D Finisher.



2 During preparation with XP-3D Finisher.



4 After obturation with EndoSequence® BC Sealer™ and EndoSequence® BC Points™.



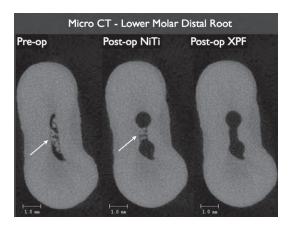
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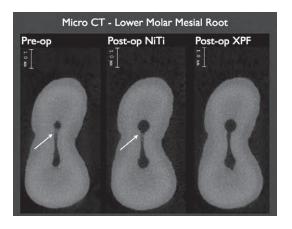
CLINICAL CASES

CASE 1

Micro CT of the Distal and Mesial roots of a lower molar instrumented to 35/.04 with round NiTi files and then after final cleaning with the XP-3D Finisher.

- · Pre-Op and Post-Op NiTi Pictures: Show debris in the canal and in the isthmus areas.
- · Post-Op XP-3D Finisher Pictures: After final cleaning with the XP-3D Finisher, no debris is seen.





CASE 2

Internal resorption case demonstrating the expansive potential of the XP-3D Finisher. Cases with irregular shaped canals and roots which are structurally compromised are ideal beneficiaries of the new XP-3D Finisher. This new technology allows us to preserve critical root structure while thoroughly disinfecting the canal.





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RESEARCH/BIBLIOGRAPHY

1. Bao P, Shen Y, Lin J, Haapasalo M. In Vitro Efficacy of XP-3D Finisher with Two Different Protocols on Biofilm Removal from Apical Root Canals. *JOE*. 2016; Dec 7. DOI: 10.1016/j.joen.2016.09.021.

Subject: The purpose of this study was to evaluate the effectiveness of the XP-3D Finisher in biofilm removal in comparison with conventional needle irrigation (CNI) and passive ultrasonic irrigation (PUI) using an infected tooth model with an artificial apical groove.

Results/Conclusions: XP-3D Finisher showed the best biofilm removal efficacy inside and outside the groove followed by PUI and CNI (P < .05).

Significance: Biofilm removal is one of the most challenging phases in endodontic instrumentation. In this study the XP-3D was most effective compared to the most popular methods used to this point.

2. Keskin C, Sariyilmaz E, Sariyilmaz O. Efficacy of XP-3D Finisher File in Removing Calcium Hydroxide from Simulated Internal Resorption Cavity. *JOE*. 2017; Jan. DOI: 10.1016/j.joen.2016.09.009.

Subject: The aim of this study was to evaluate the effect of supplementary use of XP-3D Finisher file, passive ultrasonic activation (PUI), EndoActivator (EA), and CanalBrush (CB) on the removal of calcium hydroxide (CH) paste from simulated internal resorption cavities.

Results/Conclusions: XP-3D Finisher and PUI removed significantly more CH than SI, EA, and CB (P < .05), showing no significant difference between them (P > .05). Differences among SI, EA, and CB were also non-significant (P > .05).

Significance: Removal of calcium hydroxide is an indirect indicator of cleaning effectiveness against microbes. XP-3D Finisher was equal to PUI and superior to other traditional methods.

There was no indication in this study that the teeth or irrigating solution were heated above body temperature, which is required for optimal effectiveness of the XP-3D Finisher.

3. Alves FR, Andrade-Junior CV, Marceliano-Alves MF, Perez AR, Racas IN, Versiani MA, Sousa-Neto MD, Provenzano JC, Siquera JF JR. Adjunctive Steps for Disinfection of the Mandibular Molar Root Canal System: A Correlative Bacteriologic, Micro-Computed Tomography, and Cryopulverization Approach. *JOE*. 2016; Nov. DOI: 10.1016/j.joen.2016.08.003

Subject: This study evaluated the disinfecting ability of chemomechanical preparation with rotary nickel-titanium instruments, followed by 2 distinct adjunctive procedures in the root canals of extracted mandibular molars by means of a correlative analytical approach.

Results/Conclusions: Both XP-3D Finisher and passive ultrasonic irrigation exhibited antibacterial effectiveness, but only the former caused a significant reduction in the bacterial counts after chemomechanical preparation.

Significance: Showed superior antibacterial effectiveness compared to PUI which has been considered "state of the art".

4. Wigler R, Dvir R, Weisman A, Malalon S, Kfir A. Efficacy of XP-3D Finisher files in the removal of calcium hydroxide paste from artificial standardized grooves in the apical third of oval root canals. *International Endodontic Journal*. 2016, Jun. DOI: 10.1111/iej.12668.

Subject: To compare the efficacy of the XP-3D Finisher file (XP) (FKG Dentaire, La Chaux de Fonds, Switzerland) to that of passive ultrasonic irrigation (PUI) and conventional syringe and needle irrigation (SNI) in the removal of calcium hydroxide paste from an artificial standardized groove in the apical third of root canals.

Results/Conclusions: XP-3D and PUI were more effective in removing Ca(OH)2 from artificial standardized grooves in the apical third of root canals than SNI.

Significance: Removal of calcium hydroxide is an indirect indicator of cleaning effectiveness against microbes. XP-3D Finisher was equal to PUI and superior to other traditional methods.

There was no indication in this study that the teeth or irrigating solution were heated above body temperature, which is required for optimal effectiveness of the XP-3D Finisher.

RESEARCH/BIBLIOGRAPHY

 Alves F, Marcelano-Alves M, Sousa JC, Silveira S, Prvenzano J, Siqueira J. Removal of Root Canal Filling in Curved Canals Using Either Reciprocation Single- or Rotary Mult-Instrument System and a Supplementary Step with the XP-3D Finisher. JOE. 2016; 42(7). DOI: 10.1016/j.joen.2016.04.007.

Subject: This study compared the efficacy of a reciprocating single-instrument system and a rotary multi-instrument system followed by a supplementary approach with a finishing instrument in removing the filling material from curved canals during retreatment.

Results/Conclusions: The rotary multiple-instrument system was more effective and faster than the reciprocating single-instrument approach in removing previous root canal fillings. The adjunctive finishing instrument XP-3D Finisher significantly improved filling material removal.

Significance: The XP-3D Finisher resulted in additional cleaning after the use of round files for retreatment purposes.

 Elnaghy AM1, Mandorah A2, Elsaka SE. Effectiveness of XP-3D Finisher, EndoActivator, and File agitation on debris and smear layer removal in curved root canals: a comparative study. Odontology. 2016, May. DOI: 10.1007/s10266-016-0251-8.

Subject: The purpose of this study was to assess the efficacy of the XP-3D Finisher (FKG Dentaire SA, La Chaux-de-Fonds, Switzerland) file on debris and smear layer removal in curved root canals in comparison to different irrigation regimens.

Results/Conclusions: Irrigation of curved root canals using XP-3D Finisher and EndoActivator methods appears to be more effective on debris and smear layer removal than the other tested groups.

Significance: XP-3D Finisher shows value in removal of debris and smear layer, which should contribute to improved success.

There was no indication in this study that the teeth or irrigating solution were heated above body temperature, which is required for optimal effectiveness of the XP-3D Finisher.

 Azim A, Aksel H, Zhuang T, Mashtare T, Babu J, Huang G. Efficacy of Four Irrigation Protocols in Killing Bacteria Colonized in Dentinal Tubules Examined by a Novel Confocal Laser Scanning Microscope Analysis. *JOE*. 2016; 42(6). DOI: 10.1016/j.joen.2016.03.009.

Subject: The aim of this study was to determine the efficiency of 4 irrigation systems in eliminating bacteria in root canals, particularly in dentinal tubules.

Results/Conclusions: XP-3D appears to be more efficient than other 3 techniques in disinfecting the main canal space and up to 50 µm deep into the dentinal tubules.

Significance: Microbial reduction is the key to endodontic success. Therefore this result shows the XP-3D superiority in that regard.

8. Leoni GB, Versiani MA, Silva-Sousa YT, Brniera JFB, Pecora JD, Sousa-Neto MD. Ex vivo evaluation of four final irrigation protocols on the removal of hard tissue debris from the mesial root canal system of mandibular first molars. *International Endodontic Journal*. 2016, Apr. DOI:10.1111/iej.12630.

Subject: To evaluate the efficacy of four final irrigation protocols on the reduction of hard-tissue debris accumulated within the mesial root canal system of mandibular first molars using micro-CT analysis.

Results/Conclusions: The PUI technique and XP-3D Finisher instruments were associated with significantly lower levels of AHTD compared with conventional irrigation and modified SAF system protocol in the mesial root canals of mandibular molars. The PUI method was most effective in the coronal half of the canal while the XP-3D Finisher was most effective in the apical half of the canal.

Significance: Less debris particularly in the apical half of the canal is associated with higher success.

9. Sanabria-Liviac D, Moldauer BI, Garcia-Godoy F, Antonio-Campos A, Casaretto M, Torres-Navarro J, Scalercio JM. Comparison of the XP-3D Finisher File System and Passive Ultraonic Irrigation (PUI) on Smear Layer Removal after Root Canal Instrumentation Effectiveness of Two Irrigation Methods on Smear Layer Removal. *Journal of Dental and Oral Health*. 2017; 4: 1-7.

Subject: The purpose of this study was to evaluate the effectiveness of two different final irrigant activation methods in removing the smear layer at 3 and 7 mm from the apex.

Results/Conclusions: The XP-3D Finisher NaOCI/EDTA group was more effective than PUI with and without EDTA for smear layer removal at both middle and apical canal thirds.

Significance: Smear layer removal is thought to be critical for optimal success in endodontics.













