EASYINSMILE Root Canal Activator

Clinical Evaluation Report

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Contents

I. Product Introduction

The root canal activator under the umbrella of Type II medical equipment and with a classification No. of 17-03-03 belongs to the oral cleaning equipment and accessories of oral treatment equipment under stomatological equipment.

The root canal activator powered by AA No.5 dry cells is constituted of a motor, an eccentric shaft, a main-board, an outer shell, an oscillating needle and the soft cover, which uses mechanical vibration of the oscillating needle to clean the root canal. Since its vibration frequency is between 100 and 300Hz, therefore, the activator is classified as a sonic activator.

Model number of the activator is EASYDO Activator-M1082.

The root canal activator is applied to clean root canals of teeth.

II. Clinical Documents Evaluation

The root canal therapy removes unhealthy irritation to periapical tissues by cleansing the root canal of infected dental pulp and dentin and disinfecting and filling the canal, so as to prevent periapical diseases or accelerate healing of periapical diseases. The therapy is popular for treating pulposis and periapical diseases. The therapy generally includes three steps of root canal preparation, disinfection and filling. Anatomical structure of the root canal is very complex, which is consisted of not only the main root canal, but also lateral and accessory root canals , root canal divergence and ramus communicans. Mechanical preparation can only clean the main root canal besides formation. Studies show 35%-40% of the root canal surface remains untouched, wherein infected substances will stay and can only be cleaned off by rinsing and disinfecting the root canal with chemicals. Currently, in clinical practices, sodium hypochlorite, EDTA and chlorhexidine are mainly used to rinse root canals. Studies show that rinsing efficacy not only depends on chemicals being used but also on mechanical factors.

The root canal activator will enhance efficacy by using mechanical vibration to irrigate rinsing solution into various micro-structures of the root canal. Herein, the dental microscope commonly used during stomatological clinical diagnosis and treatment will be adopted to evaluate the rinsing efficacy.

1. Materials and Method

Collect 5 single-canalled premolars extracted because of periapical diseases and orthodentics, follow instructions of the supplier and use mechanical Ni Ti instrument (Waveone Gold, Dentsply USA) to prepare the root canal by opening and extirpating pulp of the extracted teeth. Fill soy sauce and salt into the canal and submerge the teeth in soy sauce and salt for 2 days before taking the teeth out to dry for 1 day, then use purified water to clean the teeth before using the root canal activator to rinse it. Use dental microscope to observe and take pictures.

2. Results

After experimenting on the 5 extracted teeth, it is found that after using the activator to rinse the teeth for 2 minutes, their root canals become clean. In the process of experiment, the worst conditions were emulated by using the activator for 20 minutes incessantly and applying pressure to the oscillating needle consistently.However, the oscillating needle did not break. Moreover, experiments were also done on contraindications, it is found risks of the product were under control. Therefore, it is found that the root canal activator lives up to its expected functions, and its risks are under control.

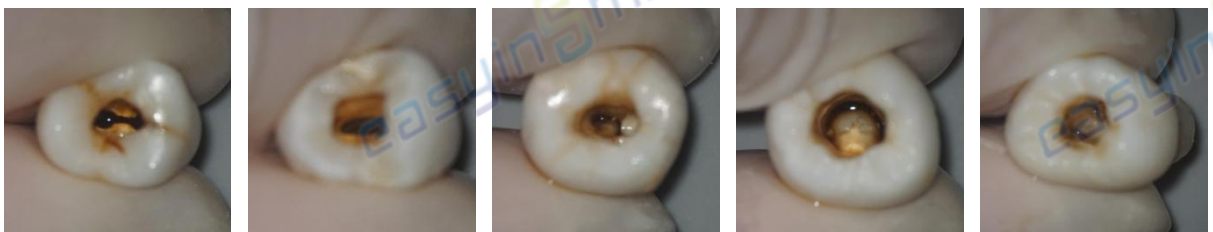### 2.1 Pictures of Extracted Teeth before Pre-processing

The extracted teeth are clean in surface and finish pulp opening and extirpating and canal preparation.

2.2 Pictures of Extracted Teeth 3 Days after Being Processed

Surface of the extracted teeth becomes dark brown.

2.3 Pictures of Inside of the Root Canal after the Extracted Teeth Being Rinsed for 1 Minute

After being rinsed for 1 minute, root canals of the 5 teeth still looked dark brown inside. Smear layer of the root canal wall was colored and a large amount of dentin detritus was observed on the root canal wall.

2.4 Pictures of Inside of the Root Canal after the Extracted Teeth Being Rinsed for 2 Minutes

After being rinsed for 2 minutes, dark brown dyeing could still be observed inside root canals of the 5 extracted teeth. Coloring of the smear layer of the root canal wall has not been removed and a large amount of dentin detritus could still be observed on the root canal wall.

2.5 Pictures of Root Canal before Using the Oscillating Needle

Root canals of the 5 extracted teeth looked dark brown inside while a dark brown smear layer and a large amount of dentin detritus was observed on the root canal wall.

2.6 Pictures of the Root Canal after Applying Pressure on Working Oscillating Needle for 10 Minutes

Root canals of the 5 extracted teeth discolored prominently, the smear layer and dentin detritus was completely removed from the root canal wall.

3. Conclusion

The root canal activator can safely and effectively clean the root canal of the smear layer and dentin detritus and significantly enhance effects of traditional rinsing.

III. Clinical Comparison and Analysis

Currently, root canal therapy is most effective in treating periapical diseases and pulposis. Root canal rinsing plays an important role in cleaning and disinfecting root canals, it is indispensable for root canal preparation. During clinical practices, root canal rinsing is usually performed with a syringe manually, which may impair penetration of rinsing solution and removal of detritus. Studies both at home and abroad show supersonic method can be used to improve root canal rinsing efficacy. However, existent supersonic root canal activating equipment and apparatus have the following weaknesses: 1. metallic oscillating files and needles are poor in flexibility which makes it difficult to reach and clean the root apex of a bent root canal; 2. metallic oscillating files and needles during high-speed movement will produce cutting effects, which can easily pierce the root canal wall or create steps on the root canal wall; 3. metallic oscillating files and needles must be used and disinfected repeatedly, which brings about higher risk of cross infection; 4. the supersonic equipment is generally larger, less portable and uneasy to use, which restricts clinical application of supersonic root canal activating equipment and apparatus. This product can overcome the above weaknesses and is expected to be used widely in clinical practices.

The purpose of this study is to use the electron microscope scanning method to compare rinsing effects of EASYDO ACTIVATOR-M1082 root canal activator with that of traditional syringes, so as to find evidence to support clinical promotion and application of root canal activating techniques and improve quality of root canal filling.

1. Materials and Method

1.1 Sample Collecting and Grouping

Collect 30 single-canalled premolars being extracted because of periodontal diseases and orthodontics and preserve them in sodium chloride solution with concentration of 0.9%. Separate the 30 premolars into two groups: Group A of 15 premolars will be rinsed using traditional syringes; Group B of 15 premolars will be rinsed using EASYDO ACTIVATOR-M1082 root canal activator.

1.2 Root Canal Preparation

Pulp of both groups of teeth will be opened and extirpated as usual. Operating range on the root canal will start from the occlusal surface until 1mm to the apical foramen. The apical foramen is closed with wax. Mechanic Ni Ti series instrument (Waveone Gold, Dentsply USA) is used to prepare the root canal by following instructions of the supplier. In the process of

preparation, both groups of teeth are cleansed with 5ml NaCIO. For Group A's post-preparation rinsing, traditional syringes will be used to inject 10ml 17% EDTA into the root canal, tip of the needle will be positioned at the interface between 1/3 of the mesial root canal and 1/3 of the apical foramen and not in direct contact with the root canal. For Group B's post-preparation rinsing, traditional syringes will be used to inject 10ml 17% EDTA into the root canal and EASYDO ACTIVATOR-M1082 root canal activator will also be used in the meantime to help with the cleaning. After rinsing, both groups of teeth will be injected with 2ml sodium chloride solution with concentration of 0.9% to deter further effects of the rinsing solution. Finally, use paper points to stop the root canal orifice for preventing external detritus from falling into the root canal.

1.3 Instruments and Materials

Scanning Electron Microscope JAM-IT100 (Japan), Root Canal Activator (EASYDO ACTIVATOR-M1082, Changsha Easyinsmile Intelligent Technology Co., Ltd), Oscillating Needle (3504, Changsha Easyinsmile Intelligent Technology Co., Ltd), Mechanic Ni Ti Root Canal Apparatus ProTaper, G drill, Diamond Bur, ETDA, NaCIO, glutaraldehyde solution, tertiary butanol, phosphate buffer solution.

1.4 Preparation and evaluation of SEM samples

Open circular grooves on the cemento-enamel junction of prepared teeth and longitudinal grooves through the labial surfaces and lingual surfaces. Groove depth should be close to but not touch the root canal. Use chisel and hammer to split the prepared teeth. Use diamond bur to mark positions of root cap 1/3, root middle 1/3 and root tip 1/3 on a piece of tooth that can clearly show the root canal wall. Then, use 0.1mol/L PBS to rinse before using 4% glutaraldehyde solution to pre-fasten and using 50%-100% tertiary butanol to perform gradual dehydration, after which, process the sample with coarse vacuum drying method. Finally, fix the sample on the stage with conducting resin and use vacuum ion beam sputtering technique to apply a platinum coating on the sample. Adopt the Single-Blind Trial method to observe the sample with a JSM-IT100(Japan) SEM and take pictures randomly under 1500 times magnification.

Evaluate and score root canal surface cleanliness on the basis of thickness of the smear layer and exposure of dentin tubule. 1 point : no smear layer and openings of dentin tubules are clear or with a small amount of embolism; 2 points: a thin smear layer and most dentin tubule openings are exposed; 3 points : thin or homogeneous smear layer and 50%-60% of dentin tubule openings are exposed; 4 points: flaky or crumby smear layer and less than 50% of dentin

openings are exposed; 5 points: thick smear layer and almost no dentin tubule opening is exposed.

Technical Road-map
30 extracted single-canalled human teeth
↓
Ordinary pulp opening and extirpating and root canal preparation
↓
Rinse with traditional syringe
Sample preparation and SEM observation
↓
Sum up results, compare and analyse

2. Results

2.1 SEM Observation Result

You can refer to Picture 1 (1500 times magnification) and Picture 2 (3000 times magnification) for SEM observation results of various root canal parts respectively of Group A (rinsing with traditional syringe) and Group B (rinsing with EASYDO ACTIVATOR-M1082 root canal activator). For Group A, a large amount of detritus and a smear layer is found at the cap, middle and tip of the root canal and most dentin tubules are covered. For Group B, at the cap and middle of the root canal a very small amount of detritus and smear layer is observed and nearly all the dentin tubule openings are exposed with larger diameters while at the root tip only a small amount of detritus is observed and most dentin tubule openings are exposed.

Picture 1. SEM Pictures of Different Root Canal Parts Being Rinsed with Traditional Syringe and EASYDO ACTIVATOR-M1082 Root Canal Activator (X1500)

	根冠1/3	根中1/3	根尖1/3
A 组			
B 组			
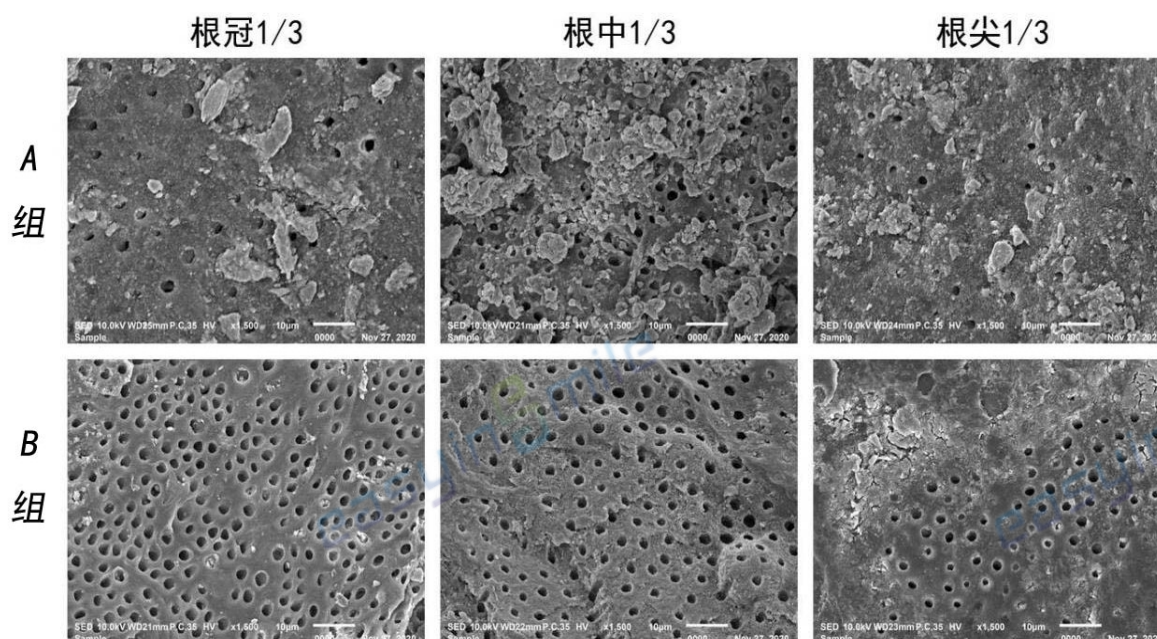
Picture 2. SEM Pictures of Different Root Canal Parts Being Rinsed with Traditional Syringe and EASYDO ACTIVATOR-M1082 Root Canal Activator (X3000)

	根冠1/3	根中1/3	根尖1/3
A 组			
B 组			
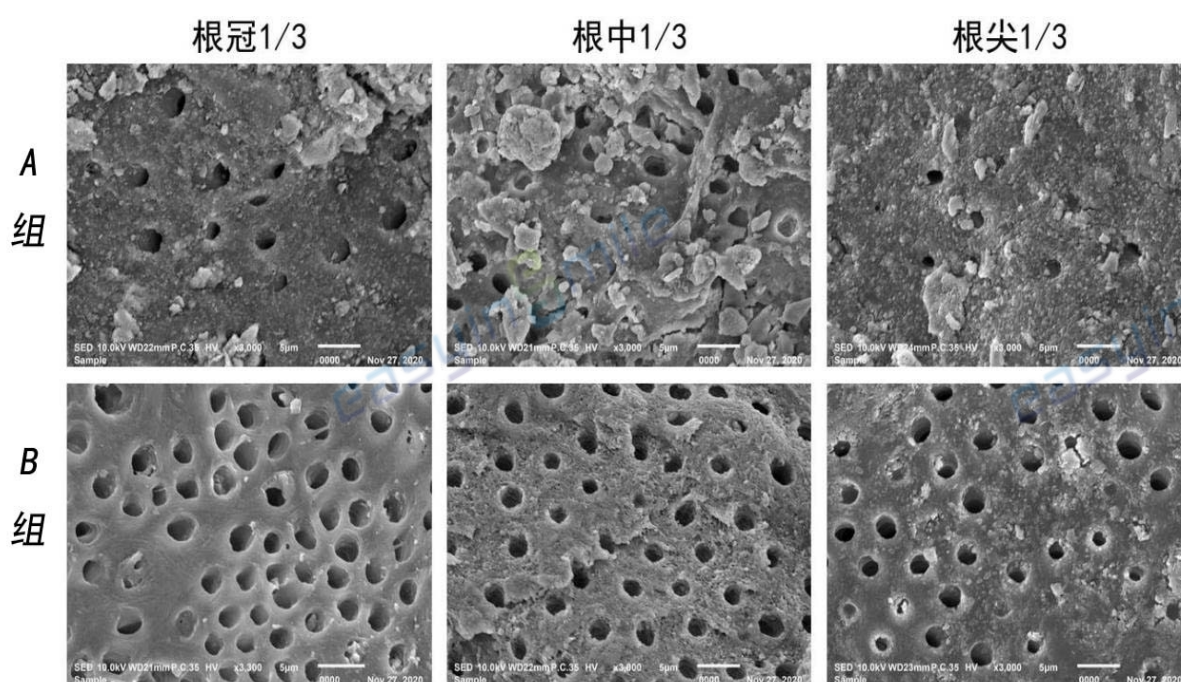
2.2 Groups' Cleanliness Comparison

Please refer to table 1 for root canal wall cleanliness at the cap, middle and tip positions.

Table 1. Comparison of Both Groups' Root Canal Cleanliness (n=15，$\overline{X}$±s)

Detecting Part	Group A	Group B
Root Cap 1/3	2.112±0.725	0.854±0.647*
Root Middle 1/3	3.511±0.562	1.112±0.523*
Root Tip 1/3	4.654±0.685	1.812±0.608*

Note: Comparison of same parts between both groups,* $P < 0.05$

It is found that EASYDO ACTIVATOR-M1082 root canal activator can effectively remove the smear layer and detritus inside the root canal, while it works more effectively on cleaning the root tip.

3. Conclusion

EASYDO ACTIVATOR-M1082 root canal activator can effectively remove the smear layer and dentin detritus inside the root canal, expose dentin tubules, eliminate pathogenic microorganism and improve tightness of root canal filling. Therefore, it excels over the traditional syringe when rinsing root canals.
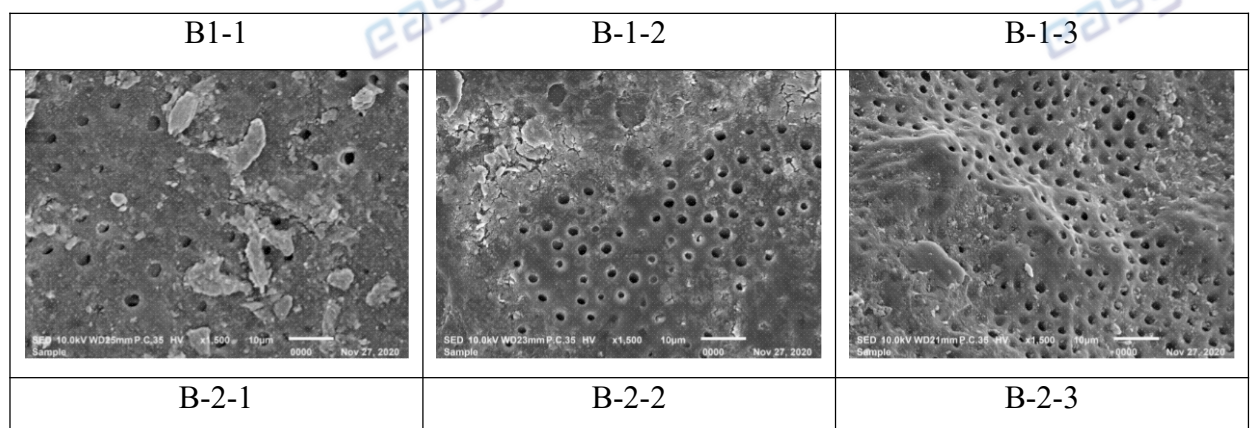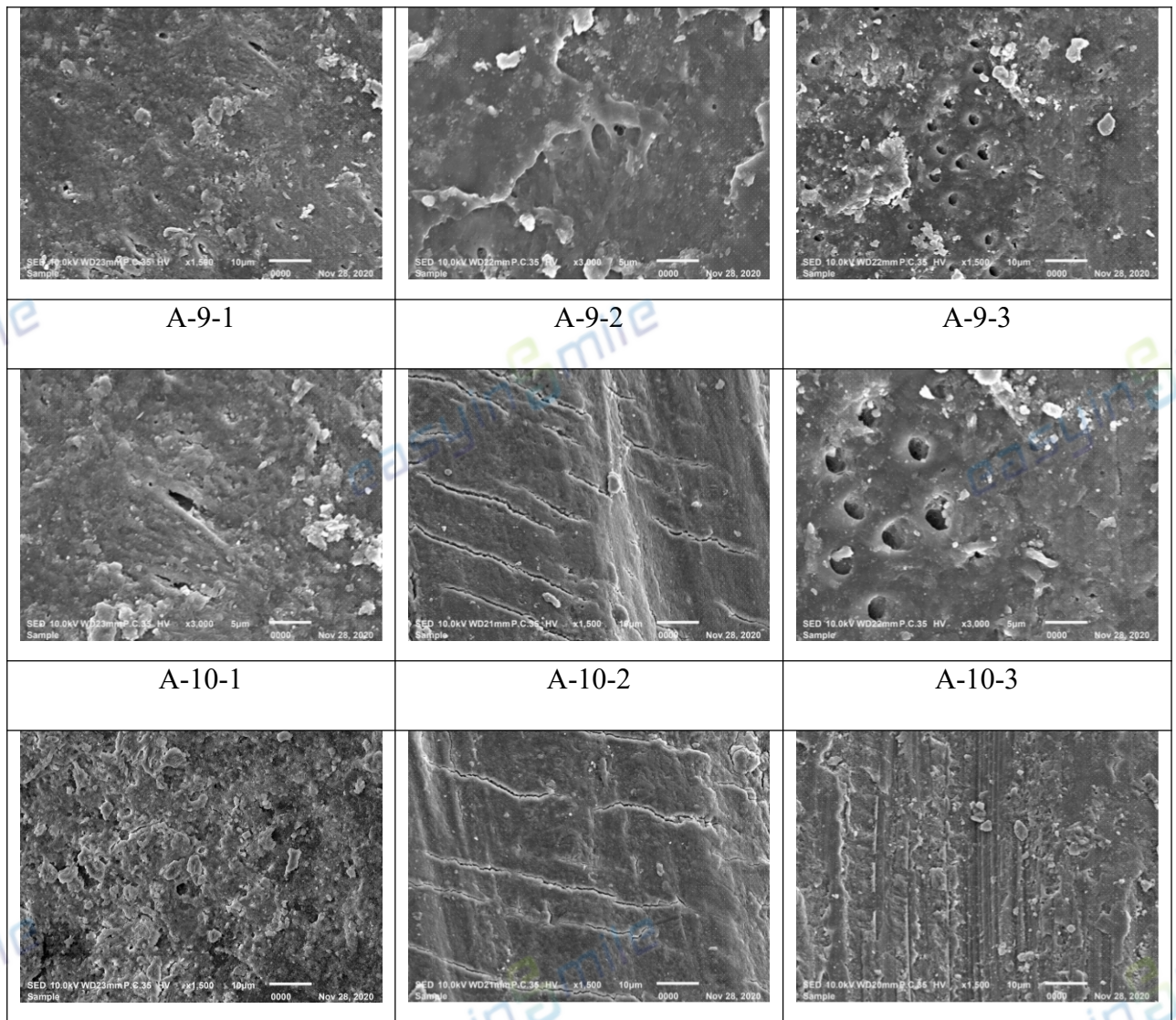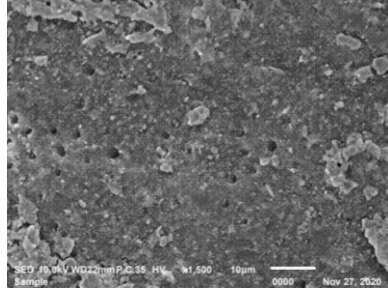
IV. Clinical Documents Evaluation and Conclusion

Success of the root canal therapy largely depends on whether or not the infecting bacteria inside the root canal can be removed effectively. Even though mechanic and chemical methods can be used to significantly reduce bacteria and bacterial products in the root canal, they can not meet desirable expectations when cleaning bacteria and detritus inside branches and divergences of a root canal and the dentin tubules due to the complex anatomical structure of a root canal. Therefore, the importance of root canal rinsing is further highlighted.
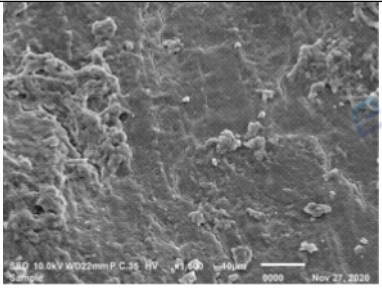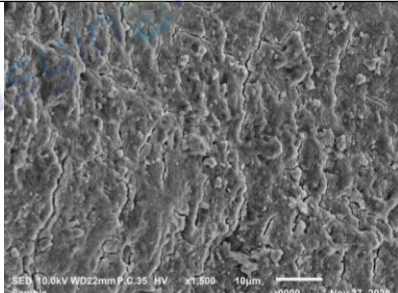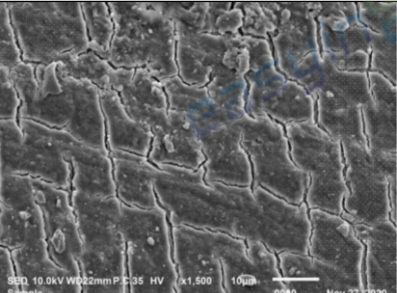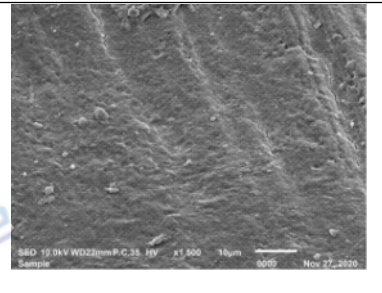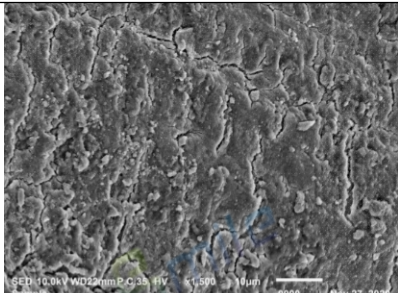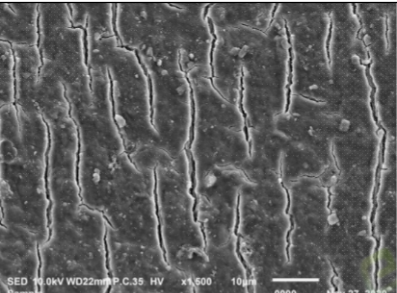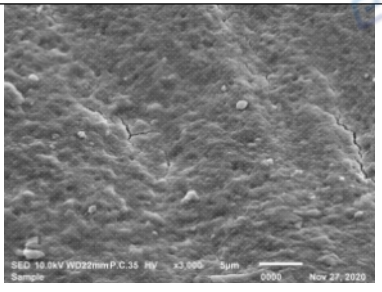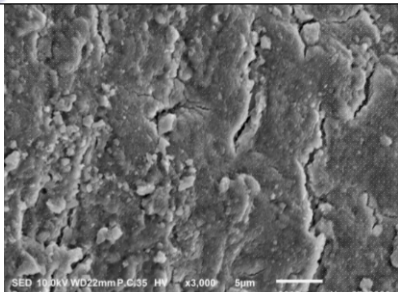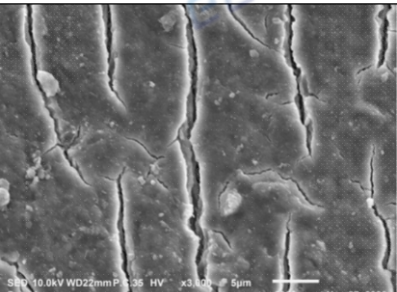
According to the commonly used root canal rinsing method, apparatuses are adopted to rinse the root canal. The rinsing solution can reach the place where the apparatus can not arrive and penetrate into the minute branches of the root canal system. Rinsing effects depend on mechanical washing of the rinsing solution, tissue absolving and disinfection. Since good cleaning and anti-bacteria effects can only be guaranteed by close contact of the rinsing solution with the root canal wall, EASYDO ACTIVATOR-M1082 root canal activator uses oscillation to transport the rinsing solution into the root tip which greatly helps enhance the rinsing effects.
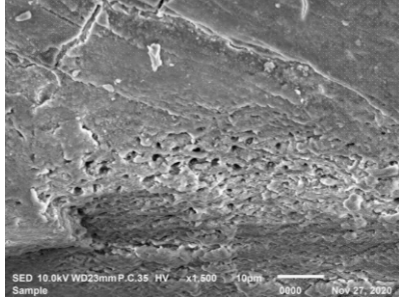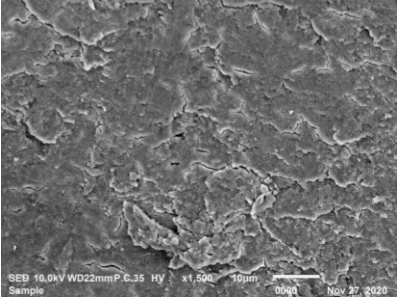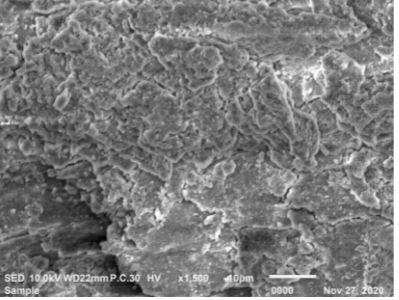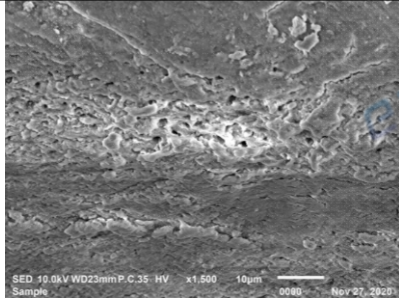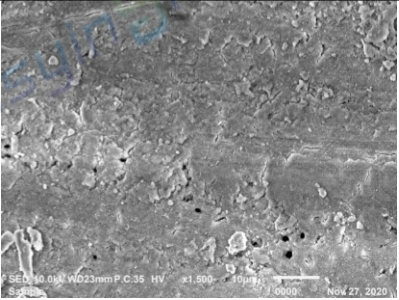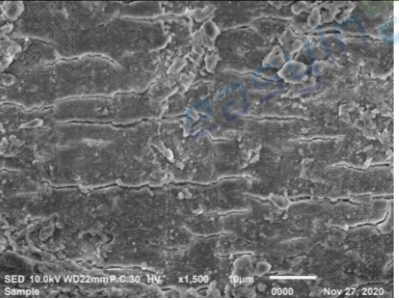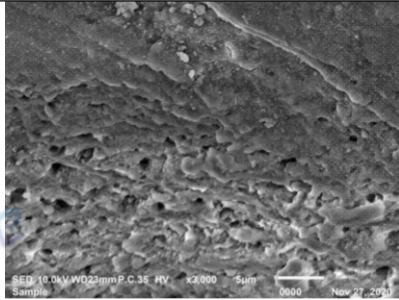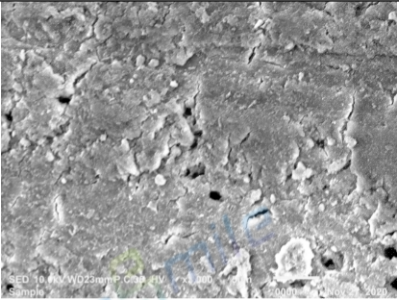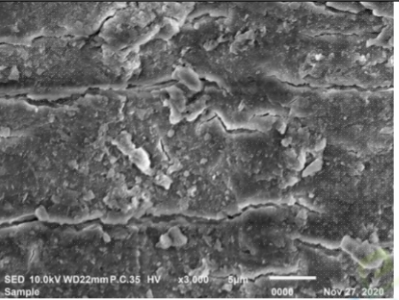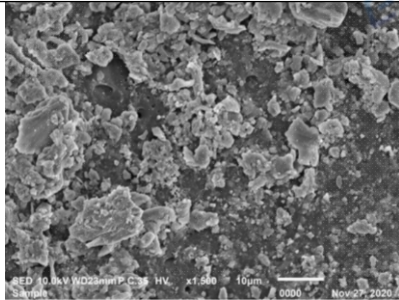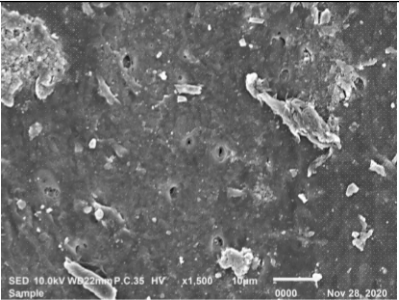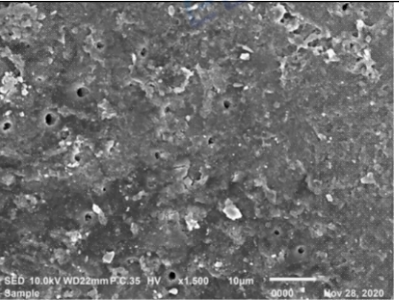
From the above experiments, it is concluded that EASYDO ACTIVATOR-M1082 root canal activator can safely and effectively clean the smear layer and dentin detritus inside the root canal, expose dentin tubules, enhance the ability to eliminate pathogenic microorganism and improve tightness of root canal filling, therefore, it excels over the traditional syringe when rinsing root canals.
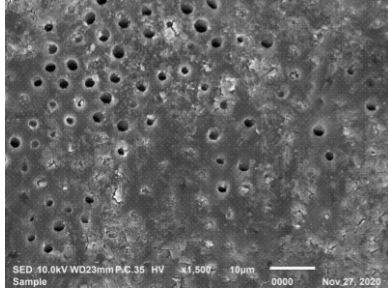
V. Appendix
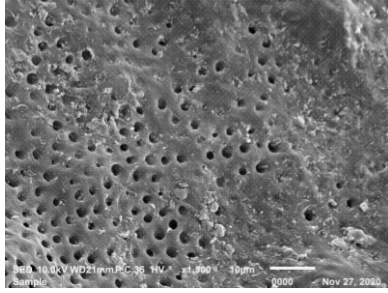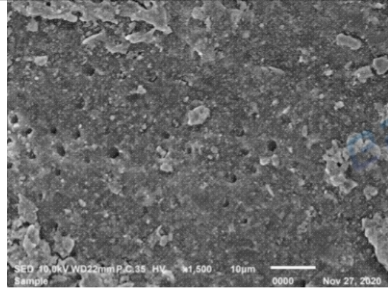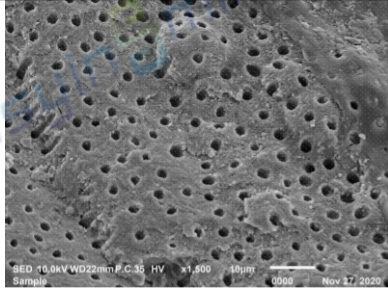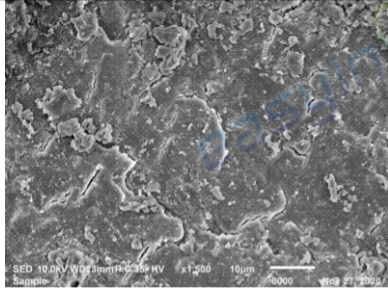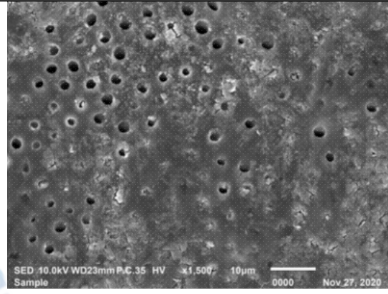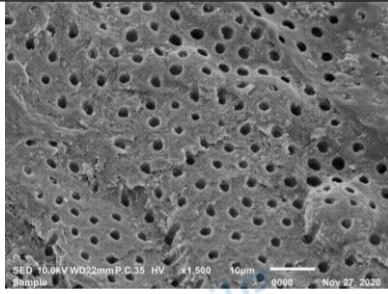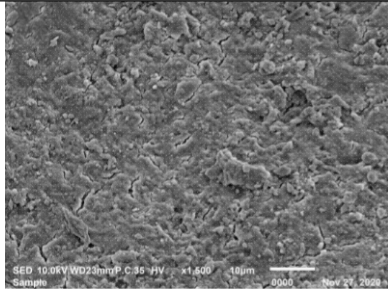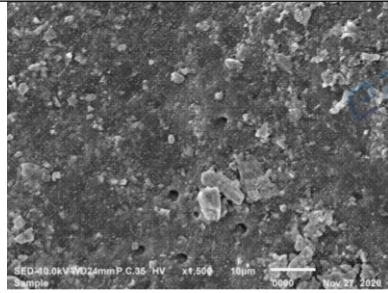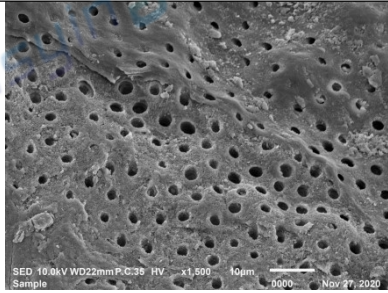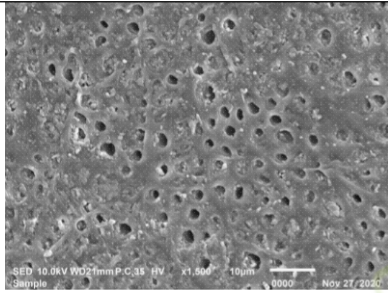
Attachment 1. Some Electron Microscope Scanning Pictures
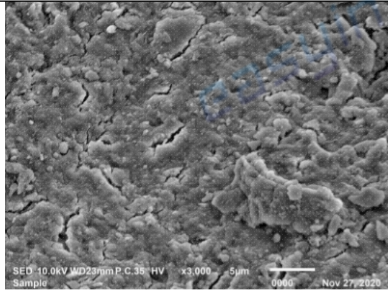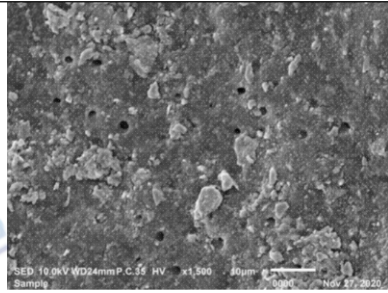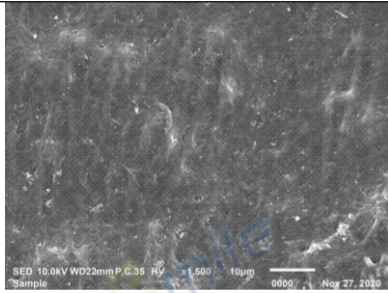
Using the following method to number teeth of Group A and B, A-1-1 refers to the root tip of the 1st tooth in Group A, A-1-2 refers to the root middle of the 1st tooth in Group A, A-1-3 refers to the root cap of the 1st tooth in Group A. Others follow suit.

A-1-1	A-1-2	A-1-3
A-2-1	A2-2	A-2-3
A-3-1	A-3-2	A-3-3
A-4-1	A-4-2	A-4-3

A-5-1	A-5-2	A-5-3
A-6-1	A-6-2	A-6-3
A-7-1	A-7-2	A-7-3
A-8-1	A-8-2	A-8-3

A-9-1	A-9-2	A-9-3
A-10-1	A-10-2	A-10-3
B1-1	B-1-2	B-1-3
B-2-1	B-2-2	B-2-3

B-3-1	B-3-2	B-3-3
B-4-1	B-4-2	B-4-3
B-5-1	B-5-2	B-5-3
B-6-1	B-6-2	B-6-3
B-7-1	B-7-2	B-7-3

 B-8-1	 B-8-2	 B-8-3
 B-9-1	 B-9-2	 B-9-3
 B-10-1	 B-10-2	 B-10-3