

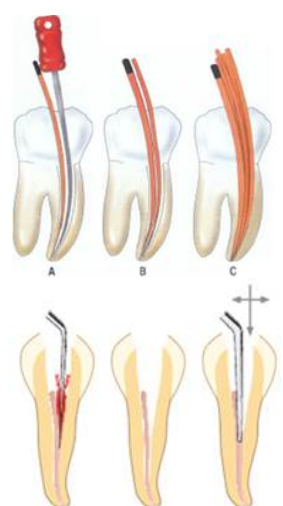
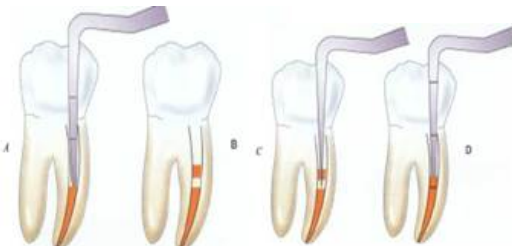



CeraSeal

Calcium Silicate-based Bioceramic Root Canal Sealer





■ Type of the Obturation Technique : Conventional Type

 <p>Cold / Warm Lateral Condensation</p> <p>→ Put the GP into the canal and condense them laterally</p>	 <p>with EQ-V</p>  <p>Continuous Wave Condensation</p> <p>→ Melt the GP with device and fill the melting GP into the canal</p>	  <p>Thermafil and Guttacore</p> <p>→ Use specific instruments to fill the canal</p>
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→ All of these techniques are **time consuming** and have **high cost** in common



■ New Type of Obturation Technique

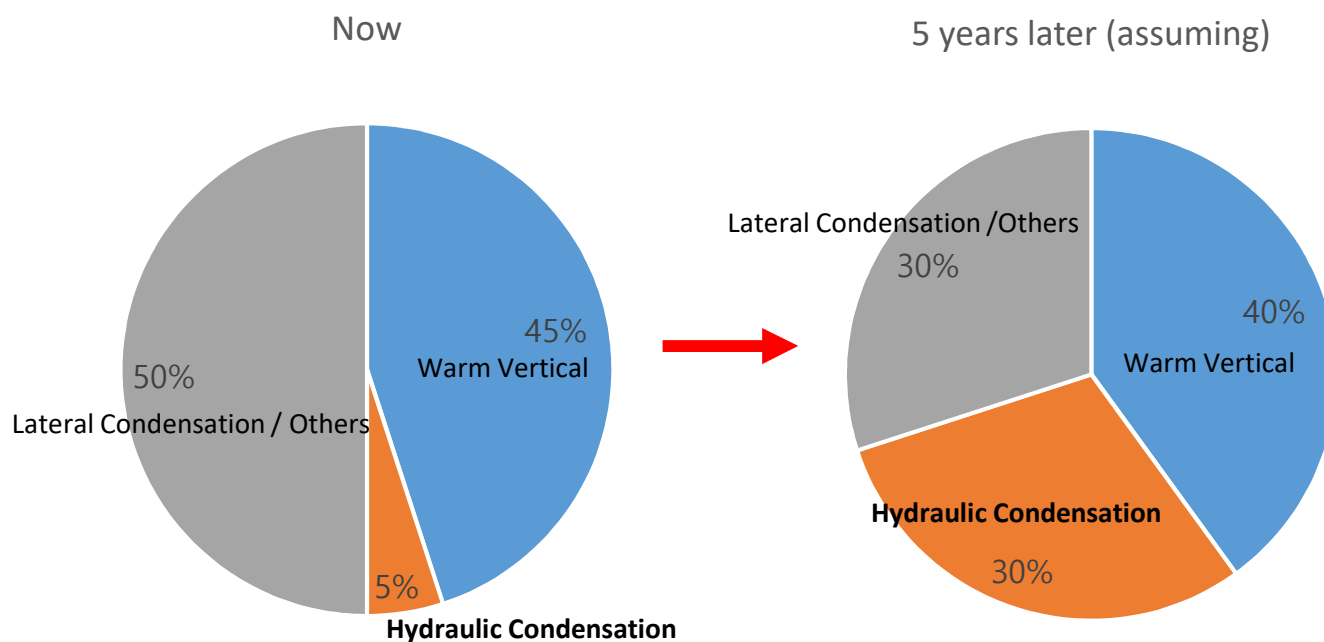
<Hydraulic Condensation with Bioceramic Sealer>



1. It seems like 'Single cone' technique but it use Bioceramic Sealer which has **hydraulic setting properties**.
2. It has **biocompatible** properties which can have **healing effects**.
3. In general, **the treatment's results were either similar or better** than conventional endodontic sealers as observed in in-vitro and in-vivo animal studies.
4. **No more equipping** expensive devices **or time wasted** in chairside. All you need is one master-cone and Bioceramic Sealer.



Market Overview



→ Today, Hydraulic condensation is estimated to be **less than 5%** of market share.

→ Due to lower entry barrier than others, experts expect a growth of **20~25% after 5 years.**



Sales Message

CeraSeal is Premixed Calcium Silicate-based Bioceramic Sealer
with *exceptional flowability and healing effects*.

1. No need to equip expensive device like System B

- Costs over \$1,000~\$3,000

2. Simplification of complicated conventional treatment stages (reduced from more than 10 steps to 3 steps)

Chair-time reduced by 90% max (from more than 5 mins to 30 sec)

- Continuous Wave Condensation: 1) Select master cone and check the tug back 2) Insert pack tip and set the rubber stop 3) Apply sealer to the master cone and put it into the canal 4) Cut the excess GP 5) Compact 6) Insert pack tip and cut 2/3 of GP inside the canal 7) Compact 8) Put GP bar into the device and set the temperature 9) Inject melted GP 10) Compact 11) Repeat steps 9&10 until obturation is completed.
- Hydraulic Condensation: 1) Select the master cone 2) Insert the master cone with CeraSeal 3) Cut the excess GP

3. With such exceptional flowability, a perfect root canal treatment can be achieved with minimal skill set.

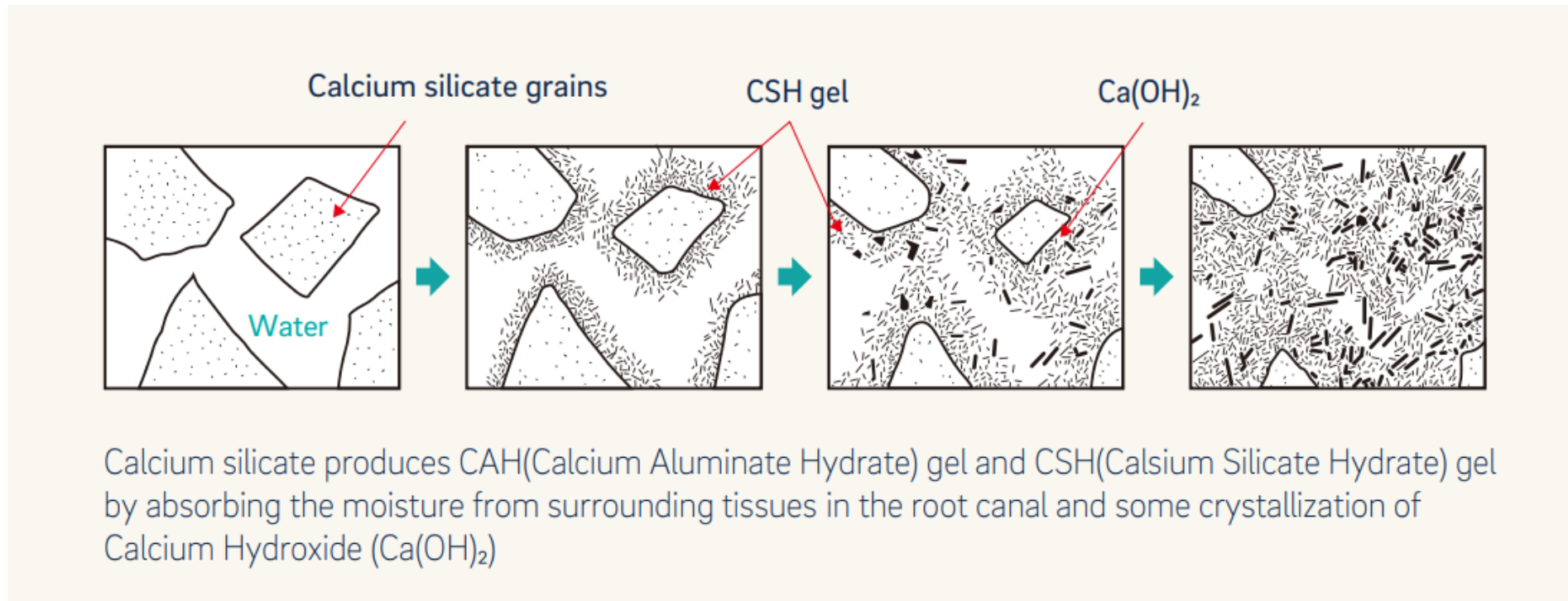


Feature & Benefit

#	Feature	Benefit	Customer Value	
1	Antimicrobial effect	- Suppress the bacteria in the root canal.	- Success probability of RCT increased	
2	Non toxic (High cell viability)	- Healing effect - Harmless to human		- Customer satisfaction increased
3	High volumetric stability (No Shrinkage/expansion)	- One cone technique is possible thanks to hermetic sealing		- Chair-time reduced
4	High flowability	- All aspects of canal anatomy can be reached, which wasn't possible with System B.		
5	Appropriate setting time (3h 30m)	- Prevents washout phenomenon		



Antimicrobial Effect



→ Calcium Hydroxide Ion made by chemical reactions of Calcium Silicate releases high pH which has **antimicrobial effect**.



Non-toxic (High-cell viability)

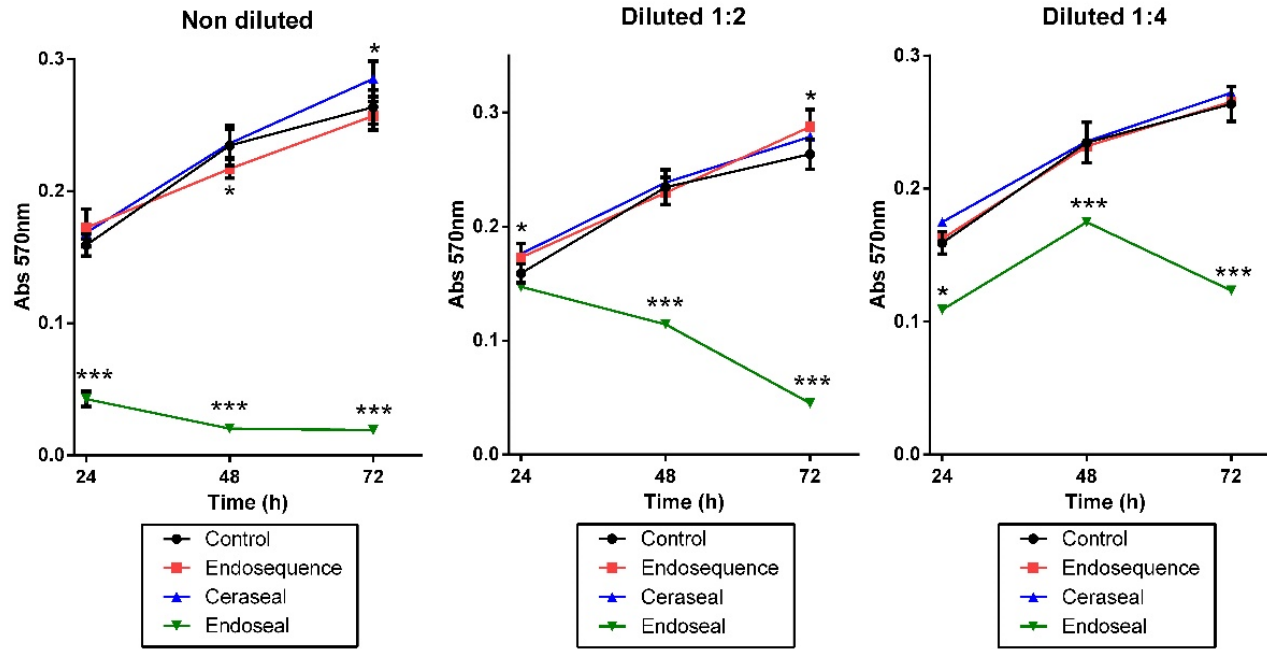


Figure 2. Cell viability was determined using the 3-(4,5-dimethyl-thiazol)-2,5-diphenyl-tetrazolium bromide (MTT) assays. Asterisks represent significant differences compared with the control group (* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$).

「CYTOCOMPATIBILITY, BIOACTIVITY POTENTIAL, AND ION RELEASE OF THREE PREMIXED CALCIUM SILICATED-BASED SEALERS.」
 AUTHORS: FJ Rodríguez-Lozano and Team. University of Murcia, Murcia, Spain

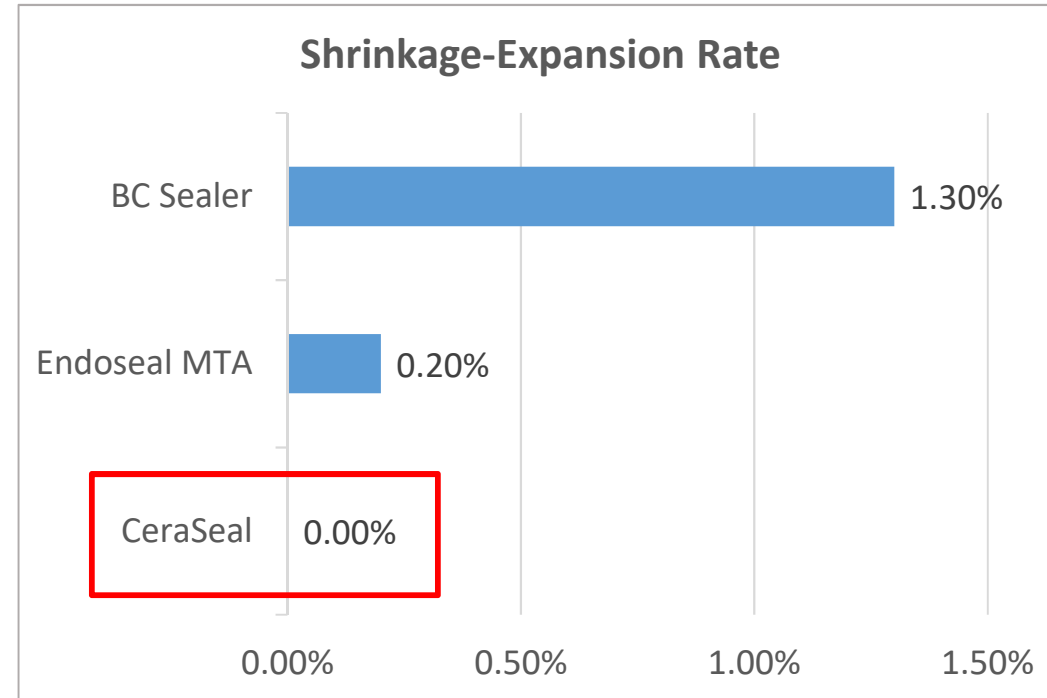
This MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) analysis results of cell viability are presented in Fig 2. After 72 hours, compared to control, significant differences in cell viability was observed after incubation with Endoseal, compared with control (without cements). (* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$). Surprisingly, after 72 hours, no difference between CeraSeal and Endosequence BC Sealer were present..

→ As CeraSeal is non-toxic and has **excellent biocompatibility** (as seen compared to Control condition) there is **no problem** even with its high pH (12.73) level.



High Volumetric Stability (No Shrinkage/Expansion)

	#	Height(mm)		Length Change (mm)	Average Length (mm)	Shrinkage-Expansion Rate
		First Stage	30days After			
CeraSeal	1	12.08	12.08	0.00	0.00	0.00%
	2	12.08	12.08	0.00		
	3	12.08	12.08	0.00		
Endoseal MTA	1	12.05	12.10	0.05	0.023	0.2%
	2	12.11	12.12	0.01		
	3	12.11	12.12	0.01		
BC Sealer	1	12.03	12.21	0.18	0.157	1.3%
	2	12.02	12.14	0.12		
	3	12.07	12.24	0.17		



- Most conventional RC Sealer has shrinkage/expansion, and also other Bioceramic Sealers commonly has expansion as well. Compared to its competitors, CeraSeal doesn't shrink/expand.
- Therefore CeraSeal is completely safe to fill in the root canal and also after setting.



High Flowability

	CeraSeal	BC Sealer	Endoseal MTA	ISO6876:2012
Flowability	24~25mm	24~25mm	25~26mm	17mm or more

- CeraSeal has high flowability which makes **great accessibility** to not only main canal but also small accessory canal where System B can't reach with melted GP.
- Therefore CeraSeal can make 3D obturation like CWC does.



Video Play
Courtesy of Dr. Johnny Onori



Video Play
Courtesy of Dr. Filippo Cardinali



■ Appropriate Setting Time

	CeraSeal	BC Sealer	Endoseal MTA	ISO6876:2012
Setting Time	3.5h	72h (3days)	30m (0.5h)	within 72 hours

(The setting time data is based on data measured when fully set. Its Initial Setting time is about **10min**)

→ The wash-out phenomenon often occurs to Bioceramic sealer, which means the root canal sealer is washed away by physical forces.

→ MTA wash-out phenomenon hardly occurs with use of CeraSeal due to its appropriate setting time.



Differences between Premixed & Non-Premixed



- These Sealers can be categorized as Bioceramic Sealer but they're all dual-syringe type. **Not PREMIXED.**
- They all **need to be mixed by user.** (No related patent issue.)
- In some region, their price is lower than the premixed ones.
- These are **totally different from CeraSeal** and shouldn't be compared to.



Competitors Overview (Premixed Bioceramic Sealer)



1. **EndoSequence BC Sealer (Brasseler USA) & TotalFILL (FKG)**

- Both are same product from IBC (Original Patentee, USA)
- They take up most of the US and EU market share.

2. **Endoseal MTA (Maruchi)**

- They take up most of the Korean market share.
- One of the first Bioceramic Sealer launched in the Korea market

- **BIO-C SEALER (angelus), Well-Root ST (Vericom), One-Fil MTA (Medicus), Bright Endo (Dentium), DIA-ROOT (Diadent)**

There are more than 40 bioceramic sealers, including the above in the market.

And recently, even **UDG**, a NiTi file manufacturer in China, launched a new Bioceramic Sealer called **ConceptRoot-SP**



Competitor: *BC Sealer (Brasseler USA)*

[Strength]

- High brand awareness especially in US, EU
- Tons of clinical reports/papers

[Weakness]

- Long setting time (72h from our lab test)
- It only contains 10 tips and 2g

[Our Advantages]

- CeraSeal sets faster than BC Sealer but not too fast

(In our lab test, Setting time of BC Sealer is more than 72 hours, CeraSeal is 3.5h)

- As per the test result, CeraSeal has almost same cell viability comparing with BC Sealer





Competitor: *Endoseal MTA (Maruchi)*

[Strength]

- High brand awareness in Korean market
- It provides 20 Tips and 3g

[Weakness]

- It's **setting too fast** that it's happening even during treatment.
So, more than one tip is used, which causes the product to be contaminated.
- Lacking aesthetics due to color not being white.

[Our Advantages]

- CeraSeal **hardly sets without water**.
- Unlike Endoseal MTA, user **doesn't need to change the disposable tip during treatment**.
- CeraSeal is never colored and is **white**.





Competitor: Overall

	CeraSeal	BC Sealer	Endoseal MTA	ISO 6876:2012 standard
Composition	Calcium Silicates Zirconium Oxide Thickening Agent	Tricalcium Silicate Dicalcium Silicate Zirconium Oxide Calcium Hydroxide Thickening Agent	Calcium Silicates Calcium Aluminates Calcium Sulfate Radiopacifier Thickening Agent	N/A
Flowability (mm)	23~24	23~24	25~26	17≤
Radio-opacity (Al/mm)	8	6.3	7.1	3≤
Setting time (hour)	3.5	>72	0.5	≤72
Dimensional change(%)	0	1.3	0.2	-
pH	12.76	12.48	11.86	-
Film thickness (μm)	9	-	-	≤50



FAQ

Q: What if I have extrusion?

A: [Accidental extrusion shouldn't be a problem](#) due to CeraSeal being a Bioceramic Sealer with biocompatibility.

Q: Is it possible to use heating device together?

A: Only if you use the heating device to cut the excess GP.

Like other Sealer, its physical properties changes when it gets in contact with heat.

Q: Is obturation of the canal possible with only CeraSeal, without GP?

A: [It is recommended to use with GP](#). But normal GP don't bond well to Bioceramic Sealer, so we recommend you use with Bioceramic GP (which has proper physical properties for bonding with the sealer). Our Bioceramic GP and CeraPoint will launch by 2021, within the 2nd quarter!



FAQ

Q: Is it possible to do one-day treatment using CeraSeal?

A: Yes. **One day treatment** (more than 2visits/1day) **is possible** thanks to its appropriate setting time (3.5h)
But I don't think one visit treatment (1visit/1day) is possible.

Q: Is it okay sell to US & Europe?

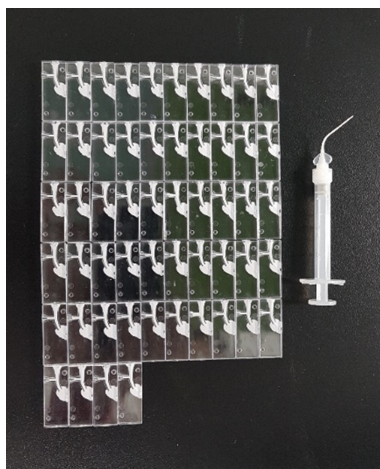
A: According to USP8475811 / ES2535006 / CNP101668550 of patent,
CeraSeal is **not allowed to be sold in the US, Spain and China**. We're now developing patent-free Bioceramic Sealer, which will be launched within 2 years.



FAQ: Disposable Tips (10EA)

[Case 1] Assuming the user didn't use tips

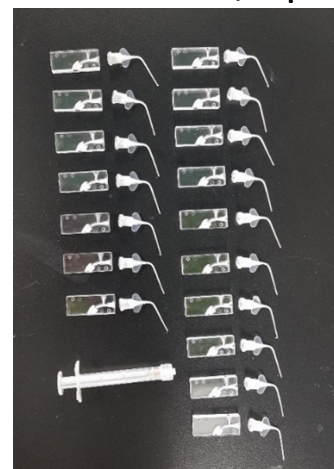
→ In this test, only used 1 tip for 2g



54 canals/2g

[Case 2] Assuming the user used different tips during every treatment

→ In this case, tip was used in every canal (endo block)



17 canals/2g

→ According to clinicians feedback, usually **2g of syringe** can be used on **30~40 canals** (assuming the user used all 10 tips and afterwards used the rest with mixing pad to coat the GP)



Application

- Permanent root canal filling after vital pulp extirpation
- Permanent root canal filling after pulp gangrene and temporary filling treatment

CeraSeal can be used in daily endodontic practice as a root canal filling material (sealer) with the use of single-cone obturation technique.

It also can be used in other special clinical applications like in;

- Long and curved root canals,
- Wide canals, and open apices,
- C-shaped root canals,
- Perforating and non-perforating internal resorptions.
- Canals with strip perforations,
- After bypassing broken instruments,
- Periapical lesions (bioactivity),
- Vital Pulp Therapy.

*Suggested by
Prof-Dr. Talal Al-Nahlawi*





Clinical Cases

[Case.1]

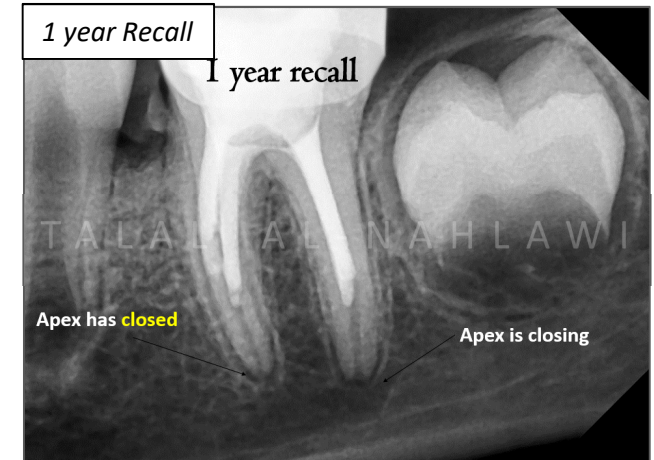
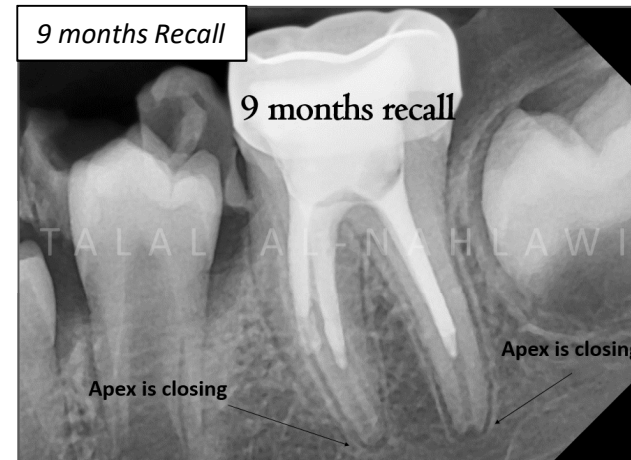


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Clinical Cases

[Case.2]

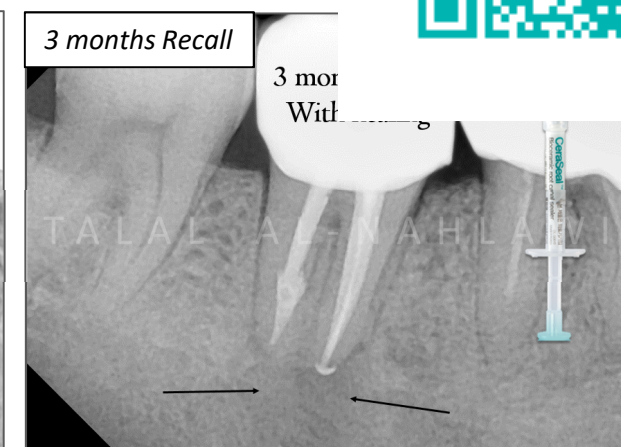
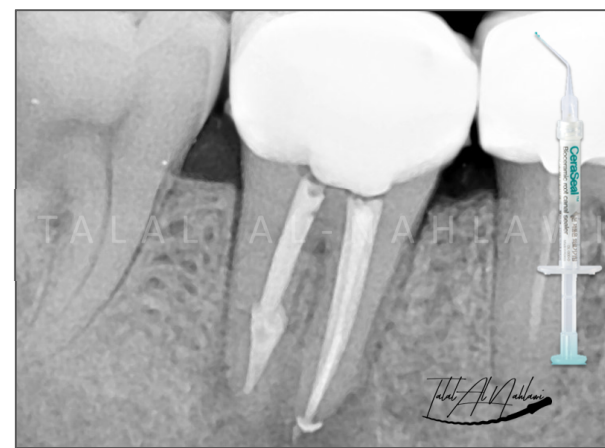
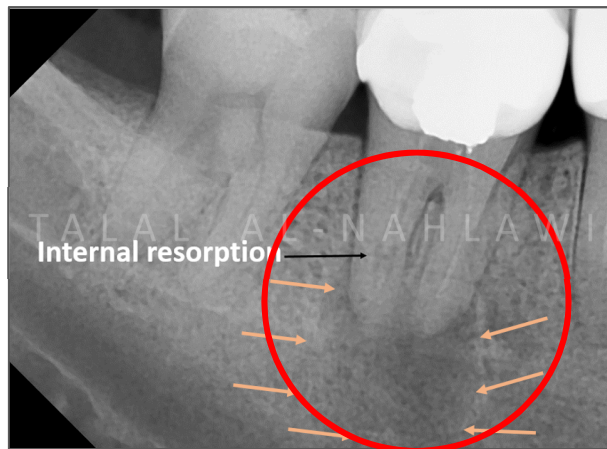


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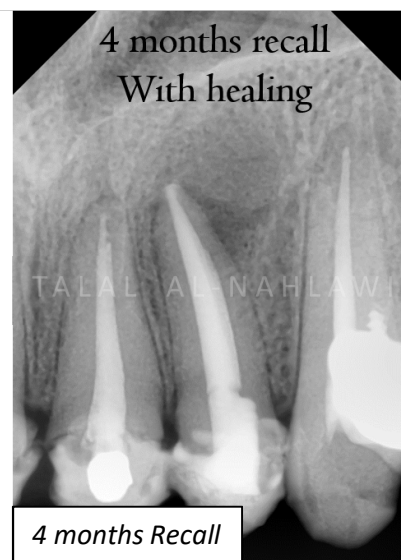
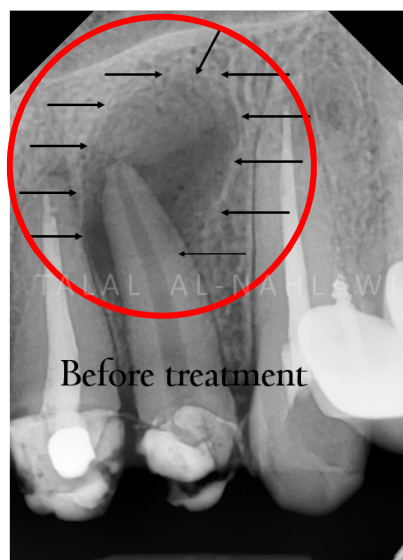
Clinical Cases

[Case.3]



Prof-Dr. Talal Al-Nahlawi

[Case. 4]





Specification

► Registration status

→ KFDA, CE, FDA: Done

► Setting Time: 3.5 hours

► Net weight: 2g (Syringe type)

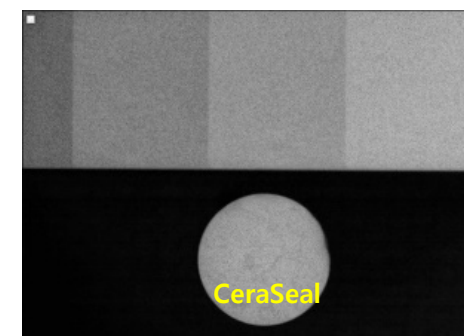
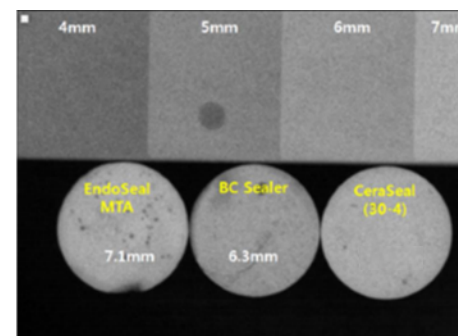
► pH: 12 or higher

	CeraSeal	BC Sealer	Endoseal MTA
pH	12.4	12.48	11.86

► Radiopacity: 8mm or higher

	CeraSeal	BC Sealer	Endoseal MTA	ISO6876: 2012
Radiopacity	8.0mm(AI)	6.3mm(AI)	7.1mm(AI)	3.0mm(AI) or more

► EXP Date: 2 years from production date



Saving the Natural Tooth

