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Deven D. Parghi PhD, James L. Gutmann PhD, DDSFeaturing research from: Franklin R. Tay BDS (Hons), PhD,
M. Jane Gillespie MS, PhD, John F. Hatton DMD

INTRODUCTION

When planning the treatment of a tooth with a diseased root canal, the overriding goal of the clinician—as any student of dentistry can tell you—is to “save the tooth”. The goal of any patient lying in the dentist’s chair is to leave the operatory with precisely the same number of teeth as when they arrived.

The primary treatment option for saving a tooth with a diseased root canal is endodontic therapy. The procedure involves excising the diseased contents of an otherwise structurally intact tooth, cleaning and shaping the root canal system, then disinfecting, sealing, obturating and finally restoring the tooth. The procedure not only saves the tooth but is generally considered to be the only aesthetically acceptable option with the minimum number of patient appointments.

Cleaning and shaping of the root canal following a pulpotomy is generally performed with metallic instruments in the presence of a suitable lubricating medium which may have disinfecting or debris-removing properties. Use of the right disinfecting agent to irrigate the root canal system *after* instrumentation, however, is key to a successful procedure [1].

This White Paper reviews the most common options for irrigation available to clinicians performing root canal procedures. The paper also presents QMix[®] 2in1, a novel irrigating solution that can help clinicians more effectively meet their needs for cleansing and disinfecting the root canal system prior to obturation.

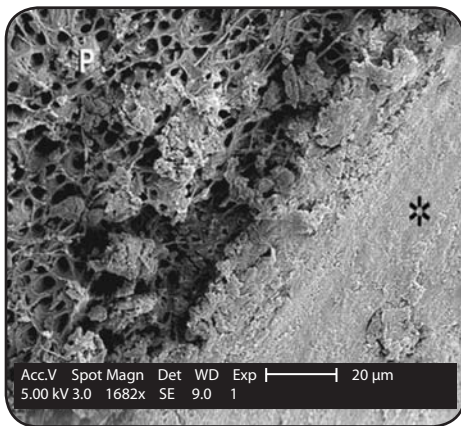


FIGURE 1:
Smear layer (*) formed on the instrumented part of the root canal wall (P)

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SMEAR LAYER

The abrasive action of endodontic files against dentin produces a “smear layer” that coats the instrumented surface [2] of the root canal walls (figure 1). Effective removal of this film-like layer and elimination of the bacteria secreted within or below the smear layer is paramount for a successful procedure [3].

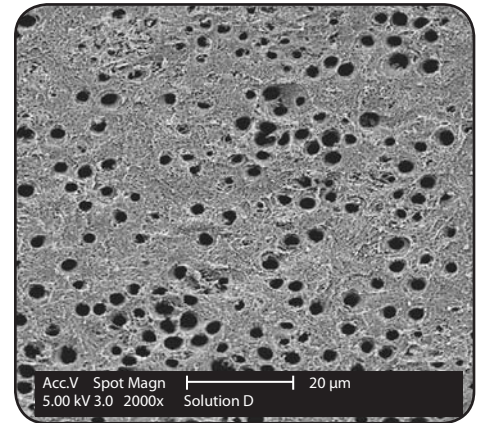
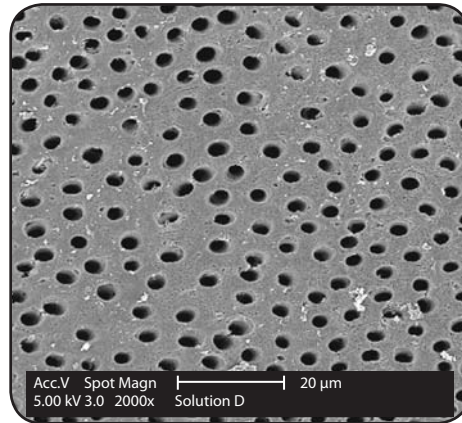
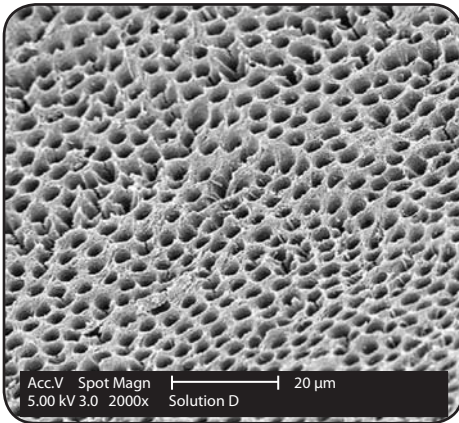
Smear layer consists of both organic and inorganic biological material [4]. Vital and necrotic pulp tissues, embedded bacteria and bacterial fragments form the bulk of the organic component of smear layer. Remnant dentin fragments form the inorganic component. Presence of the smear layer prevents contact of a sealant with the dentinal walls, hindering the formation of an effective internal seal [5].

SODIUM HYPOCHLORITE: THE UNIVERSAL PRIMARY IRRIGANT

Sodium hypochlorite has excellent utility as a primary irrigant on account of its ability to dissolve both vital and necrotic remnant pulp tissues [6]. Its ability to disinfect the exposed surfaces of the root canal system is limited, however, by its inability to act on the inorganic components that support the smear layer. Bacteria embedded within or below the smear layer may be isolated from the effects of this irrigant, and may gradually repopulate the root canal system, necessitating future retreatment.

SMEAR LAYER REMOVAL

Irrigants comprised of chelating agents such as 17% EDTA [7] or Citric Acid [8] can be used to remove the smear layer. These types of irrigants are often fortified with detergents to enhance their effectiveness. While EDTA dismantles smear layer by chelating calcium ions from remnant dentin fragments, Citric Acid dissolves the dentin fragments *via* a combination of chelation and acidic dissolution due to its low pH. Both irrigants may continue to dissolve calcium ions present in the canal walls below the smear layer, potentially weakening the underlying dentin [9].



FIGURES 2A – 2C:

Smear layer was completely removed from the dentinal walls of instrumented teeth following a final rinse with QMix® 2in1 at the coronal, mid and apical sections of the teeth (a, b, and c, respectively).

Images courtesy of
Dr. Franklin Tay, Medical College of Georgia

SECONDARY DISINFECTION

A second disinfection step facilitates more complete cleaning of the root canal system once free of smear layer. Due to the tissue-dissolving properties of sodium hypochlorite, however, this solution can erode the collagen matrix of the underlying dentin [10]. Other antibacterial agents, such as 2% Chlorhexidine [11], may be used in place of NaOCl to leave the dentinal walls otherwise unaffected. Furthermore, chlorhexidine arrests the release of MMPs from the dentin. These substances, which are held “in check” in dentin in the presence of the dental pulp, can be released upon pulp and smear layer removal and prevent adherence of root filling materials to the cleaned dentin [11]. It is generally accepted that a minority of clinicians incorporate Chlorhexidine into every root canal procedure [12].

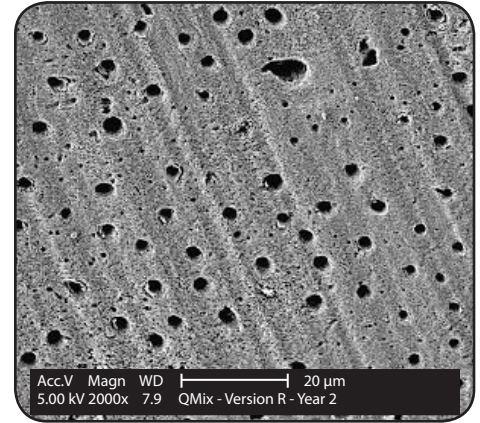
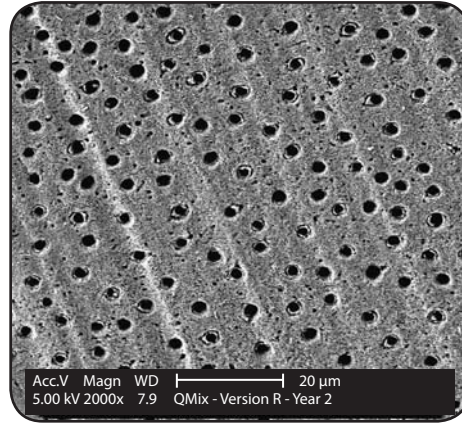
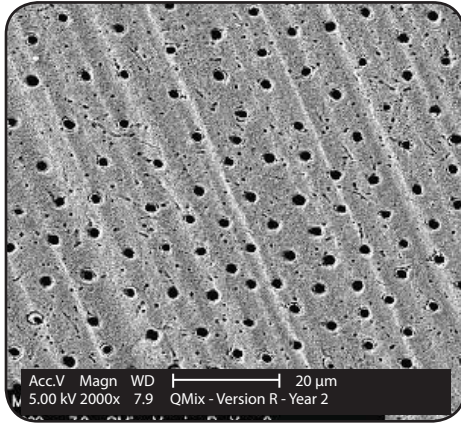
THE CHALLENGE:

ONE READY-TO-USE SOLUTION WITH TWO

FUNCTIONS? Currently, no single widely-accepted protocol for effective irrigation during endodontic therapy is recognized. The challenge for DENTSPLY Tulsa Dental Specialties was to develop an irrigating solution that combines the dual functions of smear layer removal and disinfection after initial irrigation with standard sodium hypochlorite solution. In taking the clinician’s broader needs into consideration, the irrigant would ideally be available as a single, premixed solution that is simple to use, has no special handling requirements, and that is shown to be effective in a relatively short space of time. In completing the wish-list of attributes that make-up an “ideal” final irrigant, it should also be stable at room temperature for up to two years, and free of antibiotics.

THE SOLUTION: QMIX® 2in1 — A DUAL-FUNCTION IRRIGANT

QMix 2in1 is a proprietary blend that comprises an effective smear layer-remover and a powerful antimicrobial agent. The solution is an FDA-cleared endodontic irrigant that is indicated for the cleaning and disinfection of the root canal system in a single step following initial use of standard sodium hypochlorite solution. QMix 2in1 is packaged for immediate use without premixing and has a working time of 60 – 90 seconds. Aging studies have demonstrated the solution is effective for up to two years when stored at room temperature. The solution has been shown to kill bacteria on contact without the use of antibiotics.



IN VITRO & EX VIVO STUDIES

The ability of the solution to remove smear layer and kill bacteria was evaluated via a combination of *in vitro* and *ex vivo* studies performed by academic researchers and an independent laboratory.

SMEAR LAYER REMOVAL

Human extracted single-rooted teeth ($n = 10$) were instrumented and irrigated with 5.25% NaOCl as initial irrigant and finally with QMix 2in1 for a period of 60 seconds. Both irrigants were delivered via a 30-gauge side-vented irrigation needle within 1 mm of the apex. Scanning Electron Microscopy revealed clean canals and open tubules indicative of the complete removal of smear layer (opp. page figures 2a – 2c) ^[13].

In a further study that compared the solution to 17% EDTA the investigator observed that QMix 2in1 “completely removes the smear layer and smear plugs” but was “less aggressive than EDTA in that there is less demineralization of the intact dentin collagen” ^[14].

The effectiveness of the solution in comparison with 17% EDTA was also studied by two other investigators. Their study also concluded that QMix 2in1 was able to completely remove smear layer and that it was actually “superior to 17% EDTA in removing the smear layer from instrumented tooth roots” ^[15].

The ability of the novel solution to remain effective at removing smear layer was also examined after accelerated aging. Figures 3a – 3c show the canal wall of an instrumented human tooth following initial irrigation with 5.25% NaOCl and final irrigation with QMix 2in1 aged for the equivalent of two years at room temperature. The smear layer was completely removed demonstrating the continued effectiveness of QMix 2in1 ^[14, 16].

FIGURES 3A – 3C:

QMix® 2in1 continued to effectively remove smear layer after aging at 60 °C for 8 weeks (equivalent to 2 years' storage at room temperature) at the coronal, mid and apical levels of the tooth (a – c, respectively).

*Images courtesy of
Dr. Franklin Tay, Medical College of Georgia*

DISINFECTION

TABLE 1A:

QMix® 2in1 demonstrates an in vitro kill rate of greater than 99.99% against *Enterococcus faecalis*.

The disinfection capabilities of QMix® 2in1 were tested using a standard time kill protocol by an independent laboratory^[17]. *Enterococcus faecalis* extracted from human root canals was selected as the target bacteria due to the occurrence of this strain in the vast majority of secondary root canal infections. Different batches of the solution consistently demonstrated a kill rate of 99.99% or greater of *Enterococcus faecalis* in 5 seconds (Table 1a).

Test Article: QMix® 2in1

Test Article	Exposure Intervals	0 Hour Control Titer (CFU/mL)	Test Article Titer (CFU/mL)	Percent Reduction (%)	LOG ₁₀ Reduction
<i>Enterococcus faecalis</i> , ATCC #4082	5 seconds	1.4 x 10 ⁷	<2.0 x 10 ²	>99.998	>4.83

TABLE 1B:

QMix® 2in1 continued to achieve a kill rate of greater than 99.99% against *Enterococcus faecalis* after aging for the equivalent of two years.

Accelerated aging of the solution for the equivalent of two years did not diminish the ability of QMix 2in1 to kill this resilient strain (Table 1b).

Test Article: QMix® 2in1 — 2 YR ACCELERATED

Organism	Exposure Intervals	0 Hour Control Titer (CFU/mL)	Test Article Titer (CFU/mL)	Percent Reduction (%)	LOG ₁₀ Reduction
<i>Enterococcus faecalis</i> , ATCC #4082	5 seconds	~1.8 x 10 ⁷	<2.0 x 10 ²	>99.998	>4.96

CONCLUSION

A novel dual-function endodontic irrigating solution, QMix 2in1, was evaluated for its ability to remove smear layer *ex vivo* and kill bacteria *in vitro*. The proprietary solution demonstrated the ability to completely remove the smear layer and kill greater than 99.99% of *Enterococcus faecalis* (obtained from human root canals). Testing following accelerated aging confirmed the shelf life of the solution for two years at room temperature.

REFERENCES:

- [1] Goldman L, Goldman M, Kronman J, et al. The efficacy of several irrigating solutions for endodontics: a scanning electron microscopic study. *Oral Surg Oral Med Oral Pathol* 1985;52:197-204.
- [2] Davis SR, Brayton SM, Goldman M. The morphology of the prepared root canal: a study utilizing infectable silicone. *Oral Surg Oral Med Oral Pathol* 1972; 34:642-8.
- [3] Torabinejad M, Handysides R, Khademi AA, et al. Clinical implications of the smear layer in endodontics: a review. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2002; 94:658-66.
- [4] Sen BH, Wesselink PR, Türkün M. The smear layer: a phenomenon in root canal therapy. *Int Endod J* 1995;28:141-8.
- [5] i) Economides N, Liolios E, Kolokuris I, Beltes P. Long-term evaluation of the influence of smear layer removal on the sealing ability of different sealers. *J Endod* 1999;25:123-5;
ii) von Fraunhofer JA, Fagundes DK, McDonald NJ, Dumsha TC. The effect of root canal preparation on microleakage within endodontically treated teeth: an in vitro study. *Int Endod J* 2000;33:355-60.
- [6] Baumgartner JC, Mader CL. A scanning electron microscopic evaluation of four root canal irrigation regimens. *J Endod* 1987; 13:147-57.
- [7] Zehnder M. Root canal irrigants. *J Endod* 2006; 32:389-98.
- [8] Loel DA. Use of acid cleanser in endodontic therapy. *J Am Dent Assoc* 1975;90:148-51.
- [9] i) Driscoll CO, Dowker SE, Anderson P, Wilson RM, Galabivala K. Effects of sodium hypochlorite solution on root surface dentine composition. *J Mater Sci Mater Med* 2002;13:219-23;
ii) Marending M, Luder HU, Brunner TJ, Knecht S, Stark WJ, Zehnder M. Effect of sodium hypochlorite on human root dentine – mechanical, chemical and structural evaluation. *Int Endod J* 2007;40:786-93;
iii) Sim TP, Knowles JC, Ng YL, Shelton J, Galabivala K. Effect of sodium hypochlorite on mechanical properties of dentine and tooth surface strain. *Int Endod J* 2001;34:120-32.
- [10] i) Tay FR, Gutmann JL, Pashley DH. Microporous, demineralized collagen matrices in intact radicular dentin created by commonly used calcium-depleting endodontic irrigants *J Endod* 2007;33:1086-90;
ii) Moreira DM, Almeida JF, Ferraz CC, Gomes BP, Line SR, Zaia AA. Structural analysis of bovine root dentin after use of different endodontics auxiliary chemical substances. *J Endod* 2009;35:1023-7.
- [11] Hebling J, Pashley DH, Tjäderhane L, Tay FR. Chlorhexidine arrests subclinical degradation of dentin hybrid layers in vivo. *J Dent Res* 2005;84:741-6.
- [12] Unpublished data from DENTSPLY Tulsa Dental Specialties marketing surveys, 2010, 2011.
- [13] Tay FR, Dai L, Khan S, Gillen B, Loushine B, Wimmer C, Pashley D, Gutmann JL, Khechen K. The effect of QMix, an experimental antibacterial root canal irrigant, on removal of canal wall smear layers and debris. *J Endod* 2011; 37:80-84.
- [14] Tay FR. The effect of 2-year and 3-year accelerated aging on the efficacy of QMix to remove canal wall smear layers (unpublished report), 2010.
- [15] Gillespie J, Hatton J, *in press*.
- [16] Tay FR. Stability testing – effect of different aging conditions on the ability of QMix to remove dentin smear layers (unpublished report), 2010.
- [17] Nelson Labs, Salt Lake City, STP #0158. 1 Time Kill Study Protocol.

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