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RUDDLE ON The Radar

GentleWave

Cliff Ruddle Shares His Candid Opinions on the GentleWave 3D Disinfection Technology and its Associated Controversies.

Q: It seems there is a disruptive trend in the endodontic marketplace concerning 3D disinfection technology. What's up?

A: Predictably successful endodontics is predicated on eliminating the contents of the root canal system, like the extraction. With this in mind, a few technologies have emerged in the past decade that allow clinicians to significantly improve cleaning and disinfection potential. These technologies range from lower-cost sonic, ultrasonic, and vacuum devices to higher-cost technologies, such as laser- and multisonic-activated irrigation methods. Recently, Sonendo commercially launched the multisonic disinfection technology, termed GentleWave. This technology has become disruptive and polarizing in the endodontic marketplace due to both unintended consequences related to its clinical use and Sonendo's marketing approach and claims.

Q: Okay, would you describe this method for 3D disinfection?

A: The GentleWave protocol embraces the concept of minimally invasive endodontics (MIE). As such, a more restrictive access cavity is emphasized, and then more mineralized canals are negotiated, catheterized, and minimally prepared. In the instance of more open canals, little or no instrumentation is said to be required. Subsequently, the GentleWave handpiece is connected to the cavo surface of the tooth via a platform composed of an impression-type material. GentleWave treatment consists of cycling specific reagents through this closed system. Sonendo claims that this disinfection method is superior to all other disinfection methods and can clean into all aspects of the root canal system, including deep into the dentinal tubules.

Q: That sounds like good news. Then what are the reported deficiencies regarding using the GentleWave method for 3D disinfection?

A: Certainly, there are some GentleWave users who enthusiastically endorse this 3D disinfection method. However, from what I can see, hear, and read, a considerable number of users are, in fact, reporting the following issues and reporting them *frequently*.

Platform and Disinfection Time: Although some clinicians complain about the extra time required to build a platform and/or monitor the relatively long disinfection cycle, these procedural steps are essential to the GentleWave protocol.

Hemorrhagic Episodes: Growing frustration is being reported regarding hemorrhage following the disinfection cycle. Additionally, in several live broadcasts featuring GentleWave, a hemostatic agent was used to control bleeding, followed by a brief flush with an irrigant. It is naïve to think that a quick flush with an irrigant will eliminate the residual coagulum. The question begs, will residual irritants left within the preparation, lateral ramifications, and dentinal tubules affect future success?

Shape-Shifting Schemes: Sonendo's peer-to-peer collaboration platform reveals enormous differences in approaches, abilities and outcomes. For example, some GentleWave users are altering their shaping protocol and advocating working 1, 2, or 3 mm short to mitigate bleeding. Astonishingly, some endodontists are now advocating to not even catheterize a canal. As such, it should be appreciated that the apical portion of these preparations, which are minimally prepared, or not at all, are relatively *parallel*. Importantly, the GentleWave protocol does not advocate *deep shape*, yet it is root-appropriate deep shape that serves to restrict the flow of irrigants into the attachment apparatus, subsequently mitigating hemorrhage and/or NaOCl accidents.

Obturation Challenges: It is astounding that Sonendo launched a new 3D disinfection technology when, currently, there is no serious obturation method available to fill these minimally prepared or non-instrumented canals. Although there are instances in which Hess-type anatomy is demonstrated radiographically, the fact remains a substantial number of cases show incomplete obturation. This can be largely attributable to a lack of deep shape, inadequacies in cleaning, or the fad of using a cold single cone in conjunction with a bioceramic-based sealer. Yet, evidence shows this class of sealers is more soluble than traditional sealers, is not miscible in a solvent, nor can it be completely removed mechanically in the retreatment situation. Has our discipline already forgotten Hydron, Resilon, and other industry misadventures?

Post-Treatment Pain: Perhaps the most alarming criticism is the report of post-treatment pain following the GentleWave procedure. It should not be a mystery that leaving a vital inflamed pulp stump because of incomplete cleaning, or inadvertently pumping NaOCl into the attachment apparatus, is the most likely etiologic culprit.

Q: Beyond the clinical issues, you had mentioned that there is growing concern regarding Sonendo's marketing campaign. Can you elaborate?

A: There are countless North American endodontists who are expressing concern with Sonendo's marketing methods and claims. For example, on the AAE discussion forum (which, interestingly, has been removed), there were provocative narratives from GentleWave advocates that played to clinician's fears. One post implied that, if a dentist does not use GentleWave and the case fails, then this doctor could risk a future class-action lawsuit. Another advocate claimed that GentleWave treatment is somehow superior and defines a new standard of practice, if not a new standard of care; however, this claim of superiority was directly challenged in the July 2019 issue of the *Journal of Endodontics (JOE)*. Perhaps Sonendo's most divisive marketing advertisement implies that general dentists should only refer to GentleWave users; yet, it is ironic that a number of general dentists are choosing to NOT refer their patients to GentleWave users so as to protect their patients from the reported bleeding and pain issues.

Q: Are there any new competing disinfection technologies on the immediate horizon that will challenge Sonendo's disinfection claims and provide a safer, faster, and far more affordable method than that of GentleWave?

A: Absolutely. There has been a great deal of progress related to improving 3D disinfection through reagents and mechanical, light, and multisonic energies. I am aware of at least 3 new disinfection methods that will launch in 2021. Each of these technologies promises to deliver an evidence-based, highly effective disinfection method that *will not* require platform theatrics and excessive chairtime, and *will* allow the clinician to easily implement disinfection at *any time* during the treatment procedure, and at a fraction of the cost of GentleWave.

Q: So perhaps competition will force Sonendo to raise its game. What is your opinion regarding the future of GentleWave?

A: For this technology and disinfection method to succeed, Sonendo must focus on improving both its existing technology and protocol. Further, greater emphasis must be placed on case selection and respecting the interrelationship between appropriately-shaped canals, 3D disinfection, and filling root canal systems. Although, the clinical goal is 3D disinfection, the technologies launched to support this noble aspiration should support evidence-based obturation. Further, these emerging new technologies should not be divisive, sacrifice patient safety, or compromise treatment outcomes. In the final analysis, GentleWave is not good, is not bad, rather... GentleWave just is. It would be wise to recall the centuries-old proverb that states, "Good, Better, Best…Never let it rest, until your good is better, and your better is best."▲

The opinions expressed in this article are solely those of the author, based on over 40 years of endodontic practice and product development, direct personal observation, fellow colleague reports, and information gathered from online discussion forums.

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