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Response

Water content of ampoule packaged with ProRoot MTA

Dear Editor

Thank you for the opportunity to reply to the letter from Dr Nekoofar *et al.* about the water ampoules supplied in ProRoot® MTA packages.

The water ampoules are made of low-density polyethylene, which enables the user to open and squeeze the ampoules easily. However, it a known phenomenon that water can migrate through low-density polyethylene, and this has been monitored by DENTSPLY Tulsa Dental Specialties. Moisture absorption by the ProRoot® MTA powder and moisture loss from the ampoules are the two factors that have been considered for the shelf-life determinations of 3 years for the ProRoot® MTA kits.

Dr Mohammad H Nekoofar *et al.* performed a very careful weighing experiment to determine the net water contents with an assortment of ProRoot® MTA root canal repair material ampoules. However, he didn't present any data on the age of the ampoules, or even what the lot number was of such kits from which the ampoules have been taken. Without the lot numbers, we cannot determine whether these ampoules were from expired kits or not. If available, Tulsa Dental Specialties or the Maillefer Division of DENTSPLY would gladly take the information as a complaint and investigate the issue. Any clinician with a complaint is welcome and encouraged to contact DENTSPLY to express their dissatisfaction.

Storage of the ampoules does make a difference on the water loss rate from the ampoules. The shelf life determination for the ampoules was determined at room temperature (25 °C) and 50% relative humidity. Drier conditions will accelerate the water loss from the ampoules, but will be beneficial for the powder.

The ampoules are filled with 0.35 gm of water, knowing that it can be difficult to express that last 0.02 gm of water. The target powder to water ratio has been 3 : 1.

Dr Nekoofar's *et al.* discussion of the setting of Portland cement is interesting, and the setting of ProRoot MTA material is similar, but not identical to that of Portland cement because a different additive is used (bismuth oxide), which participates in the setting reaction. The development of calcium hydroxide during setting is a benefit to the ProRoot MTA material, as its known ability to have calcium phosphate precipitate on its surface in phosphate buffered solutions.

Dr Nekoofar's *et al.*'s other specific comments are addressed as follows:

This lack of consistency in the amount of water inside ProRoot® MTA packages is of concern and may explain the uncontrolled and undesirable characteristics of the material in certain clinical and laboratory situations.

- We are not sure to what characteristics Dr Nekoofar refers. However, we would suggest he register his complaint with DENTSPLY. The investigation of dissatisfaction is an essential element of our product improvement process to increase customer satisfaction.

Dr Nekoofar *et al.* also quotes the manufacturer's directions for use.

Note: 1: Adding too much, or too little liquid will reduce the ultimate strength of the material.

- We agree that supplying the precise and accurate amount of water is important for ProRoot® MTA material. We use a pharmaceutical resource to ensure that the grams of powder are properly and accurately filled into the packets and ampoules. Quality Assurance personnel check every batch for accuracy.
- ProRoot® MTA material sets over a wider range of powder to liquid ratios than is usual with other chemical setting materials, some of which must be mixed precisely. The powder to liquid ratio of 4 : 1 creates a very dry mixture that can be used more like a dough, and powder to liquid ratio of 2 : 1 creates a looser, less viscous mixture.
- In a recent article, (Pelliccioni *et al.* 2007) the researchers found that even when no water was added to samples during the preparation of the cement, the microleakage did not affect the *in vitro* sealing ability of ProRoot® MTA material. This indicates that ProRoot® MTA material will absorb water, ever present in a tooth, to ensure the powder is hydrated. Therefore, not having enough water, as Dr Nekoofar determined, may not be so detrimental as feared.
- Fridland & Rosado (2003) tested various powder to liquid ratios. For the samples with less water content, the material was less soluble and less porous, both desirable characteristics. Therefore, even if a clinician used the ampoules with less water, the results would not be adverse.

Mixing the inconsistent and underweight amount of water…..may also be one of the reasons that the material does not set or solidify occasionally after its placement at the first appointment, which is the indicator of an incomplete hydration process.

- Nonsolidifying material is indicative of too much water, not too little. Too much water leads to an inability of the colloidal particles to coalesce and form a hard, strong mass.

According to the optimized water to cement ratio, which is 1 : 3

- The ratio of powder (not cement) to liquid is not optimized at 3 : 1, but is an appropriate ratio for mixing the material and placement intra-orally. The acceptable ratio is a wider range, which allows users to mix the materials to their preferred consistency. A ratio of about 4 : 1 is often used to make delivery to a surgical site easier, whereas a ratio of 2.5 to 1 may be easier for a pulp-capping procedure.

In the long term, the development of a different delivery system is suggested.

- We agree that clinicians may prefer a different delivery system. Usually a preference for a bottle of powder has been expressed. Because of our interest in serving the clinician, this is being taken very seriously.

Dentsply Tulsa Dental Specialities

References

Fridland M, Rosado R (2003) Mineral trioxide aggregate (MTA) solubility and porosity with different water-to-powder ratios. *Journal of Endodontics* **29**, 814–7.

Pelliccioni GA, Vellani CP, Gatto MR, Gandolfi MG, Marchetti C, Prati C (2007) ProRoot mineral trioxide aggregate cement used as a retrograde filling without addition of water: an in vitro evaluation of its microleakage. *Journal of Endodontics* **33**, 1082–5.