DENTINE HYPERSENSIVITY EXPERIENCE USING TOOTHPASTE WITH ADDED BIOGLASS: A CLINICAL TRIAL

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In our clinical practices dentine hypersensitivity "DH" has always been a challenge. Our best approach was to suggest at home solutions such as sensitivity toothpaste or mouth rinse but often there was no significant relief experienced by our patients.

Last year we met Richard Whatley, CEO of BioMin Technologies, who gave us some samples of BioMin F toothpaste to provide relief from "DH" and he explained the technology behind the effectiveness of this novel bioactive glass-based toothpaste.

The Bioglass particles contained in BioMin F toothpaste adhere to dental hard tissue and then slowly dissolve in saliva to release calcium, phosphate and fluoride ions which precipitate on nucleation sites as fluorapatite crystals to occlude open dentine tubules.

It is believed that dentine hypersensivity is due to the movement of pulp fluid inside the dentine tubules (hydrodynamic theory) on application of evocative stimuli such as cold – first of all – but also hot and sweet food and beverages.

According to the Branstrom theory, fluid movement inside the tubules stimulates the odontoblast fibres/ nerve endings creating a short and acute pain, like an electric shock, which is what patients refer to as pain from dentine hypersensivity.

A special polymer in the toothpaste is able to chemically bond the calcium from the Bioglass to the hydroxyapatite "HAp" of enamel. This adhesion is similar to that of glass-ionomer cements to tooth surfaces. Saliva slowly dissolves these Bioglass particles. This enables the release of ions from Bioglass particles over 8-12 hours after brushing to create new crystals of fluorapatite which form on nucleation sites like peritubular dentine and the internal surfaces of dentinal tubules. The growth and development of these fluorapatite crystals closes exposed dentinal tubules and provides relief from the pain of dentine hypersensitivity. (figs. 3-6)

It is important to note that the fluoride concentration in BioMin F toothpaste is much lower than that of other dentine hypersensivity "DH" or caries prevention toothpastes which often utilise several thousand parts per million "p.p.m." of fluoride (from 1,000 to - in some countries - almost 5,000 p.p.m.). BioMin F has a fluoride concentration of only 530 p.p.m. and this concentration is sufficient to promote the growth of fluorapatite crystals on the tooth surfaces.

Soluble Fluoride toothpastes (typically including Sodium Fluoride or Sodium Monofluorophorphate) require a high concentration of fluoride because most of the available fluoride is washed away by the salivary flow and, but at such high concentrations, it forms amorphous crystalline Calcium Fluorite on dental hard tissue and not Fluorapatite mineral.

It is very important also to start remineralisation on initial caries lesions such ICDAS (International Caries Detection and Assessment System) codes 1 and 2 (Bibl. 7)

A scientific paper on Caries Research published in 2013 by Prof. R. Hill and his coworkers (*Bibl.1*) shows that only a fluoride concentration below 45 p.p.m. is effective in promoting remineralisation when combined with calcium and phosphate to form fluorapatite crystals. It is in its crystalline phase where it is able to exchange ions in the oral environment (equilibrium between remineralisation/demineralisation).

The crystalline phase of fluorapatite developed by Bioglass also has enhanced acid resistant features. (*Bibl. 2*) Most concentrated fluoride dental products, such as toothpaste and varnishes, might be able to form an amorphous crystalline phase on enamel, but that is not remineralisation, as cited above, it is calcium fluorite.

Calcium fluorite is not acid-resistant like fluorapatite crystals which is a very important feature for overcoming the dentine hypersensivity "DH" challenge. In fact an amorphous and not acid resistant layer is prone to dissolve in contact with erosive beverages or foodstuffs thereby re-starting dentine hypersensivity "DH" pain due to the re-exposure of dentine tubules.

CLINICAL TRIAL WITH BIOMIN F FOR DENTINE HYPERSENSIVITY:

The clinical trial ran from November 2018 until July 2019. The patient selection criteria was limited to those with diffused dentine hypersensitivity "DH" from mild to severe.

Every participant was given a sample of BioMin F and we suggested they used the toothpaste twice a day for two weeks before recall.

The evaluation sheet given to the participants contained some general questions such their experience of the flavour of the toothpaste, the texture, its foaming capabilities

and some specific questions, such as their prior use of other toothpastes for dentine hypersensivity "DH".

In particular, the questionnaire asked the patients to grade the scale of relief from dentine hypersensivity "DH" after using BioMin F on a scale from 0 to 10. We considered that an average score of 9-10 meant that the dentine hypersensitivity "DH" has been completely resolved using BioMin F toothpaste for only two weeks.

The clinical cases shown below (*figs.1* and 2) were cases where patients reported diffused dentine hypersensivity "DH" in the cervical area of the teeth which was treated with BioMin F for two weeks. This is an approach which substantially reduced or eliminated their pain from dentine hypersensivity.





Fig.1: small areas of cervical loss of enamel with exposure of dentine to dentine hypersensivity "DH" pain to evocative stimuli, in particular, cold and air.

Fig.2: large areas of cervical loss of enamel due to powerful phenomena of abrasion and erosion of enamel and high dentine hypersensivity "DH" pain.

Fig. 3 shows the percentage of patients included in the clinical study who reported pain after eating or drinking cold, hot or acidic food and also after brushing their teeth with cold water.

Most patients included in the report had diffuse (59%) or occasional (38%) dentine hypersensitivity.

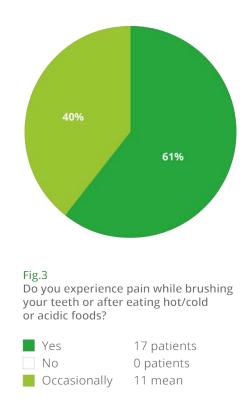


Fig.3: percentage of patients included in the clinical trial who reported dentine hypersensivity "DH" pain to the dentist after eating or drinking hot, cold or acidic foodstuffs or brushing their teeth.

Of those patients included in the clinical trial (28 patients), a majority (50%) reported that they were already using a toothpaste to specifically address dentine hypersensivity and the graph below shows this data as percentages. (Fig.4)

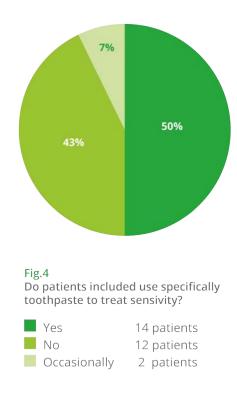


Fig.4: 48% of patients reported prior use of dentine hypersensitivity "DH" toothpaste.

It is interesting to note, as shown in the next graph, (*fig.5*) how many patients using BioMin toothpaste twice a day for two weeks experienced a reduction in dentine hypersensivity "DH" pain. Most of the patients using BioMin F found it relieved their pain from dentine hypersensitivity "DH".

In particular, 28% of patients treated with BioMin F for two weeks reported an elimination of sensivity while in 53% the pain had been significantly reduced. Just 21% reported no obvious change after using BioMin F for two weeks. Importantly, no patients reported an increase in DH pain.

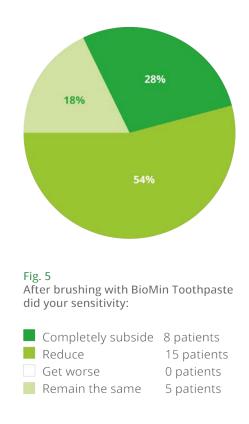


Fig.5: 27% of patients treated with BioMin F had no further "DH" pain and 52% of patients reported a reduction.

One of the last questions asked of patients was whether they felt if there was a greater benefit to using BioMin F, rather than their previous toothpaste, to tackle dentine hypersensivity "DH" and a large number (73 %) reported a positive response as shown in the graph below. (*fig.6*)

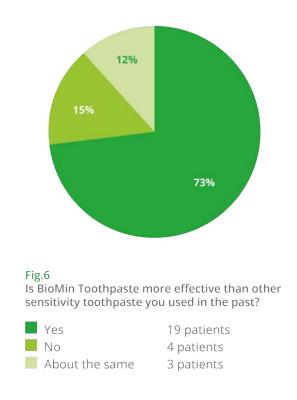


Fig.6: 73% of patients included in the trial reported that BioMin F toothpaste is more effective than other sensitivity toothpastes in reducing "DH" pain.

We would now like to describe in detail one particular clinical case from the trial which demonstrates the acid resistant features of fluorapatite crystals produced by the Bioglass within BioMin F.

The subject M.L., female, 44 years old with high dentine hypersensivity "DH" started the BioMin F trial according to our instructions (twice a day) and after just a few days she reported greater relief from dentine sensitivity and she was very satisfied.

In the following days M.L. had repetitive bouts of vomiting with gastric acid reflux with a very low pH (around pH: 1) capable of removing any mineral pellicle or aggregate covering tubule orifices and which would be likely to cause dentine hypersensivity pain to reoccur. Naturally, M.L feared this would happen.

At the conclusion of these episodes, M.L. checked her sensitivity pain by rinsing her teeth with cold water after brushing during the cold air of winter and she told us that the benefit from using BioMin F remained unchanged. (fig.7)

This suggests, as per the microscopy studies undertaken at Queen Mary University of London that Bioglass contained in the toothpaste does not produce an amorphous mineral layer on the tubule orifices but produces a true mineralisation process with formation of fluorapatite crystals that seem to be acid- resistant as the S.E.M. pictures below show. (*fig.8*, *fig.9*, *fig.10*)



User Evaluation Form for BioMin Toothpaste

13. On a scale of 0-10, how well did the Biomin Toothpaste address your tooth sensitivity? Circle a number

.(did not address sensitivity) 0-1-2-3-4-5-6-7-8-9-10 (completely resolved sensitivity)

14. Do you have any comments about your experience brushing with BioMin Toothpaste?

DURING THESE TWO WEEKS OF USE I HAD

A DAY IN WHICH I HAD REPEATED EPISODES

OF VAMITING

Fig.7: M.L. evaluation questionnaire where she reported vomiting during BioMin F treatment but a complete absence of dentine hypersensitivity (scale n.9) despite this severe acidic challenge.

All SEM pictures from research at Queen Mary University of London

Fig.8 Fig.9 Fig.10

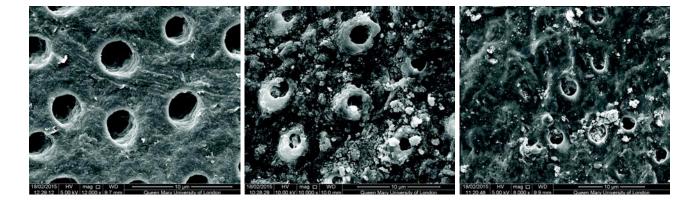


Fig.8: open tubules on dentine surface.

Fig.9: tubules occluded after brushing with BioMin F.

Fig.10: tubules remained occluded after acid challenge.

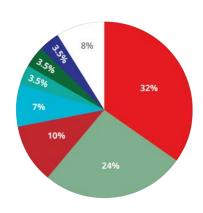


Fig.7 Which brand of toothpaste do you regularly use to brush our teeth?



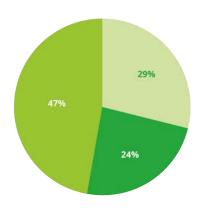
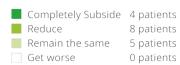


Fig. 8
Those patients exhibiting diffuse dentine sensitivity (17) reported the following results after brushing with BioMin Toothpaste for 2 weeks:



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