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Fluoride ingestion from toothpaste: conclusions of European Union-funded multicentre project

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Abstract – An important challenge encountered in this multicentred project was the need to take account of the different cultural and legal differences between the seven sites when agreeing the protocol. Examples such as access to registers of births and subject consent dictated that there were some differences in the methods used in the different sites. The data presented showed that it was possible to train and calibrate a number of examiners in a standardized photographic method for recording enamel fluorosis. This method has a number of important advantages for the objective monitoring of enamel fluorosis over time. There were considerable differences between the seven sites in the formulations of the toothpaste used and in the pattern of their use. The results indicate that it is possible to agree and adopt a standardized method for measuring fluoride ingestion from toothpaste. The aesthetic impact of enamel fluorosis seemed low in the populations included in this project, but further work is required on this issue.

Key words: fluoride; fluorosis; ingestion; measurement; opacities; toothpaste

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The study reported in this series of articles describes the studies undertaken by seven European Oral Health Research Centres. As recounted in the opening article (1) the study came about as a result of a growing public-health debate in Europe on the alleged link between ingestion of fluoride toothpaste by young children and the reported increased prevalence of dental fluorosis in permanent incisor teeth. Perhaps one of the most important challenges faced in this project was the meticulous planning required when attempting to ensure that all seven partner countries, each with their individual culture and background, would interpret the scientific methods in the same way. In general the authors feel that this challenge was successfully met. However, as can been seen in a number of instances, local rules and customs dictated that some compromises had to be accepted. For instance, it was interesting to note that the rules regarding access to birth registers in different member states varied. This explains why the method of sample selection for the toothpaste ingestion studies varied from state to state. Another example of how cultural differences can affect multicentre studies was the degree of consent to urine sample collection in the different member states. In view of the growing need for multicentre and multinational studies (2), it is important that funding agencies and principal investigators in such studies are aware during protocol development that these factors are taken into account. One of the general objectives of the EU 4th Framework Programme in Research and Technological Development (RTD) was that the programme would contribute to the improvement of the health of the citizen and population as well as strengthen the scientific basis of the competitiveness of the European Health Industry. It is anticipated that the work reported in this study will contribute to the growing partnership between the health industry, public-health workers and health agencies.

Standard method for recording enamel opacities including fluorosis

At the outset the co-ordinators of this project were aware of the fact that previous attempts to develop a photographic method for recording enamel opacities on permanent maxillary incisors were complicated by the fact that both the equipment and technique varied. With this in mind, the seven partners decided that the purchase of high-quality camera equipment and materials was crucial to success. Having obtained expert advice from a number of sources the camera system outlined by Cochran et al. (3) was purchased at a cost of 3500.00 Euros (approximately US $ 3500.00). Eight cameras were purchased. Whilst this might seem a substantial investment in what would appear to be a commonly used technology it is interesting to note that all eight cameras have been in constant use in different studies throughout Europe since completion of the field work of the studies reported in this project. For example in Greece there is currently a national survey of children's dental health in progress in which the photographic method described in this issue (3, 4) is being used to measure dental fluorosis. Similarly in Ireland a national survey of children's dental health is also in progress at the moment and again the same photographic method is being used. In the case of the latter study, colleagues in Northern Ireland (non-fluoridated water supply) are conducting a parallel study in which dental fluorosis is being measured again using the photographic technique described in the FLINT Project. Experience to date indicates that the training and calibration programmes described here (3) are repeatable when other examiners are being recruited to take the photographs in large-scale studies. It is interesting also that the Portuguese partners have decided that the photographic technique has a possible place in evaluating the outcomes of orthodontic treatment and a study is currently in progress. Clearly, when the technique is being used so widely throughout Europe the opportunity exists now for the photographs to be graded using different indices by different examiners. Also, of course, it allows all the data collected in the FLINT Project and all further studies to be archived so that the level of dental fluorosis can be looked at retrospectively in years to come.

One of the more difficult decisions taken by the research team at the start of the FLINT Project was not to use digital technology. At the time the advice given was that the technology did not quite match the methods required in the project. However, it would appear that because of the recent rapid advances in digital camera technology it would be feasible to use it in future studies. However, the methodological issues addressed in this series (3, 4), such as drying time, camera angulation and flash set-up, will also be relevant when digital cameras are in use. Another development that is likely to become part of the photographic technique is that newer method for measuring colour differences in the photographic images are likely to be adopted as part of the overall photographic package for measuring dental fluorosis.

A further technology that needs to be considered at this stage is quantitative light fluorescence. To date this technique has been developed largely with a view to measuring early enamel changes in the caries process (5). However, it would appear that enamel colour changes in various stages of dental fluorosis could also be quantified with this new technology.

Standard method for measuring fluoride ingestion from toothpaste

One of the major findings of the FLINT Project was the large choice of toothpastes available to the consumers in Europe, especially children. All the toothpastes that the parents of the participants claimed to have been using at the time of the project were collected and analysed in the Fluoride Laboratory in the Oral Health Services Research Centre in Cork. It was interesting that many of the 'paediatric' toothpastes used contained $\geq$1000 ppm fluoride; this was of particular concern when the fluoride content was not marked on the toothpaste tube. It was also found that on occasion the concentration measured was at considerable variance from the amount marked on the tube. A number had added flavours to make them particularly attractive to children. It is important that manufacturers are aware that such flavourings are likely to increase the extent to which young children will swallow these toothpastes. Another important finding in this part of the project was the wide variation in the age at which parents claimed to have started brushing their children's teeth with a fluoride toothpaste. In some sites it was found, for example, that 50% of parents claimed to have started brushing their babies' teeth before the age of 1 year. Recent data indicate that the critical time for the development of fluorosis of permanent maxillary incisor teeth is between the ages of 15 and 24 months for males and 21 and 30 months for females (6). A fruitful area of further research would be to establish a benefit, if any, from a caries point of view if parents were advised that brushing with fluoride toothpaste should not commence until the second primary molars had erupted, at about

2–2.5 years; prior to this age teeth could be brushed with a toothbrush and water.

In the late 1980s there was a general agreement amongst toothpaste manufacturers that some guidance on the amount of toothpaste to be placed on the brush when brushing children's teeth was appropriate. It was decided that a pea-sized amount would be clear to the consumer and would be adequate to provide the necessary protection against caries. Of the 250 samples collected most of them were of toothpaste from tubes that included the advice to use a pea-sized amount for children under the age of 7 years. Based on the data reported in this project, however, it would appear that this advice goes largely unheeded for a high proportion of the age group studied. Clearly some further work needs to be done to make sure that the recommendation regarding the amount of toothpaste placed on the brush is more frequently adhered to. Strategies such as clearer labelling on the toothpaste tubes and advice specifically directed at parents of young children should be considered. A specimen size of toothpaste dose could be incorporated in the tube labelling. Furthermore, nozzle apertures of the toothpaste tubes, which were found to vary greatly, could be made smaller in an attempt to reduce the chance of overdosing. A factor linked to the amount placed on the brush is of course the amount swallowed and ingested. On the basis of the urinary analysis conducted in this project it would appear that the amount of fluoride ingested from toothpaste is sufficiently high amongst a small percentage of the users to give rise to fluorosis of the permanent maxillary central incisors. As stated previously the idea of recommending that tooth brushing with a fluoride toothpaste should start no sooner than 2–2.5 years is a strategy worth considering.

The researchers who participated in the project described in this series of papers are currently seeking funding to follow-up the children at each site who participated in the fluoride ingestion from toothpaste study (7, 8). The main purpose of this follow-up study will be to measure the level of dental fluorosis in the permanent maxillary incisors and link these measurements with the estimate of the amount and pattern of fluoride toothpaste used and ingested when the children were aged 1.5–2 years old.

Public-health impact of dental fluorosis

A number of commentators have addressed the fact that there is currently little information on the public-health impact of different grades of dental fluorosis (2, 9, 10) It was interesting in the current study that the main reason given by parents for being unhappy with their children's teeth was alignment. It was only when the parents of subjects with Thylstrup and Fejerskov (TF) index grade 3 fluorosis were questioned that any appreciable concern about the aesthetic appearance of the teeth emerged. Interestingly, a high proportion of parents whose children had a TF score of 0 also declared that they were unhappy with the colour of their children's teeth. Clearly further work is required on this important issue.

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