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Fluoride ingestion from toothpaste: background to European Union-funded multicentre project

Denis M. O'Mullane, Judith A Cochran and Helen P. Whelton

Oral Health Services Research Centre, University College Cork, Ireland

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Abstract – As in most other established market economies throughout the world the prevalence of dental caries has declined in most Member States of the European Union (EU). There is evidence that the increased use of fluoride toothpaste has been a major factor in this improvement. Recently there has been increasing debate on the alleged link between increased use of fluoride toothpaste, particularly by infants and young children, and increased levels of enamel fluorosis. Central to these discussions are two issues, namely measurement of the amount of fluoride ingested by infants and young children and measurement of enamel opacities including fluorosis. The aims of the project described in this special issue addressed these two measurement issues. Seven EU Partners participated. Standardized methods for recording the amount of fluoride ingested when using fluoride toothpaste were developed and used in the seven sites. Similarly a standardized photographic method for recording enamel opacities, including fluorosis, was developed.

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

Professor Denis O'Mullane, Oral Health Services Research Centre, University College Cork, Ireland
Tel: +353 214 90 1210
Fax: +353 214 54 5391
e-mail: d.omullane@ucc.ie

Since 1983 the European Union (EU) has co-ordinated its research and technical development activities through multiannual Framework Programmes. These programmes are implemented through specific research and technological development (RTD) activities dealing with selected areas of research, such as environment or health. In April 1994 the 4th Framework Programme was adopted, with a duration of 5 years and a budget of 12.3 billion Euros. BIOMED 2 was a specific programme within the 4th Framework Programme and its general objective was to 'contribute to the improvement of the health of the citizen and population as well as strengthening the scientific basis of the competitiveness of the European Health Industry'. Public-health research, including health-services research, was one of the eight areas covered in BIOMED 2 with 'standardization of methods for outcome measurement of health care' specifically mentioned as a subject requiring attention [Biomedicine and Health Research (BIOMED 2) European Commission 1994]. The 11 papers included in this Special Edition are based on a project funded under BIOMED 2. Seven research groups from seven EU Member States participated.

During the last 50 years many epidemiological studies of dental caries have been conducted in Europe. As in many other developed countries, there was a decline in the prevalence of dental decay during the 1940s and early 1950s, probably as a result of sugar rationing during and immediately following the Second World War. This was followed by a sharp increase in the prevalence of dental caries in the 20-year period prior to the mid-1970s. By that time dental caries had become a major public health problem and the restoration, extraction or replacement of decayed teeth for children and adults was

becoming an increasing burden for health agencies, dental care accounting for approximately 7–8% of the total health-care budgets in most EU States. Despite this large investment however, the oral health in the EU remained poor. For example, in Ireland over 60% of those aged over 60 years were edentulous (1). The late 1970s and 1980s saw a welcome change in the above patterns: decay levels declined in children and adults and an increasing proportion of the population began to retain some or all of their natural teeth into old age (2, 3). Whilst a number of factors are likely to account for this improvement in the oral health of Europeans, one factor common to all EU communities where it has been recorded has been the introduction of fluoride toothpastes to the oral health-care market in the early 1970s and their increased availability and use in most EU Member States over the past 20 years (4). Since 1990 it is estimated that over 95% of toothpaste sold has contained fluoride (5).

The first clinical trial of a fluoride toothpaste reported was that conducted by Bibby (6) in which the caries-preventive effect of a paste with 0.1% NaF and a $CaCO_3$ abrasive was assessed. No reduction in dental caries was recorded, probably as a result of formulation difficulties which resulted in a rapid decline in available fluoride in the paste following manufacture. No further studies were reported until the 1950s when, as well as further studies on toothpastes containing NaF, trials of formulations containing SnF_2 were initiated by Muhler (7, 8). Both formulations produced significant reductions in caries. The Council of Dental Therapeutics of the American Dental Association recognized the SnF_2 formulation as a therapeutic toothpaste in 1964. Since 1965 numerous clinical trials of fluoride toothpastes have been conducted to establish the best formulation for the prevention of dental caries (9, 10). Different fluoride salts, abrasives and different concentrations of the fluoride ion have been tested. In the case of the latter the formulations tested usually contained between 500 and 2500 ppm fluoride. The results show that increased fluoride levels give a greater reduction in the incidence of dental caries; the increased benefit is of the order of 6% for each 500 ppm over 1000 and up to 2500 ppm fluoride (4, 9, 10). The effectiveness of toothpastes containing less than 500 ppm has not been established. In 1978 the EU recommended that toothpastes sold over the counter in Member States should contain no more than 1500 ppm F.

Since 1996 there has been considerable discussion in Europe and elsewhere on the alleged link between increased use of fluoride toothpaste, particularly by infants and young children, and increased levels of enamel fluorosis in permanent teeth. At present there would appear to be two schools of thought emerging on this issue amongst research workers and public-health workers. On the one hand, there are those who recommend that the fluoride concentration in toothpastes should be reduced to less than 500 ppm for children aged 6 years and younger (11, 12). This view is based on the belief that children under age 6 years swallow some of the toothpaste they use and subsequently develop unacceptable levels of enamel fluorosis on their permanent incisors. The other opposing school of thought points to the fact that the major risk factor of dental caries, namely sucrose consumption, has not declined uniformly across Europe, and, in fact, has increased in some countries (13), hence reducing fluoride concentrations in toothpastes below 500 ppm would inevitably lead to an increase in caries levels throughout Europe. This school of thought also claims that the levels of enamel fluorosis reported are minor and their public-health significance has not been established (14). It is accepted that a very small number of children who misuse the product when aged 6–60 months will suffer from unsightly fluorosis on the permanent maxillary incisors. The members of this latter school of thought argue that this problem could be solved by adopting procedures or technologies aimed at controlling the amount of toothpaste used at each brushing by young children and by ensuring that children under the age of 7 years are supervised when brushing. Indeed since 1990 most toothpaste manufacturers in the EU include these latter recommendations on toothpaste tubes.

This is a classical public-health dilemma in which, as a result of inappropriate use by a minority of the population of a very effective public-health measure such as fluoride toothpaste, the benefits of this measure may be considerably reduced within the population as a whole. The toothpaste industry has become increasingly concerned about this issue and in some countries 'low' fluoride toothpastes or 'fluoride-free' have become available even though their effectiveness against caries has not been established. Central to this debate are two measurement issues, namely the measurement of fluoride ingestion by young children when using fluoride toothpaste and the measurement of enamel fluorosis. Variations in the methods used to measure both of these

parameters have resulted in health agencies receiving conflicting advice based on nonstandardized data.

A number of investigators have reported that the younger the age at which children begin to have their teeth brushed with a fluoride toothpaste the higher is the likelihood of developing enamel fluorosis on permanent incisor teeth (12, 15–17). These studies are based on the appearance of permanent maxillary incisors in 7–9-year-old children and on reported patterns of use of fluoride toothpastes some 5–7 years previously, during infancy and childhood. Few studies have been conducted in which the amount of toothpaste ingested and absorbed by infants and young children during toothbrushing has been measured (18–25). The methods used in these latter studies vary and probably account for the wide range of results reported. Since the original work of Dean (26) a number of methods and indices have been developed to measure enamel fluorosis in epidemiological studies (27). These may be divided into aetiological indices, where the epidemiologist is required to make a clinical decision that the opacity/discoloration noted on the enamel has been caused by excessive amounts of fluoride being absorbed during amelogenesis (26, 28–30) and descriptive indices where all the opacities/discoloration of the enamel are simply recorded. In the case of the latter no effort is made by the epidemiologist to assign a cause for the appearance of the enamel (31, 32). A major problem for clinical examiners using any of these indices is the subjective nature of the diagnostic criteria. Despite extensive training and calibration the intra- and interexaminer reproducibility remains poor. Hence the wide variation in levels of enamel opacities, including fluorosis, which have been reported in the literature may in fact be attributed to various interpretations of the diagnostic criteria used. This problem is particularly relevant when attempting to estimate changes in enamel opacities including the prevalence of fluorosis over time. A review suggesting that fluorosis has increased in the USA over the last 40 years (33) highlighted the difficulty in comparing data recorded in the 1960s with that recorded in the 1990s.

A number of workers have investigated the possible use of a photographic method for recording the appearance of the labial surfaces of permanent maxillary incisor teeth with a view to providing a permanent record of tooth surfaces used to estimate the prevalence of enamel opacities including fluorosis (34–37). Despite considerable progress in this technology however, a number of methodological issues remain unresolved which are likely to result in varying photographic images when the technique is adopted by different researchers in different locations. For example, variations in photographic equipment, such as lens and focus, film, drying time of the tooth surfaces and camera angle, can all lead to variations in the photographic image obtained. Hence the reproducibility of the scores recorded by different researchers would be poor and comparisons between studies of enamel opacities including fluorosis would remain problematical.

The project reported in this supplement (Project FLINT: FLuoride Intake from Toothpaste) therefore has two main aims:

To develop standardized methods for:

- Measuring fluoride ingestion and absorption from toothpaste
- Measuring enamel opacities, including fluorosis

The authors of each paper are those that took the major role in data collection, analysis and/or paper writing in each case. However, the work was carried out in seven countries and obviously there were contributions from far more people than would be considered normal for authorship. These contributions were, nevertheless, significant and are therefore recognized/acknowledged in boxes at the beginning of each paper.

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