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## Effect of 1000 or More ppm Relative to 440 to 550 ppm Fluoride Toothpaste – A Systematic Review

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### 1. Introduction

During the last three decades a significant worldwide reduction – of dental caries has been observed. Experts agree that fluoride in its multiple presentations has played an important role, together with changes in oral hygiene habits among different populations. Fluoride toothpastes has gained interest as a relevant strategy in prevention because of its important role in dental caries reduction, that can reach up to 40% (7,8,14). However, at the same time, they have contributed to an increase in the prevalence of dental fluorosis in children. There is concern about dental fluorosis related to the chronic intake of excessive quantities of fluoride in children under 6 years of age. Some authors have reported that the early use of fluoridated toothpastes in young children is a very important risk factor (13,17,22,33,34). Beside fluoride concentration, the duration and age of exposure are important factors in fluorosis prevalence (2).

In order to reduce the risk of dental fluorosis, the use of toothpaste with 440 to 550 ppm F in children less than six years old has been recommended (5). The efficacy of these toothpastes in reducing dental caries is still unknown and controversially among the scientific community (1,3). In Colombia, the fluoride concentration of toothpastes for preschool children below the age of 6 years was limited several years ago to 500 ppm in order to control dental fluorosis.

According to the Oral Health National Study (NSOH III)(13), the prevalence of dental fluorosis in Colombian children between 6 and 7 years old is 25.7%. The highest prevalence of moderate and severe dental fluorosis was found in Bogotá with 4.5% of the children being affected. Another study carried out in 2002 in four Colombian cities, to evaluate fluoride intake in 2 to 4 year olds from meals, beverages and toothpastes reported that in all cities except one, the total fluoride intake was above optimal limits (0.07 mgF/Kg of body weight) and even some were above the risk limit (0.1 mgF/Kg of body weight). From the three

studied sources, the lowest fluoride intake was from beverages at 4.3%, followed by meals at 26%. The highest fluoride intake came from toothpastes which comprised 69% of the total ingested fluoride (15).

The use of 500 ppm fluoride pastes raised the question of how effective this toothpaste is compared with the 1000 or more ppm F toothpastes, in the prevention of dental caries.

Therefore, the aim of this study was to carry out a quantitative systematic review assessing the efficacy of toothpastes with low fluoride concentrations between 440 and 550 ppm in the reduction of dental caries in children under 14 years old compared to toothpastes that contain 1000 or more ppm F.

2. Methods

Search strategy: A literature search on Medline MeSH, Cochrane Library, Ovid, Sciencedirect and Embase databases between January 1970 to November 2003 was conducted, with the key words dental caries, toothpaste, fluoride, caries prevention or control, dentifrices, caries control, cariostatic agents, dental caries susceptibility.

The inclusion criteria were randomized controlled clinical trials, quasi-experimental and cohort studies in all languages, where all participants were less than fourteen years old and the main variable evaluated was dental caries reduction using the DMF or dmf index, comparing fluoride toothpaste concentrations between 440-550 ppm and toothpaste with 1000 ppm or more regardless of the initial dental caries level, treatment and nationality (see Table 1).

| Author Year          | Systemic Fluoride                                  | Type                | Participants                               | Intervention*       |
|----------------------|--|---------------------|--|---------------------|
| Reed<br>1973(27)     | Non fluoridated<br>comunity                        | RCT double<br>blind | 1525 children<br>between 5 and 14<br>years | 500 ppm<br>1000 ppm |
| Winter<br>1989(37)   | Low (0.08 to 0.5<br>ppm ) fluoridated<br>community | RCT double<br>blind | 2177 children<br>between 2 and 5<br>years  | 1055 ppm<br>550 ppm |
| Davies<br>2002(10)   | Non fluoridated<br>community                       | RCT blind           | 5028 children<br>between 1 and 6<br>years  | 440 ppm<br>1450 ppm |
| Biesbrock<br>2003(6) | Non fluoridated<br>community                       | RCT double<br>blind | 657 children<br>between 9 and 12<br>years  | 500 ppm<br>1450 ppm |

Only groups related with the meta-analysis objectives were included.

Table 1. Description of studies

Missing or unreported data were directly requested to the authors by e-mail. In the Reed (27) trial, the standard deviation was not reported, standard error was used to recalculate it assuming equal variances following the mean difference formula by Student’s t-test.

Winter et al. (37) did not report the standard error or standard deviation; although one of the authors was contacted, the information could not be compiled. This standard deviation

was calculated using the standard error which was obtained from confidence interval reported.

Ammari et al. (1) did not include both the Winter et al. (37) and Reed(27) trials. They argued high drop out percentages (29% and 28% respectively) and lack of explanation for these drop-outs. However, they included a drop-out percentage in their sample size estimation.

For the characteristic description of the studies found initially, the reviewers used an information extraction format, based on the format developed by Sally Hollis y Tina Leonard, Piel Cochrane Group(18).

The Chalmers criteria were used to evaluate the quality of these studies accepting those that had a score of 70% from 100 possible points (24).

The methodological procedure used to evaluate the studies consisted of an individual review by each examiner to verify the quality criteria of each study that complied with the inclusion criteria and graded them in a scorecard design for each of the different content indicators of the instrument. Afterwards, the research group evaluated as a team and assigned individual points to each study, trying to reach a consensus around those in which noticeable differences existed (assigned extreme values). A design format was used to total the final scores of each study. Studies that scored at least 70% were included in the final meta analysis. One trial could not be included in the meta-analysis (see Table2).

| Study          | Reason for exclusion   |
|----------------|--|
| Holt, 1994(19) | Although groups to compare acomplished inclusion criteria, this study used the sample and data of a previous study (Winter, 1989). It was considered a secondary analysis of the mentioned study |

Table 2. Excluded studies

This study was free of any conflict of interest, given that no company or pharmaceutical laboratory sponsored its execution, and its final result was not related to any commercial brand that distributes toothpastes in Colombia.

According to the Antioquia Health Secretary’s resolution 008430 of 1993, this project was considered a “non risk investigation”. It includes literature review techniques and no intervention or intended biological, physiological, psychological or social variable modifications were done on individuals.

3. Data analysis

In addition to the complete reading of each of the included articles and its quality evaluation, the following procedures were followed:

Mantel-Haenzel test of homogeneity was used to evaluate the null hypothesis that the included studies were homogeneous. Statistical calculations were carried out following the Mantel-Haenzel Q heterogeneity statistical formula. This test was compared with Chi square distribution with n-1 degrees of freedom and a confidence level of 95%, where n was the number of studies included in the meta analysis, which in this case was n=4. If under these circumstances the calculated  $Q_{MH}$  value was above the tabulated value of  $X^2$ , the

homogeneity hypothesis was not rejected and no heterogeneity between the included studies was considered.

The estimated effect was measured in terms of average dental caries in each of the studied groups according to the dmf and DMF index. The final analysis evaluated the mean difference between the groups by applying the DerSimonian-Laird method for random effects.

A metaview graphics illustrated the estimated values of the individual studies and the combined estimated effect.

Once the first meta-analytic approach was completed after combining the results from the independent studies, a sensibility analysis was done to establish the solidity of the combined estimated effect after one or more studies with extreme high or low values were withdrawn from the meta analysis.

#### 4. Results

The data presented in the dental literature to answer the question of the efficacy of toothpastes with fluoride concentrations between 440 and 550 ppm in dental caries prevention in children are very limited. Four randomized controlled clinical trial were selected from five references yielded by electronic and hand searches. The studies included in the meta-analysis are listed in chronological order in Table 1. The included trials comprised a total of 5657 participants under similar conditions regarding variables, such as no systemic fluoridation and positive participation in oral health programs. Baseline caries levels were reported in all studies. Winter et al.(37) did not report specific baseline caries data. they explained that they decided to conduct the trial on 2-year-old children based on the expectation that most would be caries free given that according to epidemiological evidence very few children aged 2 years or less have caries which would be limited to the main lesions affecting the upper incisors. Of the 2177 children examined only 32 (1.5 per cent) had caries of this type with a difference of only 2 children between the groups. As a further analysis on the validity of the approach, they repeated the analysis of data related to dental caries, omitting the 32 children, with no effect on the outcome.

#### 5. Meta-analysis

The results of different estimations of the combined effect following the meta-analytic procedures with heterogeneous criteria, using the Dersimonian-Laird random effect model are shown in the metaview (7,8,14,17).

All procedures done to estimate the summary measure of effect, both as standardized mean difference and odds ratio, suggest that 440 to 550 ppm F toothpastes are not as effective in preventing dental caries in the primary and permanent dentition as pastes with 1000 ppm F or more.

Although the differences are statistically significant, the confidence intervals of all summary measures of effect are close to zero, both as standardized mean difference and odds ratio with the same results for the primary and permanent dentition.

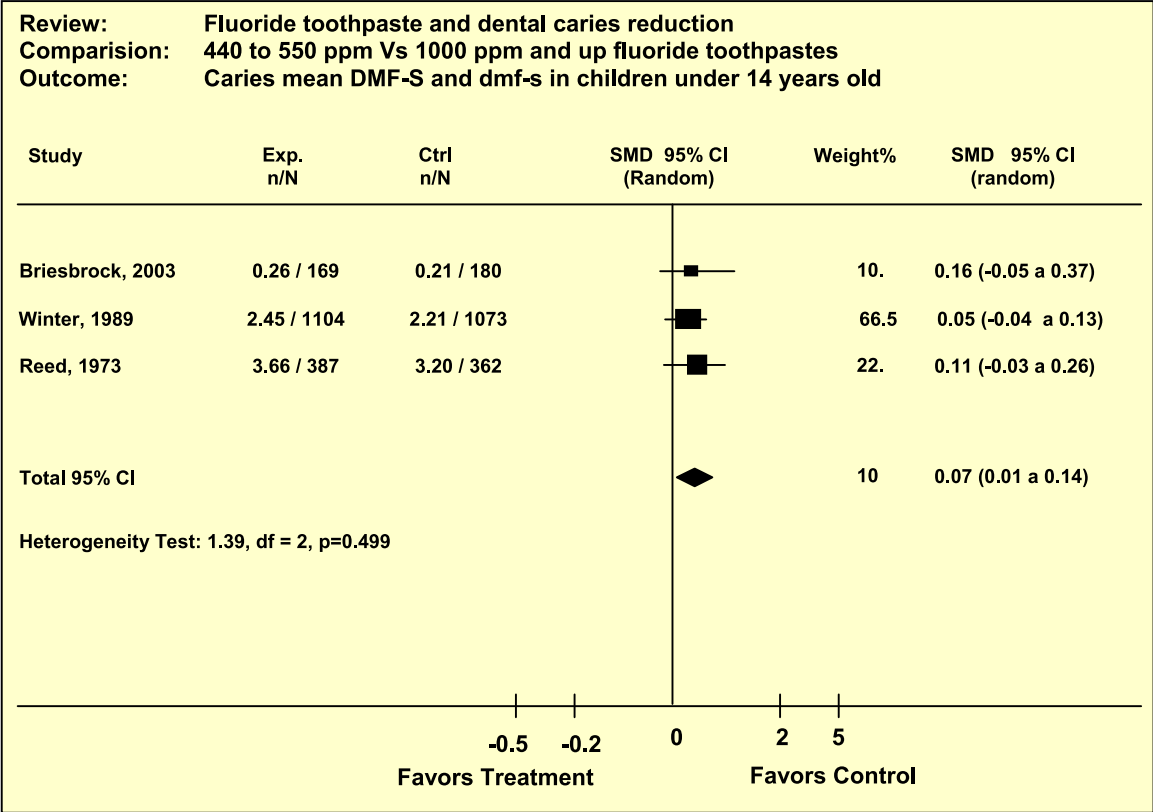


Fig. 1. DMF-S and dmf-s in children under 14 years old: Metaview

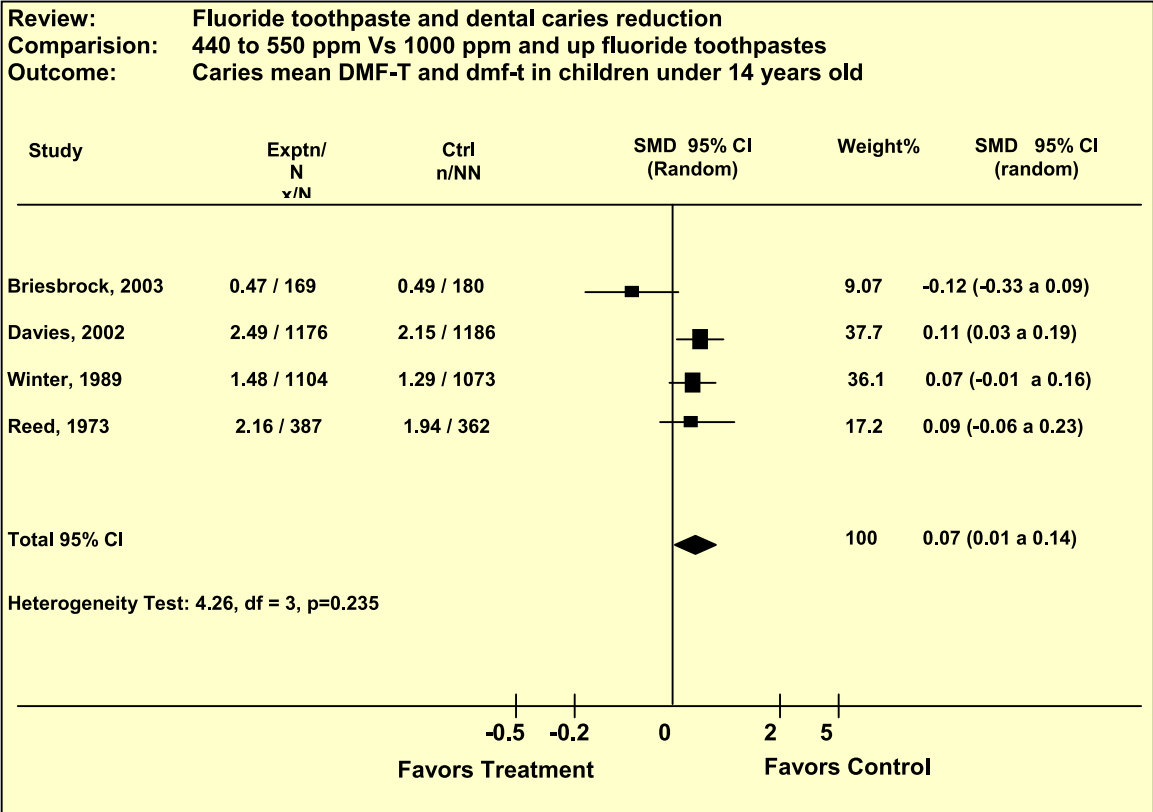


Fig. 2. DMF-T and dmf-t in children under 14 years old: Metaview

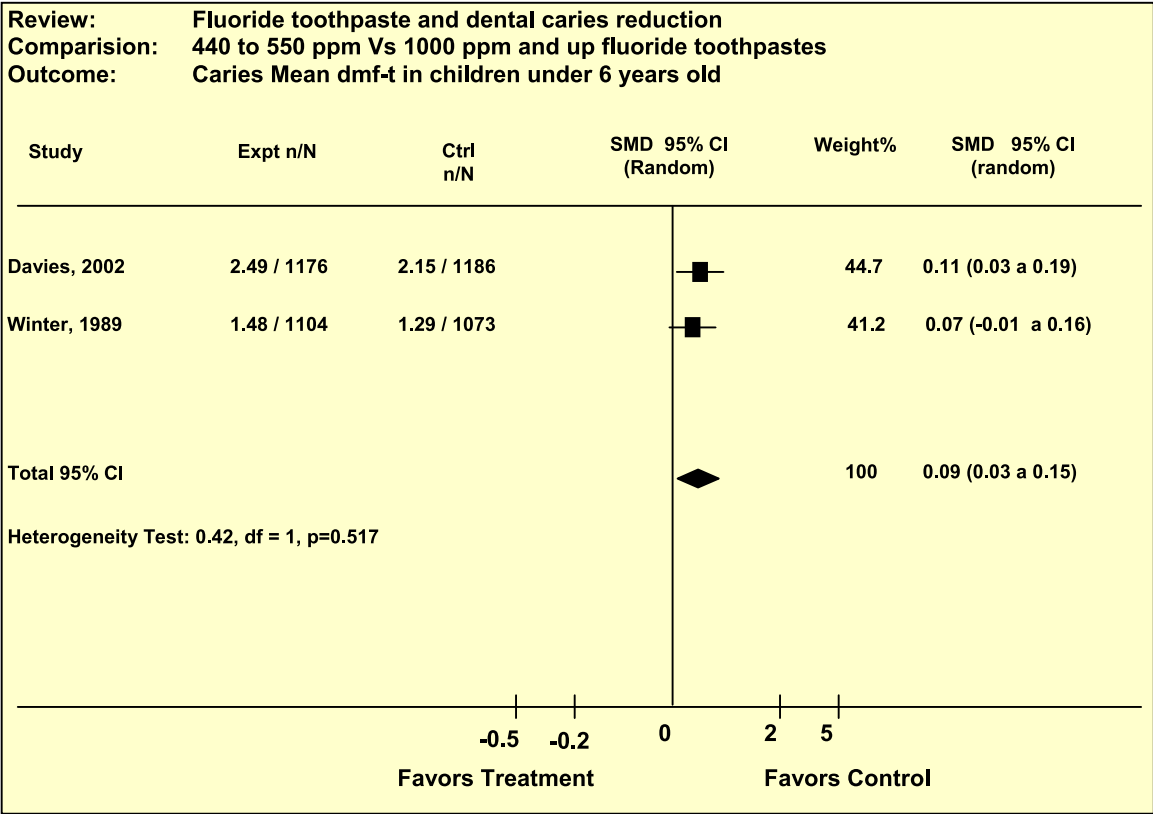


Fig. 3. dmf-t index in children under 6 years old: Metaview.

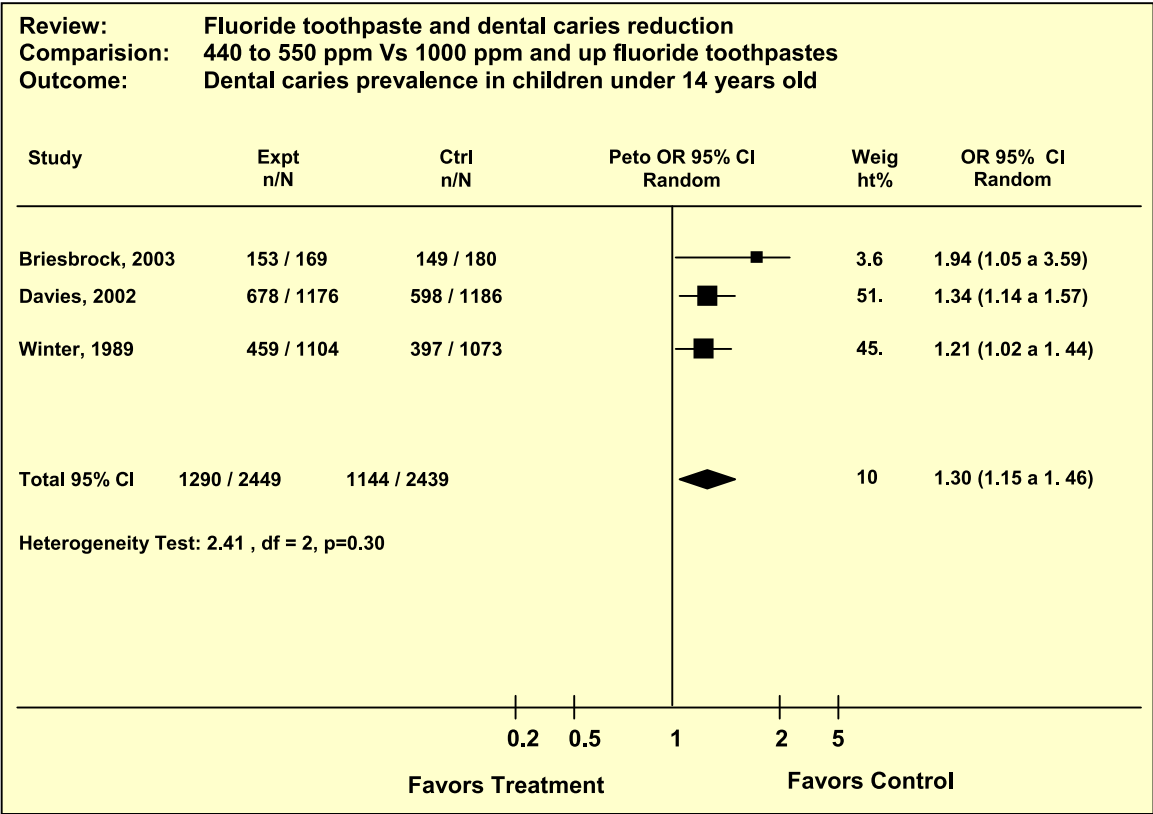


Fig. 4. Odds ratios to dental caries prevalence in children under 14 years old: Metaview.



Sensitivity Analysis: The study by Biesbrock et al.(6) was different in participation number with less weight than the other studies. Considering that this could influence the results, a sensitivity analysis was carried out by repeating the meta-analysis excluding this study. The odds ratio was not affected and the difference between the two groups was still significant (OR: 1.28 - CI<sub>95%</sub>: 1.13 to 1.44) in favor of toothpastes with 1000 ppm F or more.

Given that the results are in favor of toothpastes with 1000 ppm F or more, in dental caries prevalence reduction in children under 14 years old, the combined odds ratio was estimated again in order to determine the absolute risk reduction, assuming that these are more effective than those with 440 and 550 ppm F in dental caries prevention (see Table 3).

| Groups                  | Dental caries |      | Total | OR - 95 % CI  |
|-------------------------|---------------|------|-------|---|
|                         | Yes           | No   |       |   |
| Fluoride > 1000 ppm     | 1144          | 1305 | 2449  | 0.76 (0.66 – 0.88)<br><br><i>p</i> value:<br><br>0.0002 |
| Fluoride 440 to 550 ppm | 1290          | 1159 | 2449  |   |
| Total                   | 2434          | 2464 | 4898  |   |

Table 3. Summary estimate of odds ratio. random-effects model.

According to these results there is a lower proportion of caries in children treated with dental toothpastes with 1000 ppm F or more, with an attributable risk factor of 0.0596 (6%) (p<0.00001). This demonstrates how children under 14 years old using toothpastes with 1000 ppm F or more have approximately 6 percent more protection against caries than when they use toothpastes between 440 and 550 ppm F. To learn more about the impact and efficacy of this therapy the number needed to be treated to prevent one event was calculated (NNT= 14.6 IC<sub>95%</sub> 11 a 32).

6. Discussion

Fluoride concentrations used in toothpastes are an important factor concerning toothpaste efficacy in reducing dental caries. Literature reviews such as the one done by Richards et al.(28) conclude that the optimal fluoride concentration in toothpaste is 1000 ppm F. This concentration has shown to provide best benefits in reducing dental caries and fluorosis. Meanwhile with fluoride concentrations less than 1000 ppm the efficacy in the reduction of dental caries is diminished (29).

Recently, some meta-analysis has been published to describe the efficacy of different fluoride concentrations used in toothpastes to prevent dental caries in children and teenagers (1,20,21,33). However, none of them obtained conclusions regarding toothpastes with 440 and 550 ppm F.

There were a limited number of studies comparing low F (440 to 550 ppm) to high F (1000 or more ppm) toothpastes. For this meta-analysis only five studies were found, out of which four were selected.

The total sample size of children under 14 years old included in the 4 selected studies was 5657, the fluoride compounds in the toothpastes used were sodium fluoride in 440, 500, 550 and 1450 ppm; and sodium monofluorophosphate in 1000, 1055 and 1450 ppm, as they are the most used in general population.



Winter et al. (37) reported the first clinical controlled trial in children under 2 years old followed during three years. All included trials in comparison experienced relative high percentage of subjects at baseline who dropped out during the course of studies. However in all of these studies they considered this at the moment of the sample size estimation. Davies et al (10) were the only ones to report the reason for these drop outs.

In some cases it was necessary to contact the author to obtain additional data (DMF-T) such as the Biesbrock et al.(6) study in order to compare it with the other three studies.

The diagnostic system used in all the studies was the DMF and dmf indices at the level of cavity (D3) (16,25); The Biesbrock study was the only one that included opacity lesion with microcavity data in their analysis (D2) (16,25). Regardless of some authors considering that there may be some differences between primary and permanent enamel in reactivity to caries challenges (1,32), this is not clear. Thus we combined primary and permanent dentition.

Some clinical studies have shown that with 1000 to 2500 ppm F toothpaste an increase of 6% is obtained in dental caries protection for each 500 ppm (23,35).

Combined evidence from the included assay suggest that toothpastes with concentrations of 1000 ppm and more are more effective in caries reduction, showing a higher prevalence of dental caries in children under 6 years who used lower fluoride concentrations (440 to 550 ppm) toothpastes. It is important to note that precisely the group of children younger than 6 years is the main consumer of this toothpaste because this is the group in which traditional 1000 ppm F toothpaste is being replaced.

The results of this meta-analysis show that 440 to 550 ppm F toothpaste is less effective in preventing dental caries than 1000 ppm F toothpaste, and it is interesting to note that it is necessary to double the fluoride concentration to have a risk difference of only 6%. Similar results were reported by Amari et al.(1), as they found a caries Indexes Weighted Mean Difference of 0.6 between dental toothpastes with 250 ppm F and 1000 ppm F, and they emphasized that a fourfold increase in F concentration is necessary to obtain such a difference.

Twetman et al.(30) reported for daily use of fluoride toothpaste compared to placebo in the young permanent dentition (Prevented Fraction: 24.9%) and for toothpastes with 1500ppm F compared with standard toothpaste with 1000 ppm F in young permanent dentition( PF 9,7%), These were greater than the results of this meta-analysis where PF, expressed as percentage, was 6% in favor of 1000 ppm F as was expected.

Despite the fact that there were few studies included, it is important to note the homogeneity found between them as well as the quality even considering studies like Winter et al.(37) and Reed(27) which date back to 13 and 30 years respectively.

Similar conditions of the included studies related to variables as the non-public water or salt fluoridation and their participation in health supervised programs are in favor of the obtained results.

As there were a limited numbers of studies, asymmetry was difficult to asses, by funnel plot. However, comparing their sample size, the Biesbrock et al. (6) study, which had lowest sample size (n=349) did not alter the combined estimation of the effect when it was withdrawn from the sensibility analysis.

These results are an approach to answer the question of the efficacy of low fluoride toothpastes (considered for reducing fluorosis risk in children) in reducing dental caries incidence in a population in which dental caries is still a public health problem.

The fact that low fluoride concentration toothpaste is currently being recommended for children younger than 6 years old without enough scientific evidence must concern the scientific community, as the impact is greater in the population which does not have knowledge of these circumstances.

This study did not attempt to report possible adverse effects of fluoride toothpaste like dental fluorosis. Although some authors state that concentrations of 440 a 550 ppm F reduce the risk of developing dental fluorosis (19), there is a lack of clinical assays and cohort studies to confirm said hypothesis, leading to a lack of major clinical evidence in relation to the efficacy of low fluoride toothpaste in reducing dental caries in children younger than 6 years old and its impact on this population. This systematic review, increases the available evidence in this topic.

Recommendations for specific fluoride doses in toothpastes requires combined studies about dental caries incidence and dental fluorosis.

In order to learn the epidemiological significance of the clinical difference between these fluoride concentrations, it would be beneficial to promote community studies with different systemic fluoridation levels and high caries risk groups that would allow for the evaluation of fluorosis risk and caries risk, in order to more firmly establish if the use of low fluoride toothpastes is justified, in high caries risk children.

The concentration of fluoride in toothpaste is a protective factor for dental caries but is clear that in children less than 5 years is a risk factor for dental fluorosis. Dental caries is the most common chronic disease of childhood and continues been a public health concern (4,11,12,26,31). For dental caries management and disease control in children under 5 years the emphasis must be focus in other than fluoride concentration, is important to propos combined preventive approaches providing early access to dental services, medical approaches, no operative intervention and specific educational and informational actions for mothers and the newborn.

Recent Meta-analysis and clinical trials confirm the great effect of high concentration fluoride dental toothpaste (36). Although 6% sounds little its effect must not be underestimated, mainly in this age group when the relation between dental toothpaste quantity and fluoride concentration combination could be important and pertinent.

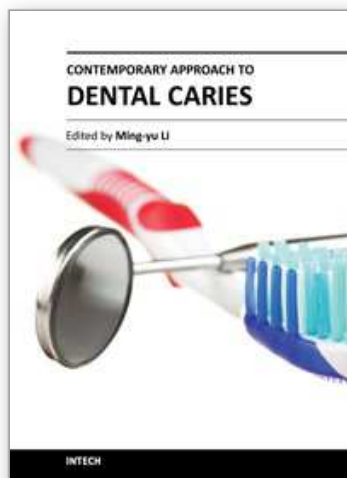
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## **Contemporary Approach to Dental Caries**

Edited by Dr. Ming-Yu Li

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With an update of the recent progress in etiology, pathogenesis, diagnosis, and treatment of caries, it may be said that the final defeat of dental caries is becoming possible soon. Based on the research in this area in recent decades, "Contemporary Approach to Dental Caries" contained the caries in general, the diagnosis of caries, caries control and prevention, the medical treatment of caries, dental caries in children and others such as secondary caries. This book provides the reader with a guide of progress on the study of dental caries. The book will appeal to dental students, educators, hygienists, therapists and dentists who wish to update their knowledge. It will make you feel reading is profitable and useful for your practice.

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