High Fluoride Toothpaste

Full Summary

Description:

Fluoride dentifrices were first introduced in the 1950s. [1] The first fluoride dentifrice contained stannous fluoride and was first marketed in 1955. Since then many studies have investigated the level of dose and the form of fluoride that is optimum in dentifrice formulations. Higher caries reduction was reported in the 70s in clinical trials that investigated the potency of using high fluoride dentifrices (i.e., fluoride greater than 1,000 ppm). [2] The maximum concentration of fluoride in over-the-counter products is 1,500 ppm. [3] In the recent years, prescription-only toothpastes developed for high caries risk adolescents, adults and elderly are available.

Prescription-strength fluoride toothpaste has a high concentration of sodium fluoride (NaF). The maximum strength of sodium fluoride in high fluoride toothpastes is 1.1% or 5,000 parts per million (ppm). Prescription fluoride toothpaste is recommended to be used once daily for adults. It is not recommended for children.

Use and Application:

Prescription fluoride toothpastes are used in the same manner as regular toothpaste. The ease of use increases patient compliance. It is not recommended for children. High fluoride toothpastes may be effective in arresting root caries lesions among those who have exposed root surfaces. Cancer patients who have undergone head and neck radiation are at high risk for developing rampant caries. In these patients, prescription fluoride toothpaste may be beneficial in decreasing caries activity; however, there are no studies to support this claim.
**Effectiveness and Efficacy:**

**Studies on 1,500-2,800 ppm fluoride dentifrice:**

Prescription fluoride toothpaste has been used for several years in preventing caries and arresting existing caries. In the 1970s, five clinical trials conducted in Europe evaluated the caries incidence in children following use of high-potency fluoride dentifrices compared to children who did not use fluoride dentifrices. [2] The fluoride concentrations in these trials ranged from 1,500 ppm to 2,600 ppm. On average among the trials there was a statistically significant caries reduction of 24%. Following this in the 1980s, six clinical studies compared 1,450-2,800 ppm sodium fluoride or sodium monofluorophosphate dentifrices to conventional fluoride dentifrices. Four of these studies were conducted in the U.S. The studies reported that the use of high-potency fluoride dentifrices significantly decreased the DMFS when compared to the conventional dentifrices.

In a recent Cochrane review (2010) 75 studies were included, of which 71 studies comprising 79 clinical trials contributed data to the meta-analysis. For 66 studies that contributed to the meta-analysis of D(M)FS in the mixed or permanent dentition, the caries preventive effect of fluoride toothpaste increased significantly with higher fluoride concentrations. The (D(M)FS for permanent dentition when compared to placebo was 23% for 1,000/1,055/1,100/1,250 parts per million (ppm) concentrations and increasing to 36% for toothpastes with a concentration of 2,400/2,500/2,800 ppm). Lower concentrations of 440/500/550 ppm and below showed no statistically significant effect. In this Cochrane review, six studies that assessed the effects of fluoride concentrations on the primary dentition showed similar results that depended on the fluoride concentrations in toothpastes.

The anti-caries efficacy of four different fluoride toothpastes were evaluated in a large clinical study that included 5,439 schoolchildren aged 6-15 years. [6-8] The four concentrations of toothpastes that were evaluated in this study are 1,100, 1,700, 2,200,
and 2,800 ppm. The subjects were recruited from an urban area in Ohio with low fluoride in the water supply (<0.3 ppm). Evaluations were done at baseline and at 1, 2, and 3 year periods. The participants were randomly assigned to the groups and DMFS scores were recorded. The authors reported a statistically significant reduction in DMFS scores at the end of the first year among the two groups that were assigned 2,200 ppm and 2,800 ppm fluoride toothpastes when compared to the 1,100 ppm fluoride toothpaste. The caries reduction was 18.6% and 20.4% respectively. The group that used 1,700 ppm fluoride toothpaste showed 11% decrease in DMFS but this was not statistically significant.

Four fluoride concentrations were compared in a meta-analysis. [9] Fluoride dentifrices containing 1,700, 2,200 and 2,800 ppm were compared to 1,100 ppm in double-blinded randomized clinical trials conducted over 2-3 years. A total of 1200-2000 male and female schoolchildren in grades 1-8 were included in this study. The results showed a statistically significant lower rate of caries with the use of 2,800 ppm versus 1,100 ppm fluoride dentifrice (p<0.011).

**Studies on 5,000 ppm fluoride dentifrices:**

High-concentration or prescription fluoride toothpaste (5,000 ppm) has been shown to decrease caries rate by approximately 70% when compared to regular toothpaste. [10] This review reported a dose-dependent linear relationship between the level of fluoride in toothpaste and level of anti-caries effect (r=0.85). Higher concentrations such as 5,000 ppm fluoride concentrations in dentifrices showed higher anti-caries than 1,000 or 1,450 ppm concentrations.

A study of arrested root caries compared the use of 1,100 ppm fluoride dentifrice and 5,000 ppm brush-on gel versus using 1,100 ppm fluoride dentifrice alone. Findings show that 88% of the subjects had arrested root caries lesions when using the combination treatment versus only 28% having arrested lesions when using only the 1,100 ppm
fluoride dentifrice. [11] The 5,000 ppm gel used in this study has been reformulated and is used as a fluoride dentifrice containing 5000 ppm fluoride.

In other clinical studies the effectiveness of 5,000 ppm fluoride toothpaste and 1,100 ppm fluoride gel in arresting root caries was compared. [12, 13] A total of 201 subjects with at least one root carious lesion were recruited and randomly assigned to 5,000 ppm fluoride toothpaste or 1,100 ppm fluoride gel. Caries lesions were measured at baseline and after 3 months by a single examiner. At the end of 3 months, arrested caries lesions were observed among 38% of those who used the 5,000 ppm toothpaste compared to 11% of those who used the 1,100 ppm gel. The short duration of this study is a limitation.

Overall, few studies have been conducted on assessing effectiveness of 5,000 ppm fluoride toothpaste. The studies that have been conducted have limitations. Therefore, the evidence for the highest concentration of fluoride toothpaste, while promising it is still insufficient. More studies are being conducted and future evidence may shed more light on the effectiveness of high-fluoride toothpaste of 5,000 ppm.

**Summary and Recommendations:**

Based on the findings from the literature, the use of high fluoride dentifrice is effective in overall caries reduction for concentrations above 1,500 ppm and up to 2,800 ppm. The evidence for the highest concentration of 5,000 ppm is insufficient. The benefits of conventional fluoride dentifrices may not suffice for those at high risk for caries. [3] High concentrations of fluoride may also be effective in arresting root caries lesions. [13] Most of the studies on 1,500-2,800 ppm fluoride toothpastes have reported the effectiveness in caries prevention. In contrast, most of the studies on 5,000 ppm fluoride toothpaste report effectiveness in arresting existing caries. There is a need for future studies to include assessment of 5,000 ppm fluoride toothpaste on caries prevention. When compared to treatment procedures for caries in the dental office the use of high fluoride toothpastes are more beneficial, easy to use and cost-effective. However, excellent patient compliance is necessary. Safety in the use of these high concentration fluoride
dentifrices is emphasized in that individuals are advised to expectorate thoroughly after brushing. [14] Also, these high-concentration toothpastes should be kept out of reach of young children.

References:
