Estimation of Fluoride Intake From Milk-Based Infant Formulas and Baby Foods

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Abstract
The aim of this study was to examine the amount of fluoride ingested from infant formula and baby food in infants aged up to 6 months in South Korea. The fluoride content of 20 commercially available formulas and 8 baby food samples from 4 different brands was measured using a modified microdiffusion method and fluoride ion selective electrode. The amount of fluoride (F) ingested by infants was estimated assuming that the samples were reconstituted with water containing 0, 0.5, 0.8, and 1.0 ppm F. When the reconstituted formulas and baby foods contained 0.8 ppm F water, the infants were estimated to ingest fluoride in the range of 0.018 to 0.298 mg/kg/day. The findings of this study suggest that there is a need for clear guidelines for fluoride consumption by infants that should be followed by manufacturers and parents.

Keywords
baby food, fluoride intake, infants, infant formula, microdiffusion method

Introduction
The use of fluorides has been one of the most effective and widespread methods for preventing dental caries. However, excessive use of various fluoride modalities during the enamel-formation period can lead to enamel fluorosis, which is mostly a cosmetic issue with white streaks or patches on the tooth enamel surfaces. In severe cases, although rare, dental fluorosis can be problematic with brown stains and pitting on the tooth enamel structure.

Because of the increased prevalence of dental fluorosis and the reduced incidence of dental caries, there has been concern regarding the proper amount of fluoride ingestion during the

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pre-eruptive tooth development stage. The most critical period for enamel fluorosis to develop is during the early years of life when enamel formation occurs. Hong et al reported that the first 2 years of life constitute the most critical period for fluorosis development in permanent, maxillary, and central incisors. Levy et al found that the first year of life is the most important for fluorosis development in the primary dentition. Burt proposed, from various study results, that the optimum fluoride intake for infants ranges from 0.05 to 0.07 mg/kg. On the other hand, the American Academy of Pediatrics Committee on Nutrition reported that infants from birth to 6 months do not need fluoride supplements.

The major sources of fluoride intake during infancy include breast milk, formula (ready to feed, concentrated liquid, and powdered), baby food (any food other than breast milk or infant formula), fruit juices, and dry cereals. Evidence shows that infant formula, infant food, and fluoridated water are risk factors for enamel fluorosis. Heilman et al found the highest level of fluoride concentrations in infant food containing chicken (at 8.38 µg/g). The review article by Fomon et al reported that the fluoride concentrations of infant formulas ranged from 0.400 to 1.600 µg/g and baby food from 0.090 to 6.0 µg/g. Tomori et al reported that fluoride concentrations of infant formulas ranged from 0.30 to 1.00 µg/g and baby foods from 0.02 to 0.88 µg/g in Japan.

Due to rising concerns about the increased amount of fluoride ingestion by young children from multiple sources and increased prevalence of enamel fluorosis, the American Dental Association offered interim guidelines on infant formula and fluoride dosages for infants in 2007. In 1997, the Institute of Medicine (IOM) reported the adequate level of fluoride intake at 0.01 mg/day and the tolerable upper limit of fluoride intake at 0.7 mg/day for infants from birth to 6 months. An adequate intake of 0.01 mg/day is the estimated intake that would reduce the occurrence of dental caries in a population without causing unwanted side effects, including moderate dental fluorosis. The tolerable upper limit level of 0.7 mg/day is the lowest observed adverse effect level for enamel fluorosis, calculated from 0.10 mg/kg/day multiplied by the body weight (up to 7 kg) for infants from birth to 6 months.

Many countries including the United States have recommendations regarding fluoride intake from infant formulas and baby foods for their own markets. However, currently there are no guidelines about fluoride intake from infant formulas and baby foods in Korea. Recently, adjusted community water fluoridation has been started in several regions of South Korea to prevent dental caries.

The present study assessed the fluoride content of infant formulas and baby foods available in the Korean market and estimated the amount of fluoride intake from them in hypothetical cases assuming that they were reconstituted with water containing 0, 0.5, 0.8, and 1.0 ppm F. The aim of this study was to investigate whether the amount of fluoride ingested by Korean infants was within the range set by the IOM.

**Methods**

**Formulas and Baby Foods**

To estimate the amount of fluoride intake for infants, one sample from 20 different brands of milk-based powdered formula (substitutes for breast milk) were used. There were 8 formulas from company A, 5 formulas from company B, 5 formulas from company C, 2 formulas from company D, and 8 baby foods (referred to as strained foods as a supplement for breast milk or formula) of which 2 baby foods were from company A, 2 baby foods from company B, 3 baby foods from company C, and 1 baby food from company D. Samples were collected from the 4 most popular manufacturers in Korea between May and October 2005 (Table 1). There were 5...
We specifically selected the commercially available milk-based powdered formula products that targeted infants from birth to 3 months old and infants from 4 to 6 months old. All the powdered baby foods were for 3- to 6-month-old infants. For each product, manufacturers provided instructions for the recommended amounts of formula and the reconstitution ratio for specific age groups (in months), and we estimated the mean fluoride contents based on the recommended amounts (Table 1).

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<tr>
<th>Table 1. Fluoride Content of Powdered Formulas and Baby Foods.</th>
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*Manufacturers’ direction depends on products.

²Baby foods are marked.

³Baby food for spoon feeding.

⁴Infant formula for both 2- to 3-month-old infants and 5- to 6-month-old infants.

⁵First amount for 2- to 3-month-old infants; second amount for 5- to 6-month-old infants.
Fluoride Content Analysis

The fluoride content of the samples was analyzed using the hexamethyldisiloxane microdiffusion method modified by Hinoide et al.\textsuperscript{16} The fluoride content of each sample was analyzed 3 times, and we used the mean value. See Tomori et al\textsuperscript{10} and the Noh et al\textsuperscript{17} for more details concerning the methods. A brief description of the methods used in this study is as follows.

Daily amount of formula and baby food recommended by manufacturers. The samples were powdered and needed to be reconstituted with water before being fed to the infants. To estimate the amount of fluoride intake from infant formulas and baby foods, the directions recommended by the manufacturer of each product were followed including mixing a measured amount of powder with water to make a certain volume of formula and baby food (Table 1).

Estimation of fluoride intake under the assumptions of varying fluoride concentration of reconstituting water. We estimated the amount of fluoride ingested by infants based on age (month): 2 to 3 months and 5 to 6 months. The 2 groups of infants were further divided based on common feeding patterns of infants in Korea: (a) infants aged 2 to 3 months (formula only), (b) infants aged 5 to 6 months (formula only), (c) infants aged 5 to 6 months (baby food only), and (d) infants aged 5 to 6 months (combination of both formula and baby food; assuming baby foods were fed once a day instead of formula). To estimate the amount of fluoride intake per kilogram body weight, the average body weights of infants by the Korean National Growth Chart for Infants (6.25 kg for 2- to 3-month-old infants and 7.74 kg for 5- to 6-month-old infants) were used.\textsuperscript{18}

The daily amount of fluoride intake from each sample was estimated by multiplying the fluoride content of each formula or baby food by the recommended daily amount of each sample for the ages in months. The following equation was used:

\[
\text{The amount of daily fluoride intake of each sample} = \text{Fluoride content of formula or baby food (µg/g)} \times \text{Daily amount of sample (g)}
\]

The fluoride intake from the formulas and baby foods reconstituted with 0, 0.5, 0.8, and 1 ppm F water was calculated using the following equation:

\[
\text{The amount of daily fluoride intake of each sample and each concentration of water per body weight} = \frac{(\text{Fluoride concentrate of formula or baby food (µg/g)} \times \text{Daily amount of sample (g)} + \text{Fluoride concentration of water [ppm F]} \times \text{Amount of water to reconstitute infant formula or baby food [ml]})}{\text{Body weight (kg)}}
\]

The fluoride concentration of 0.8 ppm (current F concentration standard of Korean community water fluoridation) was used in the case of reconstituted formulas and baby foods to estimate the amount of fluoride intake in infants. In addition, different fluoride concentrations (0.5 and 1 ppm) were used in the assumption of reconstituting the formulas and baby foods to assess the changes in the amount of estimated fluoride intake among infants. The estimated amount of fluoride was compared with IOM’s adequate intake level (AI) of 0.01 mg/day and the tolerable upper limit (UL) of 0.7 mg/day of fluoride intake from the formulas and baby foods.\textsuperscript{12}

Results

The fluoride content of the 12 formulas for 2- to 3-month-old infants ranged between 0.270 ± 0.018 and 2.139 ± 0.265 µg/g, whereas the fluoride content for the 8 formulas for 5- to 6-month-old infants ranged between 0.213 ± 0.008 and 2.544 ± 0.257 µg/g. The 8 baby foods had fluoride...
content ranging between 0.626 ± 0.011 and 14.283 ± 0.515 µg/g. Two baby food products had high fluoride contents of 14.173 ± 0.403 and 14.283 ± 0.515 µg/g (Table 1).

Based on the recommendations by each manufacturer, the daily amount of formula intake for infants aged 5 to 6 months (1000 mL/day) was greater than that fed to infants aged 2 to 3 months (900-1000 mL/day). The recommended volume of baby food was 252 to 950 mL/day for both bottle feeding and spoon feeding, so their intake range was larger than for the formula (Table 1).

Company D’s products had low-range fluoride content. However, company A had both the lowest and highest fluoride content in infant formula of all the samples tested.

Table 2 shows the estimation of the infants mean fluoride intake from formula and baby food reconstituted with water containing various fluoride concentrations (0, 0.5, 0.8, and 1.0 ppm F). Infants who are 2 to 6 months old might gain 0.032 to 2.887 mg per day of fluoride from each of the 12 formulas and 8 baby foods reconstituted with water containing 0, 0.5, 0.8, and 1 ppm F. The amount of ingested fluoride from infant formula was a little higher among 5- to 6-month-old infants than 2- to 3-month-old infants. Among the 5- to 6-month-old infants, those who were fed formula only ingested higher amounts of fluoride than those who were fed both formula and baby food once a day instead of infant formula. The amount of fluoride intake varied depending on the fluoride concentration of water.

Figure 1 shows the amount of fluoride intake per body weight for 2- to 3-month-old infants and for 4- to 6-month-old infants based on formula samples reconstituted with water containing 0, 0.5, 0.8, and 1.0 ppm F water. Also, it shows the amount of fluoride intake per body weight for 4- to 6-month-old infants who consumed formula and baby food once a day instead of formula reconstituted with water containing 0, 0.5, 0.8, and 1.0 ppm F water. All formulas, when assumed to be reconstituted with fluoride-free water, provided less than 0.1 mg/kg/day (UL) of fluoride; however, 2 baby foods exceeded the UL.

Estimates showed that 1 formula for 2- to 3-month-old infants (6.25kg) and 3 baby foods for 4- to 6-month-old infants (7.74 kg) reconstituted with 0.5 ppm F water would provide more than 0.1 mg/kg/day (UL) when infants are fed the manufacturer’s recommended volume of formula or baby food (Figure 1). Five- to 6-month-old infants fed 4 baby foods and 6 formulas reconstituted with 0.8 ppm F water had estimated fluoride intakes of more than 0.1 mg/kg/day (UL) (Figure 1). All the formulas for the 2- to 3-month-old infants reconstituted with more than 0.8 ppm F water were confirmed to exceed the UL, whereas the intake from the 4 baby foods, which ranged between 0.017 and 0.048 mg/kg/day, were lower than the UL.
Figure 1. Estimated mean fluoride intake from infant formulas and baby food diluted with fluoridated water.

*Babyfood.
†Infant formulas for both 0 to 3 months and 4 to 6 months.
‡Mean body weight: 0-3 months for 5.66 kg; 4-6 months for 7.72 kg.
§Product information addressed in Table 1.
Discussion

The present study was conducted in South Korea in 2005. We estimated the amount of fluoride intake for infants between birth and 6 months based on the manufacturers’ recommended reconstitution ratio and the amount of powdered infant formula and baby food, stratified by food product and age group.

The results of this study indicate that no infant formula (powdered concentrate only) was estimated to have higher fluoride concentrations than IOM’s tolerable upper limit (0.10 mg/kg/day). This finding is consistent with the previous reports indicating that infant formulas contain low contents of fluoride ranging from 0.3 to 1600 µg/g.3,10 In the present study, the estimated fluoride content of formulas (0.213-2.544 µg/g) was a little higher than earlier studies,3,10 but are still lower than IOM’s tolerable upper limit.12

On the contrary, 2 of the 8 baby foods (especially the organic products) contain enough fluoride to exceed the tolerable upper intake level (0.7 mg/day). If infants are fed baby foods with 408 mL of fluoride-free water, they will consume 1.0 mg/day of fluoride. When they are fed with 730 mL of fluoride free water, infant ingests 1.7 mg/day of fluoride from the other baby food—a fluoride concentration almost 7 times higher than infant formulas (>14 µg/g). This finding is consistent with previous reports indicating that the fluoride concentration of baby food is higher than that of infant formulas.1,10

We could not determine the source of the high fluoride contents in some baby foods from this study because Korean milk-based powdered baby food samples contain milk, vegetables, fish, meat, chicken, and others. The amount of baby foods consumed by infants and toddlers may vary because the methods of feeding and the daily intake amounts vary depending on babies’ and caregivers’ priorities rather than the infant formula. There is no published research about the actual volume of infant formula or baby food intake at an individual level, so we estimated the amount of fluoride intake in infant from manufacturers’ recommendations. The manufacturers’ recommendations were supported by the Korean medical and nutritional academic societies.19 However, no such standard guidelines are available for the amount of baby food intake for infants aged 4 months and older.19

The findings of our study suggest that the amount of fluoride ingested from baby foods could be substantial enough to cause dental fluorosis (ie, the volume of baby foods consumed by a child can range from 252 to 950 mL a day, based on the manufacturers’ recommendation). Therefore, it is necessary to recommend that manufacturers monitor and reduce the fluoride contents of baby food, similar to what they do for infant formula, because caregivers usually follow the product directions when reconstituting the formula and baby food.

Heilman et al reported that baby food containing chicken had the highest fluoride concentrations (8.38 µg/g) in the United States.8 On the other hand, Tomori et al found that fluoride concentration in baby food with chicken products were not very high and ranged from 0.08 to 0.34 µg/g, whereas fluoride concentrations of rice gruel was the highest at 5.22 µg/g.10 The baby food samples used in this study were combined with various ingredients including milk, vegetables, rice, fish, meat, and chicken. However, it is not clear why some organic products contained such high concentrations of fluoride.

The results of this study suggest that infants could ingest excessive fluoride, ranging from 0.423 to 0.713 mg/day (0.075-0.126 mg/kg/day) for 2- to 3-month-old infants and ranging from 0.463 to 0.766 mg/day (0.06-0.09 mg/kg/day) for 4- to 6-month-old infants, if formulas are reconstituted with water containing more than 0.5 ppm F. This is especially an issue when formulas are the infants’ primary source of nutrition. The findings of this study also confirm that the primary source of fluoride intake of infants comes from the water used to reconstitute baby formulas.9 In South Korea, currently only about 3 million out of 50 million people receive
optimally fluoridated (0.8 ppm F) water in their house.\textsuperscript{15} Although not widespread, some babies who are living in fluoridated areas could be at risk of excessive fluoride intake from infant formula and baby food.

There are many studies that determined fluoride intake in children. Children ingest fluoride from toothpaste, water, juice, carbonate drink, fluoride supplements, and other sources.\textsuperscript{20-22} However, recommendations are that infants from birth to 3 months old be fed breast milk exclusively or infant formula only.\textsuperscript{19} Infants 4 months and older should be fed substitute food once a day and to gradually increase the amount over time.\textsuperscript{19}

This study found that the 2- to 3-month-old infants could ingest higher amounts of fluoride per body weight (kg) than the 5- to 6-month-old infants. This is consistent with previous reports.\textsuperscript{23,24} This can be explained by the changing consumption patterns of baby formula as a child grows. Furthermore, baby foods usually do not require reconstitution with water whereas baby formulas do.

The American Dental Association announced an interim guideline that infant formula should be diluted with fluoride-free or low-fluoridated water; also, some countries have established guidelines for fluoride intake for infants to prevent enamel fluorosis.\textsuperscript{25} There is a need to establish such guidelines concerning fluoride intake for infants in South Korea, because there are about 3 million people supplied 0.8 ppm F water in South Korea.\textsuperscript{26} Additionally, guidelines need to be set for manufacturers that limit the amounts of fluoride in infant formulas and baby foods. Health care professionals and parents also need to be further educated about the appropriate uses and dosages of fluoride in infant formulas and baby foods.

The mean decayed, missing, or filled teeth (DMFT) among 12-year-old South Korean children in 2006 was 2.17, which is higher than the average DMFT score (1.6) of the Organization for Economic Co-operation and Development countries.\textsuperscript{27} Since 1981, water fluoridation (0.8 ppm F) has been in operation in South Korea, though only in limited areas. It benefits only about 6.6% of the people who are served by the municipal water system despite efforts to expand the area.\textsuperscript{28} Currently, the prevalence of moderate or severe fluorosis in Korea is negligible. However, it is reported that 18% of children who lived in fluoridated areas had mild fluorosis.\textsuperscript{29} With the expansion of water fluoridation, it is expected that the prevalence of enamel fluorosis will increase.\textsuperscript{9} It is well studied that fluorides are ingested from a various sources including dentifrice, fluoride supplement, and infant food apart from fluoridated water.\textsuperscript{1,30} It is also well known that the fluoride concentration in fruit juice, breast milk, and milk based formula is relatively low.\textsuperscript{1,22}

The present study did not collect any individual-level data regarding the amount of infant formula and baby food intake and infants’ bodyweight. Instead, in our estimation, we used the standard bodyweight of Korean infants and manufacturers’ feeding directions for amount an infant should consume for each product.\textsuperscript{18} Therefore, our results of the estimation of the amount of fluoride intake in infants could be different from the actual fluoride intake. However, we analyzed the fluoride concentration of every milk-based powdered infant formulas and baby food products that were being sold in South Korean markets from May to October 2005. Since then, there have been some new products of infant formulas and baby foods introduced in the South Korean market. Therefore, the findings from this study may not be fully reflective of the current products available in the South Korean market. More research will be needed to investigate infant formula intake patterns to determine the actual amount of fluoride intake an infant receives from the formulas and baby foods currently in the market.

To our knowledge, there has been no published research about the fluoride intake of infants from formulas and baby foods in South Korea. We expect the findings of this study would trigger awareness and interest from the public and policy makers as well as professionals about fluoride intake in infancy in South Korea.
The results of this study indicate that infant formula may need to be reconstituted with water containing fluoride less than 0.5 ppm to prevent enamel fluorosis. However, considering the high prevalence of dental caries and limited areas with water fluoridation in South Korea, abrupt reduction of the use of fluoridated water or instituting such a policy may result in hampering caries prevention, which could further the deterioration of the public’s oral health. Therefore, caution should be taken when creating such policies and guidelines regarding fluoride use and infant nutrition in order to enable a balance between maximizing fluoride’s benefits while preventing enamel fluorosis caused by infant nutrition containing a high fluoride concentration.

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