The Medicinal Effectiveness of R.O.C.S. Toothpastes in Improving the Oral Health of Elementary School Children

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Abstract

A two-year program of supervised toothbrushing carried out in schools on children aged 6-7 using R.O.C.S. (Remineralizing Oral Care System) toothpastes has shown very effective results in reducing the OHI-S index scores by 53-57%, the GI index scores by 57-73% and the 2-year DMFT scores by 29-32%. Remineralizing toothpastes without fluorine, containing 500 ppm AmF or 1000 ppm NaF, were as effective in terms of improving the oral health of the schoolchildren.

Key words: oral disease prevention, school oral hygiene program, toothpastes.

According to multiple international studies, toothpastes containing fluorine have been found to be highly effective in preventing tooth caries [6]. However, no clear recommendations as to which toothpastes can be used for which age group exist. Likewise, it is unclear whether calcium/phosphate based mineralizing toothpastes are a viable substitute for fluorine toothpastes, in cases when the consumer specifically does not want to use them or when they clearly put the patient at risk of fluorosis.

In medical circles, one can often hear about the need to limit the use of hygiene products containing fluorine when it comes to young children, who have a tendency to swallow some of the toothpaste, and when talking about areas affected by endemic fluorosis. At the same time, dentists are concerned that a complete rejection of fluorine toothpaste use will worsen the epidemiological status of tooth caries in the population. Only a clinical trial testing the effectiveness of existing oral hygiene products that contain either no fluorine at all or very small amounts of it, can give an answer to this problem. In compliance with WHO regulations for clinical studies of hygiene product effectiveness, the clinical trial must last at least for two years, and involve a large group of patients, whose oral hygiene would be tested regularly, including tests for caries.

Several years ago, a new range of R.O.C.S. (Remineralizing Oral Care System) children's toothpastes containing either no fluorine or low amounts of it was registered in Russia and Belarus. Since the World Health Organization recommends that medicinal effectiveness of toothpastes should be defined for a specific situation [6], R.O.C.S. toothpastes underwent clinical trials as part of a controlled toothbrushing program in Minsk and Bobruisk from 2007 to 2009. The children's toothpastes, containing the MINERALIN Kids® (calcium glycerophosphate, magnesium chloride and 12% xylitol) and AMIFLUOR® (Olaflur amine fluoride – 500 ppm F^-, 10% xylitol) compounds, were found to be highly effective at improving oral hygiene and reducing the intensity of chronic gum diseases [1, 2, 4]. Also, a tendency of reduced caries occurrence in permanent teeth was noted [3, 5]. Never before have lengthy clinical trials, which would allow the medicinal effectiveness of remineralizing products without fluorine and fluorine-containing toothpastes at preventing tooth caries to be evaluated and compared, been carried out in Belarus.

Aim of the study

Evaluating the medicinal effectiveness of compounds used in the new R.O.C.S. children's toothpaste range at improving the oral health of young school children.

Materials and methods

At the start of the program, 810 children aged 6-7 were participating. Out of all the children who had then finished the program 180 had been using the R.O.C.S. Kids toothpaste with the MINERALIN Kids® compound, 188 had been using the R.O.C.S. Kids toothpaste containing the AMIFLUOR® – 500 ppm F^- compound (raspberry-strawberry), 185 had been using a toothpaste containing sodium fluoride – 1000 ppm F^- (active control group), and 173 had been provided with oral hygiene education (passive control group). The program was carried out in six Minsk and three Bobruisk primary schools. All the schools had been selected in a way so that the different groups of children lived in areas with approximately the same food and water quality.

Brushing sessions with toothbrushes and toothpastes were organized daily at the schools after the second breakfast (Fig. 4). Teachers would squeeze out the correct toothpastes (approx. 1ml or 0.5cm^3) onto the brushes and made sure that the children would follow the correct brushing procedure for three minutes. The participation of the schoolchildren was agreed to by their parents, and was part of the National Program for Tooth Caries and Gum Disease Prevention, which was started by the Belarussian Ministry of Health in 1978.

Dental workups were carried out in schools in identical conditions by the same clinically calibrated dental team. As part of the first workup, the OHI-S (Greene-Vermillion, 1964) index, the GI (Loe-Silness, 1963) index and the DMF (Decayed-Missing-Filled) index for permanent teeth were scored for the patients. Consequent workups were carried out at the 6, 12 and 24 month marks. Statistical results of the studies were processed using the Anova program.

The medicinal effectiveness of the R.O.C.S. toothpastes in improving oral hygiene: in the R.O.C.S. MINERALIN Kids® group – the starting OHI-S score of 1.74±0.04 decreased to 1.12±0.03 (down by 35%) after 6 months ($p<0.001$), to 0.83±0.02 (down by 52%) after 12 months ($p<0.001$), and to 0.75±0.03 (down by 57%) after 24 months ($p<0.001$); in the group using R.O.C.S. AMIFLUOR®, after 6 months the OHI-S hygiene index score decreased by 34% from 1.66±0.05 to 1.10±0.03 ($p<0.001$), after 12 months the OHI-S score decreased by 38% from the starting score, down to 1.03±0.05 ($p<0.001$), after 24 months a further decrease down to 0.78±0.02 (down by 53% from the starting level) ($p<0.001$); in the "active control" group using the sodium fluoride, the OHI-S index score decreased by 36% from the starting level of 1.70±0.03 to 1.08±0.02 ($p<0.001$), down by 44% of the starting level to a value of 0.95±0.03 ($p<0.001$) after 12 months, and down by 61% of the starting value to 0.66±0.02 ($p<0.001$) after 24 months; the "passive control" group (where the children did not participate in the brushing procedures) also saw a decrease of the OHI-S index score from 1.71±0.03 to 1.53±0.04 ($p<0.01$) after 6 months (down by 11%), a decrease of 26% from the starting value at the 12 month mark, and a decrease of 32% from the starting value after 24 months, then measuring 1.17±0.03, which is regarded as "satisfactory" (Table 1, Fig. 1).

Table 1. **The changes in the OHI-S index scores for the children aged 6-7 participating in the 24 month controlled brushing program**

Group	Number of children	Average OHI-S±S.E.			
		Starting (1)	After 6 months (2)	After 12 months (3)	After 24 months (4)
MINERALIN Kids (A)	180	1.74±0.04	1.12±0.03	0.83±0.02	0.75±0.03
AMIFLUOR (B)	188	1.66±0.05	1.10±0.03	1.03±0.05	0.78±0.02
Sodium Fluoride (C)	185	1.70±0.03	1.08±0.02	0.95±0.03	0.66±0.01
Passive Control (D)	173	1.71±0.03	1.53±0.04	1.26±0.02	1.17±0.03

The medicinal effectiveness of the R.O.C.S. toothpastes in decreasing the intensity of chronic gingivitis: in the group using the R.O.C.S. Kids MINERALIN® formula without fluorine, the starting value of the GI index (0.79±0.04) decreased to 0.56±0.02 (down by 29%) after 6 months ($p<0.001$), to 0.47±0.007 (down by 40%) after 12 months ($p<0.001$), and to 0.34±0.01 (down by 57%) after 24 months ($p<0.001$); in the group using the R.O.C.S. Kids AMIFLUOR® formula, the starting level of the GI index was measured to be 0.80±0.05, it then decreased by 25% to 0.60±0.03 ($p<0.01$) after 6 months, by 34% to 0.53±0.017 ($p<0.001$) after 12 months, and a further decrease, down by 73% of the starting value to 0.22±0.01 ($p<0.01$) was recorded after 24 months; in the "active control" group of children using the sodium fluoride toothpaste a decrease of 29% from the starting measurement of 0.76±0.03 to 0.54±0.02 ($p<0.01$) was recorded after 6 months, a decrease of 45% from the starting value to 0.42±0.008 ($p<0.001$) was recorded after 12 months, and a 51% decrease from the starting measurement to a level of 0.37±0.007 ($p<0.001$) was recorded after 24 months; in the "passive control" group, where the children did not participate in the brushing procedures, yet again, a decrease of the GI score was recorded – down by 4% from the starting measurement of 0.74±0.03 to 0.71±0.03 ($p<0.01$) after 6 months, a 14% decrease was recorded after 12 months ($p<0.05$), and a 32% decrease was recorded after 24 months ($p<0.05$) (Table 2, Fig. 2).

The medicinal effectiveness of the R.O.C.S. toothpastes at preventing tooth caries: in the R.O.C.S. Kids MINERALIN® group, a starting measurement of 0.29±0.13 for the DMFT index increased to 0.95±0.10 after 24 months, with the increase measuring 0.66; in the group using R.O.C.S. Kids AMIFLUOR®, the starting DMFT index value of 0.35±0.16 increased to 0.93±0.12 after 24 months, with the increase measuring 0.58; in the "active control" group using the sodium fluoride toothpaste, the DMFT index value increased from 0.40±0.15 to 0.96±0.12 after 24 months (a 0.56 increase); in the "passive control" group the increase was recorded to be 0.94, with the measurement increasing from 0.42±0.12 to 1.36±0.14 after 24 months (Table 3, Fig. 3).

Table 2. **The changes in the GI index scores for the children aged 6-7 participating in the 24 month controlled brushing program**

Group	Number of children	Average GI±S.E.			
		Starting (1)	After 6 months (2)	After 12 months (3)	After 24 months (4)
MINERALIN Kids (A)	180	0.79±0.04	0.56±0.02	0.47±0.007	0.34±0.01
AMIFLUOR (B)	188	0.80±0.05	0.60±0.03	0.53±0.017	0.22±0.01
Sodium Fluoride (C)	185	0.76±0.03	0.54±0.02	0.42±0.008	0.37±0.007
Passive Control (D)	173	0.74±0.03	0.71±0.03	0.64±0.008	0.50±0.01

Discussion of results

When comparing the medicinal effectiveness of the R.O.C.S. Kids toothpastes containing MINERALIN Kids® and AMIFLUOR® compounds, no statistically significant differences could be found in the first 6-month period ($p<0.06$). In the 12-month period, the MINERALIN Kids® compound proved to be more effective when compared to the AMIFLUOR® compound – 52% and 38% respectively ($p<0.01$), however, at the end of the 24-month period, this difference decreased significantly, with the values measured to be 57% for MINERALIN Kids® and 53% for AMIFLUOR®, with a statistically significant difference in the OHI-S measurement values. When comparing the MINERALIN Kids® and AMIFLUOR® compounds to the "active control" group using a sodium fluoride toothpaste, the difference in results after 6 months was not large enough to be statistically significant, with the OHI-S index improving by 34-36%. After 12 months of the brushing, the group using the sodium fluoride toothpaste was in the middle between the MINERALIN Kids® and the AMIFLUOR® groups (which measured 52% and 38% respectively), and after 24 months the pa-

tients from the group using the sodium fluoride toothpaste had the best results from the three – a 61% decrease to the level of 0.66±0.01 in OHI-S measurement, compared to decreases of 57% and 53% of MINERALIN Kids® and AMIFLUOR® respectively. The slight differences in the measurements at the end of the 24-month period (0.66±0.01; 0.75±0.03; 0.78±0.02) were large enough to be statistically significant, which is undoubtedly related to the large number of children in the groups being observed and an accurate reproduction of the measurement method across the groups. However, from a clinical point of view, there are no findings in this study, on the basis of which one compound could be judged better than another. The measurements collected from the "passive control" group are significantly different from those for the MINERALIN, AMIFLUOR and sodium fluoride groups. It is important to note that in this group as well, the oral hygiene measurements improved over time from the starting level of 1.71±0.03 to 1.17±0.03 at the end of the program (p<0.001). It is obvious that the oral hygiene instruction sessions in the "control" schools have also had a positive effect on the children's oral health.

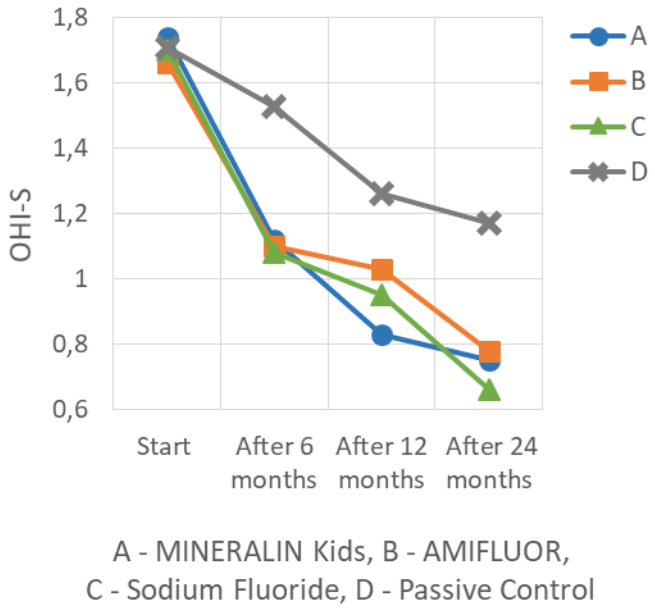


Fig. 1. **The changes in the OHI-S index scores for the children aged 6-7 participating in the 24 month controlled brushing program**

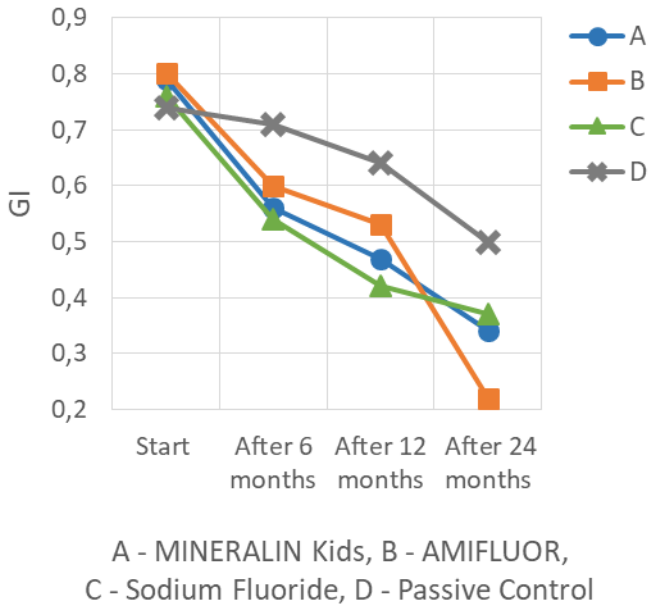


Fig. 2. **The changes in the GI index scores for the children aged 6-7 participating in the 24 month controlled brushing program**

The medicinal effectiveness of the R.O.C.S. Kids toothpastes containing the MINERALIN Kids® and the AMIFLUOR® compounds in decreasing the GI index measurements was statistically identical after 6 months (p>0.03). After 12 months, MINERALIN Kids® had shown a higher effectiveness than the AMIFLUOR® compound – 40% and 34% respectively (p<0.01). After 24 months, AMIFLUOR® performed better – 73%, compared to 57% for MINERALIN Kids®. It is possible that the amine fluoride present in the R.O.C.S. Kids AMIFLUOR® compound was having an additional anti-inflammatory effect on the gums. When compared to the "active control" group, the R.O.C.S. Kids toothpastes containing the MINERALIN Kids® and the AMIFLUOR® compounds performed no different in improving the GI measurements after 6 months, with the results showing a 25-29% decrease from the starting level. After 12 months, the GI index measurements in the sodium fluoride group were significantly lower than in the MINERALIN Kids® and the AMIFLUOR® groups – 45%, 40% and 34% respectively. However, this was not the case at the 24-month mark. After 24 months, the biggest decrease in the GI measurement was recorded for the AMIFLUOR® group (down by 73% from the starting level to 0.22±0.01), with the decrease for MINERALIN Kids® and sodium fluoride being 57% and 51% respectively. The GI measurements in the "passive control" group differed greatly from the measurements in the other three groups. It is important to note that in this group as well, a decrease of the gingivitis intensity was recorded: down from 1.74±0.03 at the start to 0.50±0.01 at the

end ($p<0.05$). Therefore, the oral hygiene improvement that these kids experienced did indeed play a role in preventing periodontal diseases.

Comparing the R.O.C.S. Kids toothpastes with the MINERALIN Kids® and AMIFLUOR® compounds using the DMFT index shows no statistically significant difference at the 24-months mark: 0.95±0.10 and 0.93±0.12 respectively ($p>0.9$). Compared to the "passive control" group, the differences in the increase of decayed-missing-filled teeth were 32% lower for AMIFLUOR® (-0.41) and 30% for MINERALIN Kids® (-0.41). We suppose that these minute differences cannot be sufficient to declare the AMIFLUOR® compound to be more effective at treating dental caries than the MINERALIN Kids® compound. Comparing the medicinal effectiveness of the R.O.C.S. compounds to the "active control" group using sodium fluoride had shown no significant differences in the reduction of the growth of the DMFT index measurements. Compared to the "passive control" group, the sodium fluoride group performed 29% better (-0.40). No statistically significant difference in performance between the sodium fluoride and the MINERALIN Kids® and AMIFLUOR® groups had been recorded, suggesting that the three toothpastes have a similar effectiveness in preventing caries.

Table 3. **The changes in the DMFT index scores for the children aged 6-7 participating in the 24 month controlled brushing program**

Group	Average DMFT±S.E.		Difference compared to the DMFT measurement growth in the control group
	Starting	After 24 months	
A - MINERALIN Kids (n = 180)	0.29±0.13	0.95±0.10	-0.41 (30%) t=2.5; p<0.02
B - AMIFLUOR (n = 188)	0.35±0.16	0.93±0.12	-0.41 (32%) t=2.4; p<0.05
C - Sodium Fluoride (n = 185)	0.40±0.15	0.96±0.12	-0.40 (29%) t=2.3; p<0.05
D - "Passive Control" (n = 173)	0.42±0.12	1.36±0.13	–

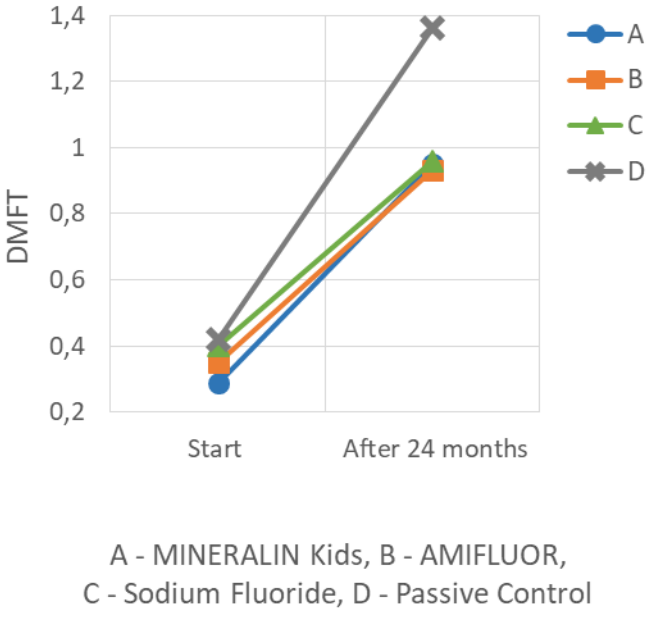


Fig. 3. **The changes in the DMFT index scores for the children aged 6-7 participating in the 24 month controlled brushing program**



Fig. 4. **The first graders of Minsk school #24 undergoing the brushing procedure under the supervision of their teacher**

Conclusion

The R.O.C.S. Kids toothpastes containing the MINERALIN Kids® (fluorine free) and AMIFLUOR® (F⁻500 ppm) were both highly effective at improving the children's oral hygiene, reducing the Greene-Vermillion index measurements by 53-57% in 24 months. The medicinal effectiveness of the children's toothpastes was comparable to that of the sodium fluoride toothpaste (F⁻1000 ppm). In addition to an improvement in oral hygiene, a lowering in the measurement of the GI index values relating to chronic gingivitis by 57-73% from the starting level was recorded. The medicinal effectiveness of the R.O.C.S. children's toothpastes in preventing diseases of the periodontium (chronic gingivitis) is comparable to that of the sodium fluoride toothpaste (F⁻1000 ppm).

During the lengthy clinical trial of supervised brushing, a high efficiency of the R.O.C.S. toothpastes in preventing caries among elementary school children was recorded – the reduction in the growth of the DMFT index values was 0.41, or 30-32% when compared to the "passive control" group. There were no statistically significant differences discovered between the toothpaste containing no fluorine (MINERALIN Kids®) and the one containing it (AMIFLUOR®). The effectiveness of the R.O.C.S. children's toothpastes was identical over the 24-month period to that of the sodium fluoride toothpaste (F⁻ 1000 ppm), which was used in the "active control" group.

The trial has proven that there is a worthy alternative to fluorine toothpastes in terms of oral hygiene. Toothpastes without fluorine can be used as a means to help negate the effects of a high fluorine content in drinking water, also when parents cannot ensure that the child will use fluorine-containing oral hygiene products properly, or when using certain preventive methods. The combination of amine fluoride and xylitol helps lower the concentration of active fluorine without reducing the clinical effectiveness of the compound, which decreases the risks associated with the use of the toothpaste by children.

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