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## Introduction

A preliminary report on the planning and establishment of a clinical trial of the efficacy of calcium sucrose phosphate, in the form of a food additive, as a cariostatic agent was published in 1967.<sup>(1)</sup> The results after one year indicated reductions in the dental caries increment for all children in the ages 5-17 years.

A further report published in 1968<sup>(2)</sup> covering the results observed after two years showed an overall reduction of 25 per cent in caries increment which was mainly demonstrated in the proximal surfaces of posterior teeth in the order of 50 per cent.

Initially 1506 children were examined and participated in this clinical trial. Normal exodus of children from the Homes was

anticipated and it was hoped that approximately 800 of the original subjects would remain in the trial for at least two years. Based on the data presented in Barnard's survey<sup>(3)</sup> these numbers would yield significant results if the difference were of the order of 20 per cent of the Control Group score.

The loss of subjects in the first two years was approximately as anticipated; their replacements participated in the project and observations of their dental caries experience have been recorded.

The circumstances which determined the initial selection of institutions, namely numbers of boys and girls in appropriate age groups, accessibility to the source of supply and control of treated foods, and agreement to participate in the project, restricted the location and numbers of children. Factors beyond the control of the institutions and of ourselves have brought about greater losses in the numbers of subjects over the three years.

Table 1 shows the distribution of the children between Control and Treatment Groups over the period 1965-1968. It will be seen that the rate of loss was somewhat greater than expected and only 527 children of the original groups remained for the final examination at the end of three years.

The mean ages at the time of the first examination (1965) of these children were:

Control	(361)	12.0 years
Treatment	(166)	10.8 years

\* Financial support for the conduct of this trial was given by the Colonial Sugar Refining Co. Ltd., Sydney, and the processing of the data was carried out in the Computer and Operations Research Services Group of that company.

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<sup>(1)</sup> Harris, R., Schamschula, R. G., Gregory, G., Roots, Miriam, and Beveridge, J.—Observations on the cariostatic effect of calcium sucrose phosphate in a group of children aged 5-17 years. Preliminary report. Austral. D. J., 12:2, 105-113 (Apr.) 1967.

<sup>(2)</sup> Harris, R., Schamschula, R. G., Beveridge, J., and Gregory, G.—The cariostatic effect of calcium sucrose phosphate in a group of children aged 5-17 years. Austral. D. J., 13:1, 32-39 (Feb.) 1968.

<sup>(3)</sup> Barnard, P. D.—Dental survey of State school children in New South Wales, Jan. 1954-June 1955. N.H.M.R.C. Sp. Rpt. Series No. 8, Canberra, 1956.



TABLE 1

Numbers of children included in observations for the three-year programme who were present at all examinations 1965-1968

Date of examination	Control	Treatment	Total
1965	885	621	1,506
1966	632	408	1,040
1967	479	242	721
1968	361	166	527

Between the 1965 and 1966 examinations 245 additional subjects (Control 123, Treatment 122) entered the trial and were present at the 1967 examination; of these, 161 (Control 83, Treatment 78) were also present at the 1968 examination. Between the 1966 and the 1967 examinations 274 additional subjects (Control 136, Treatment 138) entered the trial and were present at the 1968 examination.

Of the 361 subjects in the Control Group 195 were members of the one boys' boarding-school participating in the trial. The reason for this disparity in average ages of the Control and Treatment Groups developing since the earlier examinations is largely the lower turnover rate of students at that school.

This difference in ages means that direct unweighted comparisons between the two groups could be misleading.

The conditions of the trial and examinations (both dental and medical) and the dietetic supervision have remained as described in the previous reports.<sup>(1)(2)(4)</sup> Medical evidence shows that the physical status of both groups remains similar and this will be reported in detail elsewhere.

Results\*

All subjects

Table 2 presents a summary of the mean DMF teeth per child for all subjects who were present at two or more examinations. The annual increment in mean DMF teeth for each age group present at all examinations (1965-1968) should allow measurement of any overall difference between Control and Treat-

\* Extensive supplementary tables are available from the authors.

<sup>(4)</sup>Harris, R., Roots, Miriam, Gregory, G., and Beveridge, J.—Calcium sucrose phosphate as a cariostatic agent in children aged 5-17 years. III. Dietary factors. Austral. D. J., 13:5, 345-352 (Oct.) 1968.

TABLE 2

Mean DMF teeth per child at each annual examination (All subjects 1965-1968)

Date of first examination	Date of subsequent examination(s)	N	Average age in 1965	DMF teeth 1965	Difference 1966-1965	DMF teeth 1966	Difference 1967-1966	DMF teeth 1967	Difference 1968-1967	DMF teeth 1968
1965	1966, 1967, 1968	C .. 361	12.0	8.67	2.45	11.12	2.23	13.35	1.61	14.96
		T .. 166	10.8	5.75	1.64	7.39	1.95	9.34	2.35	11.69
1965	1966, 1967	C .. 479	11.9	8.53	2.45	10.98	2.12	13.10	—	—
		T .. 242	11.4	6.85	1.71	8.56	1.89	10.45	—	—
1965	1966	C .. 632	11.7	8.19	2.45	10.64	—	—	—	—
		T .. 408	11.9	7.75	1.93	9.68	—	—	—	—
1966	1967, 1968	C .. 83	8.6	—	—	5.82	1.94	7.76	1.77	9.53
		T .. 78	10.4	—	—	6.18	2.01	8.19	2.19	10.38
1966	1967	C .. 123	9.1	—	—	6.59	2.05	8.64	—	—
		T .. 122	10.5	—	—	7.25	1.78	9.03	—	—
1967	1968	C .. 136	8.1	—	—	—	—	6.19	1.90	8.09
		T .. 138	9.3	—	—	—	—	7.87	1.90	9.77

C=Control subjects. T=Treatment subjects. N=Number of subjects.



TABLE 3

The increment of dental caries expressed as mean DMF teeth and DMF surfaces in the Control (189) and Treatment (132) groups of children aged 9-13 years for the years 1965-1968

Age at first examination	Group	N	Increments in DMF teeth and DMF surfaces per child							
			1965-1966		1966-1967		1967-1968		1965-1968	
			Teeth	Sur-faces	Teeth	Sur-faces	Teeth	Sur-faces	Teeth	Sur-faces
9 years ..	C	22	1.54	4.87	2.23	3.73	2.23	7.00	6.00	15.60
	T	19	1.05	2.26	1.05	2.27	2.00	4.05	4.10	8.58
10 years ..	C	24	1.12	2.87	2.88	5.63	3.17	7.42	7.17	15.92
	T	20	0.85	3.25	2.35	5.90	3.85	8.80	7.05	17.95
11 years ..	C	29	4.07	7.34	3.59	9.73	1.72	9.45	9.38	26.52
	T	31	1.87	4.68	3.16	6.39	3.19	8.42	8.23	19.49
12 years ..	C	29	3.04	8.07	3.10	8.41	1.48	5.66	7.62	22.14
	T	37	2.73	5.60	2.57	6.94	2.62	9.33	7.92	21.87
13 years ..	C	85	3.06	7.79	2.65	8.40	1.73	6.89	7.44	23.08
	T	25	2.09	6.30	1.00	4.74	1.48	5.83	4.57	16.87
9-13 years	C	189	2.57	6.19	2.89	7.18	2.07	7.28	7.53	20.65
	T	132	1.72	4.42	2.03	5.25	2.63	7.29	6.38	16.96
Difference (per cent)	DMF teeth		33.1	—	29.8	—	-27.3	—	15.3	—
	DMF sur-faces ..		—	28.6	—	26.9	—	-0.1	—	17.9

Difference =  $\frac{100 (\text{Average Control} - \text{Average Treatment})}{\text{Average Control}}$

C=Control subjects. T=Treatment subjects. N=Number of subjects.

TABLE 4

The increment of dental caries expressed as DMF surfaces in the Control (335) and Treatment (147) groups of children for the years 1965-1968. (Non-fluoridated areas)

Increments in DMF surfaces for boys and girls

Sex	Age (1965) (years)	N	1965-1966	1966-1967	1967-1968	1965-1968	Difference (per cent)
Boys ..	5-10	C 56	4.07	3.94	5.29	13.30	22.78
		T 24	2.91	3.13	4.29	10.33	
Boys ..	11-17	C 239	7.20	7.97	7.29	22.46	10.55
		T 76	5.66	6.10	8.33	20.09	
Girls ..	5-10	C 21	3.76	5.00	5.81	14.57	3.43
		T 28	2.71	4.50	6.86	14.07	
Girls ..	11-17	C 19	6.58	7.11	6.47	20.16	18.55
		T 19	5.63	4.63	6.16	16.42	

Difference =  $\frac{100 (\text{Average Control} - \text{Average Treatment})}{\text{Average Control}}$

C=Control. T=Treatment. N=Number of subjects.



ment Groups. However, since depletion of subjects has greatly reduced numbers in some age groups, Table 3 shows these data restricted to the ages 9-13 years (1965) where the number in *both* groups is at least 19.

The mean increment of DMF teeth for the Control Group is 7.53 and for the Treatment Group 6.38, a difference of 15.3 per cent; and of DMF surfaces for the Control Group is 20.65 and for the Treatment Group 16.96, a difference of 17.9 per cent.

Table 4\* shows the increments in all surfaces for boys and girls present at all examinations (1965-1968) in the age groups 5-10 years and 11-17 years. The difference is greatest in the boys aged 5-10 years (22.78 per cent) followed by the girls aged 11-17 years (18.55 per cent).

If the results for the proximal surfaces in the bicuspid and molar teeth in the age groups for all children 9-13 years (Table 5) and for the boys and girls in the age groups 5-10 and 11-17 years (Table 6\*) are examined, it will be seen that for children aged 9-13 years there is a reduction in the dental caries increment of 29.5 per cent for the period 1965-1968 (Table 5). For all children there is a range in reduction from 3.95-36.06 per cent (Table 6). It should be noted that for the boys aged 11-17 years (the group in which the largest numbers remained) the reduction 25.18 is significant at the 1.0 per cent level.

*Subjects from fluoridated area*

Four institutions (2 Control, 2 Treatment) were located in an area where fluoridated water supplies existed since November, 1961. These institutions were treated in the trial exactly as the other institutions, but because of the fluoride factor the results of the dental examination have not been included where significance tests were carried out in the previous sections of this report. A summary of the results in terms of age and DMF teeth is given in Table 7. It will be noted that the subjects of the Treatment Group had a lower increment of caries (4.21 DMF teeth) than those of the Control Group (5.85 DMF teeth), a difference of 28 per cent.

The mean DMF surfaces (all and proximal) of the remaining 45 children in the fluoridated area are compared with those of the non-fluoride groups in Tables 8 and 9. The increment of DMF surfaces for children aged 5-17 years in the fluoride area ranges from 10.27-18.45 in the Control and from 8.08-17.00 in the Treatment Group. In the non-fluoride area the corresponding ranges are 13.65-22.29 for the Control Group and 12.35-19.36 for the Treatment Group.

**Discussion**

The problem of loss of subjects from the trial has been referred to above. Nevertheless, sufficient remained to enable observations to be made which show a general benefit in terms of a lower dental caries incidence for the Treatment Group. This can be demonstrated by statistical significance tests in a number of cases.

TABLE 5

*The increment of dental caries on the proximal surfaces of the bicuspid and molar teeth of 321 children aged 9-13 years for the period 1965-1968*

Age (1965) (years)	N	Differences in mean DMF proximal surfaces per subject			
		1965-1966	1966-1967	1967-1968	1965-1968
9	C 22	1.32	1.27	2.45	5.05
	T 19	0.26	0.16	1.47	1.89
10	C 24	0.75	1.67	3.17	5.58
	T 20	0.70	1.80	3.45	5.95
11	C 21	3.17	3.28	3.90	10.34
	T 31	1.35	1.16	4.39	6.90
12	C 29	3.03	3.24	3.21	9.48
	T 37	1.05	2.16	4.46	7.68
13	C 85	2.64	3.89	3.33	9.86
	T 25	1.22	1.04	3.70	5.96
9-13	C 189	2.18	2.67	3.21	8.06
	T 132	0.92	1.26	3.49	5.68
Difference (per cent)		57.8	52.8	-8.7	29.5

Difference =  $\frac{100 (\text{Average Control} - \text{Average Treatment})}{\text{Average Control}}$

C=Control subjects. T=Treatment subjects. N=Number of subjects.

\* This age grouping in Tables 4 and 6 was used in the previous report.<sup>(2)</sup> Also in these tables, subjects at institutions in fluoridated areas were omitted in order to present homogeneous groups for statistical significance testing.



TABLE 6

The increment of dental caries on the proximal surfaces of the bicuspid and molar teeth of the 482 children aged 5-17 years for the period 1965-1968. (Non-fluoridated areas)  
Increments in DMF surfaces for boys and girls

Sex	Age (1965) (years)	N	1965-1966	1966-1967	1967-1968	1965-1968	Difference (per cent)
Boys ..	5-10	C 56	0.90	1.23	1.73	3.86	32.12 N.S.
		T 24	0.12	0.92	1.58	2.62	
Boys ..	11-17	C 239	2.90	3.22	3.53	9.65	25.18**
		T 76	1.26	1.50	4.46	7.22	
Girls ..	5-10	C 21	0.53	1.23	2.29	4.05	3.95 N.S.
		T 28	0.78	0.97	2.14	3.89	
Girls ..	11-17	C 19	2.00	3.53	2.79	8.32	36.06 N.S.
		T 19	1.21	1.06	3.05	5.32	

$$\text{Difference} = \frac{100 (\text{Average Control} - \text{Average Treatment})}{\text{Average Control}}$$

\*\* Significant at 1% level.

N.S. = Not significant. C = Control subjects. T = Treatment subjects. N = Number of subjects.

#### All subjects

The New South Wales survey of Barnard (1956)<sup>(3)</sup> showed that although the annual increments in DMF teeth were almost equal in the years 6-15 there was a temporary increase in the rate around the age of 11 or 12 years. Such considerations make direct comparisons of these DMF rates invalid, except perhaps in cases where the distribution of ages is similar in the two groups.

In subjects who were present at all examinations it will be seen (Table 2) that some of the reduction in caries increment gained in 1967 has apparently been lost, since the difference in the mean DMF teeth per subject between the 1967 and 1968 examinations is greater in the Treatment than in the Control Group. It is suggested that this largely arises from the differences in age of the two groups which, because of losses of subjects, have become greater as the trial continued.

At the final examination in 1968 the average age of subjects in the Control Group was 15 years, whilst for those in the Treatment Group it was 13.8 years. In the Control Group 126 children were 17 years of age or over at the 1968 examination compared with only 10 children in the Treatment Group. Since it can be expected that children over 16 years of age have a lower annual increment of DMF teeth than younger children, the age difference referred to above favours the Control Group. Figures for all subjects are in fact weighted means of the different age rates, the weights being the numbers in the group of each age.

When allowance for age imbalance is made, the data in Table 2 for subjects present at all examinations suggest that the reduction in caries increment, significantly demonstrated<sup>(2)</sup> in the data from the 1965-1967 examinations, was maintained in the 1965-1968 examination.

TABLE 7

Mean DMF teeth per child of 45 children of both Control and Treatment groups living in a fluoridated area (1965-1968).

	Number of children	Average age (years)	DMF teeth per child				Difference 1965-1968
			1965	1966	1967	1968	
Control ..	26	9.8	3.50	5.23	7.42	9.35	5.85
Treatment	19	10.1	4.42	5.58	6.84	8.63	4.21



A comparison of increments in DMF teeth and surfaces (Table 3) shows a reduction of approximately 30 per cent for each of the first two years in DMF teeth followed by an increase of 27 per cent in the third year. DMF surfaces show a similar reduction followed by approximately equal increments in the third year.

TABLE 8

*The mean DMF surfaces increment of all children (527) aged 5-17 years living in both fluoride and non-fluoride areas, 1965-1968*

	Age (years)	Mean DMF surfaces increment			
		Fluoride		Non-fluoride	
		No.	DMFs.	No.	DMFs.
Control ..	5-10	15	10.27	77	13.65
	11-17	11	18.45	258	22.29
Treatment	5-10	13	8.08	52	12.35
	11-17	6	17.00	95	19.36
Total		45		482	

As a tooth needs only one DMF surface to be classified as DMF, the above data suggest that further surfaces have been attacked in the Control Group without appreciably increasing the DMF teeth rate. This indicates, as does the data from Table 2, that the curve relating DMF surfaces to age for the Treatment Group may have shifted positively by a distance of two years on the age scale.

The data in Table 5 again support the results reported<sup>(2)</sup> for the two-year period, namely that there is a reduction in caries increment on the proximal surfaces, although this has fallen to 29.5 per cent by the end of the third year.

The average effects for the age range (9-13 years) produced reductions for the Treatment Group of:

- DMF teeth 15.3 (Table 3)
- DMF surfaces 17.9 (Table 3)
- DMF proximal surfaces 29.5 (Table 5)

Examination of data for DMF surfaces grouped on an age and sex basis for subjects present at institutions in the non-fluoridated areas (Tables 4 and 6) will show reductions in increments both for all surfaces and for proximal surfaces in the Treatment Group.

For the 11-17 years age group containing the largest numbers of boys (Table 6) statistical significance was found at the 1 per cent level. [Similar significance was found in the 1965-67 data (Table 4).<sup>(2)</sup>] In other cases where high reductions were obtained, for example 36.06 per cent for girls aged 11-17 years, the limited numbers in the group and the inherent variability in the data prevent the same degree of significance, as was found after two years, from being obtained.

For subjects present at the last two and three examinations only, DMF rates for both teeth and surfaces are shown in Table 2. Statistical significance is at the 5 per cent level for boys and girls aged 11-17 years but the numbers of subjects are small.

The reduction gained by the Treatment Group for these two years is less than that reported for the first two years. This may be due to the extra variability caused by the subjects entering the trial at any time between the 1966 and 1967 examinations, whereas all original subjects entered the trial at the same time.

TABLE 9

*The mean DMF increment for the proximal surfaces of the bicuspid and molar teeth of all children (527) aged 5-17 years living in both fluoride and non-fluoride areas, 1965-1968*

	Age (years)	Mean DMF surfaces increment			
		Fluoride		Non-fluoride	
		No.	DMFs.	No.	DMFs.
Control ..	5-10	15	2.27	77	3.91
	11-17	11	7.18	258	9.55
Treatment	5-10	13	1.85	52	3.31
	11-17	6	4.33	95	6.84
Total		45		482	

*Subjects from fluoridated area*

Because of the reduced numbers, statistical significance should not be placed on the figures from the fluoridated area. However, they are consistent with an overall benefit for fluoride and an additional benefit for the calcium sucrose phosphate additive which is of the same order as it was in the non-fluoride institutions. This follows the pattern of the significant results found in the two years' data.<sup>(2)</sup>



Sixteen subjects joined these Homes in 1966 and of these only one joined a Control Group Home, and therefore reliable comparison could not be made between new Control and Treatment subjects. In subjects who were present from 1966-1968 in the Treatment Groups the average increments for all DMF surfaces and DMF proximal surfaces were 8.28 and 3.56 respectively and corresponding values in non-fluoride groups were 13.06 and 5.57. This does not in itself add anything to the purpose of the trial, except that it is consistent with the accepted results from fluoride trials and is evidence of the general reliability of the trial data.

It is true that in a large and complex trial in which subjects leave and enter the study it is possible to select and interpret data which apparently confirm a preconceived hypothesis. In our report for the first two years<sup>(2)</sup> it was noted that the Groups initially had a difference in mean DMF teeth per subject but the initial erupted caries-free teeth per subject were almost identical (12.95 for Control Group and 12.96 for Treatment Group). Furthermore, at the end of two years the mean number of teeth per subject was 24.76 and 24.82 respectively and the difference in the proportion of new carious teeth was 40.4 per cent in favour of the Treatment Group.

TABLE 10

Comparison of DMF increments as a proportion of available surfaces and teeth for different populations in trial 1965-1968

Population	Average age at initial examination		Number of subjects		DMFS*/100 available surfaces				DMFT*/100 available teeth			
	C	T	C	T	C	T	C-T	$\frac{C-T}{C}$	C	T	C-T	$\frac{C-T}{C}$
1 1965-1968	12.0	10.8	361	166	17	14	3	17	34	27	7	20
1' 1965-1967	11.9	11.2	480	242	11	9	2	20	26	19	7	28
1'' 1965-1966	11.7	11.9	632	408	7	5	1	20	17	13	4	23
1''' 1966-1967	12.5	12.3	603	364	7	5	1	22	16	12	4	28
2 1966-1968	9.6	11.4	83	78	12	10	2	20	26	20	6	22
3 1967-1968	10.1	11.3	136	138	7	6	1	15	15	13	2	17

C=Control subjects. T=Treatment subjects.  $\frac{C-T}{C}$  = Percentage reduction due to treatment.

\* All figures of DMFS and DMFT rounded off to nearest whole numbers.

Population 1 consists of all children present at all four examinations.

1' consists of all children present at the first three examinations.

1'' consists of all children present at the first two examinations.

1''' consists of all children present at the second and third examinations.

Thus population 1 contains some of the children who would also have been in populations 1', 1'' and 1'''.

Population 2 consists of children who were present at the last three examinations but not the first.

Population 3 consists of children who were present at the last two examinations but not the first two.

Thus populations 2 and 3 are entirely different populations from one another and from population 1.

## APPENDIX A

From the subjects present and examined throughout the trial two groups of 92 were selected from the Control and Treatment groups. Each of these two groups had a mean age of 10.6 years and a mean DMF surfaces per subject of 11.36 at the initial examinations. The caries incidence for these subjects during the trial was :

	Examina-tions	1965	1966	1967	1968	Difference (per cent)
DMF surfaces ..	Control ..	11.36	16.87	23.00	29.22	17.80
	Treatment	11.36	15.70	20.00	26.04	
DMF teeth ..	Control ..	4.90	7.36	9.80	11.62	16.60
	Treatment	5.35	6.97	8.75	10.95	
DMF surfaces (proximal bicuspids and molars)	Control ..	3.40	5.09	7.12	9.78	31.70
	Treatment	3.76	4.64	5.45	8.33	



It is important to reiterate that because of increased imbalance in age and the decreased numbers in the Groups after three years, the major analysis has been applied to the age groups 9-13 years.

However, an alternative to the method of analysis we have used is based on DMF teeth and surfaces as a proportion of available teeth and surfaces and which is less subject to variation with age and DMF per subject.

If the analysis is made on data based on caries-free teeth at the initial examination which became carious during the trial, the results (Table 10) closely approximate those which we have demonstrated above. This table summarizes data for the subjects present for different annual periods throughout the trial. It is submitted as further evidence. This analysis has been extended to the data on proximal surfaces of bicuspid and molar teeth and also supports our interpretation.

Because of loss of subjects from the original Groups and the creation of a certain imbalance in terms of mean age and DMF, a further analysis has been carried out on data from Control and Treatment subjects balanced for age and dental caries. On this basis it is possible to examine data for 92 subjects in each Group present throughout the trial, and these are presented in Appendix A.

This analysis supports the results we have demonstrated for all subjects present at the four examinations: a reduction for the Treatment Group of 17.8 per cent in DMF surfaces, 16.6 per cent in DMF teeth, and 31.7 per cent for DMF bicuspid and molar proximal surfaces.

### Conclusions

1. One of the major difficulties of conducting a clinical trial of this nature lies in the loss of subjects originally examined.

2. The clinical trial of calcium sucrose phosphate used as a food additive for a period of three years in 527 children (Control 361, Treatment 166) aged 5-17 years demonstrated a lower incidence of dental caries for those children receiving the additive.

3. The results reported previously for the first two years of the trial have been confirmed after three years and this has been demonstrated by statistical significance in a number of cases.

4. There is also a consistent pattern of reduced incidence of dental caries in the Treatment Group in comparisons in which, due to the relatively small numbers involved, significance testing produces non-significant results.

5. In the age groups 9-13 years there are reductions for the Treatment Group of:

DMF teeth	15.3 per cent
DMF surfaces	17.9 per cent
DMF proximal surfaces	29.5 per cent

6. Strong evidence supports the earlier findings that most benefit is gained on proximal surfaces which accounted for approximately 40 per cent of all lesions found.

7. The medical investigations showed no differences in the physical status and general health between the children of the Control and Treatment Groups.

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