

Evidence for putting the calculus: caries inverse relationship to work

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Abstract – Objectives: To report previously unpublished data from three different types of clinical study to show the strength of the evidence purporting to demonstrate the existence of an inverse relationship between subjects' calculus and caries experience. **Methods:** Data have been analysed from: a 3-year caries clinical trial of six toothpastes conducted in Lanarkshire, Scotland that involved 3000 children, Study 1; a caries epidemiological study in the Isle of Lewis that involved 228 children, Study 2; a calculus formation study carried out at Port Sunlight using a wide age range of adults, Study 3. **Results:** Baseline data taken from Study 1 show that caries prevalence is highly significantly lower in calculus-prone than in calculus-free subjects ($P < 0.0001$). The inverse relationship is also demonstrated by the 3-year caries increment data for subjects who had used non-zinc toothpastes. Results from Study 2 show that a similar association arose for 8-year olds over a 6-year period, based on their erupting teeth alone. Finally, data from Study 3 show that whilst the extent of caries and calculus experience are both positively linked to age, within specific age groups the relationship between the two dental conditions on an individual subject basis is clearly of an inverse nature. **Conclusions:** The present work confirms that calculus status has a direct bearing on both current and future caries experience. Baseline calculus status could be, and has subsequently been demonstrated to be, a useful stratifying factor for caries clinical trials.

Key words: caries; calculus; clinical trial; toothpaste

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From a mechanistic viewpoint it is reasonable to anticipate an inverse clinical relationship between calculus and caries. Calculus formation is essentially a *mineralization* process. The development of a caries lesion is the result of the net *demineralization* of tooth enamel by plaque acid. These processes both involve crystalline calcium phosphate phases in contact with liquid, saliva and/or plaque fluid, containing their constituent ions. The oral environment also contains other salivary constituents and bacteria, which either inhibit or promote crystal growth or dissolution.

This topic has potential importance. An inverse relationship would mean that the absence of calculus could be a useful predictor of caries. Historically, caries prevalence has been the best predictor of future caries incidence. However, such

an association is clearly a mixed blessing. Until recent years, the use of calculus as a predictor appeared limited as the expected inverse association appeared to be largely unproven in fact. The relationship may well have been obscured by other factors. First, the prevalence of both calculus and caries increases with increasing age (1, 2) and, secondly, both conditions are expected to correlate positively with poor oral hygiene (3–5). These trends could be the reason why Schroeder (1) found no consistent relationship between clinical observations of calculus and caries experience in the first major review of the topic.

The aim of this paper is to report previously unpublished data from three different types of clinical study to show the strength of the evidence purporting to demonstrate the existence of an

inverse relationship between subjects' calculus and caries experience. The first data set is taken from a 3-year caries clinical trial that was conducted in Lanarkshire, Scotland between 1983 and 1986 (6). Next, we discuss results from a 6-year epidemiological study that took place in the Isle of Lewis from 1968 to 1974 (7). Finally, the above results derived from children are contrasted with data from a calculus formation study carried out in Port Sunlight in 1987 using a wide age range of adults (8).

Materials and methods

Study 1: Lanarkshire

This, double-blind, 3-year caries clinical trial involved 3000 children, aged 11–13 years at baseline. Subjects used one of six possible test toothpastes during the trial, which comprised three fluoride concentrations (1000, 1500 and 2500 ppm F as sodium monofluorophosphate, Na_2FPO_3) combined with one of two concentrations of zinc citrate, 0% and 0.5%. Two calibrated examiners recorded caries status (DMFS index) and the presence (1 = calculus on anteriors only; 2 = calculus on molars) or absence of calculus (score = 0) at baseline and at the end of each of the 3 years of the study. Whilst both inter- and intra-examiner reliability checks were undertaken for the primary study measure, caries score, no such checks were done for secondary measures, of which calculus was one (6). The children received no dental prophylaxes as part of the study.

Study 2: Isle of Lewis

This double-blind study comprised a 3-year clinical trial followed by a further clinical examination 3 years later. Children, of which 228 completed the study, were 8 years old at baseline and used either a nonfluoride toothpaste or a paste that contained 2500 ppm F as Na_2FPO_3 for the duration of the clinical trial. A single examiner recorded caries status (DMFS index) and calculus status (1 = no calculus, 2 = sub-gingival calculus, 3 = supra-gingival calculus, 4 = sub- and supra-gingival calculus) at baseline, at the end of each of the 3 years of the trial and after a further 3 years. As for Study 1, intra-examiner repeatability checks were carried out for caries but not for calculus (7). The children received no dental prophylaxes as part of the study.

Study 3: Port Sunlight

This calculus clinical trial involved 437 adults in the age range 20–65 years. Inclusion criteria were: propensity to form calculus, no excessive gingival recession or large restorations on the lingual surfaces of the six lower anterior test teeth, no medical contraindication to participation. All subjects used a control toothpaste, which contained 1000 ppm F as Na_2FPO_3 , for a 3-month lead-in period following a scale and polish. At the end of that time, a single trained assessor scored calculus using the Volpe–Manhold index (9). The procedure for assessing examiner reproducibility followed that recommended by Volpe et al. (9). Caries status was recorded at baseline using the DMFT index.

Ethical review

Details of the ethical measures taken for Studies 1 and 2 are given in the corresponding source references (6, 7). Before commencement of Study 3, the local ethics committee approved the study protocol and all subjects gave their informed consent.

Statistical analyses

For Studies 1 and 2, two-sample *t*-tests were used for data comparisons between calculus-free and calculus-prone groups. For Study 3, Pearson correlation coefficients were determined to assess the significance of the caries–calculus association within subject subgroups.

Results

Tables 1a and b show the data from Study 1. The baseline data (Table 1a) show that caries prevalence is highly significantly lower in calculus-prone subjects than in calculus-free subjects ($P < 0.0001$) for the 2316 children who completed the trial. The inverse relationship is also manifested in the 3-year increment data (Table 1b) for the three non-zinc citrate groups. Data for the three groups of children who had used pastes that contained zinc citrate are excluded to avoid the possible confounding influence of the presence of this well-known anticalculus agent. Children classified as calculus-formers at the start of the trial developed 29.6% fewer caries lesions on average than their initially calculus-free counterparts. This difference appears to be independent of the fluoride content of test toothpaste used ('fluoride content \times calculus status interaction

Table 1a. Relationship between caries and calculus prevalence at baseline for Study 1

Calculus-free subjects		Calculus-prone subjects		Caries difference ^a (%)	Statistical significance (<i>P</i> -value)
<i>N</i>	DMFS, mean (SE)	<i>N</i>	DMFS, mean (SE)		
1538	11.08 (0.22)	778	8.40 (0.25)	24.2	<0.0001

^a[DMFS (calculus-free) – DMFS (calculus-prone)]/DMFS (calculus-free).

Table 1b. Relationship between calculus prevalence and caries incidence at end of Study 1 (only users of non-zinc toothpastes, *N* = 1172)

Fluoride (ppm F)	1000		1500		2500	
Calculus status at baseline	% Calculus formers at end	Mean DMFS increment (SE)	% Calculus formers at end	Mean DMFS increment (SE)	% Calculus formers at end	Mean DMFS increment (SE)
Free	11 (37/325)	7.59 (0.36)	11 (30/284)	7.06 (0.36)	6 (9/147)	6.76 (0.52)
Former	40 (58/144)	5.10 (0.54)	51 (91/180)	5.03 (0.36)	51 (47/92)	3.65 (0.46)

Table 2. Relationship between caries incidence and calculus prevalence at the end of Study 2

Toothpaste used during trial ^a	Calculus-free subjects		Calculus-prone subjects ^b	
	<i>N</i>	Mean DMFS (SE) ^c	<i>N</i>	Mean DMFS (SE) ^c
Control	59	15.80 (1.16)	51	14.04 (1.17)
2500 ppm F	47	13.87 (1.21)	71	10.07 (0.84)
All	106	14.94 (0.84)	122	11.73 (0.69)

^aSubjects not supplied with paste during years 4–6.

^bSubjects with calculus status coded 3 or 4.

^cSix-year caries increments for teeth unerupted at baseline.

effect' is of nonstatistical significance by analysis of variance using data within Table 1b, although this could be due to low statistical power).

Table 2 shows that the 6-year caries increments recorded in the Isle of Lewis study were lower for children who had exhibited supra-gingival calculus at some time during the study than for those who were always calculus free (*P* < 0.005). This tendency was found for both users of the 2500-ppm F toothpaste and the nonfluoride control paste.

Data from the Port Sunlight calculus trial are listed in Table 3. The study population is subdivided

Table 3. Relationship between 3-month Volpe–Manhold (V–M) calculus scores and caries prevalence for 20–65-year-old adults in Study 3

Age (years)	<i>N</i>	Calculus incidence (mean V–M score)	Caries prevalence (mean DMFT)	Correlation coefficient
<30	62	5.02	11.58	0.033 (ns)
31–35	73	5.89	17.01	–0.092 (ns)
36–40	98	6.40	17.72	–0.228 (<i>P</i> < 0.05)
41–45	85	6.88	18.69	–0.247 (<i>P</i> < 0.05)
46–50	70	8.20	18.66	–0.500 (<i>P</i> < 0.001)
>50	49	8.79	19.12	–0.252 (<i>P</i> < 0.08)

ns, Not significant.

into groups of narrow age range. Both mean calculus increment and mean caries prevalence generally increase with increasing age across the subgroups. Despite this trend, within many subgroups, 3-month calculus increment scores are significantly inversely correlated with corresponding caries prevalence scores on an individual basis.

Discussion

Caries clinical trials have traditionally involved large numbers of subjects and been very costly and time-consuming to undertake. For the most part the major aim of such trials has been to compare the performance of various treatments such as toothpastes and mouthwashes. Because of the large statistical inter-subject variation inherent in such studies, various means of balancing the study groups at baseline have been used over the years in attempts to improve the potential ability of trials to discriminate between investigational products. From the point of view of study sponsors and researchers alike, the ability of a study to generate results that truly reflect the relative performance of products under evaluation should be optimized as

far as practically possible in order to justify the huge investment involved.

The presence of calculus can be readily detected by a dentist and so would make a good selection criterion, if a relationship to caries can be demonstrated convincingly. In all three of the diverse studies presented here, an inverse association between calculus and caries is observed.

In the large caries clinical trial, Study 1, calculus prevalence at baseline was highly correlated with corresponding baseline caries prevalence and, key to its use as a caries predictor, was also clearly inversely associated with subsequent 3-year caries increment (Tables 1a,b). Children classified as calculus formers at the start of the trial were 24% less likely to have caries at that time than their caries prone counterparts and 29% less likely to develop caries over the 3-year trial period. These differences are clinically significant. They are of the same magnitude as the anticaries benefit conferred by the 2500 ppm F toothpaste compared with the 1000 ppm F toothpaste in the trial and also observed for 1000 ppm F toothpastes compared with corresponding non-F control pastes averaged over the many clinical trials conducted previously on such formulations (10, 11).

It is perhaps not surprising that a similar relationship exists between baseline calculus status and both mean baseline caries prevalence and corresponding mean 3-year caries increment. This is because a direct relationship between caries prevalence and subsequent caries increment has long been known (12–14). For example, Fig. 1, in which data for all three fluoride groups have been combined, shows such a relationship for the current trial. Notwithstanding this relationship, however, Fig. 2 demonstrates that when the same data

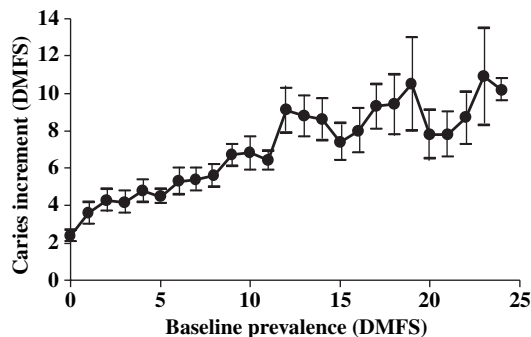


Fig. 1. Dependence of 3-year caries increment on baseline caries prevalence for Study 1: mean increments \pm 1 standard error.

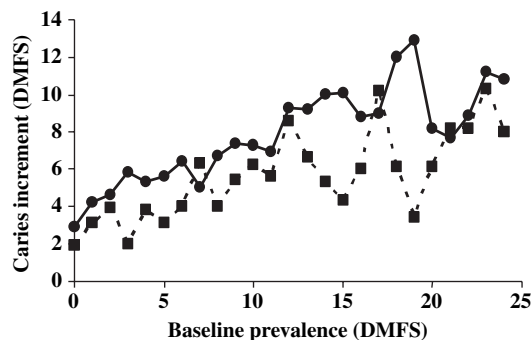


Fig. 2. Influence of calculus status on relationship between 3-year caries increment and baseline caries prevalence for Study 1: calculus-free (●) and calculus-prone (■) groups at baseline, respectively.

are separated into baseline calculus-prone and calculus-free groups, the former group has a consistently lower caries increment over the entire range of baseline caries prevalence. The wide fluctuations at the upper end of the prevalence range are because of the progressively lower numbers of subjects with high caries.

The data in Table 1b also highlight the fact that the inverse calculus–caries relationship appears to be largely independent of fluoride treatment.

Essentially similar observations are seen in Table 2, which shows the results of the Isle of Lewis study, Study 2. The 6-year caries increments were lower for children who exhibited calculus at some time during the course of the study than for those who were always calculus free. This trend was found for both the children who had used the fluoridated toothpaste, at least in the first 3 years, and those who had likewise used the fluoride-free control. The data also suggest a tendency for the presence of fluoride to be more beneficial against caries in calculus formers than in subjects who were calculus free. A possible explanation for this behaviour could be that calculus provides a reservoir for orally retained fluoride.

It is important to appreciate that the findings presented here are mirrored by corresponding (and likewise previously unreported) results from several other Unilever-sponsored caries clinical trials, in which calculus was assessed in a similar way. Duckworth and Huntington give more details elsewhere in a separate review (15). Average differences in caries increments between calculus-prone and calculus-free subjects for each fluoride concentration in the toothpastes tested were all in the range 20–27%.

The above studies involved children within a narrow age span. Calculus is more prevalent in adults than in children and it was therefore of interest to test for the calculus–caries relationship in an older population. The results of a large calculus study conducted with subjects in the age range 20–65 years are summarized in Table 3. Within many subgroups of narrow age range, 3-month Volpe–Manhold calculus increment scores are significantly inversely correlated with corresponding caries prevalence scores on an individual basis, even though only calculus formers took part in the study. Only in the youngest age group was there no negative correlation. The relatively weak correlation in the oldest age group is partly because of the low number of subjects. In addition, tooth loss because of periodontal disease may have been a confounding factor in the DMFT scores for this subgroup.

A notable feature of this last study is that both calculus and caries increase with increasing subject age, as expected. This behaviour masks the relationship between the two parameters when the whole data set is used, and could well be a reason for the apparently inconsistent findings by other authors.

Table 4 lists published clinical studies that concern caries and calculus, together with the present work. The published studies provide varying degrees of support for an inverse relationship. Whereas there appears to be a number of different reasons for why studies failed to show a significant inverse relationship, factors common to

those studies demonstrating significance are: a large study population and/or a narrow age range (in total or in relevant subgroups). The last mentioned factors are consistent with the present findings.

In the first major review of the literature on calculus in 1969, Schroeder (1) cited four clinical studies in which the relationship between calculus and caries was investigated, of which only two showed the anticipated negative correlation that predominates in the Unilever-sponsored trials. The other studies showed no relationship. Furthermore, Schroeder pointed out that in one of the two examples of a negative correlation the relationship was misleading. The subject population were Eskimos in whom caries prevalence was markedly lower for ages over about 18 years old, the opposite of the usual trend. This finding was thought to be caused by a change in diet of the younger age groups. The only convincing, and statistically significant, negative correlation between supra-gingival calculus and caries up to that time, therefore, was by Marthaler and Schroeder (16). They probably achieved this result because the age range of their subjects was narrow, 8–15, and the study population was large, 4300.

Of the studies that indicated no relationship, that reported by Stones et al. (17) involved small population subgroups whilst in that by Little et al. (18) caries appeared to decrease with increasing subject age, which casts doubt on the validity of the caries–calculus comparison.

Table 4. Relationship between caries and supragingival calculus in various studies

Reference	Subject no.	Calculus–caries relationship	Comments
1	Not known	Inverse, significant	But correlation attributed to diet change
16	4300	Inverse, significant	Large population, narrow age range
17	280	Positive/inverse, ns	Small population subgroups
18	295	No correlation	Questionable study?
19	1131	Inverse, significant	Large population, significance achieved by dividing subjects into subgroups of narrow age range
20	149	Inverse, significant; inverse, ns	For primary teeth; for permanent teeth; lower no. than primary teeth
21	1993	No correlation	Wide age range
22	2000	Inverse	Relatively narrow age range
23	602	Inverse, significant	Weak significance may be because of wide age range
24	273	Positive, ns	Root caries study
25	439	No correlation	Inappropriate comparison?
This work [Study 1]	2316; 1172	Inverse, significant; inverse	Baseline prevalence; baseline calculus vs. caries incidence
Study 2	428	Inverse, significant	Calculus prevalence vs. caries incidence
Study 3	437	Inverse, significant/ns	Inverse relationship observed in subgroups of narrow age range

ns, Not significant.

Few papers that mention a possible link between calculus and caries have been reported since Schroeder's time. In the most direct of these, Manji et al. (19) presented data from an oral health study involving 1131 Kenyans aged 15–65 years. By dividing the subjects into narrow age bands, these authors were able to demonstrate an inverse, but weak, association between calculus and caries. They concluded that the correlation was not strong enough to be of clinical significance. Of six further relevant studies (20–25), an inverse association between calculus and caries was reported in three (20, 22, 23). In each case, the correlations were weaker than those found in the present work.

Crossner and Holm (20) observed a significant inverse correlation between supra-gingival calculus and caries in the primary teeth of 149 eight-year-old children, but not between calculus and caries in the permanent teeth. These authors commented that their careful clinical diagnosis of calculus (as indicated by the higher prevalence of calculus found than in an earlier study) was the probable explanation for their study confirming the inverse relationship in such a young age group. The lack of a significant correlation in the permanent dentition would have been due to the relatively low number of such teeth erupted in the children.

Cahen et al. (21) found that both calculus and caries increased with age in an oral health study of 1993 young adults but did not report any correlation between the two parameters. In an earlier study (22) of 2000 children, the same research group estimated calculus to be fourth in the order of factors influencing caries prevalence after subject age, social group of father and sex. The correlation between caries and calculus was negative, in agreement with expectation.

A weak, but statistically significant, negative correlation between calculus and caries incidence was found by Berkey et al. in a 10-year longitudinal study of caries lesion progression in 602 adults (23). Calculus correlated much better with plaque, gingivitis and pocket depth, whilst caries correlated best with plaque, baseline caries and subject age. Overall this study highlights another probable masking factor of any calculus–caries relationship, general oral hygiene.

DePaola et al. (24), in a study of the clinical profiles of 273 adults with and without root surface caries, found that those without root caries had less coronal caries and less calculus, as well as more teeth, less recession, less debris, less gingivitis and

more abrasion, than subjects with root caries. They attributed 'most, if not all, of the differences' to one underlying factor, oral hygiene.

Pattanaorn and Navia (25) reported a study of calculus, caries and gingivitis in a young Thai population of high calculus prevalence. They found no relationship between calculus and caries, which may have been because their 'no calculus' group was not actually calculus free and/or because caries prevalence was low, 42% of subjects being caries free.

Calculus status has been successfully employed, in the sense that sensitivity increased, in recent trials sponsored by Unilever (26–28). One example is the 3-year caries clinical trial of Stephen et al. (26), which involved 4294 children at the outset and compared the efficacy of six different toothpastes. The factors used for stratification were: clinician (of which there were two), gender (male/female), presence of supragingival calculus on lower incisors (yes/no) and caries status at baseline (four categories). The general linear model used for data analysis included all of these factors together with: active type (NaF or SMFP), fluoride concentration (1000 or 1500 ppm), plus all two-level interactions. After excluding nonsignificant terms, the model reduced to: DMFS increment = linear function of (baseline caries status, baseline calculus, interaction between baseline calculus and baseline caries, active type). The result of this analysis revealed mean DMFS increment to be highly significantly associated with baseline caries status ($P < 0.0001$), baseline calculus ($P < 0.0001$) and the interaction between these two parameters ($P < 0.0003$).

The above authors noted that both subsets of subjects, with and without calculus, showed the expected monotonic increase in DMFS increment with caries status category. However, the difference between subjects with calculus and those without calculus at baseline increased progressively with caries status. In a later clinical trial, of simpler design but in which a similar stratification procedure was adopted, mean 3-year DMFS increment was again highly significantly associated with baseline calculus (27). These findings confirm the presence of supragingival calculus to be a good indicator of caries susceptibility.

There are many oral factors that may help to explain the observed relationship between caries and calculus. These are discussed by us in more detail elsewhere (15). Briefly, as found by other authors when seeking models for caries prediction and/or investigating the mode of action of salivary

components, no single determining parameter stands out. Of the many salivary and plaque factors that can potentially influence calculus and caries, only oral calcium and inorganic phosphate levels appear to make a significant independent contribution.

In conclusion, we submit that as our results from large-scale clinical studies show calculus to be a good indicator of caries (albeit with the potential limitation of the lack of examiner reliability measures being taken for calculus in Studies 1 and 2), baseline calculus status could be a useful stratifying factor or exclusion criterion for caries clinical trials. This approach should mean fewer subjects are needed to run a successful trial—benefits that should be more marked for a narrow age band. Indeed, Unilever has subsequently utilized calculus in the belief that such benefits are worthwhile.

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