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What is This?
The Influence of dft Index on Sealant Success: A 48-month Survival Analysis

M. Bravo1, E. Osorio2, I. García-Anllo1, J.C. Llorda1, and P. Baca1

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Abstract. Early loss of pit and fissure sealants is considered to be primarily dependent on inadequate isolation of the tooth from salivary contamination during application. Gradual additional loss is considered to be caused by occlusal wear, shearing forces, and marginal failure. Our hypothesis is that the caries risk of the child may be an additional factor in sealant loss. The objective of this study was to analyze the influence of caries history in primary teeth (dft index) on the success of sealants. Delton light-polymerized sealant was applied in 104 six- to eight-year-old children, followed for four years on a six-month-visit basis. All sound permanent first molars were sealed during the study. A survival analysis was used to describe sealant success over time. A Cox proportional hazards regression model was built to test the influence on sealant success of the dft index and site of sealant application (mandibular occlusal surface, maxillary fossae, and maxillary disto-lingual fissure), controlling for some potential confounders. Sealant half-life was 46 months. Site and dft index were related to sealant survival. The maxillary fossae showed the best retention, followed by the mandibular occlusal site and the maxillary disto-lingual fissure. The higher the dft, the higher the risk of sealant failure. This study has implications for sealant study designs and public sealant programs.

Key words: Dental caries, pit and fissure sealant, survival analysis.

Introduction

The first series of clinical trials on sealants was conducted with a half-mouth design, in which caries prevention in sealant-treated teeth was compared with that in untreated teeth in the same mouth. Once sealants were accepted as an adequate measure for the prevention of pit and fissure caries, this type of design was no longer considered ethical. Early papers on first-generation sealants demonstrated that effectiveness was a direct function of sealant retention, so total retention became the usual way to address sealant effectiveness when no control teeth were available (Ripa, 1985; Weintraub, 1989).

Initial sealant loss is caused by errors in technique, most prominently the failure to isolate the tooth adequately from salivary contamination during application (Ripa, 1985, 1993; Weintraub, 1989). Gradual additional loss is considered to be caused by occlusal wear, shearing forces, and marginal failure (Feigal et al., 1993).

The presence of small caries lesions in fissures does not seem to have an adverse effect on resin-bonding to enamel (Silverstone, 1974). Furthermore, a 24-month clinical trial with 1766 sealed teeth among 12- to 14-year-old children reported similar retention figures in sound and carious posterior teeth (Handelman et al., 1987). There is evidence that bacteria decrease in the fissure when sealed (Going et al., 1978; Jensen and Handelman, 1980; Mertz-Fairhurst et al., 1986; Chapko, 1987; Kramer et al., 1993) and that intact sealants prevent further progression of a sealed caries lesion, both visually and radiographically (Mertz-Fairhurst et al., 1979a,b; Handelman et al., 1986).

However, the success of sealants in children with high caries activity has not been studied extensively. The hypothesis tested in this study is that the caries risk of the child may be a factor in sealant loss. Children with high caries activity could be more likely to experience demineralization of the enamel around the sealant, since the sealant per se does not reduce the individual's caries risk, as measured by the numbers of mutans streptococci in saliva (Carlsson et al., 1992; Songpaisan et al., 1994). Also, artificial demineralization progression in vitro is arrested with a
Materials and methods

Sample of children
The study was carried out in Granada (where water is fluoridated at 0.07 ppm), a city in Andalucia (Southern Spain) with a population of 250,000. The seven-year-old Andalusian schoolchildren had an average dmft (decayed, missing, and filled primary teeth) of 3.54 and an average DMFT (decayed, missing, and filled permanent teeth) of 0.66. About 95.5% of the DMFT was attributed to decay (Salas-Wadge, 1994), indicating little restorative attention, attributable to the virtual absence of community oral health programs and limited access to dental care.

This study was part of a larger caries-prevention clinical trial which began in 1990 (Bravo et al., 1996). Grades 1 and 2 students from two of the 21 primary schools in the city’s northern district (pop. approx. 30,000, middle and lower-middle socio-economic levels) were selected to receive sealants (sealant group). There is no preventive school-based dental program in Granada (brushing, fluoride rinse, fluoride tablets, etc.), and none was implemented during the study period. This study was approved by the Ethics Committee, Faculty of Dentistry, University of Granada. A total of 112 children or 87% of the parents consented to allow their children to participate in the study. Of the children in the sealant group, eight (7%) did not receive any sealant because either they had no sound permanent first molars (n = 5) or no molar was fully erupted during the study (n = 3). Therefore, results refer only to the 104 children who received at least one sealant.

Application of sealants
Delton® light-polymerized opaque fissure sealant (Johnson & Johnson Dental Products Co., East Windsor, NJ, USA) was applied. Isolation was maintained by means of cotton rolls, and the manufacturer’s instructions were followed. Technique specifications include: use of pumice slurry, one-minute liquid acid-etching, washing with air-water spray for 20 s, 40 s of polymerization light, and 20-second re-etch when saliva contamination did occur. Following each application, the sealants were tested with an explorer for verification of retention. Sealants were applied to all sound permanent first molars at three different sites: mandibular occlusal, maxillary fossae, and maxillary disto-lingual fissure. A complete occlusal eruption, including the lingual extension of the disto-lingual fissure for the maxillary molar, was a prerequisite for the molars to be sealed. After 6, 12, 18, 24, and 36 months, sealants were applied to newly erupted molars during the study, and existing sealants were re-applied (repaired or replaced) when there was partial or total loss in any site. Total retention was considered when the site remained completely sealed or when the loss was considered clinically insignificant (i.e., loss in secondary fissures). Sealants not considered as total retentions were recorded as partial retention or partial loss when the sealant was detected in the site but with some area of the fissure without sealant, and total loss was scored when no sealant was detected.

All sealant application was carried out by a single dentist with an assistant. Portable equipment was used in the schools, as were a light source and a Heliolux® polymerization lamp (Vivadent Dental GmbH, Ellwangen, Germany).

Data collection
Caries was scored according to the criteria of the World Health Organization (1988), by means of an explorer and a flat mirror. Oral examinations were carried out every 6 months, except for the final one (in 1994), when more variability occurred during the time elapsed since the previous examination. Also recorded were birth date, sex, and socio-economic status according to the profession of the parent or guardian listed in the school registers (Registrar General, 1980). Following the first examination, a report on the need for restorative treatment was given to all the children.

Three dentists carried out the examinations—the first during the years 1990 to mid-1992, the second from mid-1992 to 1993, and the third during 1994 (the final examination). A fourth dentist participated during part of the study, but only as an experienced and external observer for inter-examiner reliability.

During the study, intra- and inter-examiner diagnostic concordance was analyzed, with the examinations being repeated in at least 10% of the children, at intervals of between one and seven days. Analysis was carried out by means of the Kappa test (Fleiss, 1981). Caries concordance data were calculated on the basis of the children participating in the large trial, rather than only those in the sealant group. Although the information available from the main records permitted a site-specific analysis, repeated examination records did not differentiate between sites in the maxillary molars. The Kappa coefficient was greater than 0.70 in all measurements (Table 1), indicating that examiners’ reliability was “very good” (Landis and Koch, 1977).

Data analysis
The sealed site was the unit of analysis for survival calculations. Only the first application of each sealant was considered, since re-applied sealants had a lower follow-up time, were placed when the children were older, and it could be argued that their retention could depend on a possibly undetectable amount of sealant remaining in the fissure. Nevertheless, as additional information of no direct relevance to this study, each site sealed during the first visit in children followed throughout the study received an average of 0.56 re-applications throughout the study (i.e., 56% re-application rate).

Final sealant status and their associated survival times in days were considered as follows:

Status censored: if the sealant was still in place (total retention) and the site was sound at the last examination for the child concerned. Survival time was calculated by subtraction of his/her last visit date from the date the sealant was placed. Other site status which in theory could be described as censored includes
restorations placed in the occlusal area because of proximal caries, and teeth lost due to reasons other than caries (Mitchell and Murray, 1987); however, in practice, these circumstances were not found during survival times in this study.

Status failed: if the sealant was recorded as being partially or totally lost with the site remaining sound, or if the site had become DMF (decayed, missing, or filled). Survival time was calculated in two steps: first, by subtracting the date on which the situation was first detected from the date on which the sealant was placed, and, second, by subtracting half the time elapsed between the detection date and the nearest previous examination.

Cumulative survival proportions for all the sealants were calculated by the life-table (actuarial) method (Lee, 1992), with six-month intervals, and with BMDP, subprogram 1L (Dixon et al., 1990). The standard errors were corrected for multiple sites within the mouth as explained above. The design effects in the survival proportion variances for each six-month interval were calculated by SUDAAN CROSSTAB PROC (Shah, 1989), and the median for those figures was taken as the design effect for the variances in the cumulative survival proportions. The uncorrected standard errors reported in the BMDP output were then multiplied by the square root of the design effect.

According to site and each child’s dft index, cumulative survival proportions were calculated by the product-limit (Kaplan-Meier) method (Lee, 1992), with one-month time precision, by means of BMDP, subprogram 1L (Dixon et al., 1990). After we looked at the dft distribution, we considered three different levels—dft = 0 (which represents 46%), dft = 1 to 3 (24%), and dft ≥ 4 (30%)—and computed them at the time the sealant was placed.

A Cox proportional hazards model (Lee, 1992) was developed with the hazard rate of sealant failure as the dependent variable. Site and dft index were forced into the model. Other variables include: social level, sex, age, other caries indices (dt, DMF, and DT) measured at the time the sealant was placed, school (because of the possibility of bias due to the random-clustered selection of children), and the “dft x site” interaction. Since the hypothesis to be tested was the influence of dft index, these variables were included in the model if they, alone or together, produced a change of at least 10% in the estimated coefficients of the forced variables, except for the interaction term, which was based on statistical significance (p < 0.05 according to the likelihood ratio test). Variables with a correlation to other variables in the model of 0.75 or greater were no longer considered, to avoid a collinearity effect. The model was built with BMDP, subprogram 2L (Dixon et al., 1990), and was then run in SUDAAN SURVIVAL PROC (Shah, 1989) to adjust for non-independence of multiple sites within the mouth. Since there were two different reasons for declaring a sealant failed (sealant lost but site sound, or site DMF), a second model was fitted excluding those DMF failed sealants, so that we could ascertain the effect of the dft index on the first reason for failure.

We tested the proportional hazards assumption, taking into account lack of independence of sites within the mouth, by SUDAAN LOGISTIC PROC (Shah, 1989), converting the survival times in six-month intervals, and looking at the interaction “interval x dft” and “interval x site”. Since the contrast for these interactions was not significant (p = 0.126), the model could be considered as adequate.

**Table 1. Intra- and inter-examiner diagnostic agreement**

<table>
<thead>
<tr>
<th>Type of Agreement &amp; Date</th>
<th>Variable</th>
<th>Number and Analytical Unit</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial (1990):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-examiner (A)</td>
<td>dft&lt;sup&gt;b&lt;/sup&gt;</td>
<td>47 children</td>
<td>0.92</td>
</tr>
<tr>
<td></td>
<td>DFT&lt;sup&gt;c&lt;/sup&gt;</td>
<td>150 M1&lt;sup&gt;d&lt;/sup&gt;</td>
<td>0.73</td>
</tr>
<tr>
<td></td>
<td>Sealant retention&lt;sup&gt;e&lt;/sup&gt;</td>
<td>71 M1</td>
<td>0.90</td>
</tr>
<tr>
<td>Inter-examiner (A vs. D)</td>
<td>dft</td>
<td>105 children</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>DFT</td>
<td>362 M1</td>
<td>0.79</td>
</tr>
<tr>
<td></td>
<td>Sealant retention</td>
<td>89 M1</td>
<td>0.71</td>
</tr>
<tr>
<td><strong>During the study (1991):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-examiner (A)</td>
<td>DFT</td>
<td>112 M1</td>
<td>0.77</td>
</tr>
<tr>
<td><strong>During the study (1992):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-examiner (A)</td>
<td>DFT</td>
<td>182 M1</td>
<td>0.91</td>
</tr>
<tr>
<td>Inter-examiner (A vs. D)</td>
<td>DFT</td>
<td>122 M1</td>
<td>0.82</td>
</tr>
<tr>
<td><strong>During the study (1993):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inter-examiner (B vs. D)</td>
<td>DFT</td>
<td>165 M1</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td>Sealant retention</td>
<td>78 M1</td>
<td>0.77</td>
</tr>
<tr>
<td><strong>End of study (1994):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-examiner (C)</td>
<td>DFT</td>
<td>177 M1</td>
<td>0.87</td>
</tr>
<tr>
<td></td>
<td>Sealant retention</td>
<td>64 M1</td>
<td>0.89</td>
</tr>
<tr>
<td>Inter-examiner (C vs. B)</td>
<td>DFT</td>
<td>234 M1</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>Sealant retention</td>
<td>72 M1</td>
<td>0.73</td>
</tr>
</tbody>
</table>

<sup>a</sup> A, B, C, and D refer to the examiners. D participated only as an external examiner for reliability control.

<sup>b</sup> Considering 3 categories: dft = 0, dft = 1 to 3, and dft ≥ 4 (where dft = decayed and filled primary teeth).

<sup>c</sup> DFT vs. sound M1 (where DFT = decayed and filled permanent first molars, considering only the occlusal area in mandibular molars and occlusal area with lingual extension of the distal-lingual fissure in maxillary molars).

<sup>d</sup> Permanent first molars.

<sup>e</sup> In previously sealed molars, total retention vs. failed sealant.

**Results**

Of the 104 children, 18 (17%) were lost during the study period because they moved to other schools, but there were no significant differences in the analyzed variables at baseline when they were compared with those of the other children (results not shown). They have also been considered in the survival estimations. Since baseline was from March to December, 1990, and the last examination was from January to April, 1994, the follow-up period, ranging from 38 to 49 months (mean = 42.06 months, SD = 4.31), was not the same for all the children. In each visit during the follow-up, only a low percentage of the followed children did not attend the examination (2-3%). Although the primary interest of the present study was sealant survival, a brief initial description of the children is presented. The mean age was 7.15 years
(ranging from six to eight years), 44% were male, the median socio-economic level was middle class, the dft index was 2.13 (SD = 2.44), the DMF index was 0.36 (SD = 0.77), the proportion of d, f, D, and F teeth that were restored [f+F/(d+f+D+F)] was 6.6%, the mean number of erupted first molars was 3.13 (SD = 1.46), and no sealant was present.

During the study, 556 sites were sealed, with 174, 191, and 191 being the corresponding figures for the mandibular occlusal site, maxillary fossae, and maxillary disto-lingual fissure. Seventy-three percent of the sites were sealed at the first visit, with the remaining 27% being sealed during the 6-, 12-, 18-, and 24-month visits. After that time, all sites had been sealed or were not eligible, since they were DMF. The mean number of sealed sites per child was 5.35 (the maximum possible is 6). The median survival time was 46 months for all 556 sealants (Table 2). Further results, not shown in Table 2, indicate that 207 sealants (37.2%) were coded as failures during the study. In 54 of these, the reason was DMF (39 D, 1 M, and 14 F), with the sealant being either partially (n = 33) or totally (n = 21) detached. In the other 153 sealants that failed, because of sealant loss but with the site remaining sound, 98 presented partial loss and 55 total loss.

The final Cox proportional hazards regression model included only the site and the dft index, which were statistically significant (Table 3). None of the other variables entered the model, since the social level, sex, age, DMFT, and DT, alone or together, did not produce a change of at least 10% in the estimated coefficients of the forced variables, and the dft was highly correlated to the dft index (r = 0.96). The coefficients for the dft levels were positive, indicating a higher hazard rate of sealant failure for high dft values compared with dft = 0. In the second model, fitted excluding the DMF failed sealants, the dft showed a lower, but still significant, effect (Table 4).

Cumulative survival proportions at different follow-up months can easily be obtained for each site or dft level from Figs. 1 and 2, respectively. First, a vertical line should be drawn over a certain follow-up month (horizontal axis) until it crosses a survival curve. A horizontal line should then be drawn from that point to the vertical axis, representing the cumulative survival proportions.

### Discussion

When the three sites are taken as a whole, retention figures in this study (Table 2) are within the published range. Clinical studies which have used third-generation sealants have been compiled by Ripa (1993), and the total retention at 12 months ranges from 75 to 97% (87.3% in our study), at 24 months from 60 to 98% (74.7% in our study), and at 36 months from 43 to 83% (61.7% in our study). Ripa (1993) does not report total retention figures at 48 months, but does for 60 months (48%), which is the longest period reported for this type of sealant. The possibility of a bias produced by sealants re-applied outside the study and not detected,
which would lead us to assign a longer life for those sealants, does not seem to be important in this study. The reason is the low number of sealants received by children in that population, as demonstrated by the fact that, over 24 months, only 13 molars were sealed in 214 children from other non-sealant cohorts in the large clinical trial in which the present study is included.

Although comparisons of sealant retention in molars between arches are inconsistent, most papers have stated the maxillary molars to have less retention (cf. Ripa, 1993). The reason for that could be problems with access, moisture control, and gravity (Mitchell and Murray, 1987). Our results allow us to conclude that the main reason should not be gravity, since the retention in the maxillary fossae is longer than that in the mandibular occlusal surface, so problems with access and moisture control in the maxillary disto-lingual fissure could explain its poorer retention.

With regard to the possible influence of caries risk on sealant retention, a meta-analysis that pooled information from 24 clinical studies of sealant effectiveness led us to generate such a hypothesis (Llodra et al., 1993). They found the following regression equation: 
\[ \text{Ln}(RR) = 1.51 \times I_2 + 0.51 \times F, \]

where \( \text{Ln} \) is the natural logarithm, \( RR \) is the relative risk between caries incidence in sealed teeth vs. control teeth (\( I_2/\bar{I}_2 \)), and \( F \) is 1 when the water supply is fluoridated and 0 when it is not. This equation means that as \( I_2 \) increases, so does the RR, i.e., sealants are less effective in high-risk children. If we consider from present knowledge that sites with intact sealants should remain sound, a possible explanation is that the effect of caries risk (high \( I_2 \)) occurred on sealant retention, but this hypothesis arises from aggregate rather than individual data.

The choice of the dft index as the caries-risk predictor variable to be tested was based on several arguments: first, because it was found to be associated with two-year caries increments in permanent first molars in another sample of six- to eight-year-old children in the same population (Bravo and Osorio, 1994); second, because this variable is simple to calculate and the age range from six to eight years offers enough inter-individual variability to be of use in prediction models; and third, because past caries experience, most often defined by dmfs or dft in this age group, has been shown as the best indicator of future caries activity among children in studies involving several factors (Demers et al., 1990), particularly as a predictor of caries in permanent first molars (Raadal and Espelid, 1992).

Results in this study suggest that baseline caries risk, measured by the dft index, is a predictor of sealant failure. This is not only because of the known association between dft and DMF (Raadal and Espelid, 1992) (DMF constitutes a criterion for a sealant being declared a failure), but also because dft seems to predict the retention itself, as shown when the dft effect was tested, eliminating DMF sealant failures (Table 4). The dft index should not be related to the earliest losses, which clearly depend on technique errors (Ripa, 1985); another factor, along with occlusal wear, shearing forces, and marginal failure (Feigal et al., 1993), could explain the gradual additional loss. In this study, only sound sites were sealed, but it is important to bear in mind that clinical diagnosis of fissure caries is a complicated and frequently unreliable procedure (Lussi, 1991). It could be argued that more incipient fissure caries was sealed in those children with higher dft due to the correlation between caries in primary teeth and fissures in permanent first molars (Raadal and Espelid, 1992). However, if it is assumed from previous studies that caries or defects in the fissure do not affect sealant retention, a possible explanation for the dft effect arises if we consider the enamel around the sealant to be unprotected by the sealant, thus subject to individual caries risk and demineralization, and thus facilitating the marginal failure of the sealant over time. A particular consideration about internal validity arises when we consider that children with high caries prevalence in the primary dentition have other social-behavioral problems. Therefore, we must

### Table 3. Cox proportional hazards model for sealant failure (n = 556 sealants)

<table>
<thead>
<tr>
<th>Variable</th>
<th>( \beta ) (SE)</th>
<th>( e^b )</th>
<th>F Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxillary fossae</td>
<td>-0.551 (0.192)</td>
<td>0.576</td>
<td>20.80, 2 df, p&lt;0.001</td>
</tr>
<tr>
<td>Maxillary disto-lingual fissure</td>
<td>0.522 (0.166)</td>
<td>1.685</td>
<td></td>
</tr>
<tr>
<td>Initial dft index*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dft = 1 to 3</td>
<td>0.609 (0.224)</td>
<td>1.839</td>
<td>9.08, 2 df, p&lt;0.001</td>
</tr>
<tr>
<td>dft &gt; 4</td>
<td>0.918 (0.221)</td>
<td>2.504</td>
<td></td>
</tr>
</tbody>
</table>

a. The event "failure" is comprised of sealant loss with sound site, or DMF site.

b. Adjusted for multiple sites within the mouth.

c. Converted to indicator dummy variables, with mandibular occlusal site as reference.

d. df, degrees of freedom.

e. Converted to indicator dummy variables, with dft = 0 as reference.

### Table 4. Cox proportional hazards model for sealant failure, excluding those due to DMF site (n = 502 sealants)

<table>
<thead>
<tr>
<th>Variable</th>
<th>( \beta ) (SE)</th>
<th>( e^b )</th>
<th>F Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxillary fossae*</td>
<td>-0.485 (0.231)</td>
<td>0.616</td>
<td>17.58, 2 df, p&lt;0.001</td>
</tr>
<tr>
<td>Maxillary disto-lingual fissure</td>
<td>0.650 (0.211)</td>
<td>1.915</td>
<td></td>
</tr>
<tr>
<td>Initial dft index*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dft = 1 to 3</td>
<td>0.397 (0.269)</td>
<td>1.487</td>
<td>3.90, 2 df, p = 0.024</td>
</tr>
<tr>
<td>dft &gt; 4</td>
<td>0.677 (0.244)</td>
<td>1.968</td>
<td></td>
</tr>
</tbody>
</table>

a. The event "failure" is sealant loss with sound site.

b. Adjusted for multiple sites within the mouth.

c. Converted to indicator dummy variables, with mandibular occlusal site as reference.

d. df, degrees of freedom.

e. Converted to indicator dummy variables, with dft = 0 as reference.
determine whether the high caries level or the ability of the child to cooperate during the delicate technique of sealant placement is the risk factor. It should be considered that once the dft and site were forced into the Cox regression model, the social level did not enter it, as explained above, and the social level does not test significantly if it is forced into the model (results not shown). Also, the number of sealant applications that needed repetition due to saliva contamination was low (4.1%), and no differences were found between social levels (results not shown).

If these findings are confirmed by others, two implications could be derived. The first relates to the question of the design of pit-and-fissure sealant studies. If the individual caries risk has an effect on sealant retention, selection in clinical trials of children on the basis of having four (or at least two) sound molars should be abandoned, since retention results would apply only to children with less caries risk than the general population. The second issue concerns the implications in public sealant programs. Since benefits result only when the sealant has been retained in the pits and fissures occurring on the occlusal surfaces, both the American Dental Association (1987) and the National Institutes of Health (1984) recommend a routine re-examination and repair of treated surfaces. The dft index could provide an easy and inexpensive indicator for selecting those children receiving less frequent re-examinations, thus reducing the program costs.

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