Ferric Sulfate and Formocresol pulpotomies in paediatric dental practice. A prospective–retrospective study

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Abstract

Aim To evaluate the use of formocresol (FC) and ferric sulfate (FS) as pulpotomy agents in vital pulp therapy (VPT) in primary molars by dental practitioners.

Materials and methods One hundred seventy-nine patients (aged 74.09 ± 20.75 months) who underwent pulpotomy were enrolled. The dmft, the number of visits, the filling materials, the clinical and radiological observations and complications were evaluated. Statistics: The data were analysed using chi-square, Spearman's rank correlation and odds ratio.

Results The analysis included the documentation of 179 patients with 276 pulpotomies: 50 (FS) and 226 (FC). The dmft was 8.54 ± 3.44. The therapeutic success was greater for FS pulpotomy and that of the two-appointment FC pulpotomy (90.6%) was higher than the one-appointment method (77.1%). Glass-ionomer cements (GIC) (53.6%), amalgam (30.0%), composites (15.6%), and steel crowns (1.8%) were used for tooth restoration. The risk of complications was lower for GI (OR = 2.21; 95% CI 1.09-4.88) compared to composite (OR = 2.62; 95% CI: 1.19 - 5.80).

Conclusions For primary teeth pulpotomy dental practitioners use both FS and FC. FC has been proven to be more effective in a two-appointmet treatment. When restoration with stainless steel crown (SSC) is not feasible, it is advantageous to use GIC rather than composite.

KEYWORD Ferric sulfate; Formocresol; Primary teeth; Pulpotomy

Introduction

Preserving primary teeth until exfoliation is one of the factors that determine the proper development of masticatory system. Primary teeth maintain space for permanent teeth and stimulate the growth of the alveolar process. Premature loss of primary teeth can cause occlusal disturbance and logopathy, impede proper nutrition and disrupts the psychosocial development. The main cause of premature extractions are pulpopathies that develop as a result of untreated caries. In the case of primary teeth with extensive caries and no symptoms of pulp pathology, vital pulpotomy is recommended [American Academy of Pediatric Dentistry, 2014; Carrotte and Waterhouse, 2009; Parisay et al., 2015; Rodd et al., 2006]. The condition of radicular pulp is evaluated intraoperatively, based on observation of bleeding after removal of the coronal pulp.

The aim of the treatment is the removal of inflamed coronal pulp, while leaving a vital radicular pulp. The procedure is performed under local anaesthesia, usually during one appointment. Radicular pulp haemostasis is most commonly achieved using cotton pellets soaked with a formocresol solution in 1:5 dilution for five minutes or 15.5% ferric sulfate for 15 seconds. In clinical practice other agents such as glutaraldehyde or non-pharmacological methods are less commonly used [American Academy of Pediatric Dentistry, 2014; Carrotte and Waterhouse, 2009; Parisay et al., 2015; Rodd et al., 2006]. In regenerative pulpotomy, the radicular pulp is covered with odontotropic agents, e.g. MTA. Important factors that influence the effectiveness of therapeutic treatment in the case of vital amputation are proper pulp diagnosis and operative technique. Teeth should be subjected to regular clinical and radiological follow-up. There are studies showing the effectiveness of each amputation method and evaluating the materials used for teeth restoration [Cehreli et al., 2006; Erdem et al., 2011; Guelmann et al., 2002, 2004, 2005; Huth et al., 2005, 2012; Kirzioglu et al., 2011; Lin et al., 2014; Smaïl-Faugeron et al., 2014; Stringhini et al., 2015]. Reports on the frequency of use of each method by dental practitioners are based on questionnaire surveys, which make it impossible to

determine the impact of treatment used on its effectiveness [Goyal et al., 2013; Hingston et al., 2007; Hunter and Hunter, 2003; Lone et al., 2015; Yoon et al., 2008; Togoo et al., 2012].

The aim of this study was to evaluate vital pulp therapy using formocresol (FC) and ferric sulfate (FS) as pulpotomy agents in primary molars by dental practitioners.

Method and materials

The study was conducted at the Department of Pediatric Dentistry of the Infant Jesus Clinical Hospital in Warsaw, which provides free dental services under the contract with the National Health Service in accordance with the list of guaranteed benefits. The study did not have the character of an experiment requiring the consent of the Bioethics Committee, however the committee was informed about the research. The procedures were in accordance with the ethical standards and with the Helsinki Declaration of 1975, as revised in 2000.

A prospective-retrospective study model was used. In the first stage a clinical protocol was developed, which was presented during the training of doctors in primary teeth pulpopathy diagnosis, techniques of performing the procedure, follow-up and documentation. Doctors who performed pulpotomies were not informed about retrospective studies planned. Training was conducted as a part of the continual dentists' training. In the second stage of the study, which lasted four years (2012-2015), therapeutic procedures were implemented. The final stage was the analysis of the medical documentation of patients. The selection of documentation was made using the procedure code 23.1204 – vital pulp amputation according to the International Classification of Medical Procedures ICD-9-CM, the type of treated tooth and the date of treatment. The analysis excluded documentation of patients with follow-up periods less than 6 months, and that of patients who did not return up for the first scheduled checkup. Health status, age of the child at the time of pulp amputation, type of treated tooth, number of teeth qualified for pulpotomy, type of agent used, type of filling used, period of postoperative observation, as well as presence of pathological radiological and clinical symptoms were recorded. The results were statistically analysed using the chi-squared test to compare fractions (percentages) between groups, the Spearman's rank correlation coefficient to evaluate pairs of features, and OR (odds ratio) to compare groups for chance of occurrence of specific events. The analyses were performed in the Statistica 12 program. For all analyses a significance level of 0.05 was assumed.

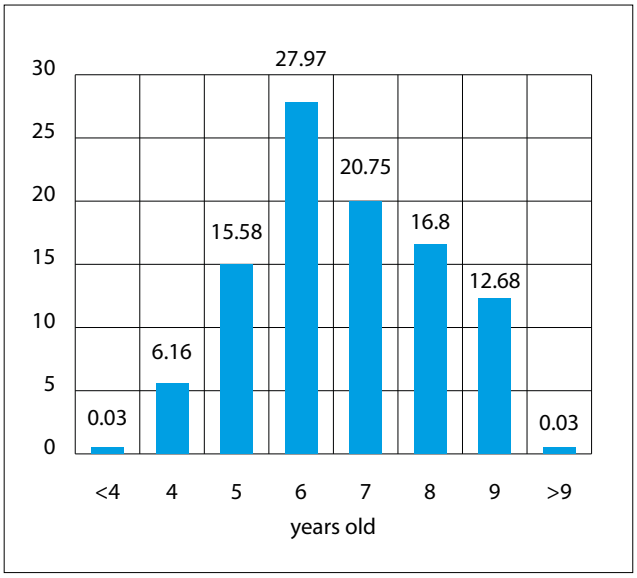

FIG. 1 Frequency of vital pulp amputation according to age of children.

Results

The vital pulp amputation procedure was performed in 305 primary teeth in 199 patients. The documentation analysis included 179 patients who had amputations in 276 primary teeth (one to six teeth in the patient). The age of children who underwent pulp amputation ranged from 23 months to 10.1 years (average age: 74.09 ± 20.75 months). Table 1 provides characteristics of the study participants, the treated teeth and relevant characteristics of the materials used for restoration. Figure 1 presents frequency of vital pulp amputation according to age of children. The procedures were performed by 8 doctors during specialisation training in paediatric dentistry under the direct supervision of a specialist. For 159 teeth, amputation was performed

Parameters		Pulp amputation			
		Ferric sulfate	Formocresol one-visit	Formocresol two-visits	Total
Average patient's age (in months)	mean ±SD	78.04±24.14	74.68±19.99	71.88±19.75	74.09±20.75
dmft		7.46±2.83	8.93±3.66	9.23±3.84	8.54±3.44
Number of teeth qualified for pulpotomy		1.41±0.66	1.42±1.01	1.65±1.14	1.52±1.02
Observation time (in months)		19.9±11.4	24.0±10.3	23.6±10.4	23.6±11.9
Glass-Ionomer Cement	n (%)	27/50 (54.0%)	51/109 (46.8%)	70/117 (59.8%)	148/276 (53.6%)
Composite		12/50 (24.0%)	19/109 (17.4%)	12/117 (10.3%)	43/276 (15.6%)
Amalgam		8/50 (16.0%)	37/109 (33.9%)	35/117 (29.1%)	80/276 (30.0%)
Steinless steel crown		3/50 6.0%)	2/109 (1.8%)	0/117 (0.0%)	5 /276 (1.8%)

TABLE 1 Age and condition of teeth of patients and materials used for the final reconstruction of tooth tissues depending on the type of pulp amputation performed.

during a single visit (50 - FS, 109 - FC). In the remaining 117 cases, two-appointment amputations were performed by placing a temporary medication consisting of a cotton pellet impregnated with diluted formocresol for three to seven days (Table 1). The reasons for two-appointment treatments were: impatience of the child not allowing to complete the procedure (n = 86) or difficulties in achieving total pulp haemostasis within four to five minutes (n = 41). In the case of 79 (28.6%) teeth, a temporary filling (zinc oxide with eugenol) was used, i.e. placement of the definitive restoration was postponed (Table 1).

The time elapsed since amputation ranged from 6 to 36 months. A total of 276 teeth examinations were performed 6 to 12 months after amputation (average 9.5 ± 2.4 months). In the period of 13-24 months from the amputation, 226 teeth (81.8%) were examined (on average after 17.9 ± 3.7 months), and in the period 25-36 months 125 teeth (45.3%) (average 33.6 ± 3.8 months).

Follow-ups were performed as part of the patients periodic comprehensive oral examination or treatment of the remaining teeth. For 32 teeth, after amputation clinical signs of infectious complications (31 fistulas, one abscess) were observed, indicating tooth extraction (Table 2). During the follow-up period of 13-24 months, 120 out of 212 teeth without clinical complications (56.6%) were radiologically checked. Radiological complications were observed in five cases (4.2%), root resorption in one case (0.85%), pulp canal obliteration in one case (0.85%). During the follow-up period of 25-36 months, 12 radiological examinations were performed in a group of 116 teeth without clinical signs of complications. One case of internal resorption was observed. The incidence of clinical complications increased with the passage of time after amputation (no statistically significant). Most complications were observed after a single-appointment formocresol amputation. There were no statistically significant differences in their incidence depending on the method used (Table 2). However, Spearman's rank correlation analysis showed a negative correlation between the occurrence of complications and the two-appointment formocresol amputation (r = -0.080; P = 0.009). Correlation coefficients for single-appointment FC amputation and FS amputation were not statistically significant (r = 0.002, P = 0.960, r = -0.047, P = 0.125 respectively). Spearman's correlation analysis showing the relationship between the occurrence of clinical complications and the age of the child during amputation, the condition of its dentition, the type of tooth treated and its location, and the technique of lost tissue restoration showed a statistically significant difference only for the material used for tissue restoration in FC amputations (Table 3). The frequency of amputation complications in each observation period, depending on the type of filling, demonstrated that significant statistical odds were recorded only in the 6–12 months follow-up period. The odds ratio of composite vs. glass-ionomer cement was 4.74 (1.21-18.50) p = 0.025, composite vs. amalgam - 23.00 (1.24-426.65) p = 0.035. As far as the complications occurring during the follow-up period of 6–36 months are considered, the reconstruction of lost tissue with glass-ionomer cement reduced the risk of complications by more than two times compared to the other materials (OR = 2.21; 95% CI: 1.09 - 4.48, P = 0.028) OR = 3.29; 95% CI: 1.37 - 7.92; P = 0.008). Composite restoration compared with other materials increased the risk of complications (OR = 2.62; 95% CI: 1.19 - 5.80, P = 0.017).

Discussion

According to the presented results, formocresol (81.9%) was significantly more commonly chosen by dentists in the treatment of pulp amputation under local anaesthesia than ferric sulfate (18.1%). Pulpotomy is still the most common treatment method in case of pulp exposure in symptom-free primary molars, but in most cases the success of pulpotomy decreases over time from over 90% during the first 6 to 12 months to 70% after 36 months or more. Although concerns have been raised about safety (i.e. mutagenicity, carcinogenicity and immune sensitisation potential) of FC application in human, no correlation between FC pulpotomies and cancer has been demonstrated and therefore FC is still regarded as the gold standard for pulpotomy [Chandrashekhar and Shashidhar., 2014; Parisay et al., 2015]. Until a biologic and reparative alternative has been identified that is clearly and reproducibly superior to formocresol, there are no scientific or toxicologic reasons to discontinue the use of FC in paediatric dentistry. When used judiciously, formocresol is a safe medicament [Chandrashekhar and Shashidhar., 2014].

Based on the Cochrane review [Smaïl-Faugeron et al.,2014] there was no evidence to identify one superior pulpotomy medicament and technique clearly. The comparisons

	Complications /amputations n (%) during follow-up period					
Amputation methos	6-12 months		13-24 months		25-36 months	
Formocresol one-appointment	6/109 (5.5%)	0.070	6/91 (6.5%)	0.638	6/54 (11.1%)	0.356
Formocresol two-appointment	2/117 (1.7%)	0.236	5/101 (4.9%)	0.656	2/53 (3.8%)	0.387
Ferric sulfate	1/50 (2.0%)	0.897	3/34 (8.8%)	0.408	1/18 (5.5%)	0.775
Total	9/276 (3.3%)		14/226 (6.2%)		9/125 (7.2%)	
Type of filling	6-12 months		13-24 months		25-36 months	
Glass-ionomer cement	4/148 (2.7%)	0.015	5/114 (4.4%)	0.092	3/47 (6.4%)	0.479
Composite	5/43 (11.6%)	0.138	4/32 (12.5%)	0.300	2/17 (11.7%)	0.917
Amalgam	0/80 (0.0%)	0.002	5/77 (6.5%)	0.521	4/58 (6.9%)	0.515

TABLE 2 occurrence of clinical complications in each observation period, depending on the type of amputation and on the type of filling material.

Material used for tooth restoration	Time of observation (in months)	Complications after amputations			
		Formocresol one-appointment	Formocresol two-appointment	Ferric sulfate	total
Glass-ionomer cement	6-12	-0.065	-0.026	0.132	-0.034
	>12-24	-0.074	-0.163	0.141	-0.076
	>24-36	0.000	0.026	-0.171	-0.025
	6-36	-0.160	-0.125	-0.030	-0.134*
Light-cured composite	6-12	0.313*	0.173	-0.080	0.202*
	>12-24	0.037	0.213*	0.027	0.106
	>24-36	0.039	-0.064	0.391	0.070
	6-36	0.157	0.164	0.081	0.147*
Amalgam	6-12	-0.173	-0.086	-0.062	-0.117
	>12-24	0.057	0.031	-0.158	0.009
	>24-36	-0.013	0.011	-0.150	-0.011
	6-36	0.011	0.025	-0.161	0.000
Steel crown	6-12	-0.033		-0.036	-0.025
	>12-24	-0.028		-0.078	-0.030
	>24-36	-0.049		-0.086	-0.044
	6-36	0.112	-	0.166	0.103

TABLE 3 Spearman rank correlations coefficients between amputation complications and final restorative material, taking into account the type of amputation agent used and the follow-up period.

between FC and FS showed no statistically significant difference between the two medicaments for any outcome at any time point. The evidence-based assessment concluded that, in human carious primary molars with reversible coronal pulpitis, pulpotomies performed with either formocresol or ferric sulfate are likely to have similar clinical/radiographic success [Loh et al., 2014]. Success rates with formocresol (FC) (85.0%) and mineral trioxide aggregate (MTA) (89.6%) are the highest among all pulpotomy methods and are not significantly different (P=0.15), with a high quality of evidence [Coll et al., 2017].

Similar or better effectiveness of ferric sulfate is emphasised [Lin et al., 2014; Smaïl-Faugeron et al., 2014; Stringhini et al., 2015]. This is consistent with our results. Based on a recent systematic review and meta-analysis by Coll et al. [2017] the FC overall success rate was 87.1% (95% CI: 78.2, 92.%), and FS's was 84.8% (95% CI: 76.2, 90.6%) with the meta-analysis favoring neither agent's success (RR 1.02 95% CI: 0.93, 1.13) (/>=0.65). In studies conducted by Huth et al. [2005] the amputation effectiveness in the 24-month follow-up were estimated to be 96.0% for the formocresol and 100.0% for ferric sulfate and after 36 months in the other study by Huth et al. [2012] 92.0% for the formocresol and 97.0% for FS. The clinical success rate of Markovic et al. [2005] at 18 months for the FC and FS groups was 90.9% and 89.2%, respectively. According to the results obtained by Erdem et al. [2011] the effectiveness of both methods was also the same (88.0%). Success rates of ferric sulphate were comparable to those of formocresol [Fuks, 2002]. No statistically significant differences were found between the assessment of the two pulpotomy agents (FC vs. FS)—96.4% clinical success rate in the FS and 97.5% in the FC groups—in the research by Ibricevic and Al-Jame [2003]. The follow-up evaluations by Sonmez et al. [2008] revealed that the success rate was 76.9% for FC, 73.3% for FS. No statistically significant differences among the four materials (FC, MTA, FS and NaOCl) were found at the 24-month follow-up (P = 0.303) in the research by Fernandez et al. [2013].

Meta-analysis has shown that in cases where lower cost of treatment is important, the use of ferric sulfate is a good choice. Despite their general knowledge of the usefulness of ferric sulfate, dental practitioners more frequently use diluted formocresol. Togoo et al. [2012] in their survey conducted among general dental practitioners in Saudi Arabia, observed that 88.0% of respondents use formocresol and only 8.0% ferric sulfate for pulp amputation. Similar studies conducted in the United States, the United Kingdom, Pakistan and India confirmed that formocresol is the most commonly used amputation agent also by dentists practicing in these countries [Goyal et al.,2013; Hunter and Hunter, 2003; Yoon et al., 2008]. Formocresol for routine pulpotomy procedure in primary teeth is used by 95% of pediatric dentists in India [Goyal et al.,2013]. Seventy-three percent of paediatric dentists practicing in the United States who used formocresol were not concerned with any adverse effects [Yoon et al., 2008].

Single-appointment amputations with the use of formocresol are effective, economic and still recommended. It is doubtful that it has a negative impact on the overall health of the child when used for amputation [Chandrashekhar and Shashidhar., 2014]. According to our observations, in the case of 42.4% procedures, a decision was made to perform a two-appointment amputation because of uncooperative child or operator's doubts about the condition of radicular pulp. Although such treatment results in much deeper radicular pulp necrosis, it has been shown to be highly effective clinically and has allowed for the preservation of teeth. The therapeutic success (90.6%)

of the two-appointment pulp amputation method using formocresol was higher than the one-appointment method (77.1%). This difference was not statistically significant, but it was on the verge of relevance. The clinical efficacy of the two-stage procedure has also been confirmed by a statistically significant negative correlation coefficient of Spearman with the occurrence of complications. Redig [1968] have proven that a one-appointment amputation technique using formocresol for five minutes produces similar results. After 18 months of clinical and radiological observation estimated therapeutic success at 82.0% for single-appointment technique and 90.0% for two-appointment, which is consistent with our results. Two stage pulpotomy is used when shorter appointments are required and for better patient management. Authors advocated two visit pulpotomy for effective management of uncooperative children.

The failure of pulpotomy treatment in primary molars has been attributed to several factors, one of which is clinical errors in diagnosis and selection of primary teeth. For example, chronically inflamed radicular pulps were believed to be non-inflamed. However, FC has proven to be a more forgivable technique because of its property of mummifying the remaining pulpal tissue, that helps to retain the tooth for a longer time. Ferric sulfate is no fixative but has bacteriostatic properties and may not act on underlying inflammatory tissue. Thus, it may not be beneficial in similar situations.

In Poland, dental caries affects 76.9% of children aged five years. The average dmft value is 4.70 ± 4.33. Every fifth five-year-olds child requires an endodontic treatment of at least one tooth, 16.3% - tooth extraction. Limiting amputation to a situation when the child well cooperates can lead to overly frequent extraction. Our results did not show a correlation between the primary dentition condition (dmft) and the number of teeth qualified for pulp amputation and complications after amputation. There was also no significant correlation between the therapeutic success of the methods used and the age of the children, the type and location of the treated tooth. Similar results regarding the type and position of the tooth were obtained by Guelmann et al. [2002]. However the authors noted that patients younger than six years old showed statistically significant higher chances for success than older children did ($P = 0.018$). The lack of significant age of patients was noted by Kirzioglu et al. [2011]. Retrospective studies by Guelmann et al. [2002] have also demonstrated that long-term complications are associated with filling leakage. Studies on the removed teeth after amputation have shown that resin-based materials provide the best marginal adaptation, and that the steel crowns placed on glass-ionomer cement are not able to provide full closure [Guelmann et al., 2004]. However, in clinical studies evaluating the effectiveness of pulpotomy, the highest success rate was achieved with steel crowns (86%), lower with the zinc oxide eugenol-based temporary restoration and Ketac Molar combined (77%) [Guelmann et al., 2005]. These results are similar to ours. We did not observe complications in teeth restoration using steel crowns, but there were only five of them. With the exception of steel crowns, irrespective of the period of observation, the smallest complications were observed using glass-ionomer cement. Kirzioglu et al. [2011] evaluated the effectiveness of pulp amputation with the use of the compomer for tissue restoration. Success of pulpotomy with FC was estimated at 95%, with FS at 79% at the end of the first year, and at 80% for FC at the end of the second year. These results are similar to those we have obtained for teeth reconstructed with composite. Composite reconstruction has been unfavourable, especially in the case of amputation with FC in the short term after amputation. However, there was no correlation between composite restoration and the occurrence of amputation complications with the use of ferric sulfate. In both methods, the paste applied to the bottom of the pulp chamber contains eugenol. The results of studies on the effect of eugenol on the polymerisation of composites vary. However, the formocresol may hinder the polymerisation. Cresol, which is part of the formocresol, diffuses into dentin canals, reacts with free radicals and inhibits polymerisation of monomers in adhesive materials, leading to a reduction in the bond strength of the adhesives and thus adversely influences the post-pulp therapy restoration. Questionnaire studies showed that endodontically treated teeth are often restored using glass-ionomer cements. They are used by 30.0% of dentists according to Togoo et al. [2012] and 26.9% to 40.0% according to Lone et al. [2015]. Composites used for teeth reconstruction after pulpotomy account for 3.3% to 11.5% in Pakistan [Lone et al.,2015]. Amalgam was the most commonly used restorative material in the study of Hingston et al. [2007]. In our research, glass-ionomer cement was most commonly used for tissue restoration. Unfortunately, steel crowns, which provide long-term restoration, have been used very rarely. However, it should be stressed that free treatment under the contract with the National Health Service does not cover the restoration using a steel crown. In the Lone et al. questionnaire study only 20.0% to 27.0% of dentists reported the use of stainless steel crown for definitive restoration after pulpotomy [Lone et al.,2015]. Similarly, in the survey conducted by Togoo et al. [2012] 24.0% dentists used stainless steel crowns. This figure, however, is far below what is quoted in literature as the standard of care.

Adverse event observation is very rare in post-operative radiographs. Radiological verification of teeth after amputation is always performed by 24.1% to 38.5% of dental practitioners in Pakistan and 59.8% in England [Hunter and, 2003; Hunter Lone et al.,2015]. In Wales, only 4.6% of dentists perform it routinely [Hingston et al., 2007]. Limitations to radiological imaging can be the age of children and the quality of the cooperation, and in Poland also the limit of only two free radiographs per year. However, the radiological diagnosis of asymptomatic teeth treated with pulp amputation is an important part of the checkup because it allows the diagnosis of progressive internal resorption, leading to primary tooth extraction thus preventing damage to the permanent tooth.

The positive aspect of our research is that doctors who performed the treatments were not aware of the planned retrospective analysis. They had the knowledge and skills to diagnose and treat pulpopathy of primary teeth. In interventional clinical trials, the procedure is strict with the protocol, which makes it possible to evaluate the effectiveness of the intervention but does not reflect the efficacy of the practitioners.

Accurate diagnosis of pulp status and proper techniques is essential for success of pulpotomy and if some doubts about condition of pulp exist, other methods such as pulpectomy or extraction must be considered. Inconsistencies of technique

and microleakage of the restorative material may also limit the success of pulpotomy. The limitation of the work is the differentiation of the clinical terms of control tests, radiological deficiencies that prevented full assessment of radiological efficacy and the small number of steel crowns used.

Conclusions

For amputation of primary teeth pulp, dental practitioners use formocresol (FC) and ferric sulfate (FS). Formocresol is used in both one and two-appointment treatment. An important determinant of effective vital pulp amputation is the type of material used for lost tissue restoration. If it is not possible to use a stainless steel crown, it is preferable to use glass-ionomer cement or amalgam rather than composite.

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