Root Canal Irrigants and Medicaments in Endodontic Malpractice Cases: A Nationwide Longitudinal Observation

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Abstract

Introduction: The aim of this study was to assess the role of root canal irrigants and medicaments in endodontic injuries verified in Finland and to estimate the rate of such events over time. **Methods:** The study material comprised all endodontic injuries verified by the Patient Insurance Centre in 2002 to 2006 (n = 521) and 2011 to 2013 (n = 449). The data, based on patient documents scrutinized by 2 specialists in endodontics, included patients' and dentists' sex and age and the service sector. We recorded the use of root canal irrigants and medicaments, each as a dichotomy. Furthermore, we dichotomized the injuries as those related to root canal irrigants/medicaments and any other injuries. The injuries were also dichotomized as avoidable (could have been avoided by following good clinical practice) or unavoidable (normal treatment-related risks). Statistical evaluation used chi-square tests and t tests; logistic regression produced odds ratios (ORs). **Results:** The verified injuries (N = 970) comprised 635 (65%) avoidable and 335 (35%) unavoidable injuries. The number of irrigant-/medicament-related injuries was 69, accounting for 7.1% of all verified injuries; all resulted from sodium hypochlorite and calcium hydroxide, and 87% were avoidable. The overall rate of sodium hypochlorite/calcium hydroxide injuries was 4.3 cases per 100,000 endodontic patients per year. Compared with other injuries, sodium hypochlorite/calcium hydroxide injuries were more likely avoidable (OR = 3.8) and more than 5-fold likely in 2011 to 2013 than in 2002 to 2006 (OR = 5.6). **Conclusions:** Extreme care is needed when applying sodium hypochlorite and calcium hydroxide into root canals to avoid increasing harmful consequences. *(J Endod 2018;44:559–564)*

Key Words

Calcium hydroxide, endodontics, injury, root canal irrigant, root canal medicament, sodium hypochlorite

Significance

We observed a marked increase in accidents related to the use of sodium hypochlorite and calcium hydroxide. Their application calls for extreme caution to avoid the harmful and potentially lifelong consequences of substance spreading into tissues outside the root canals.

Preparation of infected root canals requires plentiful rinsing to clean and disinfect the canal system. Because of its high antibacterial property, sodium hypochlorite (NaOCl) is the leading irrigant (1, 2). Interappointment medication is needed to prevent the growth of microbes between visits. To this end, calcium hydroxide ($Ca(OH)_2$) is commonly used. Both chemicals are strongly alkaline (pH = 12–14) and will cause harm when forced out of the root canals. Current guidelines for root canal treatment (3–6) stress the need for voluminous use of irrigating solution but also suggest avoiding its extrusion beyond the foramen. The same guidelines recommend $Ca(OH)_2$ as the intracanal medication during multiple treatments.

Techniques for getting a sufficient amount of irrigant to the root canal system include pipettes, syringe needles, and various machine-driven systems (7). In everyday practice, dentists have largely adapted new techniques either by lessons and self-learning of clinical series published in dental journals or under guidance given by commercial companies.

Several case reports and reviews have described harmful incidents after inadvertent contact of NaOCl or $Ca(OH)_2$ with soft tissues outside root canals (8–15). Although these incidents are relatively rare (16), their consequences are dramatic and may lead to lifelong suffering of the patient. Recently, some articles have given detailed instructions for the prevention or management of NaOCl accidents (3, 14, 17–19). Previous research on the harmful incidents related to NaOCl or $Ca(OH)_2$ consists solely of case reports, which allow no estimates of the rate of such events. Therefore, we evaluated a nationwide set of records on endodontic injuries verified in the 2000s in Finland to assess the role of root canal irrigants and medicaments in the injuries and estimate the rate of injuries at the population level.

Materials and Methods

Background

In Finland, the private and public sectors of oral health care services are almost equal in size. The public sector provides dental care to children (< 18 years) free of charge. Adults can use services from either sector, but the fees in the public sector are subsidized and notably smaller than those in the private sector, even after partial reimbursement for dental care from the Social Insurance Institute.

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Failures in health care in Finland and other Nordic countries are treated according to fairly similar systems that follow the "no blame/no fault" rule. Based on the Patient Injury Act of 1987 in Finland, all health care workers must have a patient insurance contract. The Patient Insurance Centre (PIC) handles patient health care claims and decides about the indemnity of a financial compensation for cases in which the injury could have been avoided by following good clinical practice. Patients who feel that their dental care has been substandard or has resulted in injury can submit a claim to PIC free of charge using forms available at service points and online. Submission of a claim has no restrictions regarding patient's age, service sector, or type of treatment.

Each claim is first registered in the PIC electronic database with the claimant's explanation of the incidence. After that, the PIC requests patient documents from the care provider, who is asked to give in his or her own words any additional details related to the incident. The PIC decisions are based on these documents. As part of this process, the PIC advisors assess each claim in detail and make a suggestion about whether or not there was an injury and in injury cases whether or not it had been avoidable (could have been avoided by following good clinical practice) or unavoidable (normal treatment-related risks). All PIC advisors are experienced clinicians, and they discuss the cases in monthly meetings to keep their suggestions standardized.

In 2011 to 2016, PIC handled an annual average of 7700 claims, 700 of which were related to dental care, but no detailed information about the types of injuries is given in the PIC official statistics. Previous research reports from Finland have shown that endodontics predominate in dental malpractice claims in the 2000s, reaching up to 200 claims annually (20, 21). A recent report from the United States describes a similar increasing trend in dental malpractice cases from 2004 to 2014 (22).

Ethical Considerations

Our study is based on decisions made by the PIC on endodontic malpractice claims in 2002 to 2006 and 2011 to 2013. The PIC, together with the Ministry of Social Affairs and Health, approved the study protocol. To further ensure fulfillment of ethics criteria, running numbers were the only identifiers for the cases in the database.

Data Collection

The target cases covered all endodontic malpractice claims with decisions made by the PIC in 2002 to 2006 and 2011 to 2013. We selected the 2 periods to illustrate changes in the frequency and type of injuries over time. Two dental advisors, both specialists in endodontics, scrutinized all documents gathered of the endodontic malpractice claims. For the present study, the PIC advisors first recorded the document-based raw data on a computerized platform created for this purpose. Later, we tested the data for logicality and possible errors and corrected any mistakes to fit the recordings with original patient documents, rescrutinized by 1 of the authors (O.S.). After excluding 51 incomplete cases, a total of 1271 cases formed the target data basis for this study. According to the PIC decisions, 970 of the 1271 cases had a verified injury and, thus, were analyzed here.

Data on Injury Cases

The data included the patients' sex and age; the service sector in which the treatment took place; and the dentists' sex, age, and specialization, if any. The teeth in question were categorized as anteriors (incisors and canines), premolars, or molars. Information gathered from the patient documents for this study included details about the use of root canal irrigants and medicaments, each recorded as a dichotomy and using their generic names.

The injuries recorded were perforation of the root canal or pulp chamber; a broken root canal instrument; injuries caused by any root canal irrigants and medicaments; and miscellaneous injuries such as under/overfilling, wrong diagnosis, and unnecessary treatment. For this study, we dichotomized the injuries as being or not being caused by root canal irrigants or medicaments. These statements were based on the providers' detailed information about the incidences and related symptoms and actions needed. As part of processing the claims, the PIC advisors categorized the type of injuries as avoidable or unavoidable.

TABLE 1. Characteristics of Cases with Endodontic Injuries Verified by the Patient Insurance Centre in Finland in 2002 to 2006 and 2011 to 2013

Characteristics of cases	All injuries, *n* (%)	Avoidable, *n* (%)	Unavoidable, *n* (%)	*P* value
Total (in 8 years)	970 (100)	635 (65.5)	335 (34.5)	—
Data periods (years)				
2002–2006	521 (100)	356 (68.3)	165 (31.7)	.043
2011–2013	449 (100)	279 (62.1)	170 (37.9)	
Patients				
Women	690 (100)	454 (65.8)	236 (34.2)	.732
Men	280 (100)	181 (64.6)	99 (35.4)	
Service sector				
Private	524 (100)	344 (65.6)	180 (34.4)	.896
Public	446 (100)	291 (65.2)	155 (34.8)	
Dentists				
Women	595 (100)	379 (63.7)	216 (36.3)	.115
Men	370 (100)	254 (68.6)	116 (31.4)	
General practitioner	915 (100)	598 (65.4)	317 (34.6)	.772
Specialist	55 (100)	37 (67.3)	18 (32.7)	
Type of tooth				
Anterior	104 (100)	67 (64.4)	37 (35.6)	.913
Premolar	236 (100)	157 (66.5)	79 (33.5)	
Molar	630 (100)	411 (65.2)	219 (34.8)	
Patients' age (years)				
Mean (SD)	44.2 (14.2)	43.4 (14.2)	45.9 (14.0)	.009
Range, median	12–85, 43.8	12–85, 43.0	15–85, 44.9	
Dentists' age (years)				
Mean (SD)	45.4 (10.4)	46.0 (10.5)	44.2 (10.0)	.010
Range, median	24–75, 45.3	24–75, 45.9	24–75, 44.3	

SD, standard deviation.

TABLE 2. Use of Root Canal Irrigants and Medicaments in Cases with Any Type of Endodontic Injuries Verified in 2002 to 2006 and 2011 to 2013

Root canal irrigants and medicaments	All cases *N* = 970, *n* (%)	2002–2006 *n* = 521, *n* (%)	2011–2013 *n* = 449, *n* (%)	*P* value
$Ca(OH)_2$				
Documented use	734 (76)	388 (74)	346 (77)	.349
No documented use	236 (24)	133 (26)	103 (23)	
NaOCl				
Documented use	403 (42)	139 (27)	264 (59)	<.001
No documented use	567 (58)	382 (73)	185 (41)	
EDTA				
Documented use	132 (14)	0 (0)	132 (29)	<.001
No documented use	838 (86)	521 (100)	317 (71)	
CHX				
Documented use	102 (11)	4 (1)	98 (22)	<.001
No documented use	868 (89)	517 (99)	351 (78)	
NaCl				
Documented use	58 (6)	23 (4)	35 (8)	.027
No documented use	912 (94)	498 (96)	414 (92)	

$Ca(OH)_2$, calcium hydroxide; NaOCl, sodium hypochlorite; EDTA, ethylenediaminetetraacetic acid; CHX, chlorhexidine; NaCl, sodium chloride.

The first category refers to injuries that could have been avoided had the operator followed good clinical practice, whereas unavoidable injuries refer to normal treatment-related risks. The decision between these 2 options is a standardized judgment of the PIC advisors.

Data of Endodontic Patients in Finland

The Social Insurance Institute provides annual statistics of patients reimbursed for their treatment in the private sector. In the last decade, the number of endodontic patients has been around 100,000 per year (23). In the public sector, the number of endodontic patients is at the same level (24). Based on these sources, we estimated that annually about 200,000 endodontic patients are treated in Finland.

Statistical Methods

To evaluate differences between the groups, we used chi-square tests for frequencies and *t* tests for mean values. We calculated cross product–based odds ratios (ORs) and their 95% confidence intervals to assess the bivariate relationships between various background factors and the presence of any irrigant/medicament injuries. We assessed the rates of irrigant/medicament injuries using the available information of numbers of endodontic patients as the basic population. Finally, we applied logistic regression modeling to explain factors related to the presence of irrigant/medicament injuries and calculated the corresponding ORs and 95% confidence intervals. Analyses were performed with Survo MM, software (version 3.4.1; Survo Systems, Helsinki, Finland).

Results

The verified injuries (n = 970) comprised 635 (65%) avoidable and 335 (35%) unavoidable injuries. Table 1 shows their comparisons according to background characteristics. The avoidable injuries were less frequent, and the unavoidable ones were more frequent in 2011 to 2013 than in 2002 to 2006 (P = .043). We also found differences in 2 other aspects: patients' age and dentists' age. Relative to patients with unavoidable injuries, patients with avoidable injuries were younger, and their dentists were older.

Table 2 shows the documented use of root canal irrigants and medicaments. The use of $Ca(OH)_2$ was documented in 3 of 4 cases and the use of NaOCl in almost half of the cases; for all others, their use was documented less frequently. The documented use of $Ca(OH)_2$ remained at the same level over time, whereas documentation of the use of all others increased notably.

Two cases from our data were accompanied by illustrated documentation (Figs. 1 and 2) of the damage after root canal treatment, showing the potential severity of consequences. A 46-year-old male patient had an upper first molar treated. Within the next 2 weeks, he had a large necrotic soft tissue lesion on his left cheek (Fig. 1) identified as Nicolau syndrome. The injury left an irreversible defect on his face. A 40-year-old female patient sustained long-term loss of sensation on the side of the mandible where a lower first molar was treated and $Ca(OH)_2$ had been forced into the mandibular nerve canal (Fig. 2).

Table 3 shows comparisons between the presence of NaOCl or $Ca(OH)_2$ injuries and all other injuries according to their background characteristics. Relative to all other injuries, NaOCl or $Ca(OH)_2$ injuries were more likely to occur in 2011 to 2013 than in 2002 to 2006 (OR = 5.6) and to belong to the group of avoidable injuries (OR = 3.8) and twice less likely to occur in molars than in other teeth (OR = 0.5). In these comparisons, we found no differences according to the sex (P = .449) or specialization (P = .557) of the dentist.

The total number of injuries caused by root canal irrigants and medicaments was 69, constituting 7.1% of all verified injuries; the corresponding proportions were 2.5% in 2002 to 2006 and 12.5% in 2011 to 2013 (P < .001). Half of these injuries were in molars (34/69, 49%), 36% (25/69) in premolars, and 15% (10/69) in anteriors; 87%

Figure 1. A necrotic soft tissue lesion on the left cheek of a 46-year-old male patient 2 weeks after he underwent root canal treatment of an upper first molar. The incident left an irreversible defect on his face.

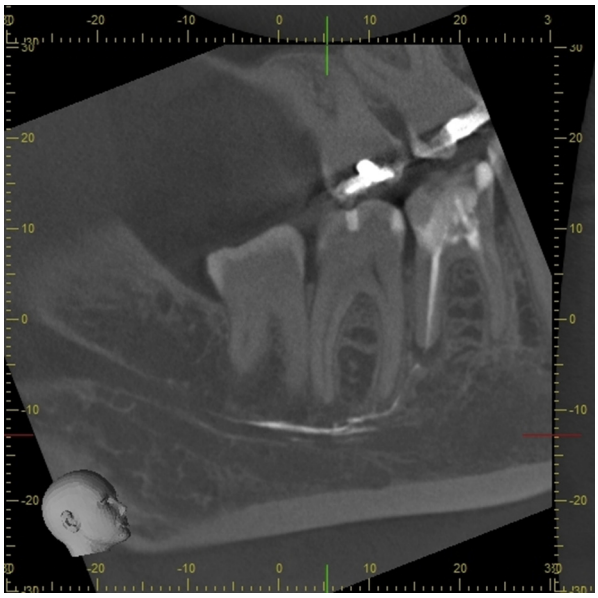

Figure 2. A 40-year-old female patient underwent root canal treatment of a lower first molar, and $Ca(OH)_2$ ended up in the mandibular nerve canal, resulting in long-term loss of sensation on the corresponding side of the mandible.

(60/69) belonged to the category of avoidable injuries. All root canal irrigant/medicament injuries were linked to the use of NaOCl and/or $Ca(OH)_2$.

The estimated occurrence of NaOCl or $Ca(OH)_2$ injuries pooled across the 8 years was 0.0043% (ie, 4.3 cases/100,000 endodontic patients per year). For the earlier 5-year period, the corresponding figures were 0.0013% and 1.3 cases per 100,000 endodontic patients per year. For the later 3-year period, the estimate was 0.0093% (ie, 9.3 cases/100,000 endodontic patients per year).

Table 4 shows 2 logistic regression models of the associations between selected background factors and the presence of NaOCl or $Ca(OH)_2$ injuries among all verified endodontic injuries. Molars were 2-fold less likely (OR = 0.49, model A) and premolars 2-fold more likely (OR = 1.84, model B) to sustain an NaOCl or $Ca(OH)_2$ injury than another injury. Among all injured teeth, those treated in the public sector were almost twice as likely (OR = 1.72–1.78) to have NaOCl or $Ca(OH)_2$ injuries than other injuries. The multivariate logistic modeling found no impact of patients' or dentists' age on the likelihood of the presence of NaOCl or $Ca(OH)_2$ injuries within all verified endodontic injuries.

Discussion

Injuries related to the use of NaOCl or $Ca(OH)_2$ as root canal irrigants and/or medicaments formed a minority of the verified endodontic injuries, showing a notably increasing trend from 2002 to 2006 to 2011 to 2013. Most of the verified endodontic injuries, particularly the NaOCl or $Ca(OH)_2$ injuries, were avoidable. These findings may indicate dentists' insufficient training with new application techniques before taking them into use. Furthermore, it can be speculated that dentists' increasing stress and demands in clinical work (ie, to be effective and to treat more patients in a shorter time) have led to more injuries. Recently, Swedish dentists have reported elevated levels of stress and frustration in performing root canal treatment (25).

In 2011 to 2013, about 9 of 100,000 patients receiving root canal treatment sustained a potentially severe complication related to the use of NaOCl or $Ca(OH)_2$. The level of damage caused by the injuries was not the focus of this study, but our most complicated cases, 2 of them illustrated here, are similar to those described in many previous articles (12, 17, 26–29). This highlights the seriousness of these relatively rare injuries. Extreme caution should always be taken when NaOCl and $Ca(OH)_2$ are applied because both agents are strongly alkaline and highly cytotoxic. A high concentration of NaOCl has been established to give a better effect than 1% and 2% solutions (7). In the United States, the commonly used concentration of NaOCl has been 5.25% compared with 2.5% in Finland. The latter may increase because the recently published Finnish guidelines for endodontic treatment suggest the use of solutions up to 6%.

An alarming finding was the increase in the rate of NaOCl and/or $Ca(OH)_2$ injuries over the years. The risk may still be considered low,

TABLE 3. Distributions (%) of All Verified Injuries according to Time and Type of Injury and Tooth and Separately for Sodium Hypochlorite (NaOCl) or Calcium Hydroxide ($Ca[OH]_2$) Injuries with All Other Injuries

Background of injuries	All verified injuries, *N* = 970 (100%)	NaOCl/$Ca(OH)_2$ injuries, *n* = 69 (7.1%)	Other verified injuries, *n* = 901 (92.9%)	*P* Value
Data periods				
A: 2002–2006	521 (100)	13 (2.5)	508 (97.5)	<.001
B: 2011–-2013	449 (100)	56 (12.5)	393 (87.5)	
B vs A: OR (95% CI)	—	5.6 (3.0–10.3)	1.0	
Service sector				
A: Private	524 (100)	29 (5.5)	495 (94.5)	.038
B: Public	446 (100)	40 (9.0)	406 (91.0)	
B vs A: OR (95% CI)	—	1.7 (1.0–2.8)	1.0	
Type of injury				
A: Unavoidable	335 (100)	9 (2.7)	326 (97.3)	<.001
B: Avoidable	635 (100)	60 (9.4)	575 (90.6)	
B vs A: OR (95% CI)	—	3.8 (1.9–7.7)	1.0	
Type of tooth				
Anterior (A)	104 (100)	10 (9.6)	94 (90.4)	.017
Premolar (P)	236 (100)	25 (10.6)	211 (89.4)	
Molar (M)	630 (100)	34 (5.4)	596 (94.6)	
A vs P + M: OR (95% CI)	—	1.5 (0.7–2.9)	1.0	.294
P vs A + M: OR (95% CI)	—	1.9 (1.1–3.1)	1.0	.017
M vs A + P: OR (95% CI)	—	0.5 (0.3–0.8)	1.0	.004

CI, confidence interval; OR, odds ratio.

P values based on chi-square tests; ORs and their 95% CIs defined as cross products.

TABLE 4. Associations of selected background factors with the presence of the NaOCl or $Ca(OH)_2$ injuries among all verified injuries (n = 970) according to two separate logistic regression models;

Models and parameters	Estimate	SE	OR	95% CI	*P* value
Model A (for molars)					
Patients' age (years)	0.003	0.010	1.00	0.98–1.02	.733
Dentists' age (years)	0.024	0.013	1.02	1.00–1.05	.068
Public service (reference private)	0.541	0.270	1.72	1.01–2.91	.010
Molars (reference other teeth)	−0.716	0.277	0.49	0.28–0.84	.009
Constant term	−3.753	0.815			
Model B (for premolars)					
Patients' age (years)	0.009	0.010	1.01	0.99–1.03	.354
Dentists' age (years)	0.025	0.013	1.03	1.00–1.05	.055
Public service (reference private)	0.577	0.269	1.78	1.05–3.02	.032
Premolars (reference other teeth)	0.610	0.275	1.84	1.07–3.15	.026
Constant term	−4.665	0.763			

CI, confidence interval; OR, odds ratio; SE, standard error of the estimate.

but these injuries are usually serious and may lead to permanent harm and excessive costs to the PIC, leading to increasing insurance fees to be paid by the dental profession. Because avoidable injuries strongly predominated here, there is much room for improvement in following good clinical practice. To date, the Good Practice Guidelines have neglected to provide detailed instructions for preventing these injuries. However, some educational articles have given sufficient practical guidance for avoiding NaOCl and/or $Ca(OH)_2$ accidents and have stressed careful use of the irrigation needle (3, 30).

Many of the previous case reports have described serious injuries in molars related to the use of NaOCl and/or $Ca(OH)_2$ (10, 12, 27, 29). Based on bivariate and multivariate analyses, molars in our study seemed to be less prone to NaOCl and/or $Ca(OH)_2$ injuries than other tooth types. Half of these injuries were in molars, but because molars also had a clear majority of all injuries, a misconception is possible. The fact is that an unfavorable outcome of root canal treatment is more frequent in molars than in other teeth (31). This highlights the challenges of endodontic procedures in molars, exposing them to higher risks of injuries of any type.

Our data covering verified injuries across 8 years confirms that Finnish dentists commonly use both NaOCl and $Ca(OH)_2$ in root canal treatment, thus following current guidelines for endodontics. The dental community and commercial companies report a rather quick transition to the use of a syringe in the application of both materials. It certainly helps in fulfilling the task of plentiful rinsing of the root canal and getting the interappointment medication up to its apical third. Because harmful incidents after the use of NaOCl or $Ca(OH)_2$ have been extremely rare, dentists may still be less aware of their consequences.

To our knowledge, no previous reports exist on the rates of NaOCl and/or $Ca(OH)_2$ accidents proportional to patient populations. Our estimates can be considered fairly reliable because they are based on exact numbers of patients treated in the private sector and sufficient reporting of the numbers of patients treated in the public sector. This assessment of the risks in endodontics provides an essential tool to monitor trends in adverse events.

A strength of our study is the large amount of material, covering incidents from both private and public sectors. No economic constraints hinder patients making a claim; it is easy and free of charge. Thus, practically all serious incidents will result in a PIC claim. The PIC decisions are based on thorough scrutiny of patient documents by specialized and highly experienced clinicians. These documents include the care provider's detailed explanation about the incident and the symptoms recognized, thus giving a reliable representation of the chairside event. About 1 in 3 claims of endodontic malpractice seemed to be based on incidents that could not be confirmed as an injury. This reflects the ease of making a claim.

A limitation of our patient document-based data is the wide variation in the quality of recordings made by dentists. Unfortunately, many dentists seem to leave several details unrecorded. However, the level of documentation has improved in the last years (21), which was also seen as an improvement in documentation of the use of root canal irrigants and medicaments in our study. Still, none of the documents scrutinized gave any information about the method of the application of root canal irrigants and medicaments (ie, syringe or not and, in case of syringe, the type of needle used). A recent systematic review reports similar findings on missing information on equipment (19). Proper and detailed documents are a valuable tool to guarantee the dentist's own safety in case of suspected injuries (32, 33). This has been emphasized long before the era of electronic patient documents; in 1987, Cohen and Schwarz (32) wrote "It is extremely important for the dentist to be sure he has complete treatment records which are legibly completed in ink." The same rule is still valid and should be strictly followed. Updated guidance for endodontic record keeping is available in various formats, as are effective methods to improve its quality (34). Dental checklists have been proposed also for endodontics (35). Because many programs for patient documentation nowadays offer options to record the details of root canal treatments as well, it would be easy to make these obligatory entries, and, thus, the recording form would serve as a checklist.

Conclusions

The vast majority of related injuries were deemed avoidable. Thus, extreme caution should be exercised in the application of NaOCl and $Ca(OH)_2$ to root canals to avoid increasing occurrence of harmful consequences caused by spreading of these highly alkaline and cytotoxic materials into tissues outside the root canals.

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