RESEARCH PAPER

Post-operative Pain after Single-Visit Root Canal Treatment Obturated with a Premixed Calcium Silicate Sealer versus an MTA-Containing Resin-Based Sealer: A Randomized Clinical Trial

Running title: CeraSeal versus MTA Fillapex and post-operative pain

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Abstract

Aim: To compare post-operative pain after single-visit root canal treatment of mandibular premolars with irreversible pulpitis obturated with a premixed calcium silicate sealer (CeraSeal) or a mineral trioxide aggregate (MTA)-containing salicylate resin sealer (MTA Fillapex).

Methodology: Forty patients aged 18–40 years, each with one single-canal mandibular premolar showing signs and symptoms of irreversible pulpitis, were allocated by sex-stratified block randomization (block size 4) to CeraSeal (Group I, n = 20) or MTA Fillapex (Group II, n = 20). A single operator performed rotary nickel-titanium preparation to 30/.06, sodium hypochlorite and EDTA irrigation with ultrasonic activation, and single-cone obturation in one appointment. Pain was recorded on a 10-cm visual analogue scale (VAS) before treatment and at 24 hours and 7 days. Groups were compared at each interval with the independent-samples t test; change over time within each group was analysed with one-way ANOVA and post hoc pairwise comparisons.

Results: All 40 patients completed follow-up. Baseline pain did not differ (8.00 ± 0.79 vs 7.80 ± 1.24; p = 0.547). At 24 hours, pain was significantly lower with CeraSeal (1.10 ± 0.45 vs 1.65 ± 0.49; mean difference −0.55, 95% CI −0.85 to −0.25; p = 0.001). By day 7 pain had resolved in both groups (0.00 ± 0.00 vs 0.05 ± 0.22; p = 0.324). Pain fell significantly over time in each group (p < 0.001 for all intragroup comparisons). No patient needed rescue analgesia.

Conclusions: Both sealers produced a marked and sustained fall in pain after single-visit treatment. CeraSeal was associated with modestly lower pain at 24 hours; the difference was small in absolute terms and had disappeared by day 7.

Keywords: bioceramic sealer; calcium silicate; CeraSeal; MTA Fillapex; post-operative pain; single-visit endodontics; visual analogue scale

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Introduction

Most patients who arrive for root canal treatment are already in pain, and most leave considerably better off. A meta-analysis of 72 studies found that pain affected roughly four in five patients before treatment, about 40% at 24 hours and about 11% after one week, with intensity falling just as steeply.[1] That residual early pain still matters. It is what patients remember, it shapes how they judge the treatment, and its reported frequency varies enormously between studies, from 3% to 58% in one systematic review of single- and multiple-visit treatment.[2]

The causes are a mix of mechanical, chemical and microbial injury to the periradicular tissues.[3] Over-instrumentation, extrusion of infected debris and irrigant contact with periapical tissue can each upset the balance between residual bacteria and host defences and provoke acute inflammation.[4] Treatment-related choices also carry weight. In a prospective study of 415 patients, 40.2% reported pain within 48 hours of obturation, and single-visit treatment emerged as one of the independent predictors.[5] The latest Cochrane review reached a similar conclusion: healing outcomes were equivalent across visit protocols, but a higher proportion of single-visit patients reported pain within the first week, particularly when the pulp was vital (RR 2.16).[6] With no inter-appointment dressing to buffer the periapex, the material sealed into the canal on the same day assumes more importance.

Sealer is the part of the root filling most likely to reach periapical tissue, through the apical foramen or lateral canals, and extruded filling material can sustain a foreign-body response.[7] Calcium silicate

("bioceramic") sealers were developed partly to address this. They set by hydration, release calcium and hydroxyl ions, and precipitate calcium phosphate on contact with tissue fluid.[8] CeraSeal is a premixed, single-component example based on tricalcium and dicalcium silicate with zirconium oxide as the radiopacifier; in cell studies it released more calcium than two comparable premixed sealers and supported periodontal ligament stem cell viability, attachment and mineralization.[9] MTA Fillapex takes a different approach. It disperses MTA particles in a salicylate resin matrix, and laboratory data on its handling and biological behaviour are mixed: one study recorded low solubility and low flow relative to an epoxy resin sealer,[10] while another found higher flow and greater cytotoxicity than the same comparator across four weeks.[11]

Whether these laboratory differences reach the patient is still unsettled. A meta-analysis of 17 randomized trials reported a small reduction in pain at 24 hours with bioceramic sealers (SMD −0.17) and no difference at later time points,[12] whereas two other systematic reviews found no meaningful difference in post-obturation pain.[13,14] Most included trials used an epoxy resin sealer as the comparator. MTA Fillapex has been tested against epoxy resin in asymptomatic molars without a difference in pain,[15] but direct clinical comparisons between a premixed calcium silicate sealer and MTA Fillapex in symptomatic teeth are scarce. This trial compared post-operative pain at 24 hours and 7 days after single-visit treatment of mandibular premolars with irreversible pulpitis obturated with CeraSeal or MTA Fillapex. The null hypothesis was that pain would not differ between the two sealers.

Materials and Methods

Trial design and ethics

This was a parallel-group randomized clinical trial with a 1:1 allocation ratio, conducted in the Department of Conservative Dentistry and Endodontics, MGV's KBH Dental College and Hospital, Nashik, between [month/year] and [month/year]. The protocol was approved by the Institutional Ethics Committee ([approval number and date]). The study followed the Declaration of Helsinki, and reporting follows the CONSORT 2010 statement.[16] Every participant gave written informed consent after the procedure, visits and follow-up had been explained.

Participants

Patients aged 18–40 years attending the outpatient department were screened. Inclusion required a carious, symptomatic mandibular premolar with a single canal, a mature apex and minimal canal curvature, with clinical findings consistent with irreversible pulpitis. Exclusion criteria were: need for treatment of two or more teeth on the same side; tenderness to percussion; restricted access, weeping canals or periapical drainage; developmental anomalies; teeth too broken down for rubber dam isolation; periodontally compromised teeth; pregnancy; systemic disease; and pre-operative use of steroids, NSAIDs, sedatives or antidepressants. Radiographic exclusions were root resorption, canal calcification, previous root canal treatment, periapical radiolucency and an immature apex. One tooth was treated per patient.

Sample size

[Insert the a priori sample-size calculation: expected difference, SD, α, power and source study. If no calculation was made, state that this was a pilot/convenience sample of 40 and list it as a limitation.]

Randomization and allocation

Participants were allocated to two equal groups using a computer-generated block randomization sequence with a block size of four. Separate sequences were generated for men and women so that the sexes were balanced between groups. [Describe who generated the sequence, how allocation was concealed (e.g. sealed opaque envelopes opened after canal preparation) and who enrolled participants.]

- Group I (n = 20): obturation with CeraSeal (Meta Biomed Co., Cheongju, Republic of Korea).
- Group II (n = 20): obturation with MTA Fillapex (Angelus, Londrina, Brazil).

Blinding

[State who was blinded. Patients can be blinded to sealer type; the operator cannot. If VAS forms were coded so the person entering and analysing data did not know the group, say so. The consent form mentions double blinding, so this section must describe exactly how it was achieved.]

Clinical procedure

The materials, instruments and equipment used are shown in Figure 1. All treatment was carried out in a single appointment by one operator. After pre-operative VAS recording, buccal infiltration of 1.5 mL of 2% lignocaine with 1:80,000 adrenaline was given and the tooth was isolated with rubber dam. Caries was removed with a round bur (BR-31, Mani Inc., Japan); where needed, a composite pre-endodontic build-up was placed. The access cavity was refined with a safe-ended bur (EX-24, Mani Inc.). Patency was confirmed with a #10 K-file, working length was determined with an electronic apex locator (Root ZX mini, J. Morita, Japan) and verified radiographically, and a glide path was created with a #15 K-file.

Canals were shaped with HeroGold rotary files (Micro-Mega, Besançon, France) in an endodontic motor at 350 rpm and 1.2 N·cm using a crown-down sequence: 30/.06 to two-thirds of working length, then 20/.04, 25/.04 and 30/.04 to full length, finishing with 30/.06 to full length. Apical patency was maintained with a #10 K-file between instruments. Approximately 2 mL of 5.25% sodium

hypochlorite was used after each file (10–15 mL in total), delivered through a side-vented needle placed 1–2 mm short of working length.

After a 30/.06 gutta-percha master cone had been fitted and confirmed radiographically, the final rinse sequence was 2 mL of 17% EDTA left for 1 minute with 15 seconds of ultrasonic activation, 5 mL of 0.9% saline, 5 mL of 5.25% sodium hypochlorite with 15 seconds of ultrasonic activation, and a final 5 mL saline flush. The master cone was disinfected in 5.25% sodium hypochlorite for 1 minute, rinsed in sterile saline and dried, and the canal was dried with matching paper points.

Group I. CeraSeal was injected directly into the canal through the manufacturer's intracanal tip, positioned 2 mm short of working length and withdrawn while dispensing a thin layer. The master cone was lightly coated with sealer and seated to length (single-cone technique).

Group II. Equal lengths of MTA Fillapex base and catalyst were mixed on a pad until homogeneous, applied as a thin coat to the master cone and seated to length (single-cone technique).

In both groups excess gutta-percha was seared off at the orifice with a heated plugger and compacted lightly, and a post-obturation radiograph was taken. Representative clinical sequences for each group are shown in Figures 2 and 3. Access cavities were restored the same day: selective enamel etching with 37% phosphoric acid for 20 seconds, BeautiBond adhesive (Shofu, Kyoto, Japan) light-cured for 10 seconds, and Beautifil Bulk Restorative (Shofu) placed in 1–2 mm increments, each cured for 25 seconds. Occlusion was checked and adjusted, and a final radiograph was taken.

Figure 1. Armamentarium and materials: (a) armamentarium; (b) diagnostic instruments (mouth mirror, probe, tweezer, explorer); (c) high-speed air turbine handpiece and burs; (d) Endoblock and hand K-files; (e) HeroGold rotary files; (f) apex locator; (g) rubber dam kit; (h) 5.25% sodium hypochlorite, 17% EDTA, normal saline, syringe and side-vented needle; (i) endomotor; (j) root canal sealers (CeraSeal and MTA Fillapex); (k) gutta-percha points; (l) paper points; (m) etching gel, applicator tip, bonding agent, composite and curing light.

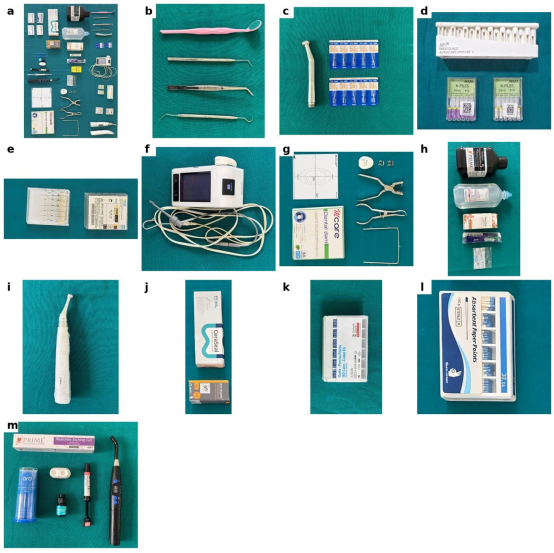


Figure 2. Group I (CeraSeal), representative case: (a) pre-operative radiograph; (b) access cavity preparation; (c) working length radiograph; (d) biomechanical preparation with HeroGold files; (e) master cone radiograph; (f) irrigation; (g) ultrasonic activation; (h) intracanal application of CeraSeal; (i) post-obturation radiograph.

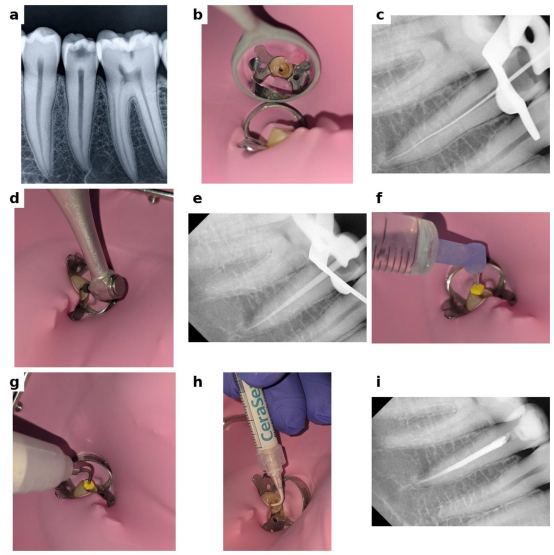
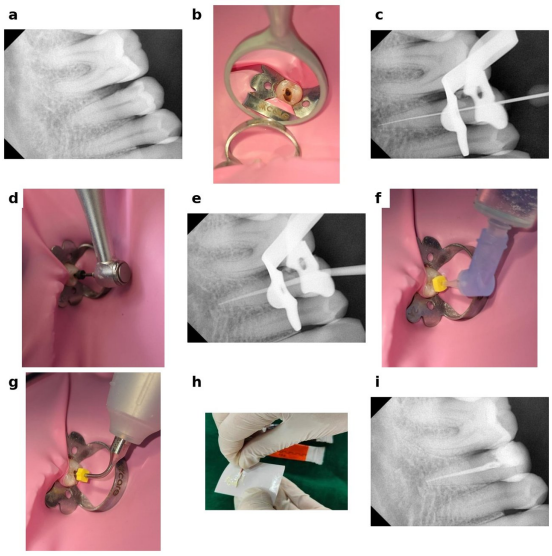


Figure 3. Group II (MTA Fillapex), representative case: (a) pre-operative radiograph; (b) access cavity preparation; (c) working length radiograph; (d) biomechanical preparation with HeroGold files; (e) master cone radiograph; (f) irrigation; (g) ultrasonic

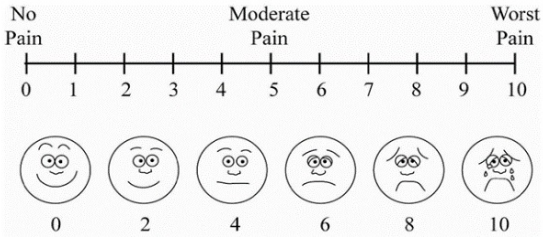
activation; (h) master cone coated with MTA Fillapex; (i) post-obturation radiograph.



Outcome measures

The outcome was pain intensity on a 10-cm VAS (0 = no pain, 10 = worst imaginable pain), a simple and widely validated instrument for acute pain.[17] Patients marked the scale (Figure 4) before treatment, at 24 hours and at 7 days, and recorded whether they took the rescue analgesic, how many tablets, and for how many days. Ibuprofen 400 mg was prescribed for use only if needed (no more than one tablet every 6 hours and three in 24 hours), and patients were asked not to chew on the tooth for 24 hours. A telephone reminder preceded each recording, and forms were collected at the 7-day recall.

Figure 4. Visual analogue scale (0–10) used to record pain intensity.



Statistical analysis

Data were entered in a spreadsheet and analysed with [software and version]. Pain scores are presented as mean ± standard deviation. Within each group, pain scores at the three time intervals were compared using one-way analysis of variance (ANOVA), followed by post hoc pairwise comparisons ([name of post hoc test, e.g. Tukey]). Between-group comparisons at each interval were made with the independent-samples t test, and the mean difference, standard error of the difference and 95% confidence interval are reported. $p < 0.05$ was considered statistically significant and $p < 0.001$ highly significant.

Results

Forty patients were randomized, received the allocated treatment and completed both follow-ups, so all 40 were analysed in their assigned groups (Figure 5). [Insert age (mean ± SD) and sex distribution per group; consider adding these as a baseline table.] Pre-operative pain was high and similar in both groups (8.00 ± 0.79 vs 7.80 ± 1.24; $p = 0.547$; Table 1). No patient in either group took the rescue analgesic, and no flare-ups or unscheduled visits occurred.

Figure 5. CONSORT flow diagram

Assessed for eligibility (n = [?])
Excluded (n = [?]): not meeting criteria / declined
Randomized (n = 40)
Sex-stratified block randomization, block size 4
Group I – CeraSeal **Group II – MTA Fillapex**
llocated and treated: n = 2 llocated and treated: n = 2
ow-up 24 h and 7 days: n ow-up 24 h and 7 days: n =
Lost to follow-up: 0 Lost to follow-up: 0
Analysed: n = 20 **Analysed: n = 20**

Within each group, pain fell sharply after treatment (Table 2, Figure 6). In Group I the mean score dropped from 8.00 ± 0.79 before treatment to 1.10 ± 0.45 at 24 hours and 0.00 ± 0.00 at 7 days ($F = 1356.696$, $p < 0.001$). In Group II it dropped from 7.80 ± 1.24 to 1.65 ± 0.49 and 0.05 ± 0.22 ($F = 549.987$, $p < 0.001$). Post hoc comparisons were highly significant for every pair of intervals in both groups ($p < 0.001$).

Between groups, pain at 24 hours was significantly lower with CeraSeal (mean difference −0.55, SE 0.148, 95% CI −0.85 to −0.25; $p = 0.001$; Table 1). No patient in either group scored above 2; most CeraSeal patients scored 1, whereas most MTA Fillapex patients scored 2. At 7 days every CeraSeal patient and 19 of 20 MTA Fillapex patients were pain-free, and the difference was not significant (mean difference −0.05, 95% CI −0.15 to 0.05; $p = 0.324$).

Table 1. Comparison of mean pain scores (VAS) between groups at each interval

Interval	Group I – CeraSeal (n = 20) Mean ± SD	Group II – MTA Fillapex (n = 20) Mean ± SD	Mean difference	SE of difference	95% CI	p value
Pre-operative	8.00 ± 0.79	7.80 ± 1.24	0.20	0.329	−0.467 to 0.867	0.547 (NS)
24 hours	1.10 ± 0.45	1.65 ± 0.49	−0.55	0.148	−0.85 to −0.25	**0.001***
7 days	0.00 ± 0.00	0.05 ± 0.22	−0.05	0.050	−0.151 to 0.051	0.324 (NS)

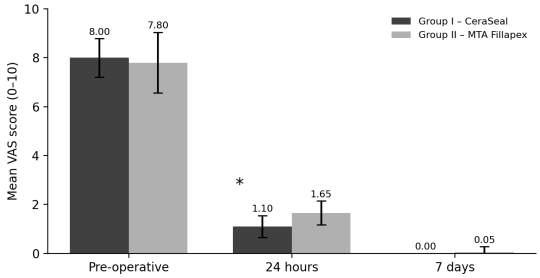
Independent-samples t test. SE, standard error; CI, confidence interval; NS, not significant. *Statistically significant ($p < 0.05$).

Table 2. Comparison of mean pain scores (VAS) within each group at various time intervals

Group	Pre-operative Mean ± SD	24 hours Mean ± SD	7 days Mean ± SD	F value	p value	Post hoc (all pairs)
Group I – CeraSeal	8.00 ± 0.79	1.10 ± 0.45	0.00 ± 0.00	1356.696	< 0.001**	< 0.001** for pre-op vs 24 h, pre-op vs 7 d and 24 h vs 7 d
Group II – MTA Fillapex	7.80 ± 1.24	1.65 ± 0.49	0.05 ± 0.22	549.987	< 0.001**	< 0.001** for pre-op vs 24 h, pre-op vs 7 d and 24 h vs 7 d

One-way ANOVA with post hoc pairwise comparisons. **Statistically highly significant ($p < 0.001$).

Figure 6. Mean pain scores (VAS) before treatment and at 24 hours and 7 days



Discussion

Both sealers were followed by a steep and lasting drop in pain, from severe pre-operative levels to mild discomfort at 24 hours and almost none at one week. That trajectory matches the pooled picture from earlier research[1] and reflects what root canal treatment is meant to do: remove inflamed pulp, reduce the bacterial load and seal the canal. Against that background the trial detected one difference between the materials. At 24 hours patients obturated with CeraSeal reported less pain than those obturated with MTA Fillapex, and the null hypothesis was rejected for that time point. By day 7 there was nothing to choose between them.

The 24-hour finding is in line with several recent trials of calcium silicate sealers. In 150 teeth with asymptomatic irreversible pulpitis, CeraSeal was associated with lower post-obturation pain than AH Plus whichever obturation technique was used.[18] Trials of other calcium silicate or bioactive-glass sealers in symptomatic irreversible pulpitis and

primary endodontic lesions have likewise reported lower pain than epoxy resin at 6–24 hours, with the gap closing by 48 hours to one week.[20,21] That early, short-lived advantage is also what the largest meta-analysis found.[12]

The evidence does not all point one way, though. CeraSeal and AH Plus gave numerically different but statistically similar 24-hour scores in teeth with apical periodontitis.[19] A split-mouth retreatment trial,[22] a 160-patient trial that also tracked extrusion,[23] a necrotic-pulp trial in single-rooted teeth[24] and a four-arm trial of newer calcium silicate sealers[25] all found no difference in pain. Two recent umbrella reviews concluded that whatever reduction bioceramic sealers offer in the first 6–48 hours is small and probably not clinically decisive, and that much of the underlying evidence is of low methodological quality.[30,31] The present result should be read in that context. A mean difference of 0.55 on a 10-point scale is modest, all scores in both groups stayed in the mild range, and no patient reached for an analgesic. What the data show more convincingly is a shift in the distribution: most CeraSeal patients reported a score of 1, while most MTA Fillapex patients reported 2.

A biological explanation is plausible but not proven by this trial. CeraSeal released more calcium and supported better cell viability and mineralization than comparable premixed sealers *in vitro*,[9] and calcium silicate materials form an ion-rich "mineral infiltration zone" at the dentine interface.[27] MTA Fillapex, despite its MTA content, sets within a salicylate resin and was more cytotoxic than an epoxy resin sealer at every interval in fibroblast culture.[11] In a recent rat intraosseous implantation model, MTA Fillapex and a resin-based sealer produced more inflammatory infiltrate and abscess formation at 7 days and slower bone healing than a calcium silicate sealer that included CeraSeal.[26] MTA Fillapex has also shown greater long-term solubility than CeraSeal in phosphate-buffered saline.[28] If small amounts of sealer reached the periapex in some cases, these differences in tissue tolerance could account for the slightly higher early pain. The suggestion that MTA Fillapex flows more and therefore extrudes more is harder to support, because flow data for this material conflict between studies.[10,11]

Two features of the protocol should be weighed when interpreting the result. First, sealer extrusion was not recorded, even though it has been linked to post-obturation pain in some trials[18] and not in others.[24] Second, the two sealers were placed differently, as their manufacturers recommend: CeraSeal was injected into the canal and also coated on the cone, whereas MTA Fillapex was applied to the cone alone. The comparison therefore tests two sealer systems as used in practice rather than isolating sealer chemistry.

Several choices in the design limited confounding. Pre-operative pain is one of the strongest predictors of post-operative pain,[23,29] and it was almost identical in the two groups. The trial was restricted to a single tooth type with one canal, vital pulps and no periapical lesion; one operator used a fixed shaping, irrigation and obturation sequence; and the coronal seal was placed the same day. Single-visit treatment of vital teeth carries a somewhat higher risk of early pain than a multiple-visit approach,[6] which makes this a reasonable setting in which to look for sealer effects.

Limitations

The sample was small and [was / was not] based on an a priori power calculation, so the trial could miss smaller differences at 7 days. VAS scores were recorded as integers, which compresses a continuous scale and creates ties. Pain was assessed only at 24 hours and 7 days; the 6–12-hour window, where several trials have found the largest between-sealer differences,[20] was not captured, and neither was 48 hours. [Blinding statement, e.g. 'The operator could not be blinded to the sealer.'] Sealer extrusion was not assessed on the post-obturation radiographs, and the trial did not measure healing or long-term outcome. The findings apply to young adults with vital, single-canal mandibular premolars and should not be extended to necrotic teeth, molars or retreatment without further study.

Conclusions

Within the limitations of this trial, single-visit root canal treatment of mandibular premolars with irreversible pulpitis produced a large reduction in pain whether the canal was obturated with CeraSeal or MTA Fillapex. CeraSeal was associated with modestly lower pain at 24 hours, and the difference had disappeared by 7 days. Both sealers can be considered clinically acceptable for this indication. Larger trials that record extrusion, include earlier time points and blind outcome assessment would show whether the early advantage is consistent and clinically meaningful.

Declarations

Ethics approval and consent: [Committee name, reference number, date]. Written informed consent was obtained from all participants.

Funding: [e.g. This research received no external funding.]

Conflict of interest: [e.g. The authors declare no conflict of interest.]

Data availability: The patient-level VAS data are available from the corresponding author on reasonable request.

Author contributions: [CRediT roles for each author]

Acknowledgements: [Optional]

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