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CLINICAL EVALUATION OF TWO DIFFERENT BULK FILL RESIN COMPOSITE RESTORATIVE MATERIALS (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

Objective: This study aimed to determine whether the clinical performance of (Sonicfill 2) and (Fill Up) bulk fill resin composite is comparable according to the modified United State Public Health Service (USPHS) criteria.

Methods: A total of 40 class II restorations were done following the manufacturer's instructions, one side of each patient's mouth received both types of restorations (SonicFill 2) and (Fill Up) in two adjacent posterior teeth. The restorations' Color match (CM), Marginal adaptation (MA), Marginal discoloration (MD), Anatomic form (AF), and Secondary caries (SC) were evaluated based on Ryge's criteria (modified USPHS) at baseline (after 1 week), as well as 6 month, 12 months, and after 18 months of follow-up by two calibrated examiners. The statistical analysis utilizing the Friedman and Wilcoxon tests, A p-value below 0.05 was deemed to be statistically significant.

Results: There were no significant differences between the two types of bulk fill resin composite at baseline, and after six months, as 100% of both restorations had Alpha (A) score. Following 18-month period, 60% of (Fill Up) rein composite restorations displayed a decline in the (A) score and revealed Bravo (B) score regarding color match and anatomical form criteria, a statistically significant difference was observed between the two restorations ($p \leq 0.05$), while in the other assessed criteria, both restorations displayed the (A) score.

Conclusion: Within 18 months clinical follow up period, the two tested bulk-fill resin composite restorative materials exhibited satisfactory clinical performance as a direct restoration for class II cavity preparations.

KEYWORDS: SonicFill, sonic activated resin composite, Fill Up resin composite.

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INTRODUCTION

In contemporary restorative dentistry, resin composites are now the most preferred restorative material for posterior teeth. Many dentists select resin composites because of their excellent aesthetics, patient acceptance, micromechanical bonding, and the availability of methods to reduce microleakage and polymerization shrinkage[1], these include using a flowable resin composite, placing resin restorations indirectly, and applying incremental layering techniques[2].

However, there are drawbacks of using this incremental approach resin application into the cavity, including the potential for void formation, adhesive failures in between restoration increments, and longer chair times. Consequently, a lot of dentists were looking forward to the release of a substitute for this extremely delicate procedure[3].

The increasing need for more efficiency and to enhance the performance of composite resin repair, particularly in the posterior regions, led to the development of bulk fill composite resins, which have good mechanical and physical properties to withstand high occlusal stresses. Because of the composite resin's greater translucency, which allows for a deeper cure for each layer, bulk fill materials can be added in thickness increments of 4 to 5 mm[4]. This facilitates quicker work and minimizes the number of clinical steps needed. Additionally, the ideal bulk-fill composite would have the ability to be used in a high C-factor preparation with minimal polymerization shrinkage stress and a high degree of curing[5].

There have been notable developments in the mechanical and aesthetic qualities of composite materials as a result of recent substantial efforts to improve filler technology. Resulting in manufacturing of a sonically activated resin composite (Sonic Fill 2), its filler system has unique rheological modifiers that respond to sonic energy delivered through the handpiece during implantation. In order to provide close adaptation between the composite and bonded surface, the sonic energy caused the viscosity to drop by up to 87% upon activation. This allowed the Sonicfill composite to flow forcefully into the cavity walls, generating an adaptation that is comparable to flowable. In contrast to conventional composites, the composite resin regains its high viscosity when the activation is released, which makes it easier to shape and carve into the appropriate anatomical shape. These advantages are paired with a high depth of cure that permits filling and curing a cavity up to 5 mm deep in a single bulk step[6].

The latest developments in the field of bulk-fill resin composites are even more appropriate for big posterior restorations than the conventional resin composites because they include more filler content and are expected to have better mechanical qualities[7]. Zinc oxide containing bulk fill resin composite (Fill Up), is a dual cure bulk fill resin composite with low viscosity and zinc oxide nanoparticles, The manufacturer states that light application is necessary to start the material's curing process; nevertheless, chemical activation occurs and assures the polymerization of deeper layers where light cannot reach when the base and catalyst pastes are mixed through self-mixing. Its resin matrix contains a chemically integrated polymerization modulator.

Dental restorations are assessed using a range of clinical criteria. The most widely used set of guidelines is called Ryge's criterion[8], sometimes known as US Public Health Service (USPHS) guidelines. The clinical effectiveness of sonic activated bulk-fill and Zinc oxide containing bulk fill resin composite restorations in permanent posterior teeth has not been thoroughly examined in clinical studies. The clinical assessment aimed to test the null hypothesis that there is no disparity in clinical performance between the dual cure zinc oxide containing bulk fill resin composite (Fill Up) and the sonic-activated bulk fill resin composite restoration (SonicFill 2).

MATERIALS AND METHODS

Restorative materials used in the study were presented in **(Table 1).**

TABLE (1) Restorative materials used in the study:

Material	Specification	Composition			Manufacturer	Batch Number
		Matrix	Filler	Filler loading		
SonicFill™ 2 bulk fill	Sonic activated bulk fill resin composite	Bisphenol A glycidyl dimeth-acrylate and Triethylene glycol dimethacrylate	Silicone dioxide, Glass oxide, Chemicals, Zirconium compound, and Ytterbium trifluoride.	84% by weight, 66% by volume	Kerr Crop., Orange, CA, USA	7352416
Fill Up bulk fill	Dual cure zinc oxide containing bulk fill resin composite	Bisphenol A glycidyl dimeth-acrylate, Triethyl-eneglycoldimeth-acrylate, Urethane dimeth-acrylate, and Trimethylolpropane trimeth-acrylate	zinc oxide, benzoyl peroxide. dental glass, amorphous silica (0.1-5μm average of 2 μm)	65% by weight, 49% by volume	Coltene Whaleden Switzerland	J26201
All-bond universal dental adhesive	One step self-etch adhesive	10-methacryloyloxydecyl dihydrogenphosphate , Bisphenol A glycidyl dimeth-acrylate, 2-hydroxyethyl methacrylate, Ethanol, Water, Initiators			Bisco, INC Schaumburg, IL, USA	1900004492
Meta Etchant	Acid Etching agent	37% phosphoric acid, distilled water, and a colloidal Silica sol			Meta Biomed, Korea	MET 1906071

Study design and settings:

The research was carried out at the clinic of the Conservative Dentistry Department, Faculty of Dentistry, Minia University, Egypt. In this prospective clinical trial, which was designed as a split-mouth and double-blinded study, participants are followed up after two years with both the clinical examiner and the volunteer unaware of the treatment. The study protocol and the template informed consent form received a comprehensive review to assure scientific precision and adherence to applicable regulations for research involving human subjects. The Institutional Review Boards/ Ethical Committees (IRBs/ECs) at the Faculty of Dentistry, Minia University, Egypt, granted approval for these documents in committee no. 102 under serial number 877. In addition, the study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The PICO question was stated, and the parameters were defined as: P: Adult patients presenting two class II cavities; I: Sonic-activated bulk fills resin composite restorative material; C: Dual cure zinc oxide containing bulk fill resin composite restorative material; O: evaluation of the restorations' Color match (CM), Marginal adaptation (MA), Marginal discoloration (MD), Anatomic form (AF), and Secondary caries (SC) were evaluated based on modified (USPHS) criteria.

Sample size calculation:

The sample size calculation was determined using the clinical success rate of resin composite restoration observed in a previous study[9], which was 93% at six months. The sample size needed for the study was determined to be 20 restorations based on

a significance level of 0.05, a power of 80%, and an equivalence limit of 20%. To account for potential dropout, 40 restorations were performed, with 20 restorations in each group. Consequently, a split-mouth design was adopted, and 20 patients were selected for the study.

Eligibility criteria of participants:

Clinical examination and X-ray evaluation revealed carious lesions in both the proximal and occlusal surfaces of patients between the ages of 18 and 40. The antagonist and opposing teeth are in contact, have a vital pulp, show no signs of pain or hypersensitivity in the teeth that need to be restored. They also have good oral health. Patients who exhibited severe bruxism habits, clenched their teeth, had wear facets on their teeth, took analgesics that could change how they perceived pain normally, had occlusal disturbances, had issues with their temporomandibular joint, or had orthodontic treatment were also not included.

Patients' randomization and allocation concealment:

Using an online program (www.randamization.com), a randomization list has been created. The two composite alternatives (SonicFill 2 and Fill up RC) were selected randomly from a list, and each patient was given an identification code (P1; P2,... P20). Each patient received one pair of class II posterior restorations on each side of the mouth (split-mouth technique), one with SonicFill 2 and one with Fill up RC. A randomization algorithm based on two restoration possibilities was constructed, and a blocked list was created. Additionally, cavities of similar sizes and locations were selected for every pair. A separate sealed opaque envelope containing a link between the randomization code and the kind of restoration was generated for each patient by an unrelated assistant throughout the clinical procedures. As a result, the operator chose one of the two opaque sealed envelopes with the randomization code for the first quadrant that needed to be restored to start the restoration process. The patient's chart, which was only used for the recall, contained the randomization codes that were broken shortly after the clinical evaluation was finished.

Grouping of teeth:

A total of 40 posterior teeth with medium-sized class II (MO/DO) were selected in this study. The selected patients were blindly classified into two equal groups (n=20) according to the types of restorative materials used (**A)**; the first group was restored by sonic activated high viscosity bulk-fill resin composite (SonicFill 2) restorative material (**A1**), and the second group was restored by dual cure zinc oxide containing bulk fill resin composite (Fill Up) restorative material (**A2**). Each group was evaluated at four different evaluation periods: baseline one week after restoration placement (**T0**), six month (**T1**), 12 months (**T2**), and 18 months (**T3**).

Clinical procedures:

Patient examination:

The participants were subjected to full clinical diagnosis visually, tactile and supported with pre-operative photographs and periapical radiographs using x-ray films (SKYDENT., Slovakia) with parallel technique and the teeth vitality test results were recorded using a Parkell Pulp vitality tester (Parkell Electronics DN, Farmingdale, NY, USA). One operator involved in the study placed all restorations, and the principal investigator monitored all clinical steps. Once the patients fulfilled the eligibility criteria, teeth were scaled and polished before the day of the restorative procedure. Each selected patient was anesthetized by (Mepecaine-L: Mepevacaine 31.36 mg/1.8 ml). Asepsis was preserved throughout the restorative procedure by the use of rubber dam.

Cavity preparation:

Class II cavities were prepared using tungsten carbide burs #245 and #330 (Komet dental Gebr brasseler GmbH and Co lemgo, Germany) with dimensions (0.8 mm in diameter and 1.6 mm in length) mounted in high-speed handpiece (NSK Inc., Japan) with copious air-water spray. Adhesive cavity design was prepared according to the principles of minimally invasive dentistry. The deep decayed tissue was removed using a large carbide round bur operated in a low-speed handpiece (NSK Inc., Japan). Additionally, the soft decay was excavated using a large spoon excavator (Maillefer, dentsply, Swizerland) in a sweeping motion. Control of the excavated preparation floor was primarily carried out through an explorer and by analyzing the color of the underlying dentin. The buccolingual width of the preparations didn't exceed one-third of this distance. The depth of the prepared cavities was up to four millimeter pulpally, and the proximal portion's gingival depth was placed 0.5mm just below the contact area, giving a depth of four millimeter to five-millimeter occluso-gingivally. The cavities' dimensions were assessed using a graduated periodontal probe. Every patient underwent the placement of two restorations, exposing them to identical clinical conditions.

Bonding Procedure:

The prepared cavity enamel surface was selectively etched using a disposable needle and 37% phosphoric acid gel (Meta Biomed, Korea) for 15 seconds. This was followed by rinsing with water for 15 seconds and gentle air drying for 5 seconds, leaving the cavity slightly moist. The bonding procedure was performed in accordance with the instructions provided by the manufacturer. A single layer of a universal adhesive bonding agent (Bisco, INC Schaumburg, IL, USA) was applied to the prepared cavity walls and floor using disposable adhesive micro brush (3M ESPE, St. Paul, MN). The surface was then rubbed for 20 seconds. The solvent was removed through a gentle drying process using oil-free compressed air for 5 seconds. The adhesive was subsequently cured for 20 seconds using blue-phase LED light-emitting diode curing unit (Blue phase, Ivoclar Vivadent, Zurich, Switzerland) with light intensity 1200 MW/cm^2.

Bulk Fill resin Composite Packing:

The restorations were conducted utilizing a metal ring equipped with a pre-contoured metallic sectional matrix band and a wooden wedge (Unimatrix System, TDV, Pomerode, SC, Bra zil).

Following the manufacturer's instructions, the Sonic-fill handpiece and KaVo multiflex coupling (Kerr Crop, USA/KaVo, Germany) were used to apply the Sonic activated bulk fill resin composite unidose tip to the cavities. Upon activation with the foot control, the sonic energy reduced the viscosity. It extruded the composite that initially had a flowable consistency adaptation similar to flowable resin composite to ensure intimate adaptation between the composite and the bonded surface. After the foot control was released, the sonic energy was stopped, and the composite resin returned to its high viscosity, non-slumping state that was perfect for carving and contouring. The operator quickly adjusted the composite to the cavity walls and margins into the prepared cavity using a Teflon composite applicator (Hilton plastic Teflon coated composite applicator, Pakistan), the material was then exposed to light curing for 20 seconds. Subsequently, the matrix was removed, and the entire restoration was subjected to light curing for 40 seconds, targeting the buccal, lingual, and palatal aspects.

The dual cure bulk fill resin composite (Fill Up) was applied following the manufacturer's instructions. The resin was administered using an Automix syringe and injected directly into the cavity. The dual cure bulk fill resin composite was applied with controlled force into the cavity, ensuring that the syringe tip remained fully submerged in the

base of the cavity. This technique was employed to prevent air voids' formation and achieve a uniform thickness. Following the thorough application of bulk fill composite. A 20-second interval allowed self-curing before subjecting to a 20-second light-curing process. Following removing the matrix, all the restorations were subjected to light curing from all aspects for 40 seconds.

Occlusal adjustment was done using carbon paper, On the other hand, interproximal radiographs and dental floss were used to evaluate the quality of the interproximal contacts and cervical adaptation. Fine-grain diamond burs (KG Sorensen, Sõao Paulo, SP, Brazil) under water cooling were used to finish the restorations. To get rid of any excess near the proximal surface, abrasive strips (3 M ESPE / St. Paul, MN) were used. During the same visit, just after the restoration processes, fine and super-fine diamond points with abrasive rubber points (Dimanto, Voco) were formed at the proximal surfaces with fine-grained strips.

Clinical evaluation of the restorations criteria

Following the restoration placement, patients underwent immediate follow-up at baseline (after 1 week), as well as 6 month, 12 months, and after 18 months. The restorations underwent clinical examination using mirrors, probes, periapical radiographs and intraoral photographs were captured using a Canon D2000 cam era with a Macro lens (Canon, Tokyo, Japan). The restorations were assessed by two proficient evaluators, unaware of the details, based on modified USPHS criteria[10]. The evaluation focused on Color match (CM), Marginal adaptation (MA), Marginal discoloration (MD), Anatomic form (AF), and Secondary caries (SC). The restorations were rated as follows: "Alpha" indicated the ideal clinical scenario, "Bravo" indicated clinical acceptance, "Charlie" indicated clinically undesirable and required replacement, and "Delta" indicated that the restorations were movable, fractured, or missing fillings that requires desperate restoration replacement.

Statistical Analysis:

The data analysis was conducted using the IBM SPSS version 25 statistical package software. The data's normality was assessed using the Shapiro-Wilk test. The data were presented as the median (interquartile range) for non-parametric quantitative data, as well as the number and percentage for qualitative data. Statistical analyses were conducted to compare the two groups. Fisher's exact test was used for parametric quantitative data, while the Mann-Whitney test was used for non-parametric quantitative data. Analyses were conducted using the Friedman test to compare all time points within each group and the Wilcoxon Signed rank test to compare each pair of time points within each group. A p-value below 0.05 was deemed to be statistically significant.

RESULTS

As an overview, all of the restorative treatments were carried out exactly as planned, with no further adjustments. For every follow-up period, there was a 100% recall rate. The Alpha and Bravo ratings were applied to 100% of the restorations under observation. With the exception of the 12- and 18-month follow-up in the Fill up bulk fill resin composite (A2 group) regarding color match and anatomic form criteria, no significant results were found when comparing the Alpha and Bravo scores in all groups for the various investigated features, **(Table 2).**

As shown in (Table 2), In group A1 (Sonic fill 2), there was no statistically significant change in all the assessed criteria over time, as all the observed restorations recorded Alpha score during the different follow-up periods. In regard to color match, the results revealed that there was a statistically significant difference in color match scores by time in Fill Up (A2 group) as only 40 % of patients recorded Alpha score at 12- and 18-months follow-up periods, but there was no significant

TABLE (2) Clinical performance (USPHS) results within 18 months follow-up periods:

Criteria	Groups	Baseline	6 months	12 months	18 months
		% Alpha	% Alpha	% Alpha	% Alpha
Color matching (CM)	**A1**	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
	A2	(100%) 20/20	(80%) 16/20	(40%) 8/20	(40%) 8/20
Marginal adaptation (MA)	**A1**	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
	A2	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
Marginal discoloration (MD)	**A1**	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
	A2	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
Anatomic form (AF)	**A1**	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
	A2	(100%) 20/20	(80%) 16/20	(40%) 8/20	(40%) 8/20
Secondary caries (SC)	**A1**	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20
	A2	(100%) 20/20	(100%) 20/20	(100%) 20/20	(100%) 20/20

difference between Alpha and Bravo scores at base line and 6 months follow-ups. For marginal adaptation, marginal discoloration, and secondary caries criteria there was no statistically significant difference between both tested groups (A1&A2) as both restorations recorded Alpha scores in 100% of patients during throughout the several follow-up times. Nonetheless, with respect to anatomical form, the score of 60 % of patients declined from Alpha to Bravo during 12- and 18-months follow-ups in (A2 group) opposite to 100% Alpha score recorded in patients receiving Sonic fill 2 restorations During the multiple follow-up appointments.

DISCUSSION

Recently, a number of novel resin composite materials with lower shrinkage and a deeper depth of cure have been offered as "Bulk-Fill" composites. By increasing their sensitivity to light activation, the majority of bulk-fill resins can cure to a minimum depth of 4mm. While some bulk-fill resins demonstrate a decrease in internal stress through lower polymerization shrinkage and stress-relieving technology, others work by incorporating new photo initiators into the composite resin and increasing their translucency to allow for more light penetration[11,12].

This in vivo study compared two bulk-fill composites: SonicFill 2 and Fill UP, a resin-based composite that contains dual cure zinc oxide. The SonicFill composite system is a single step, bulk-fill resin composite that according to the manufacture, has ultraefficient curing characteristics that ensure an optimal, full 5mm depth of cure in 20 secs[13]. According to the manufacturer, the filler system has unique rheological modifiers that respond to sonic energy that caused the viscosity to drop by up to 87% upon activation[14]. This allowed the SonicFill composite to flow ferociously into the cavity walls, generating an adaptation that is comparable to flowable composite, then regains its high viscosity when the activation is released, which makes it easier to shape and carve into the appropriate anatomical shape[15].

Fill Up, a dual cure resin composite with low viscosity and zinc oxide nanoparticles, was the other bulk fill resin composite restorative material investigated in this study. Placing big posterior composite resin restorations can be made simpler and faster by using bulk-fill resin composite, which can be cured at depths of 4-8 mm[16]. The manufacturer states that light application is necessary to start the material's curing process; nevertheless, chemical activation occurs and assures the polymerization of deeper layers where light cannot reach when the base and catalyst pastes are mixed through self-mixing. Its resin matrix contains a chemically integrated polymerization modulator[17].

There aren't many clinical reviews available for bulk-fill resin composites. A limited number of studies have examined the clinical performance of flowable bulk-fill resin composites for up to three years in class I and II restorations[18,19]. In a different investigation, three distinct bulk-fill resin composites were compared to the clinical performance of a standard posterior resin composite after a year[20]. Using mostly alpha scores, all of these investigations categorised bulk-fill restorations as acceptable.

During this study all evaluated restorations showed satisfactory clinical performance during the 6th months evaluation period in terms of color match, marginal adaptation, marginal discoloration, anatomic form, and secondary caries. This can be attributed to the brief duration of the follow-up period, which was only 6 months. While after 12 and 18 months of follow-up, the score of fill up restorations declined from Alpha to bravo score regarding color match and anatomic form criteria, as restorations rated Bravo were 60% of total examined restorations.

In respect of color matching, the findings of this study can be explained by the fact that colour stability is significantly influenced by the resin matrix's composition as well as the kind and loading of the fillers. It was formerly believed that fillers would minimise the volume of resin matrices, which would decrease the sorption and solubility of materials based on resin. When comparing bulk-fill composites' filler loadings by weight, Fill Up had lower filler loading (65%) compared to SonicFill (83.5%)[21]. Other studies[22,23] also have shown that composites with a high filler content display excellent color coordination.

During the 18-months follow-up in the current investigation, satisfactory outcomes of marginal integrity were noted. The outcomes aligned with earlier in vitro and in vivo researchs[24,25], which discovered no discernible variation in marginal integrity between bulk fill composite and traditional incremental restoration. Also, the results of the current study compatible with that of the study carried out by Van Dijken and Pallesen, 2015[19] and the study performed by Akah et al.,2016[26] and Bayraktar et al.,2017[20] they found that, following a 12-month clinical follow-up, all tested materials under inspection in their tests displayed satisfactory marginal integrity. Numerous investigations have established a close correlation between the integrity of repair margins and the tension caused by polymerization contraction and shrinkage stresses[27].

In terms of marginal discoloration, all cases (100%) for both groups had score Alpha (A) at different times, no statistically significant difference between the two tested groups and by time in each group. This may be related to the 36% phosphoric acid gel used during the cavity etching process, which improved restoration retention and resulted in lower polymerization stress values at the margins, resulting in less marginal discolouration.[28,29] in-addition All Bond Universal was the only adhesive system utilized with the two composite groups. Furthermore, numerous tests have shown cross-compatibility, suggesting that a universal one-bottle adhesive solution can be utilized with composites made by different manufacturers without endangering the bond strength.[30]

According to this study SonicFill exhibited alpha scores with regard to both anatomic form/wear and surface texture, this may be due to the high filler load of the materials (83.5% in wt.), these results were in harmony to the findings made by Rashmi NC. Et al., 2020[31]. In contrast Fill-Up restorations showed a decline from Alpha to Bravo by 60% at 12 and 18 months, this was explained duo to its low filler loading (65% by wt.), as filler loading is the most significant and well-researched factor affecting the mechanical and physical performance of dental resin composites[32,33,34,35]. An increase in surface hardness and compressive strength is directly correlated with fillers' decreased size and increased volume[36].

No one of the patients that took part in the study complained of secondary caries or showed signs of caries recurrence. The following factors could be contributing to our study's good performance and alpha scores regarding secondary caries: a) the caries was completely removed during cavity preparation; b) the patient who was chosen for participation had good oral hygiene; c) the rubber dam was used to isolate the operative area from contaminations; and d) the improved sealing ability of Sonic Fill and Fill Up resin composite, which was evident in this study. Those results matched the findings from Türkün and Oguz[37], Leinfelder[38], Cenci et al[39]., and Gianordoli Neto et al[40].

After an 18-months follow-up period, there were very little to no alterations in the clinical performance of the two tested bulk fill resin composite restorative materials. Consequently, this in vivo study's null hypothesis is accepted.

CONCLUSION

Despite the study's limitations and in light of the findings, it appears reasonable to conclude that the two tested bulk-fill resin composite restorative materials exhibited satisfactory clinical performance as a direct restoration for class II cavity preparations throughout an 18-months assessment period. And Sonicfill 2 resin composite has superior color stability and wear resistance than Fill up resin composite restorative material

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