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ORIGINAL ARTICLE

Postoperative tooth sensitivity with a new self-adhesive resin cement—a randomized clinical trial

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Abstract
Objectives This study evaluated and compared sensitivity of teeth after cementation of full-coverage crowns with a new self-adhesive resin cement (SARC). A resin-modified glass ionomer cement (RMGIC) served as control.
Materials and methods Eighty-eight full-coverage crowns were cemented to vital teeth with either the self-adhesive cement iCem (Heraeus Kulzer; n=44) or the RMGIC GC Fuji PLUS (GC, n=44). Before preparations, patients were questioned for sensitivity (patient sensitivity, PS). In addition, air was blown for 2 s onto the buccal cementoenamel junction (air sensitivity, AS), and ice spray was applied in the cementoenamel junction area (ice sensitivity, IS). Patient responses were recorded with a visual analog scale. After cementation of the crowns, patients were recalled for follow-up (f/u) visits at 1 day, 1 week, and 3 weeks. PS, AS, and IS were recorded during each visit. Data were analyzed with Mann–Whitney U tests.
Results The two groups revealed comparable sensitivity scores at baseline. SARC showed significantly lower PS sensitivity scores at 1 day (p=0.02) and significantly lower AS scores at 1-week follow-up (p=0.01). IS generally produced the highest sensitivity scores with SARC revealing significantly lower scores at all follow-up visits.
Conclusion Cementation of crowns with the SARC tested in this study resulted in overall lower postoperative sensitivity than with the RMGIC.
Clinical relevance Among other clinical advantages, some self-adhesive resin cements seem to lower postoperative sensitivity of crowned teeth.

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Introduction

Postoperative sensitivity to cold stimulation is a complicated and unwanted consequence of a newly cemented crown or fixed partial denture [1, 2]. It is a symptom characterized by a short, sharp pain when a thermal stimulus is introduced to the abutment following cementation of the restoration [3]. After crown preparation, as many as 1 to 2 million dentinal tubules may be exposed, increasing the potential for dentin sensitivity [4] by acting as hydraulic links between the site of stimulation and the nerve endings, which are located either in the pulpal ends of the tubules or in the underlying pulp. Therefore, stimuli that tend to move the fluid in the pulp–dentin complex produce pain, and this flow is increased in the tubules opened peripherally [5].

A number of reasons for stimulation of postoperative discomfort after cementation of indirect restorations have been suggested, including the extent of preparation, the type of cement used (zinc phosphate versus glass ionomer-based versus resin-based), removal of protective smear layer prior to cementation, and presence of occlusal discrepancies [6, 7]. In a survey of dentists, it was found that 59 % of respondents felt that the choice of luting agent is "very important" for preventing postcementation sensitivity; only 6 % felt that it is "unimportant" [1]. Dental luting agents should appropriately seal the interface between the restoration and the prepared tooth. It has been confirmed that sensitivity to cold after final crown cementation is evidence of a gap under the crown or a connection of a marginal gap to opened tubules leading to the pulp [1–5]. Contraction of the fluid in the gap produces a compensatory outward flow of fluid from the pulp causing postoperative sensitivity [2].

In recent years, many different types of cements for luting of single crowns and fixed partial dentures have been

developed. The usage of glass ionomer (GI) cements as luting materials has increased since their introduction to dentistry in the 1970s [8, 9]. These cements adhere to tooth structure through ion exchange and have ability to release fluoride. The major disadvantage of GI cement is the low initial pH value, which may cause postoperative sensitivity [10, 11]. However, published studies indicate that the postoperative sensitivity is comparable or less than with zinc phosphate cement [12–14]. Subsequently, resin-modified glass ionomer (RMGI) cements have been developed by coupling resin components to conventional GI cements. In general, fully set RMGI cements have superior physical and mechanical properties compared to conventional GI cements. However, the level of postcementation tooth sensitivity and clinical performance was found to be the same for conventional and resin-modified cements [6, 9, 11, 15].

Resin cements are an important part of today's dental market due to their versatility, high compressive and tensile strengths, low solubility, toughness, and favorable esthetic qualities. Until recently, resin cements were classified according to the adhesive system used to prepare the tooth structures prior to the cementation. One group utilizes etch-and-rinse adhesive systems. In the other group, enamel and dentin are prepared using self-etching primers [16–18]. Any discrepancy between etching depth and adhesive penetration is expected to lead to a large area of exposed collagen at the interface and, consequently, postoperative sensitivity [19]. To overcome the dentinal etching and sealing problems, self-adhesive cements were introduced as a new subgroup of resin cements. They etch, prime, and bond to dentin without the need of separate agents for each of these steps. Therefore, the application is very simple, and the concept of the smear layer as a bonding substrate has been reintroduced with the expectation of a low incidence of postoperative sensitivity and pulp response [11, 19, 20]. However, since many self-adhesive resin cements have been introduced only recently, independent information on their clinical behavior, i.e., postoperative sensitivity with these new cements, is limited or nonexistent.

This clinical study evaluated and compared sensitivity of teeth after cementation of crowns with a self-adhesive resin cement (SARC). A popular resin-modified glass ionomer cement (RMGIC) was the control. The specific aims of study were to determine subjective changes in postoperative sensitivity at different times (1 day, 1 week, and 3 weeks) and to determine changes in sensitivity at the same intervals after stimulation with air and ice spray. We tested the hypothesis that there would be a difference in postoperative sensitivity between the two luting agents used for crown cementation.

Materials and methods

This randomized clinical trial was performed at the University of Pennsylvania, School of Dental Medicine, Department of Preventive and Restorative Sciences, USA. The study was a prospective, controlled, randomized, open clinical trial. The study protocol, additional documentation about the study materials, and the informed consent were approved by the University of Pennsylvania Institutional Review Board.

The specific inclusion criteria used to recruit patients into the study were: between 18 and 65 years of age (selected regardless of sex, race, or other ethnic characterization), teeth that were vital and carious free and required placement of one or two full-coverage cast metal (CM) or porcelain-fused-to-metal (PFM) restorations, adequate intra-arch space allowing for satisfactory restoration of the teeth, dentition free of active periodontal disease, and willingness and ability to comply with the pre- and postoperative diagnostic and clinical evaluations required for the study. The patients were excluded from the study if they were pregnant, had significant medical conditions or drug use that could interfere with evaluation of sensitivity, or social history that indicates a risk of poor compliance with proper maintenance of restorations. Preoperative bitewing and periapical radiographs of the teeth were obtained to confirm the presence of adequate bony support and lack of any periapical lesion.

Eighty-eight vital teeth in 70 patients were prepared for CM or PFM full-coverage restorations. Therefore, in the final analysis, there were 44 crowns (38 PFM and 6 CM) cemented with RMGIC and 44 crowns (40 PFM and 4 CM) cemented with SARC. Table 1 describes some baseline demographic characteristics (gender and age) of the study participants. The crown luting systems and cementation procedures are described in Table 2.

Before preparing the teeth for crown restorations, patients were questioned for subjective sensitivity by using a visual analog scale (Patient Sensitivity, group PS) [21]. In addition, to assess sensitivity by stimulation, air (approximately 20 °C) was blown for 2 s from a dental unit syringe in a 90° angle and at a distance of 2 cm onto the buccal cementoenamel junction of the tooth (Air Sensitivity, group AS). Sensitivity was also

Table 1 Patient enrollment population by gender and age

Study cements	Patient population		Patient age		
	Male	Female	Mean	Youngest	Oldest
SARC	18	26	56	24	65
RMGIC	16	28	51	25	63

RMGIC resin-modified glass ionomer, *SARC* self-adhesive resin cement

Table 2 Luting cements, composition, and application procedures

Study cements	Composition	Lot #	Application procedure
iCem Heraeus Kulzer GmbH, Hanau, Germany	Component A: acrylic resin, camphorquinone, dimethylaminoethyl methacrylate, ethyl 4-dimethylaminobenzoate, hydroxyethyl-para-toluidine, glass filler, NaF, water Component B: acrylic resin, glass filler, cumene hydroperoxide, benzoyl peroxide, NaF	295364	Rinse the tooth with water and slightly air dry. Discard the first 2–3 mm of cement. Fill restoration with cement and seat on the tooth. Maintain positive pressure on the restoration for 2.5 min. Remove excess and light cure margins of restoration for 30 s.
GC Fuji PLUS GC Corp., Tokyo, Japan	Liquid: HEMA, polyacrylic acid, UDMA, water Powder: Fluora alumina silicate glass GC Fuji PLUS Conditioner: 10 % citric acid, 2 % ferric chloride distilled water, blue no. 1	0802225	Treat the tooth with conditioner for 20 s, rinse and slightly air dry. Activate capsule and triturate for 10 s. Fill restoration with cement and seat on the tooth. Maintain positive pressure until it gets set and remove excess.

tested with ice spray applied with a small foam pellet. The pellet was applied to the area of the cementoenamel junction (Ice Sensitivity, group IS) for 2 s. The patients' subjective findings were recorded using 10 cm visual analog scale (VAS) for every parameter.

For PFM crowns, the teeth were prepared with an occlusal reduction of approximately 1.5 mm for nonfunctional cusp and 2.0 mm for functional cusp, followed by a buccal modified shoulder of 1.5 mm and lingual modified shoulder of 1.0 mm. The shoulder was placed approximately 0.5 mm apical to the crest of the free gingiva. For CM crowns, the teeth were prepared with an occlusal reduction of 1.0 mm for nonfunctional cusp and 1.5 mm for functional cusp, followed by a modified shoulder of 1.0 mm and a circumferential bevel of 1.0 mm. The gingival tissues were retracted with retraction cord (Gingi-Pak, Belport Co., Inc. Camarillo, CA, USA) to control bleeding and expose preparation margins. Impressions were made with a light and heavy body silicone elastomeric impression material (Aquasil Ultra, DENTSPLY, York, PA, USA) in a custom tray (Triad VLC Tru Tray, DENTSPLY, York, PA, USA). All prepared teeth received acrylic (Jet Acrylic, Lang Dental Mfg Co., Wheeling, IL, USA) provisional crowns for the period between preparation and final cementation. The provisional crowns were cemented with provisional cement without eugenol (TempBond NE, Kerr Corp, Orange, CA, USA).

The patients were assigned using a computer-generated randomization list (simple equal randomization) to receive their crowns cemented with one of the study cements. At the final cementation appointment, the prepared teeth were cleaned with slurry of pumice and rubber cup, rinsed with water, and lightly air-dried. The fit of the final restorations was checked with a silicone indicator paste (Fit-checker, GC Dental, Tokyo, Japan) and an explorer, and adjusted to obtain a passive fit. Occlusal interferences were removed with a diamond bur. The intaglio surfaces of the restorations were air-particle abraded with aluminum oxide particles, cleaned with alcohol, and dried. For permanent cementation, the manufacturer's directions were followed for each luting cement (Table 2).

After cementation of crowns, the patients were recalled for follow-up (f/u) visits at 1 day, 1 week, and 3 weeks. Patients were questioned, and sensitivity tests were applied at each f/u visit. For each patient, three test groups (PS, AS, and IS) with four time periods (baseline, 1 day, 1 week, and 3 weeks) were assessed. The same operator evaluated tooth sensitivity before crown preparation (baseline), 1 day, 1 week, and 3 weeks after cementation. The operator, who was blinded to the type of cement until transferring the patient responses into the respective results sheet, asked the participants to record their level of sensitivity by using a VAS ranging from 0 to 10, on which 0 represented "no sensitivity" and 10 "most severe sensitivity."

The data were analyzed using SPSS software version 19 for Windows. For descriptive purposes, median and interquartile range (IQR) were used (Table 3, 4, and 5). Mean and range values were also reported for easier interpretation. For inferential statistics, Mann–Whitney *U* tests were used for determination of differences between medians of

Table 3 Mean and median values, and statistical comparison of patients' subjective sensitivity scores (group PS)

Patient sensitivity		Baseline	1 day f/u	1 week f/u	3 weeks f/u
RMGIC	Median (IQR)	0 (0–0)	0 (0–3)	0 (0–0)	0 (0–0)
SARC	Median (IQR)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
	p value	0.78	0.02*	0.11	0.98
RMGIC	Mean (range)	0.43 (0–6)	1.30 (0–8)	0.50 (0–6)	0.43 (0–6)
SARC	Mean (range)	0.36 (0–4)	0.52 (0–7)	0.39 (0–7)	0.48 (0–9)

Mann–Whitney tests for differences between median of two independent samples

IQR interquartile range, *RMGIC* resin-modified glass ionomer, *SARC* self-adhesive resin cement, *f/u* follow-up

*p=0.05, alpha value; statistically significant

Table 4 Mean and median values, and statistical comparison of air sensitivity scores (group AS

Air sensitivity		Baseline	1 day f/u	1 week f/u	3 weeks f/u
RMGIC	Median (IQR)	0 (0–1)	0 (0–0.75)	0 (0–1)	0 (0–0)
SARC	Median (IQR)	0 (0–1)	0 (0–0)	0 (0–0)	0 (0–0)
	p value	0.38	0.10	0.01*	0.06
RMGIC	Mean (range)	0.77 (0–5)	0.48 (0–4)	0.43 (0–3)	0.34 (0–3)
SARC	Mean (range)	0.55 (0–4)	0.23 (0–5)	0.07 (0–1)	0.09 (0–1)

Mann–Whitney tests for differences between median of two independent samples

IQR interquartile range, *RMGIC* resin-modified glass ionomer, *SARC* self-adhesive resin cement, *f/u* follow-up

*$p=0.05$, alpha value; statistically significant

independent samples. *P* value of less than 0.05 in the two-tailed test was considered to be statistically significant.

Results

Patients' responses in terms of patient sensitivity, air sensitivity, and ice sensitivity are compared in Tables 3, 4, and 5, respectively. Teeth in the two cement groups showed similar sensitivity at baseline in all response categories. In group PS, postcementation sensitivity was significantly higher ($p<0.05$) for RMGIC group at 1 day f/u. However, there was no significant difference at 1 week and 3 weeks f/ups ($p>0.05$; Table 3).

Although SARC revealed increasingly lower AS at all f/u visits, a statistically significant difference was only observed at 1-week f/u visit ($p=0.01$, Table 4). IS generally produced the highest sensitivity scores, with SARC revealing statistically significantly lower scores at all f/u visits ($p<0.05$; Table 5).

Discussion

This randomized clinical trial evaluated postoperative sensitivity of crowns cemented to vital teeth with self-adhesive resin and resin-modified glass ionomer cements for a total of 3 weeks postcementation. The patients' responses in terms of subjective, air, and ice sensitivity were compared for the two cement groups.

The pretrial stage of our study included several pilot tests using various pulp testing devices and methods to assess their reliability, consistency, and feasibility in our clinical setting. Since pulp testing was performed on crowned teeth, even sophisticated pulp test devices that would have produced quantitative measurements failed to reveal consistent results [21]. This shortcoming may soon be eliminated with the development of more sophisticated pulp test devices [21]. We, therefore, selected two common and simple test methods and also asked patients for their subjective pain sensation. VAS provides valid and reliable assessments for the effective magnitude of experimentally induced pain or chronicle pain [22]. The degree of sensitivity during each testing was assessed on a VAS of 0–10.

In the beginning of the study, both cement groups revealed comparable sensitivity scores of baseline. During the f/u visits after crown cementations, however, SARC showed less sensitivity than RMGIC in all sensitivity tests except for group PS at 3 weeks. Postoperative sensitivity usually occurs due to pulp hyperemia, and often, the consequence is hypersensitivity to cold resulting from the movement of fluids through dentinal tubules [1, 23]. In this study, cold (ice) application (group IS) caused increased sensitivity scores for both cements, approximately by a factor of 6. This confirms that cold stimulation causes the most severe reaction [12]. In that group, SARC revealed significantly less postoperative sensitivity than RMGIC at all f/u visits. The more severe reaction and greater overall as well as group-specific sensitivity scores allowed for a more distinct differentiation and statistical significance. Significant differences were more difficult to detect in the PS and AS groups, where values were generally lower and closer to each other. A greater sample size would have possibly overcome this difficulty. However, the significant differences in the IS group at all time points and the clear trends and differences

Table 5 Mean and median values and statistical comparison of ice sensitivity scores (group IS)

Ice sensitivity		Baseline	1 day f/u	1 week f/u	3 weeks f/u
RMGIC	Median (IQR)	3.5 (1.25–6)	3 (1.25–4.75)	2 (1–4)	2 (0–3)
SARC	Median (IQR)	3 (0.25–7)	0 (0–2)	0 (0–1)	0 (0–0.75)
	p value	0.36	<.001**	<.001**	<.001**
RMGIC	Mean (range)	3.91 (0–8)	3.11 (0–8)	2.45 (0–7)	1.98 (0–8)
SARC	Mean (range)	3.48 (0–9)	1.52 (0–9)	1.05 (0–8)	1.00 (0–9)

Mann–Whitney tests for differences between median of two independent samples

IQR interquartile range, *RMGIC* resin-modified glass ionomer, *SARC* self-adhesive resin cement, *f/u* follow-up

**$p=0.01$, statistically significant

in the PS and AS groups demonstrate adequate sensitivity of the measuring parameters, as well as validity and reliability of the applied materials and methods. Therefore, the results of the study approved our hypothesis that there would be a difference in postcementation sensitivity between the two luting agents.

The results of this study support the claim that the selection of an appropriate luting material for the cementation of fixed partial dentures is critical for the success of the final restoration and limits postoperative sensitivity [1]. RMGI cements were developed in the 1980s in an attempt to overcome the two significant weaknesses of conventional GI cements: low early strength and high solubility. They exhibit lower solubility and higher pH values at placement, which is expected to contribute to less postoperative sensitivity [17, 18]. Interestingly, two clinical studies did not demonstrate any significant difference between the postoperative sensitivity of RMGI and conventional GI cement [6, 15].

Self-adhesive resin cements appeared at the dental market to offer a promising new approach in cementation of crowns and fixed partial dentures by etching, priming, and bonding to dentin without separate bonding agents. A low incidence of postoperative sensitivity is expected with these luting agents [16, 17], which is confirmed by our findings, especially in the IS group, where postoperative sensitivity with SARC was less than with RMGIC at all points in time.

The differences in postoperative sensitivity between the two luting cements may be attributed to smear layer removal on dentin surfaces with the conditioner applied in combination with the RMGIC. In our study, the dentinal surfaces of the preparations were conditioned with a solution recommended by the manufacturer to increase bonding and sealing performance of the cement to the dentin. The solution contains mild citric acid to remove smear layer while dental tubules are being sealed by its ferric chloride. Chidchuangchai et al. [5] confirmed that etching exposed dentin in a normal tooth markedly increases the sensitivity of dentin to cold stimuli due to opening of the peripheral ends of the dentinal tubules by the removal of smear layer.

Similar to our results, El-Din Saad et al. [24] concluded that for cementation of PFM crowns, two self-adhesive cements caused significantly lower postcementation sensitivity than resin cement. The authors stated that smear layer alterations rather than removal with self-adhesive cements prevent any migration of cement components toward the pulp and, therefore, reduce the risk of pulpal reaction after crown cementation to vital teeth. This phenomenon was consistent with findings by de Souza Costa et al. [20], who also showed that resin composite systems that required removal of smear layer caused more aggressive effects on the pulp–dentin complex than self-adhesive resin cements. This histopathological study demonstrated an intense diffusion of resin components across the dentin, triggering a persistent inflammatory response and tissue disorganization in those teeth cemented with composite cement. However, when the postoperative sensitivity of resin cements was compared to GI cements, the sensitivity scores were found to be the same [11, 25]. One can assume that the reason for the same sensitivity scores is due to the fact that dentin surfaces were pretreated in both cement groups.

One of the limitations of our study is the wide range of age of the patients, spreading from 18 to 65 years of age. It is well known that older teeth tend to have more sclerotic and/or tertiary dentin formation [26]. This type of dentin often reduces dentinal fluid flow [27] and dentinal sensitivity. Although the highest and lowest patient ages were almost the same for both cement groups, standardization of patient ages for each cement group was not possible. It must be expected that the sensitivity scores found in our study were inevitably affected by the patients' ages. However, mean ages between groups were very similar, and there were no significant differences between baseline scores of the two cement groups with all three sensitivity tests (PS, IS, and AS). Another limitation is that, despite best efforts, the amount of coronal tooth damage as well as extent of the tooth preparation cannot be standardized in a typical clinical setting. The differences found between the cements indicate adequacy of the applied sample size to overcome this limitation.

This randomized clinical trial is one of the few to investigate postoperative sensitivity of SARC. More and long-term clinical studies are needed to evaluate the clinical long-term success of these cements.

Conclusion

Cementation of crowns with the SARC tested in this study resulted in overall lower postoperative sensitivity than with the RMGIC.

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