

An Intra-Patient Cohort Study on the Effect of Resin-Cement Types on Cement Remnants in Implant-Supported Restorations

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Abstract

Objectives: The choice of retention mechanism in implant-supported restorations (ISRs) strongly influences biological outcomes, with cement-retained ISRs linked to peri-implant complications due to excess cement. Factors such as crown design, margin location, and cement type affect the extent of residual cement and its clinical implications.

Material & Methods: This prospective, two-arm, non-randomized clinical trial compared cement remnants of self-adhesive resin (RC) and resin-modified glass ionomer (RMGIC) cement in 30 patients, and 60 ISR. Comparisons were performed on identical pairs of ISR tested within the same patients with a 1-week healing interval. The primary outcome variable was the ratio of cement-covered area to total crown area. Areas were analyzed ex-situ by standardized digital image analysis. Statistical analyses included descriptive statistics,

Wilcoxon Signed Rank and Kruskal-Wallis tests. Results: All specimens showed remnants of residual cement. In the crown-abutment interface, residual cement was detected on all four crown surfaces and for both types of cement, with total relative cement-covered areas ranging from 0.3% to 11.7% and average values between 1.5% ($\pm 0.7\%$) and 2.0%. ($\pm 2.4\%$). RMGIC resulted in higher cement residues than RC in all surfaces except the buccal surface, with differences reaching statistical significance in mesial sites ($p=0.007$). Other surface comparisons showed no statistical significance. Conclusions: RMGIC resulted in higher residue areas than RC. Within the limitations of this study, cement remnants appear to be unavoidable through standard clinical procedures, emphasizing the need for case-specific choice of the retention mechanism for ISRs. Screw-retained ISRs present a viable alternative.

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Introduction

Biological and technical aspects have gained increasing consideration for choosing the retention mechanism of implant-supported restorations (ISRs).¹⁻⁵ Especially cement-retained ISRs, compared to screw-retained ISRs, have been associated with an increased risk for biological complications, i.e. peri-implant diseases.^{1,2} Clinical investigations have demonstrated a direct causal association between these diseases and subgingival excess cement resulting from incomplete removal during cementation.⁶⁻¹⁰

Excess cement removal may depend on various factors, comprising restorative material combinations, designs, contours, the location of restorative margins, cleaning accessibility, and procedural aspects.^{7,8,11-16} Complete cement removal may become specifically difficult with subgingival crown margin positioning, which is often desired in aesthetic cases.^{7,8,10} Nevertheless, cement-retained ISRs might be preferred over screw-retained alternatives in specific clinical scenarios, e.g., prosthetically challenging situations.^{1,3,4} Other potential

advantages of cement-retained ISRs may comprise reduced costs, superior esthetics, retention, passivity of fit and clinical performance compared to screw-retained alternatives^{1,3,4,17}.

The cement type presents a further factor that might influence the ease of cement removal and the presence of residual excess cement. Different luting agents for crown-abutment cementation have been developed. A common classification divides these agents according to their durability into temporary, semi-permanent and permanent cements.^{3,11,12} Cement type selection is often based on esthetics, retentive capacity and decementation rate.¹¹ Especially permanent resin-based cements, like resin cement (RC) or resin-modified glass ionomer cement (RMGIC), have become widely recognized and accepted as a preferred option for the cementation of ISRs due to their high retentive capacity and low decementation rates.^{3,11,18,19} However, these cement types have also been associated with increased cement remnants.²⁰ Furthermore, their content in free acrylate monomers may exert potential soft tissue toxicity.²¹

The amount of excess cement around ISRs depends on several factors, including the type of crown and abutment used, the cement material, the design of the restoration, and the techniques employed during the delivery the restoration.^{2,7,8,11–16} Customized ceramic abutment crown combinations, e.g. lithium disilicate and zirconia, have recently gained popularity for the fabrication of ISRs.²² Recent in vitro investigations have indicated an effect of luting agent type on the amount of detectable cement remnants on such restorations when comparing RC and RMGIC.²³

The aim of the present study was to compare the presence of RMGIC and RC cement remnants around cement-retained ceramic crowns after intraoral cementation by adopting an intra-patient comparative approach and a standardized ex-situ quantification method. The

cementation interface of the crowns was positioned at the gingival level to facilitate excess cement removal.

Material and Methods

Study Design

This study compared optically detectable cement remnants of two different types of cement within a prospective, two-arm, non-randomized, sequentially allocated cohort clinical trial following the scheme reported in Fig 1. Particularly, this investigation compared the following types of cement in the given order: self-adhesive resin cement (RC) (RelyX U200, 3M ESPE, USA) and resin-modified glass-ionomer cement (RMGIC) (Ketac Cem Plus, 3M ESPE, USA).

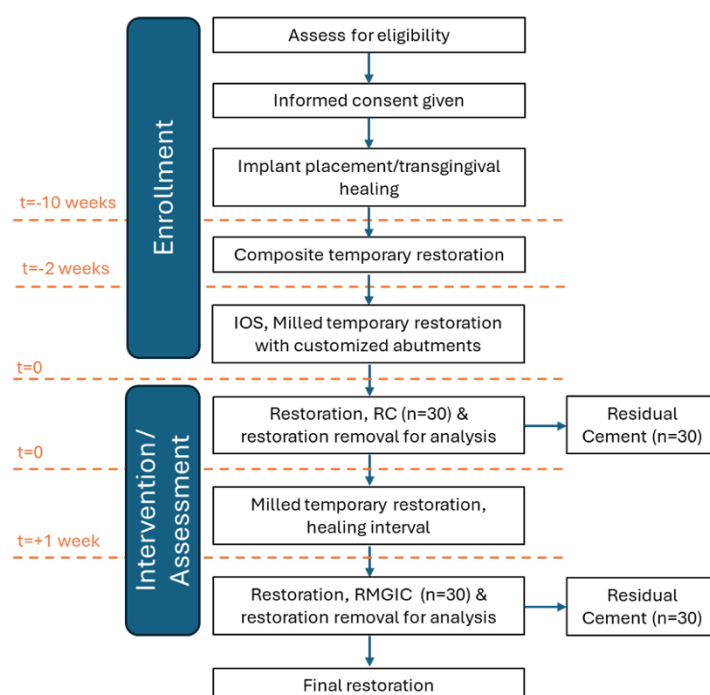


Fig 1 Study Outline illustrating enrollment procedures, intervention and examined study variables (right side).

Abbreviations: IOS: intraoral scanning; RC: Self-Adhesive Resin Cement and RMGIC: Resin-Modified Glass Ionomer Cement.

The study was carried out at [REDACTED] including 30 patients (10 men and 20 women) with ages ranging from 30 to 69 years old (mean 53,6 years) in need of single implant treatment in first-molar mandibular sites. The study was approved by the [REDACTED] regional bioethical committee (No. 2021/6-1360-834). This study adhered to the Helsinki Declaration of Ethical Principles developed by the World Medical Association. The reporting of the study followed the CONSORT (2010) guidelines.²⁴ The study was registered on clinicaltrials.gov (NCT06711237). All patients gave written informed consent to the treatment and the use of patient-related data for scientific research after receiving verbal and written study and treatment-related information about the intervention and associated potential risks.

Outcome Variables

The primary outcome was the relative ratio between the detectable area covered by cement remnants per crown site and the total crown site surface areas derived from digital image analysis. Four site areas, i.e. mesial, distal, buccal and lingual, were investigated individually. Two identical restorations cemented with two different cements, i.e. RC and RMGIC, were compared in the same patient and treatment site in a consecutive approach. A one-week healing period was given between replacing one restoration with another one using the second luting cement. Participants and clinicians were aware, while the investigating assessor was blinded toward the provided treatment modality.

Patient Selection

A convenience sample from routine patients scheduled for single mandibular first-molar immediate implant treatment was identified. Informed written consent and medical and dental

histories were collected, oral and periodontal assessments were performed, and oral hygiene instructions were provided.

Eligible patients were identified based on the following inclusion criteria: 1) physical and psychological ability to undergo implant therapy (ASA I or II); 2) presence of a single mandibular molar indicated for extraction with two adjacent healthy and present natural teeth or implant-supported restoration; 3) presence of > 6 mm width and > 10 mm height native bone ridge – presence of intact alveolar bone walls after tooth extraction and presence of interradicular bone > 4 mm to achieve primary implant stability; 4) presence of ≥ 1.5 mm distance to adjacent teeth at the bone level; 5) overall healthy, non-inflamed keratinized soft tissues.

Exclusion criteria: Presence of general conditions contributory to dental implant treatment comprising but not limited to 1) presence of active periodontitis;²⁵ 2) poor oral hygiene as determined by the Oral Health Index (OHI); 3) pregnant or lactating; 4) presence of uncontrolled medical systemic conditions, e.g. diabetes; 5) ongoing or past medical treatments affecting wound healing, terminated less than 3 months prior to the study-related intervention.

Sample Size Calculation

The sample size was estimated assuming a difference in primary outcome measure, i.e. relative crown site area displaying detectable cement, between two different cement types of $\geq 0.1\%$ based on preliminary data and existing literature.^{7,8} Further, a standard deviation of 0.1% was estimated from previous studies⁸. The alpha level was set to 0.05, and the paired study design aimed for a power (1 - Beta) of 90%, assuming a 1:1 allocation ratio. To accommodate potential dropouts, enhance the accuracy of effect size estimates, ensure robust

analysis, and yield more dependable and broadly applicable results in various prosthetic settings, we increased the calculated sample size from 22 to 30 participants.

Surgical Procedures

All surgical and prosthetic procedures were performed by a team comprised of an experienced implantologist and prosthodontist (AP & EVN). All patients underwent immediate implant therapy, receiving Straumann BLX Roxolid® SLActive® RB Ø4.5x10 mm implants (Institute Straumann AG, Basel, Switzerland) following bio-restorative principles during the surgical procedures and adopting the manufacturer's instructions for osteotomy preparation and implant placement. Bone grafting was performed using an allogenic grafting material (Maxgraft; Botiss, Germany). Implant platforms were placed with >1.5 mm distance to adjacent teeth. Implants were immediately restored with customized healing abutments mimicking the subgingival tooth anatomy using a composite material (Filtek Ultimate Flowable, 3M, ESPE, USA), and wound margins were approximated and adapted to the healing abutments by simple interrupted sutures (6-0 Prolene, Ethicon, USA) for transgingival healing.

Restorative Procedures

After 2 months, the customized healing abutments were replaced by temporary PMMA milled restorations (Bredent group GmbH & Co.KG, Germany) for 2 weeks to ensure the absence of inflammation and adequately condition the soft tissue profiles and margins. To manufacture temporary and permanent milled restorations, implant position and soft tissue emergence profile were scanned intraorally following the manufacturer's recommendations

(Trios 3, 3Shape, Denmark), and restorations were digitally designed using a computer-assisted design (CAD) software (Exocad, Exocad GmbH, Germany).

Two identical restorations for each case were manufactured. All 60 restorations (30 cases, 2 pieces per case) were produced using RB Variobase® for Crown Ø4.5mm, GH 1.5 or 2.5 mm, AH 5.5mm, TAN (Institute Straumann AG, Basel, Switzerland). Gingival height (GH) selection for each case was performed according to the 3D implant position. Special attention was put on selecting the abutment GH to ensure that the customized part (customized zirconia abutment) started at the crestal bone level. 60 customized zirconium oxide abutments (30 cases, 2 pieces for each case) (Lava Classic, 3M ESPE, USA) were designed with emergence profiles adapted to individual soft tissue contours and cementation interface consistently situated at a marginal level. Abutments were extraorally cemented (Multilink Hybrid Abutment, Ivoclar Vivadent AG, Schaan, Liechtenstein) on the standard titanium bases. 60 monolithic lithium disilicate crowns (30 cases, 2 pieces for each case) were milled (IPS Emax, Ivoclar Vivadent AG, Schaan, Liechtenstein) (Fig 2a). For study purposes, all crowns were prepared with a screw access channel to facilitate crown removal and transfer for analysis following cementation. However, these screw access channels were extraorally closed with composite material prior to cementation (Filtek Ultimate Flowable, 3M ESPE, USA) to prevent the venting of luting agent during cementation to emulate clinically realistic conditions (Fig 2 b).

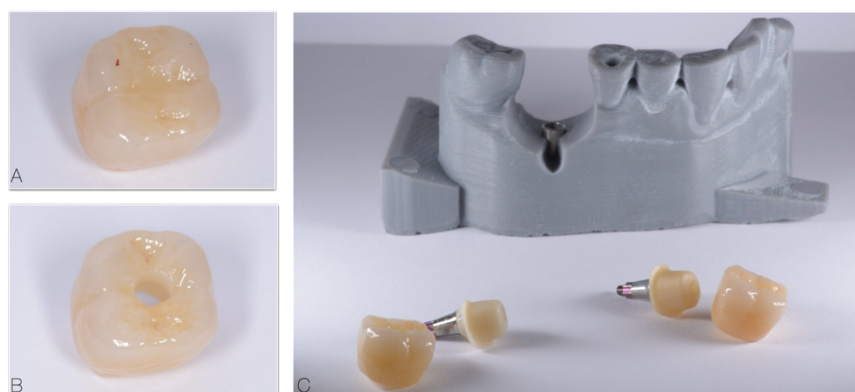


Fig 2 Representative illustration of the study crown abutment combinations. Images A and B illustrate the used ISR., i.e. before (A) and after (B) closure of screw access channels. Two identical pairs of individual Zirconium Oxide abutments on prefabricated titanium bases and lithium disilicate crowns were prepared for each patient.

After abutment delivery, abutment screw access channels were closed using Teflon tape (PTFE) to prevent cement ingress.²⁶ For the RC group (30 restorations), restorations were cemented, residual cement was removed, and the restorations were immediately retrieved for analysis. Implants were temporarily restored with the previously used temporary PMMA restorations for a healing period to ensure the same soft tissue conditions for the cementation procedure using both cements. Afterwards, the study procedures, i.e. intraoral cementation, excess cement removal, and restoration retrieval for analysis, were repeated for the RMGIC group (30 restorations). Following these test procedures and extraoral analysis, RC-cemented abutments were delivered as definite screw-retained restorations after thoroughly removing cement remnants using laboratory procedures.

Cementation procedures for RC and RMGIC groups

The applied cementation procedure is illustrated in Fig 3, following manufacturer's instructions. The same clinician performed all intraoral cementation procedures. The required

amount of cement was determined based on the treating clinician's judgment, without any weight or volume quantification, to replicate conventional clinical routine workflows. Crowns were prepared by applying and distributing a thin layer of the cement to the intaglio surface of the crowns using a micro-brush (Henry Schein Dental, Melville, New York, USA). After that, restorations were positioned on the abutments using a light, constant finger pressure and held in position for the complete light-curing or setting periods as indicated by the manufacturer's instructions, respectively (Fig 3b & d). In brief, the following conditions were used for the individual cements: RC was light tack cured for 5 seconds per crown site, cement excess was removed using a stainless-steel probe (Dentsply International Inc., Milford, Delaware, USA) and the cement was allowed to set for an additional 5 min before final cleaning (Figs 3d & e). RMGIC was light tack cured for 2 seconds per crown site, cement excess was removed as specified for RC, and final light curing was performed for 20 seconds per crown site (Figs 3b & c).

Final cleaning was performed using a stainless-steel probe (Dentsply International Inc., Milford, Delaware, USA) and dental floss (Curaprox, Kriens, Switzerland) until no residual cement was visually or tactilely detectable (Fig 3f). Afterwards, digital periapical radiographs (RVG Windows Trophy 7.0 software Trophy Radiologie Inc., Paris, France) were obtained for residual cement evaluation (Fig 3g & h)). Cleaning procedures were continued and extended in case of radiographic detection of cement remnants.

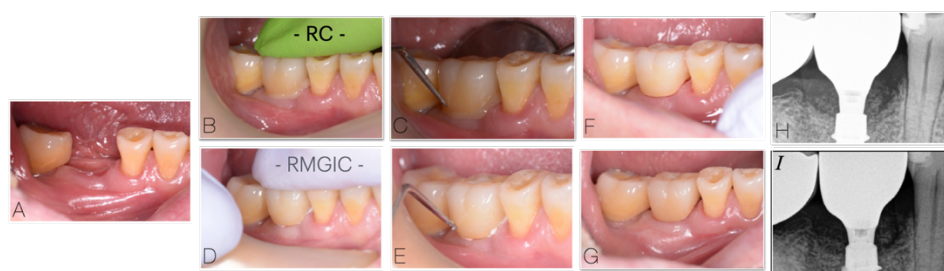


Fig 3 Representative illustration of the clinical sequence for the crown cementation and removal of excess cement. (A) Clinical situation in lateral view before abutment delivery. Upper line (B, C, F and H) shows cementation and cleaning protocol using RC, lower line (D, E, G and I) – RMGIC. Steps are as follows: initial cement excess (B and D), removal procedures (C and E), situation after removal (F and G). Radiographs after (H and I) show no evidence of residual excess cement.

Digital Image Analysis of Residual Cement

Specimens (i.e., crowns cemented on the customized abutment) were transferred for analysis. All crown sites (mesial, distal, labial and lingual) were separately analysed for residual cement based on a previously reported procedure 8. In brief, digital photographs of the specimens were obtained using custom-made equipment with a standardized distance of 16 cm between the photo camera lens (100mm EF lens and camera, Canon, Lake Success, NY, USA, Camera settings: F32, shutter speed 200, ISO 100) and the specimen. Specimens were illuminated with a ring flash during picture registration (Canon MR-14EX II ring flash, Canon, Lake Success, NY, USA). The images were analyzed using a digital imaging software (Adobe Photoshop, Adobe Systems Ltd, 2020 version 21, Europe, Uxbridge, UK). The contours of the area covered by residual cement were identified visually after optical

magnification and marked manually using the Lasso tool (L). The identified surface area per site was derived from the number of pixels (Fig 5a). The contours comprising the entire surface area of the prosthetic superstructure, i.e. customized abutment and crown, were determined in analogy. The ratio between the area covered with cement and the total surface area per site of the specimen was calculated in a spreadsheet software (Microsoft Excel, Microsoft 365).



Fig 5 The shown images illustrate cement remnant detection and quantification of the cement-covered areas using the lasso tool function at the mesial, buccal, lingual and distal crown sites.

Statistical Analysis

Descriptive statistics for the total cohort and individual test groups were reported as averages, standard deviation, medians, and first and third interquartile and total ranges. Shapiro–Vilk test revealed that derived cement to total surface area ratios were not normally distributed. Corresponding intergroup differences of the same parameters were evaluated using the paired Wilcoxon Signed Rank test and intragroup comparison between crown sites using the Kruskal-Wallis test. Statistical analysis was performed using RStudio (version 2023.09.1+494).

Results

A total of 60 restoration cemented on customized abutments were analyzed. No dropouts were registered during the study. All restorations showed good soft tissue adaptation and successful delivery without detectable cement remnants after cleaning procedures. However, a qualitative analysis of digital images revealed that all restorations and all restoration sides had residual cement, mainly around the crown-abutment interface and near the gingival margins, particularly on the approximal sides (Fig 4c and d).



Fig 4 Illustration of the residual cement remnants detection methodology using standardized digital image analysis. Representative images were obtained for analysis for all four crown sites, i.e. mesial, buccal, lingual and distal, using standardized distance and position of the crowns with respect to the camera objective.

The relative cement-covered areas per restoration varied from 0.3 % to 11.7%. Corresponding average values for the total cohort varied between $1.5\% \pm 0.7\%$ (95% CI: 1.3–1.7) and $2.0\% \pm 2.4\%$ (95% CI: 1.4–2.6), as determined at the buccal and lingual sites, respectively (Table 1).

Table 1 The relative ratio of the crown site area covered by residual cement and the total crown site area.

Site	Parameter	Total (N = 60)	Cement 1 (N = 30)	Cement 2 (N = 30)	<i>P-value</i> ^a
Mesial	Mean (SD)	0.015 (0.0077)	0.012 (0.0032)	0.018 (0.0097)	0.007
	Median (Q1-Q3)	0.013 (0.010-0.018)	0.012 (0.010-0.015)	0.014 (0.011-0.023)	
	Range	0.003-0.042	0.005-0.018	0.003-0.042	
Distal	Mean (SD)	0.016 (0.0097)	0.015 (0.0075)	0.018 (0.0113)	0.076
	Median (Q1-Q3)	0.015 (0.010-0.019)	0.014 (0.010-0.016)	0.017 (0.011-0.020)	
	Range	0.005-0.055	0.005-0.04	0.005-0.055	
Lingual	Mean (SD)	0.020 (0.0243)	0.015 (0.0067)	0.025 (0.0331)	0.763
	Median (Q1-Q3)	0.015 (0.010-0.018)	0.016 (0.009-0.020)	0.014 (0.011-0.017)	
	Range	0.003-0.117	0.003-0.024	0.005-0.117	
Buccal	Mean (SD)	0.015 (0.0066)	0.015 (0.0058)	0.015 (0.0073)	0.825
	Median (Q1-Q3)	0.015 (0.009-0.019)	0.015 (0.008-0.019)	0.015 (0.009-0.020)	
	Range	0.003-0.031	0.003-0.029	0.003-0.031	
	<i>P-value</i> ^b	0.856	0.267	0.651	

a: p-value from Wilcoxon Signed Rank test.

b: p-value from Kruskal-Wallis test.

Except for the buccal site, RMGIC resulted in consistently higher residual cement amounts at all sites than RC (Table 1). Differences in the mesial sites of the restoration reached statistical significance ($p=0.007$). Specifically, RMGIC yielded a relative residual cement-covered area of $1.8\% \pm 1.0\%$ (95% CI: 1.4–2.2) vs $1.2\% \pm 0.3\%$ (95% CI: 1.1–1.4) for RC. Values at all other restoration sites remained below statistical significance.

Corresponding p-values were 0.076 at the distal site, 0.763 at the lingual site, and 0.825 at the buccal site.

Kruskal-Wallis test finally indicated that the relative residual cement-covered areas between different restoration sites were statistically comparable, both at the total ($p=0.856$) and at the study group cohort levels ($p=0.267$ and 0.651 , respectively).

Discussion

The findings of this study provided valuable insights into the influence of resin cement types on the amount of residual excess cement around single-unit cement-retained posterior ISRs. The results demonstrated consistently higher cement remnants of resin-modified glass ionomer cement (RMGIC) compared to self-adhesive resin cement (RC). This difference was statistically significant on the mesial site, while differences at the distal, lingual, and buccal sites remained below the significance level.

To limit the influence of confounding factors, such as prosthetic design, both study cement types were compared in a well-controlled clinical setup, i.e. in the same patient and on identical implants and restorative components - a setup previously adopted only to study the effect of cementation modalities on e.g. complex biological factors.^{8,9,15,27,28} This setup further ensured that variations between groups were widely restricted to the resin types, i.e. chemical compositions and associated curing modalities, raising the question of the impact of these factors on the observed excess cement differences.¹²

Cement removal was reported to be more difficult at oral and interproximal areas than at buccal crown sites.^{7,23,29} These findings align with the results in the present study, where differences in cement remnants reached statistical significance only on the mesial restorative site. Furthermore, visible cementation interface at or above the gingival level have generally been regarded as allowing for complete cement removal.^{8,16} However, this study detected

excess cement in all cases irrespective of cement type and cementation interface at the gingival level. Likewise, these findings suggests that the adopted excess cement cleaning procedures remained ineffective. Compared to a subgingival location, residual cement remnants at the gingival margin may be considered less critical for biological complications and potentially removable by regular oral hygiene procedures.⁸ However, these assumptions remain speculative and may require further substantiation.

Various factors influencing excess cement formation were investigated in in vitro and clinical studies.^{8,15,16,23} In vitro studies comparing cement remnants between RMGIC and RC using zirconia crown abutment combinations with a 1 mm subgingivally positioned prosthetic margin have recently indicated consistent but more pronounced differences in excess cement compared to the herein-presented results.²³ However, such in vitro setups are typically limited in simulating realistic intraoral conditions, emphasizing the importance of the herein-reported clinical results.^{7,13,16,29,30}

The observed differences between RMGIC and RC may be attributed to variations in chemical cement composition, corresponding curing mechanisms and viscosities. RC, e.g., required a light curing sequence comprising a first tack cure, maintaining the material plastic to a degree allowing for excess cement removal before final curing.¹³ Curing of RMGIC, on the other hand, was based on a hybrid curing mechanism, including a fast light curing of the resin matrix followed by a slower and passive setting of the glass-ionomer phase.^{13,14} Especially the ongoing passive polymerization of the glass-ionomer phase and its potential interference with moisture from sulcus fluids have previously been associated with rendering cement removal of RMGICs less predictable.^{13,14} Finally, viscosity differences between different luting agents may influence cement expulsion and its tendency to smear over the abutment surface during cement removal. To this extent, our group has previously reported that RMGIC remained less viscous than RC, potentially contributing to the observed

differences.^{12,23} However, the clinical relevance of this statistical difference is questionable, since the difference is low and both might lead to biological complications.

Likewise, the results herein confirm previous reports that current standard visual, tactile and radiographic methods remain insufficient to detect cement remnants. The radiopacity of the herein-studied cement types was, e.g. recently reported to be 3 to 8 times lower compared to titanium and zirconium, supporting a significantly reduced detectability of resin cements on restorative materials.^{31,32} Furthermore, RMGIC and RC have previously been reported to be detectable only at extended thicknesses of 0.5 to 1 mm, while residues below 25 to 50 μm may remain radiographically undetectable.^{8,23,32,33} Furthermore, a study reporting on similar cement types as used in this study reported differences in the radiopacity, which could have a potential impact on the cleaning process.³⁴

A range of other strategies to minimize cement extrusion, e.g. limiting the amount of applied cement, extraoral prosthetic pre-seating on abutment analogues, creating vent holes or exploiting abutment screw holes as cement reservoirs, have been described.^{11,26} These more specific modalities were deliberately excluded within the present study to simulate regular clinical conditions and avoid other reported technical complications, e.g. retention loss or gap formation at the crown abutment interface potentially resulting in bacterial colonization.^{11,35,36}

Finally, the limitations of this study are potentially associated with the chosen study setup emulating clinical conditions and refraining from standardizing factors such as the applied cement amounts or optimizing the tack curing conditions for optimal initial cement removal. Furthermore, the residual cement assessment was solely optical-based using camera images; alternatively, a dye on the cement could have been used to improve visibility or a gravimetric approach, i.e. based on weighing or a combination of optical and gravimetric assessment, could have been chosen.¹⁶ A further limitation is that the excess cement was only

assessed and reported on the restorations; it was not reported if there were any findings of cement remnants observed in the sulcus after restoration removal. Furthermore, the chosen study site in the mandible could potentially impact results due to accessibility for cleaning procedures. A further limitation of this study is the absence of clinician blinding and the non-randomized order of cementation between the two tested cements. Given the study setting, it could also be assumed that the clinicians invested extensive time attempting to remove excess cement, yet they did not achieve complete removal of excess cement; therefore, it could be speculated that in a routine clinical setting even greater amounts of excess cement might present. Additionally, it needs to be acknowledged that the findings of this study may strictly apply only to the used material combinations and restorative designs and not to other materials or resins.¹¹ Furthermore, despite the observed statistical significance between the groups, the presented results do not allow any conclusion on the potential long-term clinical performance of the studied cement types or the impact of cement remnants on peri-implant health.

Conclusions

Cementation of implant-supported restorations with cementation interfaces at the soft tissue level could not fully prevent the presence of cement remnants.

Resin-modified glass ionomer cement tended to result in higher amounts of cement residues compared to resin cement.

The presence of cement remnants demonstrated a failure to completely remove or radiographically detect cement remnants or to a combination of both.

Cement remnants with the tested cement-restorative material combinations appear to be unavoidable through standard clinical procedures.

Screw-retained ISRs present a viable alternative.

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Author contribution statement

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