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Glass Hybrid Versus Nanocomposite for Restoration of Sclerotic Non-carious Cervical Lesions: 18-Month Results of a Randomized Controlled Trial

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Purpose: To compare the clinical performance and treatment times between glass hybrid (GH; EQUIA Forte Fil/EQUIA Forte Coat, GC) and adhesive/nanofilled resin composite restorations (RC; OptiBond FL, Kerr/Filtek Supreme XTE, 3M Oral Care) of sclerotic non-carious cervical lesions (sNCCL).

Materials and Methods: This is an 18-month interim analysis of a 36-month cluster-randomized trial (ClinicalTrials.gov Identifier: NCT02631161). Eighty-eight patients (50–70 years) with 175 sNCCLs were randomized to receive GH or RC restorations. Restorations were placed without mechanical cavity preparation, and treatment time was recorded. After 18 months, restorations were evaluated using FDI criteria. Factors associated with restoration survival were evaluated using multi-level Cox-regression analysis. Generalized linear mixed modelling was used to analyze factors associated with treatment time.

Results: After a mean of 18 months (min/max: 8/25), 78 patients (160 restorations) were assessed. Fifteen restorations (18%) failed in GH, and 11 (12%) in the RC, without a significant difference in survival ($p = 0.904$/Cox). Retention loss was the most common reason for failure in both groups. Restorations placed in older patients showed lower risk of failure [OR (95% CI): 0.90 (0.81–0.99) per year], while mandibular teeth showed higher risks [2.89 (1.00–8.31)]. Treatment time was significantly shorter for GH (mean ± SD: 8.6 ± 4.3 min) than RC (11.7 ± 5.7 min; $p < 0.001$).

Conclusions: GH may be a suitable alternative to RC for restoring sNCCLs, without any significant difference in survival between the two materials at this interim analysis. In addition, placing GH restorations required less chairtime than did placing RC restorations.

Keywords: composite resin, glass hybrid, glass ionomer, non-carious cervical lesion, randomized controlled trial, restoration, sclerotic dentin, treatment time.

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Non-carious cervical lesions (NCCL) are reported to be prevalent in about 50% of adults and their prevalence increases with age.[27] Etiological factors for the formation of NCCLs are complex, including wear, chemical erosion, and microstructural abfraction of tooth substrate by occlusal loading.[2,11] Identifying the impact of each of these factors on the patient level is unlikely, and therefore, a causal therapy for prevention and management of NCCLs can often prove impossible. There is still ambiguity on how and when to intervene in NCCLs. However, placement of a restoration in NCCLs is a common therapeutic option if hypersensitivity is present, if the patient is not satisfied with the esthetics, or if the structural integrity of the tooth is significantly compromised.[15,23,32]

Due to their esthetic and mechanical properties, resin composites (RCs) are widely accepted as restorative materials for various indications. For load-bearing (ie, class I and II) cavities, RC restorations have shown to be highly successful.[8] However, the restoration of NCCLs with RCs can be challenging: The

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bond strength of adhesives to dentin, the predominant substrate to bond to in NCCLs, is weaker than that to enamel.[19] Particularly in NCCLs with obturated dentin tubules (ie, sclerotic NCCLs [sNCCLs]), the ability of an adhesive to establish durable adhesion to dentin can be compromised.[29,33]

Glass-ionomer cements (GICs) can chemically bond to dental hard tissues.[17] Therefore, this material class might be a suitable alternative for the restoration of NCCLs. According to a range of studies and their syntheses, GIC restorations of NCCLs have been shown to perform equally to or even better than RC restorations.[3,20,23] On the other hand, these materials are inferior compared to RCs regarding their abrasion stability, flexural strength, and esthetics.[12]

A recently introduced "glass hybrid" (GH) system – which consists of a highly viscous glass-ionomer cement (HVGIC) and a nano-filled resin coating – aims to improve these shortcomings: changes in the power:liquid ratio, particle size, and distribution should lead to an improvement in abrasion resistance, fracture toughness, and flexural strength of the HVGIC compared to conventional GICs.[1] The coating is intended to protect the surface of the restoration during the early maturation phase and therefore improve surface hardness.[7]

According to a number of clinical studies, the survival of GIC restorations of NCCLs seems to be better (particularly in terms of retention loss) than that of RC restorations.[23] However, the comparative clinical performance between GH and RC restorations in NCCLs is not clear: as opposed to the general evidence for GIC restorations, a recent trial found GH restorations of NCCLs to have a significantly higher failure rate (all restorations failed due to retention loss) than RC restorations after 24 or 36 months.[4,5] Another trial found no significant difference in survival rates between GH and RC restorations of NCCLs after 24 months.[13] However, that trial was conducted in patients with bruxism. The divergent findings between these trials might indicate that, in addition to the choice of material, the clinical situation also has an influence on the survival of the restoration.

For sNCCLs, which are often found in elderly patients,[27] it is unclear to what extent the clinical performance differs between GH and RC restorations. Due to the direct chemical bond between material and tooth surface,[17] which does not require any adhesive technique, GH restorations may have advantages over RC in terms of retention and treatment time.

The aim of the present study was therefore to compare the survival and clinical performance as well as the time taken for treatment of GH and RC restorations in sNCCLs. Our hypothesis was that there would be no differences in (1) failure rate (survival) and (2) treatment time between the two materials.

MATERIALS AND METHODS

Study Design

This is a monocenter, prospective randomized controlled trial with clustered parallel-group design. Reporting of this trial followed the CONSORT 2010 guidelines.[16] The study protocol was registered at ClinicalTrials.gov (NCT02631161) and approved by the ethics committee at the Charité-University Berlin in October 2015 (EA4/136/15).

Patient Selection

Between December 2015 and February 2018, eligible patients visiting the Department of Operative and Preventive Dentistry at Charité-University Berlin for standard care were asked to participate in the trial. To meet the inclusion criteria, patients had to be between 50 and 70 years of age with indication for restorative treatment (eg, due to hypersensitivity, esthetic or functional reasons) of at least one primary sclerotic non-carious cervical lesion (sNCCL) classified as degree 3 or 4 dentin sclerosis, according to the modified dentin sclerosis scale as reported by Ritter et al.[22] Lesions had to be accessible for treatment and visual-tactile re-evaluation, ie, not extend proximally, and had to permit sufficient moisture control, ie, not extending subgingivally and not located in areas of the oral cavity that were difficult to access for placing RCs and GHs. The cervical margins had to be located in dentin, whereas the coronal margins had to be located in enamel, and the gingiva adjacent to the cavity could not show signs of gingivitis. Patients with allergy/hypersensitivity to any of the materials used, patients with severe systematic disorders, disabled and/or pregnant patients, and patients participating in another study were excluded.

Patients who agreed to participate in the study were assigned to a consecutive list of numbers by one of the authors. The unit of randomization was the patient, eg, each patient received either GH or RC restorations in one to three sNCCLs. Patients were allocated to the restorative material groups performed by use of a web-based randomization tool (www.randomizer.org), which created a random order (randomized permuted blocks) of patient numbers for each treatment group from the list of consecutive patient numbers. Randomization of patients and respective allocation to the treatment groups were performed by a second author, who was neither involved in patient recruitment nor in restoration placement or examination. The randomization list was not accessible for dentists responsible for recruiting and enrollment. Thus, concealment of the allocation was ensured. The patients and the examiner were not aware of which restorative material had been placed. However, due to differences in the esthetic appearance between RC and GH, in some cases, the examiner may have had an idea of which material was used during the follow-up examinations. Operators could not be blinded as to the different treatment protocols for placement of GH and RC restorations.

Sample Size Calculation

Assuming a risk of failure of 0.09 and 0.37 (constant HR = 3.94) in GH and RC restorations, respectively,[23] an alpha error of $\alpha = 0.05$, a power of $1\text{-}\beta = 0.8$, an average of 2 restorations placed per patient, an intra-patient correlation coefficient of 0.3, and an annual drop-out rate of 10%, a total of 80 patients (40 per group) were required for the study (two-sided chi-squared test). It is important to note, however, that the study upon which our sample size calculation was based assessed retention loss, while our outcome

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Table 1 Group, material, manufacturer and composition of the restorative materials

Group	Material (batch no.)	Manufacturer	Composition
GH	Equia Forte Fil (1507071, 1702241)	GC (Tokyo, Japan)	Powder: strontium-fluoroaluminosilicate glass, polyacrylic acid Liquid: aqueous polyacrylic acid
	Equia Forte Coat (1702161, 1501151)		MMA, colloidal silica, camphorquinone, UDMA, phosphoric ester monomer
RC	Filtek Supreme XTE (N724772, N714116, N693141)	3M Oral Care (St Paul, MN, USA)	Bis-GMA, bis-EMA, UDMA, TEG-DMA, silica nanofiller, agglomerates of silica nanoparticles
	Optibond FL	Kerr (Orange, CA, USA)	Primer: HEMA, GPDM, MMEP Adhesive: HEMA, trimethoxysilylpropyl methacrylate, GDMA

parameter was broader, and also encompassed other risks/failures. We used G*Power (3.1., University of Düsseldorf, Germany) for sample size estimation.

Operative Procedure

All operative procedures were performed by two dentists at the treatment facilities of the Department of Operative and Preventive Dentistry at Charité-University Berlin. It must be mentioned that according to our study protocol, we planned to include only one operator. However, the first operator left the clinic before all patients had been treated and therefore a second operator was necessary. Before beginning the treatment phase, dentists were instructed during 1-hour training sessions supported by PowerPoint slides, which contained information about the patients and lesions to be included, the characteristics of the tested materials, and treatment steps for placing the restorations.

The teeth and lesions were cleaned using a polishing brush (Prophy Brushes, Henry Schein; Melville, NY, USA) and fluoride-free prophylaxis paste (Super Polish; Kerr, Orange, CA, USA). The operative field was isolated using cotton rolls (Cotton Cellulose Rolls, Henry Schein). Gingiva adjacent to the cervical margin of the lesions was retracted by use of a cotton cord (Ultra Pak, Ultradent; South Jordan, UT, USA), if necessary. If needed, patients received local anesthesia. Restorations were placed without any prior roughening or bur preparation of the teeth. Placement of the restorative materials was performed according to the manufacturers' recommendations.

For the GH group, encapsulated Equia Forte Fil (GC, Table 1) was tumbled, activated, and mixed in a mixing device (Silamat S6, Ivoclar Vivadent; Schaan, Liechtenstein) for 10 s, and placed in bulk into the cavity. After self-curing for 2.5 min, the restoration was burnished using ultrafine diamond burs (Gebr. Brasseler; Lemgo, Germany) and abrasive disks (Sof-Lex disks, 3M Oral Care; St Paul, MN, USA). Equia Forte Coat (GC) was applied to the restoration surface using a microbrush (Roundtip Applicators, Henry Schein) and light cured for 20 s (Acteon Mini LED, Satelec SAS; Merignac, France) at a power of 1500 mW/cm^2.

For the RC group, enamel margins of the cavity were etched with 37% phosphoric acid (Omni-Etch, Omnident; Rodgau Nieder-Roden, Germany) for 30 s and dentin surfaces for 15 s, followed by thoroughly rinsing with water for 30 s. The 3-step etch-and-rinse-Adhesive OptiBond FL (Kerr; Orange, CA, USA) was applied prior to placement of the restoration. Note that use of Optibond FL was a deviation from the original study protocol, which planned to use Clearfil SE Bond (Kuraray Noritake; Tokyo, Japan) as the adhesive. The deviation occurred due to accidental usage of OptiBond FL instead of Clearfil SE Bond in the first patients of the study, as this is the standard adhesive for composite restorations in our department. In order to ensure comparability across the treatment groups, we decided to use OptiBond FL instead of Clearfil SE Bond throughout the study.

OptiBond FL primer was applied onto the dentin surface using a microbrush applicator for 30 s. After evaporating volatile compounds in the primer with an air stream, a thin layer of OptiBond FL adhesive was applied into the whole cavity and light cured for 10 s (Acteon Mini LED) with the curing device placed directly over the cavity. The resin nanocomposite Filtek Supreme XT (3M Oral Care) was placed into the cavity in a maximum of 2-mm-thick increments. Each increment was light cured for 20 s. Excess material was removed with diamond burs and the restoration was polished with abrasive disks (Sof-Lex disks). The time required for treatment (ie, time from beginning of tooth isolation until finishing of the restoration) was recorded by an assistant using a stop watch. If more than one restoration was placed in one patient, the recorded total treatment time was divided by the number of restorations placed in order to calculate the treatment time per restoration. It is possible that this approach might have led to an advantage in favor of treatment time when more than one restoration had been placed in one patient. However, given that the number of restorations placed per patient was almost equally distributed between GH (mean 1.9 per patient) and RC (mean 2.0 per patient) groups, this should not have led to relevant bias.

Clinical Assessment

One examiner assessed the restorations one week (baseline evaluation) and 18 months after the operative procedures. For the 18-month evaluation, patients were first contacted by telephone and, in the event of unsuccessful contact, received a letter by mail asking them to contact the depart-

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Table 2 FDI criteria used for evaluation of the restorations (Hickel et al, 2010)

A. Esthetic properties	1 Clinically excellent / very good	2 Clinically good	3 Clinically sufficient / satisfactory	4 Clinically unsatisfactory	5 Clinically poor
1. Surface luster	1.1 Luster comparable to enamel.	1.2.1 Slightly dull, not noticeable from speaking distance. 1.2.2 Some isolated pores.	1.3.1 Dull surface but acceptable if covered with film of saliva. 1.3.2 Multiple pores on more than one third of the surface.	1.4.1 Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary 1.4.2 Voids.	1.5. Very rough, unacceptable plaque retentive surface.
2. Staining (a. surface, b. margin)	2a.1 No surface staining. 2b.1 No marginal staining.	2a.2 Minor surface staining, easily removable by polishing. 2b.2 Minor marginal staining, easily removable by polishing.	2a.3 Moderate surface staining that may also be present on other teeth, not esthetically unacceptable. 2b.3 Moderate marginal staining, not esthetically unacceptable.	2a.4 Unacceptable surface staining on the restoration and major intervention necessary for improvement. 2b.4 Pronounced marginal staining; major intervention necessary for improvement.	2a.5 Severe surface staining and/or subsurface staining, generalized or localized, not accessible for intervention. 2b.5 Deep marginal staining, not accessible for intervention.
3. Color match and translucency	3.1 Good color match, no difference in shade and/or translucency.	3.2 Minor deviations in shade and/or translucency.	3.3 Distinct deviation but acceptable. Does not affect esthetics: 3.3.1 more opaque. 3.3.2 more translucent. 3.3.3 darker. 3.3.4 brighter.	3.4 Localized clinical deviation that can be corrected by repair: 3.4.1 too opaque. 3.4.2 too translucent. 3.4.3 too dark. 3.4.4 too bright.	3.5 Unacceptable. Replacement necessary.
4. Esthetical anatomical dorm	4.1 Form is ideal.	4.2 Form deviates only slightly from the norm.	4.3 Form deviates from the norm but is esthetically acceptable.	4.4 Form is affected and esthetically unacceptable. Intervention/correction is necessary.	4.5 Form is unsatisfactory and/or lost. Repair not feasible/reasonable, replacement needed.
B. Functional properties	**1 Clinically excellent / very good**	**2 Clinically good**	**3 Clinically sufficient / satisfactory**	**4 Clinically unsatisfactory**	**5 Clinically poor**
5. Fracture of material and retention	5.1 No fractures/cracks.	5.2 Small hairline crack.	5.3 Two or more or larger hairline cracks and/or material chip fracture not affecting the marginal integrity or approximal contact.	5.4.1 Material chip fractures which damage marginal quality or approximal contacts. 5.4.2 Bulk fracture with partial loss (less than half of the restoration).	5.5 (Partial or complete) loss of restoration or multiple fractures.
6. Marginal adaptation	6.1 Harmonious outline, no gaps, no white or discolored lines.	6.2.1 Marginal gap (<150 µm) not removable. 6.2.2 Small marginal fracture removable by polishing. 6.2.3 Slight ditching, slight step/flashes, minor irregularities.	6.3.1 Gap <250 µm not removable. 6.3.2 Several small marginal fractures. 6.3.3 Major irregularities, ditching or flash, steps.	6.4.1 Gap >250 µm or dentin/base exposed. 6.4.2 Severe ditching or marginal fractures. 6.4.3 Larger irregularities or steps (repair necessary).	6.5.1 Restoration (complete or partial) is loose but in situ. 6.5.2 Generalized major gaps or irregularities.
7. Contour and wear (a. qualitatively)	7a.1 Physiological wear equivalent to enamel.	7a.2 Normal wear only slightly different from that of enamel.	7a.3 Different wear rate than enamel but within the biological variation.	7a.4 Wear considerably exceeds normal enamel wear.	7a.5 Wear is excessive.
10. Patient's view	10.1 Entirely satisfied with esthetics and function.	10.2 Satisfied. 10.2.1 Esthetics. 10.2.2 Function, e.g. minor roughness.	10.3 Minor criticism but no adverse clinical effects. 10.3.1 Esthetic shortcomings. 10.3.2 Some lack of chewing comfort. 10.3.3 Unpleasant treatment procedure.	10.4 Desire for improvement. 10.4.1 Esthetics. 20.4.2 Function, e.g. tong irritation. Reshaping of anatomic form or refurbishing is possible.	10.5 Completely dissatisfied and/or adverse effects including pain.
C. Biological properties	**1 Clinically excellent / very good**	**2 Clinically good**	**3 Clinically sufficient / satisfactory**	**4 Clinically unsatisfactory**	**5 Clinically poor**
11. Postoperative (hyper-) sensitivity and tooth vitality	11.1 No hypersensitivity, normal vitality.	11.2 Minor hypersensitivity for a limited period of time, normal vitality.	11.3.1 Moderate hypersensitivity. 11.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed.	11.4.1 Intense hypersensitivity. 11.4.2 Delayed with minor subjective symptoms. 11.4.3 No clinical detectable sensitivity. Intervention necessary but no replacement.	11.5 Intense, acute pulpitis or nonvital tooth. Endodontic treatment is necessary and restoration has to be replaced.
12. Recurrence caries (CAR), erosion, abfraction	12.1 no secondary or primary caries.	12.2 Small and localized. 1. Demineralization. 2. Erosion. 3. Abfraction.	12.3. Larger areas of 1. Demineralization. 2. Erosion. 3. Abrasion/abfraction, dentin not exposed. Only preventive measures necessary.	12.4.1 Caries with cavitation and suspected undermining caries. 12.4.2 Erosion in dentin. 12.4.3 Abrasion/abfraction in dentin. Localized and accessible, can be repaired.	12.5 Deep caries or exposed dentin that is not accessible for repair of restoration.

Reference: Hickel R, Peschke A, Tyas M, Mjör I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD. 2010. FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig 2010;14;349–366.

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Table 3 Characteristics of patients, lesions and treatment times for the different groups

Patient Level			
Groups	GH	RC	Overall
n	43	45	88
Age (mean (SD))	62.0 (5.8)	62.3 (5.7)	62.2 (5.7)
Gender (n females / n males)	19 / 24	24 /21	43 / 45
DMFT (mean (SD))	21.0 (5.6)	21.5 (6.0)	21.2 (5.8)
Tooth Level			
n	83	92	175
Sclerosis Degree 3 (n) Degree 4 (n)	 68 15	 77 15	 145 30
Location (n teeth) Incisors and canines Premolars Molars Maxilla Mandible	 26 48 9 58 25	 29 52 11 51 41	 55 100 20 109 66
Treatment time per restoration (mean (SD) min)	8.6 (4.33)	11.7 (5.7)	10.5 (5.2)

ment for the follow-up examination. Evaluation of restorations was performed according to the FDI criteria using a dental explorer, a dental mirror, and 2.5X magnification lenses. Only FDI domains that were considered relevant for the scope of this trial (for details, see Table 2) were evaluated. The primary outcome was restoration failure (survival). Restorations were rated as a failure (did not survive) if they were completely lost or if they had an FDI score of 4 and higher in at least one of the assessed FDI domains. Failed restorations were replaced or repaired according to the patient's request and clinical indication. Replaced and repaired restorations were excluded from further analyses. The secondary outcomes were restoration quality according to the FDI criteria and time for treatment (as assessed during the operative procedures).

Statistical Analysis

The unit of analysis was the tooth. Differences in failure rate and in ratings according to the FDI criteria between the groups were analyzed using the Mann-Whitney U-test. Differences in FDI ratings between baseline and the 18-month follow-up were analyzed using the Wilcoxon test. The bivariate analyses did not account for clustering. Multi-level Cox regression analysis was performed to assess the association between restoration failure and covariates (restorative material, age, gender, degree of sclerosis, DMFT/age, operator, location of the tooth [mandible/maxilla, anterior teeth/premolars/molars]), accounting for clustering of lesions by introducing a random term for the patient. The association between treatment time and covariates (restorative material, age, gender, operator, location of the tooth [mandible/maxilla, anterior teeth/premolars/molars]) was evaluated using generalized linear mixed modelling, again accounting for clustering. The statistical tests were performed using SPSS version 25 (IBM; Armonk, NY, USA). The level of significance was set at $\alpha = 0.05$.

RESULTS

From 122 patients assessed for eligibility, 88 were randomized to receive either GH (n patients/n restorations: 43/83) or RC (45/92) restorations (Table 3). All patients were available for baseline examination and 41 patients (67 restorations) in the GH group and 37 patients (70 restorations) in the RC group, respectively, were available for the 18-month follow-up examination (Fig 1). In the GH group, one patient refused further participation and another patient could not be contacted. In the RC group, two patients refused to participate further, 4 patients could not be contacted, one patient moved away and one patient received crowns on the treated teeth for prosthetic reasons. All patients who refused to continue to participate did not give a concrete reason for this, but did not state that their refusal was related to the placed restorations.

The FDI ratings for RC and GH restorations at baseline is shown in Table 4. At the 18-month follow-up, RC restorations performed significantly better than GH restorations for the FDI domains "surface luster" ($p < 0.001$), "color match and translucency" ($p = 0.002$) and "contour and wear" ($p = 0.024$). GH performed significantly better than RC for the domain "marginal staining" ($p < 0.001$). We found a significant decline for a number FDI domains over the 18-month period, while "patient's view" in the GH group

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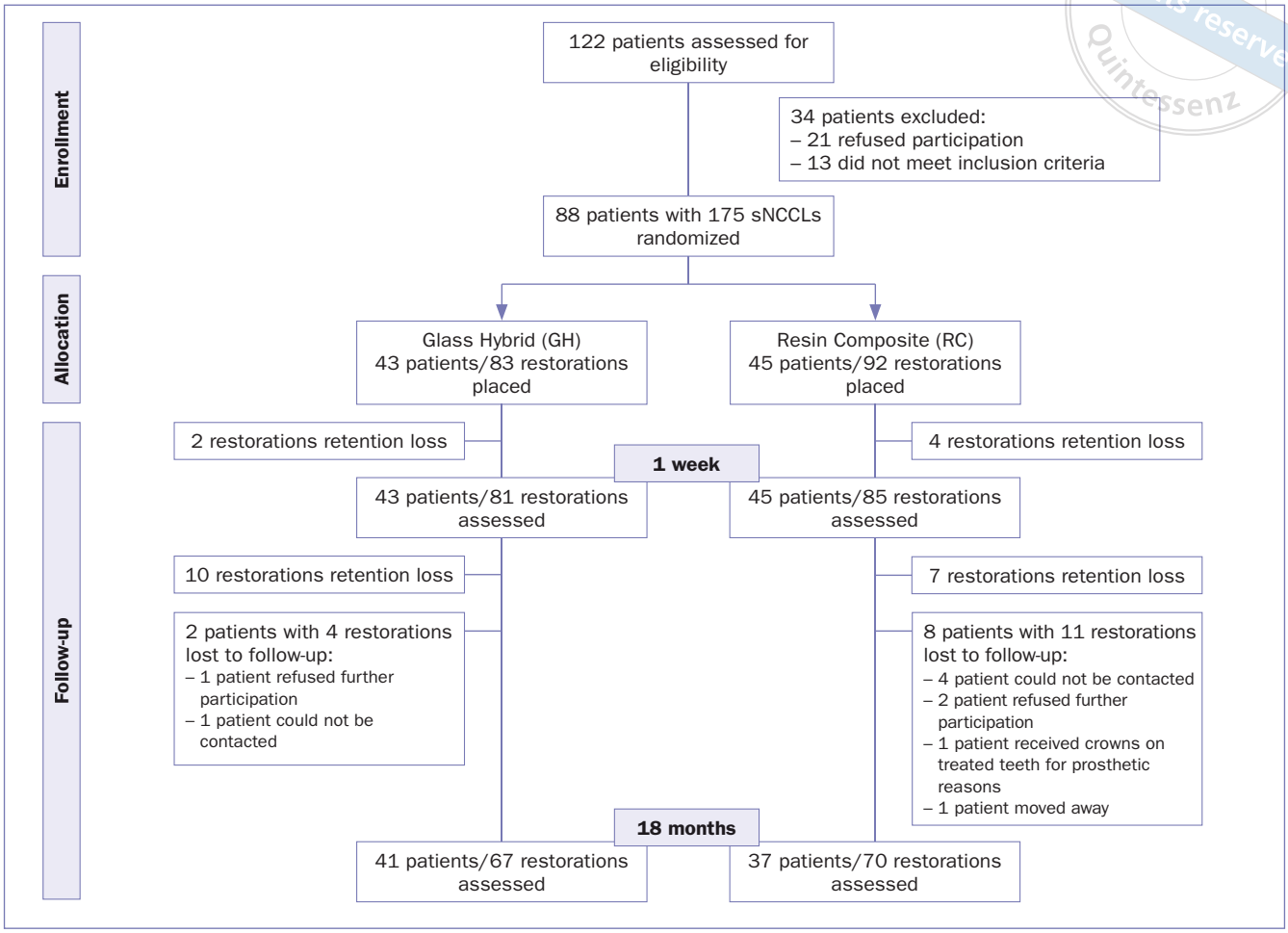

Fig 1 CONSORT flow chart indicating the numbers of patients and restorations through the different phases of the trail. sNCCLs: sclerotic non-carious cervical lesions.

($p = 0.11$) and "surface luster" in the RC ($p = 0.002$) group improved significantly. Exemplary RC and GH restorations at the 18-month follow-up are shown in Fig 2.

Overall, 12 restorations in the GH group and 11 restorations in the RC group showed total retention loss (ie, FDI rating of 5 for the domain: fracture of material and retention). In the GH group, three further restorations failed due to partial retention loss and other domains of the FDI criteria. Thus, a total of 15 restorations in the GH group and 11 restorations in the RC group were rated as failures. There was no significant difference in failure rate between GH and RC ($p = 0.373$/Mann-Whitney U-test).

Regression analyses also revealed no significant difference between GH and RC regarding restoration failure ($p = 0.904$ / Cox regression) (Table 5). Older patients ($p = 0.038$) had a significantly lower risk, and restorations in the mandible ($p = 0.05$) had a borderline significantly higher risk of restoration failure.

Treatment duration (chairtime) was significantly shorter for GH (mean ± SD: 8.6 ± 4.3 min) compared to RC (11.7 ± 5.7 min) ($p < 0.001$). The operator (operator 1: 13.4 ± 5.8 min; operator 2: 8.0 ± 3.5 min) ($p < 0.001$) also had a significant impact on chairtime.

DISCUSSION

Differences in material composition and application steps between GH and RC may influence the materials' clinical performance as well as the time required for their placement. Although we found differences in restoration quality between GH and RC, the failure rates (survival) did not differ significantly. Placement of GH took significantly less time compared to RC. Therefore, the primary hypothesis was accepted, but the secondary hypotheses were rejected.

On an annualized basis, the failure rate in our study was relatively high in both groups, with the vast majority of restorations failing due to retention loss. This is in contrast to a recent randomized trial on restorations of NCCLs, in which the failure rates were considerably lower (GH: 9%,

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Table 4 Clinical success according to the FDI-criteria for the tested restorative materials

Restorative material		GH		RC	
Interval		Baseline	18-month follow-up	Baseline	18-month follow-up
Esthetic properties	Surface luster	51 / 27 / 3 / 0 / 0	**34 / 30 / 3 / 0 / 0***	58 / 27 / 3 / 0 / 0	**60 / 10 / 0 / 0 / 0***
	Surface staining	79 / 2 / 0 / 0 / 0	63 / 4 / 0 / 0 / 0	86 / 2 / 0 / 0 / 0	59 / 11 / 0 / 0 / 0*
	Marginal staining	77 / 4 / 0 / 0 / 0	**57 / 9 / 1 / 0 / 0***	79 / 9 / 0 / 0 / 0	**40 / 28 / 2 / 0 / 0***
	Color match and translucency	**23 / 44 / 14 / 0 / 0**	**11 / 34 / 22 / 0 / 0***	**39 / 41 / 8 / 0 / 0***	**23 / 38 / 9 / 0 / 0***
	Esthetical anatomical form	56 / 19 / 6 / 0 / 0	41 / 22 / 3 / 0 / 1*	62 / 21 / 5 / 0 / 0	48 / 19 / 3 / 0 / 0
Functional properties	Fracture of material and retention	76 / 3 / 2 / 0 / 2	58 / 6 / 0 / 3 / 10*	82 / 4 / 2 / 0 / 4	67 / 2 / 1 / 0 / 7*
	Marginal adaptation	49 / 26 / 6 / 0 / 0	23 / 35 / 7 / 1 / 1*	40 / 40 / 8 / 0 / 0	13 / 51 / 6 / 0 / 0*
	Contour and wear (qualitative)	79 / 2 / 0 / 0 / 0	**60 / 4 / 2 / 0 / 1***	86 / 2 / 0 / 0 / 0	**69 / 1 / 0 / 0 / 0***
	Patient's view	74 / 6 / 1 / 0 / 0	67 / 0 / 0 / 0 / 0*	80 / 5 / 3 / 0 / 0	69 / 0 / 1 / 0 / 0
Biological properties	Postoperative (hyper-) sensitivity and tooth vitality	80 / 1 / 0 / 0 / 0	66 / 1 / 0 / 0 / 0	84 / 4 / 0 / 0 / 0	70 / 0 / 0 / 0 / 0
	Recurrence caries, erosion, abfraction	80 / 1 / 0 / 0 / 0	66 / 1 / 0 / 0 / 0	87 / 1 / 0 / 0 / 0	70 / 0 / 0 / 0 / 0
n assessed		81	67	88	70
n (%) failure (cumulative failures)		2 (2 %)	15 (18 %)	4 (4%)	11 (12%)

Numbers of restorations rated as FDI score 1 / 2 / 3 / 4 / 5 are given for the assessed FDI domains at baseline and follow-up examination. Explanations of the different FDI criteria can be found in Table 2. Significant differences in FDI criteria between GH and RC are indicated in bold (Mann-Whitney / $p \leq 0.05$). Significant changes in FDI criteria within each group at the 18-month follow-up are indicated by an asterisk (*) (Wilcoxon / $p \leq 0.05$). Note that one restoration could be rated as failure (ie, FDI score ≥ 4) in more than one domain at the same time.

RC: 0% after 24 months compared to failure rates of GH: 18%, RC: 12% after 18 months in our trial).[4] However, another trial which also included mainly older patients found a similarly high failure rate (GH 6.9 %, RC 27.6%) after an even shorter period of 1 year.[28] For RC restorations, it is known that adhesive bonding efficacy to sclerotic dentin surfaces, which are more frequent in older patients, can be highly reduced.[26] The reason why retention loss also occurred in many GH restorations could be that this restorative material is more rigid than composites.[18] During occlusal loading, tensile stresses are induced at the cervical margins of NCCLs. More flexible restorative materials are favored by some authors to reduce these stresses and thus improve restoration survival.[10]

Moreover, we did not find any significant advantage of RC, although previous studies found RC to perform significantly better than GH at 24 or 36 months.[4,5] In line with the present results, another randomized trial comparing GH and RC restorations of NCCLs in patients with bruxism observed a similarly high failure rate after 24 months (GH: 15.9 %; RC: 9.5%), and also found no significant differences between the survival of GH and RC.[13] Given the high heterogeneity of results between the different trials, it can be assumed that in NCCLs, other factors than the material choice might determine restoration performance. For the RC restorations, as mentioned, this is rather plausible, given the reduced efficacy of adhesives in bonding to sclerotic lesions.[26] Adhesion of the GH restorations may also be reduced on sclerotic dentin surfaces. In addition to chemical adhesion, GIC-based materials adhere via micromechanical interlocking by hybridization of the hydroxyapatite-coated collagen fibril network.[30] The necessary acid etching of the dentin surface generated by polycarboxylic acid of the GIC may be less effective on hypermineralized sclerotic dentin surfaces.

As expected, this study documented a significant decline in restoration quality over time, according to the FDI criteria for both groups in some domains. However, an improvement in the domain "patient's view" was also found for both materials, with the improvement in GH even being significant. During the baseline examination, some patients indicated that they were not completely satisfied with the quality of the restorations or the treatment procedure; however, a majority of patients had forgotten which teeth were treated at the 18-month follow-up and indicated that they were completely satisfied with the treatment. Patient satisfaction, although being an important outcome, has hence only a limited association with the quality of the restoration.[21]

We also found a significant improvement in the domain "surface luster" for RC restorations but a (non-significant) decline in the GH group. It may be speculated that the improvement in surface luster in the RC group might have occurred due to polishing caused by toothbrushing. However, this result is not in line with results from in vitro studies, in which toothbrushing led to an increase in the surface roughness of composite restorations.[6] The improvement in surface roughness found in our study, possibly caused by toothbrushing, could be explained by a less perfect initial surface roughness of the restorations placed under clinical conditions. In the GH group, on the other hand, toothbrushing

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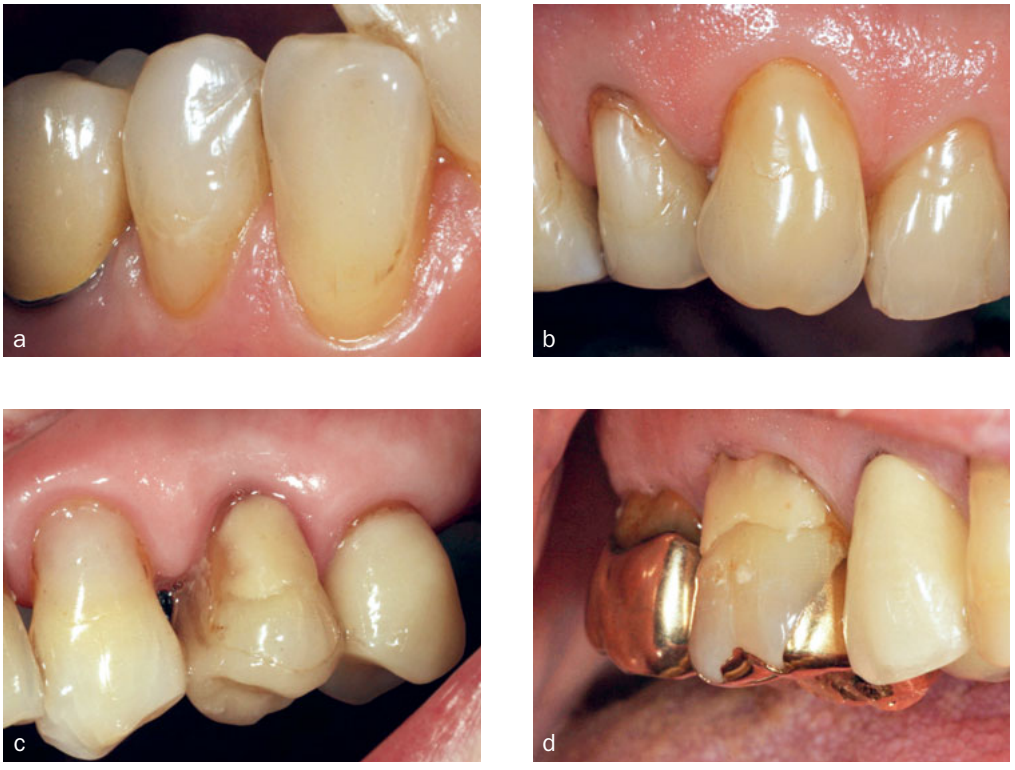

Fig 2 Exemplary clinical images of restorations obtained at the 18-month interval. Resin composite restorations on tooth (a) 44 and (b) 13 and glass-hybrid restorations on tooth (c) 14 and (d) 16

may have contributed to the removal of the coating, which is thought to help smooth the surface, among other things.

Although differences in failure rates were not detected, there were significant differences in the quality of the restorations between the two materials. GH restorations performed better in the domain "marginal staining" but worse in the domains "surface luster", "color match and translucency", and "contour and wear". Similar results were also observed in other clinical trials.[4,5,13] The inferiority of GICs compared to RC regarding esthetics and surface luster is well known. The improvement of these properties indicated by the manufacturer through the application of the coating as an additional treatment step has, at least in our study, only limited sustainability. While these quality parameters are used to assess a material's performance in clinical trials on a finer scale to detect minor differences, more obvious outcomes, eg, retention loss and fracture of the restoration, are more clinically relevant. Interestingly, as previously stated, these quality parameters do not seem to correlate with patient satisfaction.

The present regression analysis showed that restoration failure occurred significantly more often in younger patients and in mandibular teeth. This is in contrast with a previous study (on occlusal-proximal posterior restorations), where higher age was associated with a greater risk of restoration failure, but the arch was not significantly associated with restoration failure.[12] Another study did not find any association between age and restoration failure in class V restorations.[31] As already mentioned, and also reflected by the heterogeneity in the results of different trials on GH restorations of NCCLs, tooth- and patient-related factors might be relevant confounders for restoration survival in class V cavities. Further studies should assess the impact of these factors in more detail.

The time required to place GH restorations was significantly lower than that for placing RC restorations. GIC restorations are generally considered to require less chairtime than RCs, mainly as they self-adhere to the tooth substrate (ie, do not require adhesive pre-treatment) and can be placed in bulk instead of increments. Even the application of a coating in the final step of placing GH restorations did not change the fact that GH took less time than RC restorations. Although using a bulk-fill RC might have reduced this time difference, we chose Filtek Supreme XTE as a comparator in our study based on its good performance in other clinical studies as a "gold standard" material; our intent was to avoid bias by comparison with a potentially inferior material.[23]

In the present study, the operator also had a significant effect on treatment time. Regression analysis further revealed a trend that the operator might also influence restoration success, but this was not statistically significant. It is known that not only the type of restorative material, but also operator skill and experience can significantly influence the clinical performance of restorations.[25] However, both operators had a comparable level of education and were both equally trained for the purpose of the study. The difference

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Table 5 Results of the regression analyses for the factors restoration success and treatment time
a) Association between different factors and restoration success*

Factor	OR	LCI	UCI	p-value
Age (per year)	**0.897**	**0.809**	**0.994**	**0.038**
Female (ref: male)	1.598	0.523	4.876	0.411
Degree of sclerosis 4 (ref: degree 3)	0.523	0.072	3,787	0.521
DMFT/year of age	0.235	0.003	21.324	0.529
Operator	2.147	0.792	5.816	0.133
Mandible (ref: maxilla)	**2.885**	**1.002**	**8.310**	**0.050**
Premolars (ref: anterior)	1.715	0.389	7.565	0.476
Molars (ref: anterior)	1.071	0.171	6.695	0.941
Restorative material RC (ref: GH)	0.925	0.258	3.314	0.904

b) Association between different factors and treatment time**

Factor	β	LCI	UCI	p-value
Age (per year)	0.064	-0.038	0.166	0166
Male (ref: female)	0.539	-0.648	1.726	0.373
Operator	**6.521**	**5.298**	**7.744**	**<0.001**
Mandible (ref: maxilla)	- 0.823	-2.121	0.474	0.214
Anteriors (ref: premolars and molars)	-0.992	-3.010	1.026	0.335
Restorative material GH (ref: RC)	**-4.419**	**-5.643**	**-3.195**	**<0.001**

Boldface values indicate statistical significance. *Association between different factors and restoration success evaluated via multi-level Cox-Regression analysis. Odds ratios (OR), 95% confidence intervals (lower/upper limits: LCI/UCI) and p-values are given. Significant associations are indicated in bold. **Association between different factors and treatment time assessed via multilevel linear regression analysis. Standardized regression coefficient (β, in min), 95% confidence intervals (lower/upper limits: LCI/UCI) and p-values are given.

found in the treatment time nevertheless indicates that not all treatment steps were performed in exactly the same way. However, as the distribution of restorations was equable between the operators, this observation should not have affected the targeted outcome, ie, differences in the clinical performance between the restorative materials.

Given that there was no significant difference in failure rate between the restorative materials, and further assuming material costs to be equal or even lower for GH, the use of GH seems to be a cost-effective alternative to RC for the restoration of sNCCL. However, it should be noted that the quality of GH restorations was inferior to RC restorations regarding certain criteria.

This study has a range of limitations. First, the attrition rate was high and slightly inequable between patients in the RC and GH groups. In medical trials, unevenly distributed attrition between treatment arms can indicate adverse events or unsatisfactory treatment efficacy.[9] According to the CONSORT statement, this should be addressed by performing intention-to-treat analyses (ie, considering all drop-out patients as failures). However, we decided to perform per protocol analyses (ie, excluding patients who dropped out from our analyses), as it is unlikely that the reason for attrition in our trial was related to the performance of the restorative material. Second, some restorations (mainly in the GH group) already showed some qualitative shortcomings at baseline. However, except for the FDI domain "color match and translucency", where GH performed significantly worse than RC, there were no significant differences between the materials for the other domains. As none of the restorations failed for esthetic reasons, this significant difference between GH and RC at baseline did not have an impact on restoration survival. Third, as described above, we deviated from our original study protocol in terms of the unintentional use of OptiBond FL instead of Clearfil SE bond as the RC adhesive. With Filtek Supreme XTE and Clearfil SE bond, we had originally chosen materials for the comparison group which are proven to perform well. However, similar to Clearfil SE bond, OptiBond FL is also considered a gold-standard RC adhesive; its use is hence well justified. The deviation from the protocol should not have introduced relevant bias due to an intended comparison of GH with a weaker comparator.[24] Fourth, we did not determine the cavity depth and did not evaluate whether included patients suffered from bruxism. Both factors could have had an impact on the durability. However, since it can be assumed

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that randomization distributed these covariates evenly between the groups, this should not have affected the comparative effectiveness between GH and RC.

CONCLUSIONS

In this 18-month interim analysis, no significant differences in failure rate between glass-hybrid and resin-composite restorations of sclerotic non-carious cervical lesions were found. However, resin-composite restorations performed better than glass-hybrid for most quality criteria, while glass-hybrid showed significantly reduced chairtime.

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Clinical relevance: The 18-month failure rate of resin-composite and glass-hybrid restorations in sclerotic non-carious cervical lesions is similar. However, resin-composite restorations showed advantages in restoration quality, whilst glass-hybrid restorations require less treatment time. Dentists can choose the best treatment option between the two materials according to the clinical situation.