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Direct Short-Fiber Reinforced Composite Resin Restorations and Glass-Ceramic Endocrowns in Endodontically Treated Molars: A 4-Year Clinical Study

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ABSTRACT

To compare the clinical performance of direct and indirect cusp covering restorations in endodontically treated molars (ETMs). Eighteen ETMs in sixteen patients were randomly assigned into one of the two study groups:Group 1 (SFCRs) direct composite restorations with a short fiber-reinforced base, and Group 2 (GCEs) indirect glass-ceramic endocrowns. Eleven teeth were allocated to Group 1 and seven teeth to Group 2. Restorations were prepared in the student clinic between November 2012 and January 2015, and were evaluated at baseline and after 4.0 years according to modified USPHS criteria. The number of visits required for fabrication and maintenance of restorations were also compared. Two-way ANOVA was used to evaluate the differences between the groups (p=0.05). One SFCR and one GCE were lost due to secondary caries and endodontic complications, resulting in a 4-year survival rate of 90.9% and 85.7% respectively. Two SFCRs required minor grinding and polishing due to chipping or gloss loss, and two SFCRs needed repair due to secondary caries or loss of proximal contact. One GCE required occlusal adjustment. GCEs showed smoother surface texture and better-preserved anatomic morphology. SFCRs required more maintenance, were simpler to produce, needed usually one visit and repairs were easier to perform.

INTRODUCTION

Restoration of endodontically treated teeth (ETT) is a major challenge in dentistry. Loss of tooth tissue during root canal therapy makes ETT more susceptible to biomechanical failures compared to vital teeth.[1,2] Prognosis of ETT depends not only on the quality of endodontic treatment, but also on the subsequent restorative techniques.[3] A restoration with cuspal coverage is often preferred in order to prevent cuspal flexure of structurally compromised ETT.[4] However, the traditional treatment modality, full-coverage crown with or without post,[5] is nowadays a controversial topic, because this treatment option requires significant removal of sound tissue in an already biomechanically compromised tooth. The current restorative trend for ETT is tissue preserving, i.e. decay oriented and additive due to advances in adhesive dentistry. It offers various treatment modalities

such as adhesively bonded inlays, onlays, overlays and endocrown restorations.[6-10] Endodontically treated molars (ETMs) restored with adhesively luted endocrowns seem to survive similarly compared to conventional full coverage restorations.[9] The indirect restoration techniques requiring multiple visits, higher material and technical fabrication costs, however, are not in the reach of every patient.

Today, also direct resin composites are routinely used for restoring ETT, due to their good esthetic properties, low cost, ease of handling and repair, and preservation of tooth tissues through adhesive bonding. The main drawback of direct resin composites is polymerization shrinkage leading to marginal leakage, which potentially predisposes to postoperative sensitivity and secondary caries. Consequently, the risk of secondary caries, bulk fractures, marginal deficiencies and wear is increased particularly in posterior stress-bearing areas.[11] The incremental layering technique is used to decrease polymerization shrinkage related problems,[12,13] and damage tolerant base materials such as fiber-reinforced composites (FRCs) are used to support large posterior restorations and prevent fractures. The direct restorative technique utilizing FRC is known as the bilayered restorative approach and comprises an FRC base and a direct resin composite layer as a veneering material.[14-17] Various FRC types are available for the bilayered approach; bidirectional, which is used to reinforce a large direct composite restoration,[14,15] unidirectional used mainly as posts[18] and short fiber-reinforced resin composite (SFC) used as a restorative composite material.[19-22]

The advantages of using SFC for direct restorations are due to the presence of short glass fibers as fillers. Glass fibers are shown to limit polymerization shrinkage along the direction of the fibers,[23] but transmit the light to the deepest parts of the restoration.[24] Short fibers with a large aspect ratio intertwine with each other in the cavity and effectively alleviate the polymerization shrinkage stress during light irradiation.[25] Consequently, the final volumetric shrinkage of SFC is significantly lower compared to other resin composite materials.[26] Furthermore, short fibers with sufficient length and random orientation improve fracture toughness of the restoration,[27] and by deviating the crack upon fracture enable preservation of the underlying tooth structure for retreatment.[28,29] It is worth emphasizing that if the length to diameter ratio (AR, aspect ratio) of short fibers is low (low aspect ratio short fiber resin composite), short fibers behave as particulate fillers and do not reinforce the restoration.[19] The composition of the resin matrix is also of great importance. A multiphase matrix, such as the semi-IPN (semi-interpenetrating) network, containing both cross-linked (thermoset) and linear polymer (thermoplastic) phases mixed together, improves handling and bonding properties.[30-32] These properties improve the damage tolerance of the material. Indeed, posterior composite restorations with a bulk base of high aspect ratio SFC (everX Posterior, GC; Tokyo, Japan) have shown good performance also clinically.[20-22] On the other hand, in a study by van Dijken *et al.*, superior results using low aspect ratio SFCs with thermoset resin matrices (Nulite, Alert) were not identified clinically.[19]

There is an abundance of literature dealing with the restoration varieties of ETMs. However, comparison of direct and indirect adhesive methods, direct composite restorations and indirect ceramic restorations is missing and warranted.[33] The aim of this controlled clinical trial was to investigate the clinical performance and survival rate of direct SFC restorations and indirect glass-ceramic endocrowns in restoring ETMs. The null hypothesis was that there is no difference in the clinical performance of the studied restorations. In addition to primary outcome measures (survival, technical and biological complications), the number of visits required for fabrication and maintenance of restorations during the follow-up period were compared.

MATERIALS AND METHODS

STUDY DESIGN AND STUDY POPULATION

This study was carried out between November 2012 and January 2015. Fourth- and fifth-year undergraduate students performed the clinical procedures under the supervision of experienced dental practitioners. The study protocol was approved by the ethics committee (no. 23/1801/2013) and the trial was registered at the US National Institutes of Health (ClinicalTrials.gov) # NCT04111003.

Inclusion and exclusion criteria were based on anamnestic data, clinical and radiographic examination. Inclusion criteria included asymptomatic endodontically treated first and second molars in occlusion with at least one proximal contact with adjacent tooth and at least 2 mm of remaining coronal tissue. Exclusion criteria at patient level were severe bruxism, active periodontal disease and poor oral hygiene. Exclusion criteria at tooth level were periapical periodontitis, poor quality of root canal filling (≥3 mm from apex and/or poorly constructed), vertical fracture in the cavity, less than 50% of the cervical margin in enamel, more than 50% of cavity margins located subgingivally, less than 2 mm of coronal tooth tissue left and the lack of an occluding antagonist.

Only patients requiring restoration of ETMs and who met the inclusion and exclusion criteria were planned for this clinical trial. In total, twenty restorations on ETMs were designed to be divided equally (n=10) between the two groups mentioned below. An informed consent was obtained from every subject and participants were randomly allocated into one of the two study groups. The groups were direct SFC restorations (hereafter abbreviated as SFCR) and indirect ceramic endocrown restorations (hereafter abbreviated as GCE). A lottery method was used to randomize the restoration selection, that is by picking randomly an envelope containing information on either study group. This random allocation of patients into study groups was made in consecutive order.

Eighteen patients were planned for the clinical trial, but sixteen participants were able to participate. Two patients did not participate because they were no longer willing and had sought treatment elsewhere. Overall, sixteen patients enrolled in the study and eighteen restorations were placed. Two patients received both restoration types, one SFRC and one GCE per patient. In total, eleven teeth in eleven patients were allocated to the SFCR group, and seven teeth in seven patients to the GCE group.

Patients in the SFCR group received direct resin composite restorations with an SFC base (everX Posterior, GC) covered with a direct resin composite (G-aenial Posterior, A3, GC) i.e. direct SFC restorations (SFCRs). Patients in the GCE group received indirect endocrown restorations made of leucite-reinforced glass-ceramic (IPS Empress CAD, Ivoclar Vivadent AG; Schaan, Liechtenstein) (GCEs). Endocrowns were manufactured by a computer-aided design and computer-aided manufacturing (CAD/CAM) technique using a digital chair-side system (CEREC, software version 4.3, Dentsply Sirona Dental Systems GmbH; Bensheim, Germany) and milling machine (Cerec 3 Milling Unit, Dentsply Sirona). The materials used in this study are presented in Table 1.

STUDY INTERVENTIONS

All restorations in this study were made under local anesthesia if needed or requested by the patient. Old restorations and secondary caries were removed, and undermined i.e. weak cusps were reduced at least 1.5 mm for the direct resin composite restorations (SFCRs group) and 2 mm for the ceramic endocrowns (GCEs group).

Clinical protocol for direct short fiber-reinforced composite (SFC) restorations

Once the cavity preparations were completed, standardized sectional contoured metal matrices or contoured circular matrices were selected and placed. Field isolation was achieved with cotton rolls and suctions. Enamel and dentin were etched with 35% phosphoric acid gel (Ultra-etch, Ultradent products Inc.; South Jordan, UT, USA) (30 s enamel, 15 s dentin) rinsed with water spray and gently air-dried. The primer and bonding agent (G-aenial Bond, GC), were applied to all cavity surfaces with a microbrush for 20 s, gently air-thinned and light-cured for 20 s using a light-polymerizing unit (MiniLED™ Satelec; Merignac, France) at 980 mW/cm^2. SFCRs were made using the oblique incremental technique. A thin layer of flowable resin composite (G-aenial Universal Flow A3, GC) was applied at the cavity bottom and light cured for 40s. The SFC base (everX posterior, GC) was added in approximately 4 mm thick increments and immediately light-polymerized for 40s *(Figure 1A)*. Next, direct resin composite (G-aenial Posterior, A3, GC) was applied to the outer surfaces of the restorations in layers of approximately 1.5-2 mm in order to cover the SFC base and obtain full anatomic contour. Each increment was light cured for 40 s. Restorations were adjusted to occlusion and finished with rotary silicon polishing instruments (Optrafine, Ivoclar Vivadent) under water cooling *(Figure 1B)*.

Table 1. Materials used in this study

Materials	Type	Composition
G-aenial Universal Flo A3 (GC Corporation, Tokyo, Japan)	Flowable resin composite	Resin: Bis-EMA, dimethacrylate monomer, UDMA, butylated hydroxytoluene. Inorganic filler: Silica, Strontium (~ 50 vol%) Pigments Photo initiator
EverX Posterior (GC Corporation, Tokyo, Japan)	Short fiber reinforced resin composite (SFC)	Resin: semi-IPN matrix composed of Bis-GMA, TEGDMA and PMMA. Fillers: E-glass fiber, barium borosilicate (57 vol%)
G-aenial Posterior A3 (GC Corporation, Tokyo, Japan)	Direct resin composite (CR)	Resin: UDMA, co-monomers Inorganic filler content: pre-polymerized fillers: Silica, Strontium, Lanthanoid Fluoride (65 vol%) Pigments Catalysts
IPS empress CAD (Ivoclar Vivadent, Liechtenstein)	Leucite-reinforced glass-ceramic	SiO_2 (60.0-65.0 wt%) Al_2O_3 (16.0-20.0 wt%) K_2O (10.0-14.0 wt%) Na_2O (3.5-6.5 wt%) Other oxides (0.5-7.0 wt%) Pigments (0.2-1.0 wt%)

Bis-EMA: Ethoxylated bisphenol-A dimethacrylate; UDMA: urethane dimethacrylate; semi-IPN: semi-interpenetrating network; Bis-GMA: bisphenol A glycidyl methacrylate; TEGDMA: triethylene glycol dimethacrylate; PMMA: polymethylmethacrylate.

Clinical protocol for indirect leucite-reinforced glass-ceramic endocrowns

Preceding preparation, the shade was taken with a shade guide (Vita Shade guide, Vita; Bad Säckingen, Germany) and preparations were performed with diamond rotary burs (Inlay/Onlay kit, Komet; Lemgo, Germany). General guidelines for adhesive onlay preparations were followed including a minimum 2 mm occlusal reduction on functional cusps and 1.5 mm on non-functional cusps, circular butt joint and 2 mm reduction of axial walls. The pulp chamber was tapered and extended until the endodontic access cavities. A divergence angle between 8 and 10 degrees was obtained. All internal angles were rounded, preparation margins were finished with hand instruments, and impressions were taken. Orifices were sealed using primer (Clearfil SE-bond, Kuraray; Osaka, Japan),

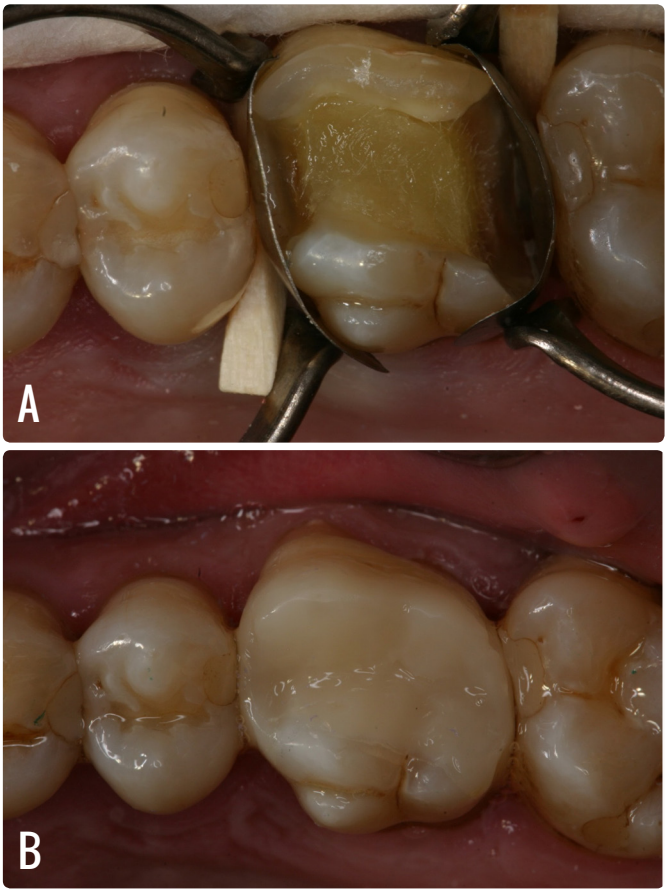

Figure 1: Restoration of a maxillary first molar with direct composite restoration with an SFC base. A) Cavity preparation with a contoured circular matrix and SFC base applied in the pulpal cavity. B) Finished direct composite restoration.

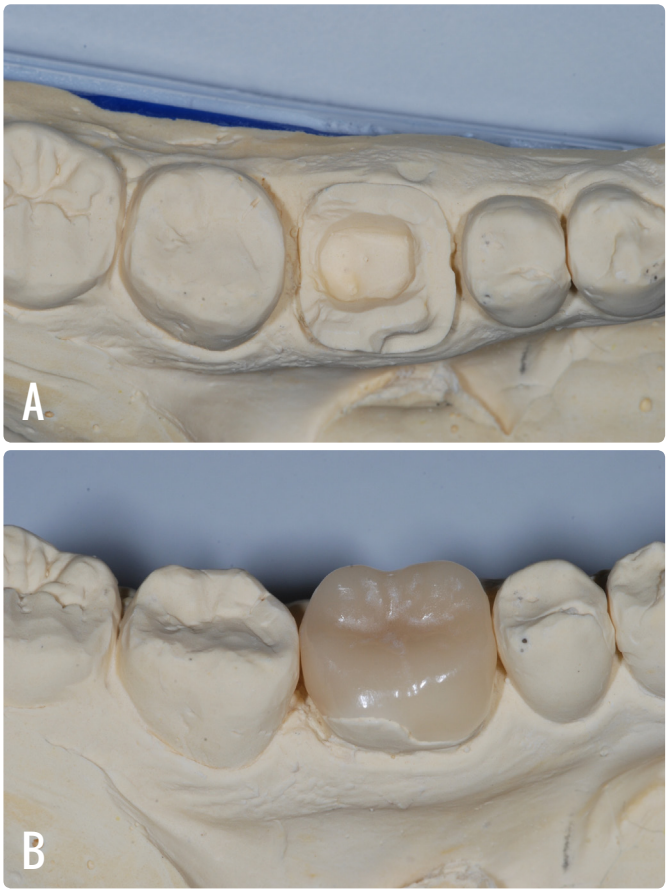

Figure 2: Photographs of a cast of mandibular first molar restored with a glass-ceramic endocrown. A) Cast of endocrown preparation. B) Endocrown fabricated from a leucite-reinforced glass-ceramic block (IPS Empress CAD LT).

applied with a microbrush for 5 s, followed by adhesive resin application (Clearfil SE-bond, Kuraray), which was air-thinned and light-polymerized for 20 s. Orifices were then filled with a thin layer of flowable resin composite (G-aenial Universal Flow A3, GC) and light-polymerized for 40 s. Margins were exposed with a retraction cord and polyether (Impregum Penta, 3M ESPE; Seefeld, Germany) impressions were taken, using an isolation gel over the flowable resin composite layer surface. The first visit was completed by placing the temporary restorations, fabricated from bisacrylate resin composite (Protemp Garant 3, 3M ESPE) and cemented with a temporary cement (Temp Bond NE, Kerr Corporation; Orange, CA, USA).

Plaster models were poured with dental stone type IV (Fujirock EP, GC) *(Figure 2A)*, gently sprayed with an antireflective spray (Sirona Optispray, Dentsply Sirona; York, Pensylvania, USA) and scanned (Cerec Omnicam, Dentsply Sirona). Endocrowns were then designed with a virtual model using a digital chair-side system (CEREC, software version 4.3, Dentsply Sirona) and fabricated from leucite-reinforced glass-ceramic blocks (IPS Empress CAD LT, Ivoclar Vivadent AG; Schaan, Liechtenstein). Upon milling (Cerec 3 Milling Unit, Dentsply Sirona), the endocrowns were finished with fine diamonds burs (Dentsply Sirona) and polished using rotary polishing instruments (Optrafine, Ivoclar Vivadent) and diamond paste (Brinell L, DDL Dental; Paarl, South Africa) *(Figure 2B)*.

During the second appointment, temporary restorations were removed, teeth were cleaned with pumice slurry and retraction cords were placed. The working areas were isolated with suctions and cotton rolls. The fit of the endocrowns were evaluated and adjusted if necessary. Prior to cementation, cleaned tooth surfaces were etched and bonded as described above. The inner surfaces of the endocrowns were etched with 9.6% hydrofluoric acid (Porcelain Etch Gel, Pulpadent; Helsinki, Finland) for 60 s, washed and dried. Finally, silane agent (Clearfil Porcelain bond activator, Kuraray) was applied for 60 s. Endocrowns were then cemented with a dual-cured resin based luting cement (Panavia F 2.0, Kuraray) following the manufacturer's instructions. Once the endocrowns were placed, excess cement was removed, oxygen barrier gel (Oxyguard II, Kuraray) was applied and the restorations were cured in situ 40 s from each surface. Occlusion was adjusted using diamond burs under water cooling and polished with porcelain polishing rotary instruments (Optrafine, Ivoclar Vivadent) and diamond polishing paste (Brinell L, DDL Dental) *(Figures 3A and 3B)*. Patients were re-evaluated after 48 hours for interproximal contacts, excess cements at the margins and occlusion.

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Figure 3: Clinical photographs of maxillary first molar restored with a leucite-reinforced glass-ceramic endocrown A) Endocrown cemented on a maxillary first molar, occlusal view. B) Endocrown cemented on a maxillary first molar, buccal view.

CLINICAL EVALUATION OF THE RESTORATIONS

At baseline and follow-up evaluation the restorations were evaluated according to modified USPHS criteria.[34] Evaluation criteria are described in Table 2. All complications and possible repair measures were observed visually and radiographically, and documented in the patients' information system (Winhit, In Net Oy; Kutajärvi, Finland). Restoration was considered as failed when it scored unacceptable in the evaluation criteria and had to be replaced, or if the tooth was extracted. Plaque index (Silness and Löe)[35] and bleeding on probing (BOP)[36] were recorded and probing pocket depth measured at four sites on restored teeth. The contralateral tooth served as a control. In case it was missing, the neighboring contralateral tooth with similar morphology was used. As a third option, the corresponding tooth in the opposing jaw was used.

Clinical intraoral photographs and periapical radiographs *(Figures 4A and 4B)* of restorations were made. The evaluation was made by independent operators (TM and VK). Examiners were calibrated by both examiners performing evaluation on three patients. In the case of disagreement, the worst score was considered.

ASSESSMENT OF REMAINING CORONAL TISSUE

The dimensions of the remaining tooth walls were measured on plaster models with a digital caliper at four locations, mesiobuccal, distobuccal, mesiopalatal/lingual and distopalatal/lingual. Height (occluso-cervical distance) was measured from the cervical margin to the most outer point of the occlusal surface, and thickness (bucco-oral distance) at the thickest part at same locations.

STATISTICAL ANALYSIS

Differences in USPHS ratings between eleven direct SFC restorations (SFCRs) and seven indirect leucite-reinforced endocrowns (GCEs) were evaluated using cross-tabulation and the χ^2 test, and in case the assumptions for the χ^2 test were violated, the Likelihood ratio test was used. The biological measurements between studied materials (SFC, leucite-reinforced glass-ceramic) and between study (restored) and control teeth were evaluated using two-way analysis of variance (ANOVA). The level of significance was $p<0.05$. Statistical analyses were performed using SAS statistical software version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

STUDY POPULATION

The mean age of patients was 43.4 years (ranging from 16.9 to 70.4 years). Altogether eighteen direct or indirect restorations covering a minimum of three surfaces of the tooth were placed in sixteen first molars and two second molars. The study population and distribution of restorations are described in Table 3.

AMOUNT OF REMAINING CORONAL TISSUE

The height of the remaining walls for SFCRs varied between 3.3 and 3.9 mm (average 3.7 mm) and between 2.2 and 4.1 mm for GCEs (average height 3.1 mm). For both preparation designs, preparation margin thickness ranged between 1.8 and 2.1 mm, the thickness of the remaining walls varied between 1.9 and 2.7 mm, and restoration height was approximately 6 mm from the gingival margin. The dimensions of prepared teeth between the studied groups did not statistically differ, neither in height (p=0.438) nor in thickness (p=0.988).

SURVIVAL OF THE RESTORATIONS

Restorations were evaluated at baseline and after 4.0 years on average (ranging from 2.0 to 5.0 years) according to modified USPHS criteria.[34] The median age of all restorations evaluated was 50.3 months, ranging from 37.5 to 55.8 months. The median age of SFCRs was 52.2 months (± 19) and the median age of GCEs was 49.5 months (± 18). At follow up investigation, 17 restorations (n=11 SFCRs and n=6 GCEs) were still in function. One tooth restored with a GCE was extracted at 3

Table 2. Evaluation criteria used for clinical evaluation based on modified USPHS-criteria

Criteria	A	B	C	D
Anatomical form	Continuous restoration with existing anatomical form	Slightly over or undercontoured	Clear loss of the restoration has occurred to expose dentin or lining, open contact between teeth, needs to be restored	Restoration is missing (in part or total), tooth is fractured
Marginal adaptation	Tight margin between tooth and restoration, no gaps or overhangs, no staining of the margin	Minor staining of the margin, minor gap or overhang	Staining that has processed to pulpal direction, needs to be restored	-
Color match of the restoration	Matches adjacent teeth	Slight mismatch, acceptable	Gross mismatch	-
Surface texture (discoloration, porosities, cracks)	Similar to enamel	Matte, opaque surface, clinically acceptable	Rough surface, needs to be polished	-
Gingival inflammation	Healthy, no inflammation	Mild gingivitis	Mild to severe or severe gingivitis	
Secondary caries	Absence of secondary caries	Early caries, no restoration needed	Secondary caries, needs to be restored	-
Occlusion	Normal occlusal contacts	Strong occlusal contacts and/or mediotrusive interference	No occlusal contacts or strong interference	-
Patient satisfaction	Satisfaction, no complaints	Criticism concerning esthetics, oral comfort, or anything else, transient symptoms	Unsatisfied, symptomatic but bearable	Very unsatisfied, unbearable symptoms, renewal of restoration required

A: success; B: acceptable; C: unacceptable, but repairable and D: unacceptable that needs replacement.

months, due to a symptomatic periapical infection. The overall survival rate of all restorations at the end of follow up was 88.9%; 90.9% for SFCRs and 85.7% for GCEs. The success rate was 54.5% and 71.5% for SFCR and GCE respectively. All patients (100%) attended the final evaluation visit. Sixteen patients (10 women, 6 men) with final n=11 SFCRs and n=6 GCEs restorations were examined at the follow up, resulting in a patient drop-out rate of 0.0%.

CLINICAL EVALUATION OUTCOMES

'A' scores for variables 'anatomical form' and 'marginal integrity' showed a trend in favor of GCEs, but the differences were not statistically significant (p=0.129 and p=0.353, respectively for the 'anatomical form' and 'marginal integrity'). Also, GCEs had significantly (p=0.05) more 'A' scores in the variable 'surface texture' compared to SFCRs. Patients were generally satisfied with their restorations (p=0.353). The distribution of evaluation criteria findings is presented in Table 4.

Less bleeding on probing and less plaque was detected on the surface of GCEs compared to SFCRs, although the differences were not statistically significant (p=0.346 and p=0.574, respectively) *(Table 5)*. Also control teeth in the GCE group had lower plaque index and BOP scores *(Table 5)*, thus demonstrating slightly less plaque and less bleeding on probing in general among patients with GCEs.

BIOLOGIC COMPLICATIONS

Secondary caries was detected in two SFCRs (18.2%), but not in GCEs (0,0%). The difference was not statistically significant (p=0.515). One SFCR with secondary caries, which was detected at the follow-up visit, needed replacement (i.e. restoration lost) and one could be repaired (i.e. restoration still in place). One tooth restored with a GCE was extracted at 3 months, due to a symptomatic periapical infection. Distribution of evaluation criteria findings at final evaluation are presented in Table 4 and biological outcome of restorations in Table 5.

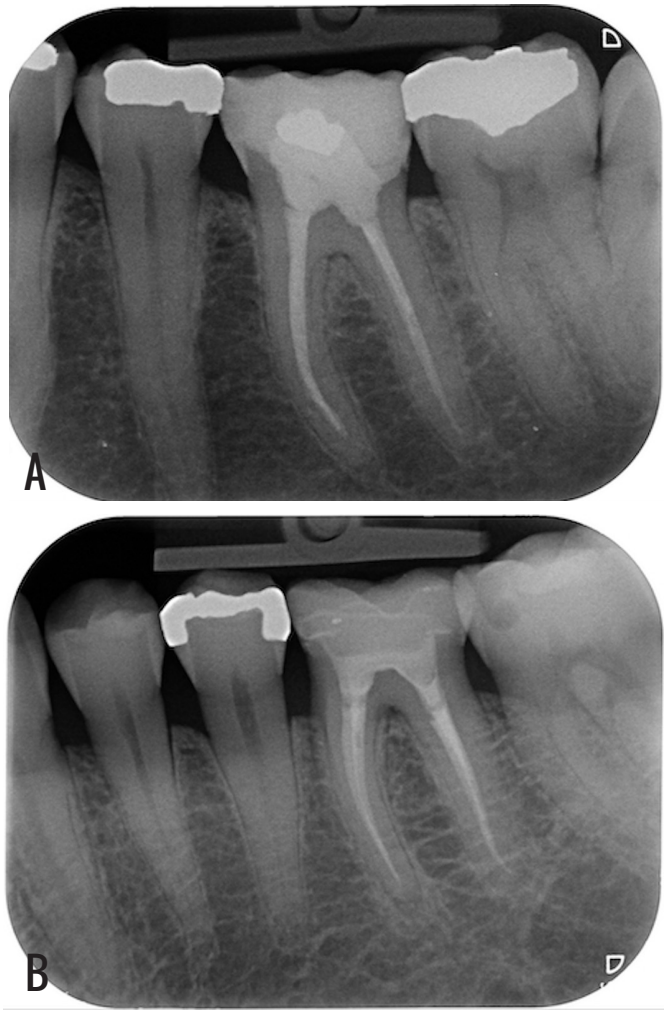

Figure 4: Radiographic images of teeth no 36 restored with A) direct composite restoration with a SFC base and B) indirect leucite-reinforced glass-ceramic endocrown restoration. Radiographs were taken at the follow-up visit.

Table 3. Type and distribution of the restorations

	Endocrowns (GCE)	SFC restorations (SFCR)	Total
Patients			16
Restorations	7	11	18
Maxillary	3	7	10
Mandibular	4	4	8
First molar	7	9	16
Second molar	0	2	2

Endocrowns: indirect restorations fabricated from leucite-reinforced glass-ceramic endocrowns (GCE group).
SFCR: direct restorations with SFC base.

TECHNICAL COMPLICATIONS

Four SFCRs (36.4%) and one GCE (14.3%) needed maintenance during the follow-up period. Two SFCRs (18.2%) required polishing due to chipping or rough surface, two SFCRs (18.2%) needed repair due to secondary caries or loss of proximal contact and one GCE required occlusal adjustment. An overview of all complications is presented in Table 6. The mean age of the restorations at the first maintenance procedure was 36 months and 55 months for the SFCRs and GCEs respectively.

NUMBER OF VISITS NEEDED FOR FABRICATION AND MAINTENANCE

When the evaluation visits for research purposes were ruled out, the number of appointments in the study groups were 1.45 visits for SFCRs and 2.14 visits for GCEs on average.

DISCUSSION

This clinical study compared the outcome of two different adhesive methods to restore endodontically treated molars. The null hypothesis was accepted, because the type of restorative technique (direct vs. indirect) did not significantly affect the survival rate of the restorations over the observation period of 45.5 months. However, direct restorations needed more maintenance than indirect restorations.

The survival rate of direct short-fiber reinforced restorations (SFCRs) in this study was good (90.9%), somewhat better than recently reported (78.6%) for SFC restorations in a 3-years follow-up,[22] and somewhat lower than previously reported (97.2%) for SFC restorations in a 2.5-years follow-up.[20] Complications needing maintenance were observed in four out of eleven SFCRs and were most commonly fractures of the superficial composite (chipping) and secondary caries. Fractures and marginal defects of composite restorations are predominant failure types in short-term (1-4 years) studies,[37] and results from the present study concur well with the earlier findings.[11,37,38] In order for the SFC base to prevent crack propagation, it must be constructed with sufficient dimensions to support the superficial (veneering) composite layer. Optimally, the thickness of the direct composite layer over the SFC base should not exceed 2 mm.[29,39] A thick overlayer could result in cohesive restoration fractures,[40] whereas superficial chipping fractures may happen if the layer of veneering composite is too thin. To meet this purpose, the SFC base should be shaped anatomically i.e. following the outline of dentin.[29] The veneering composite chippings observed in the current study could be due to the fabrication technique employed, which may have resulted in insufficient dimensions of the SFC base to support the veneering composite, thus increasing the risk for chippings. This could be avoided by constructing the approximal marginal ridges of composite restorations first, before applying the SFC base, in order to better perceive the anatomy of the restoration and desired dimensions of the supportive SFC layer.[41]

Table 4. Distribution of evaluation criteria findings at final evaluation. P-value indicates the difference in the proportion of A scores between materials

Variable	Score	Endocrown (GCE) n (%)	SFC restoration (SFCR) n (%)	P-value
Anatomical form	A	5 (83)	5 (45)	0.129
	B	1 (17)	5 (45)	
	C	0 (0)	1 (10)	
	D	0 (0)	0 (0)	
Marginal integrity	A	1 (17)	0 (0)	0.353
	B	5 (83)	11 (100)	
	C	0 (0)	0 (0)	
	D	0 (0)	0 (0)	
Color of the restoration	A	4 (67)	8 (73)	1.000
	B	2 (33)	3 (27)	
	C	0 (0)	0 (0)	
	D	0 (0)	0 (0)	
Surface texture	A	5 (83)	3 (27)	0.050
	B	1 (17)	8 (73)	
	C	0 (0)	0 (0)	
	D	0 (0)	0 (0)	
Secondary caries	A	6 (100)	9 (82)	0.515
	B	0 (0)	0 (0)	
	C	0 (0)	2 (18)	
	D	0 (0)	0 (0)	
Occlusion	A	4 (80)	5 (83)	1.000
	B+C	1 (20)	1 (17)	
	C	0 (0)	0 (0)	
	D	0 (0)	0 (0)	
Patient satisfaction	A	5 (83)	11 (100)	0.353
	B+C+D	1 (17)	0 (0)	
	C	0 (0)	0 (0)	
	D	0 (0)	0 (0)	

Endocrowns: indirect restorations fabricated from leucite-reinforced glass-ceramic endocrowns (GCE group).
SFCR: direct restorations with SFC base.
A: success; B: acceptable; C: unacceptable, but repairable and D: unacceptable that needs replacement.

Secondary caries is usually detected after 5 years of restoration service,[37] but in the present study was detected in two restorations, after 3 and 4 years, and required one restoration replacement and one restoration repair. Interestingly, the BOP scores were higher for the patient that received direct restorations including also their control teeth. This finding suggests that the difference between the groups could also be related to patient-related factors, and not only to the type of restorative material. Therefore, secondary caries could also be explained by factors such as higher caries risk and non-controlled oral hygiene protocol over the observation period. Nevertheless, caries recurrence earlier than the estimated 5 years is not uncommon.[38,42]

The survival rate of GCEs in the present study (85.7%) is slightly lower than previously reported in the literature for similar restorations. Survival rates for single ceramic restorations vary between 80% and 100% depending on observation time and type of restoration.[6,38,43-50] The small sample size (only 7 endocrowns in total) is likely to influence the survival rate of the present study. However, since only one restoration was lost, and the cause of failure was endodontic and not directly related to the restoration, the clinical performance of leucite-reinforced ceramic endocrowns can be considered very good.

Major technical complications, such as cusp fractures or catastrophic tooth failures were not observed for any of the materials investigated in this study. In general, the main technical complications for ceramic restorations are fractures and chippings,[8,38,43,44,46-50] whereas large direct restorations usually fail due to cohesive material fractures.[38,51] The lack of major technical failures for the direct SFCRs may be attributed to the presence of short fibers in the SFC base. Short fibers behave as crack stoppers, hence deviating the crack.[27,28] By arresting the fracture propagation, bulk material fractures and catastrophic tooth failures could be diminished, and teeth preserved for future treatment.[28,29] Indirect restorations (GCEs), on the other hand, were monolithic ceramic restorations utilizing the pulp chamber for retention and for obtaining sufficient thickness of the restoration. The space provided by the pulp chamber enables maintaining adequate endocrown thickness even after the occlusal adjustment. Finishing and polishing procedures were carefully performed after the occlusal adjustment, hence, cracks leading to later cohesive ceramic fractures were diminished. In addition, both restoration types were cusp covering, which have favorable compressive load characteristics, prevent excessive cuspal flexure and stresses at the adhesive interface.[52,53]

Using the available depth of the pulp chambers could have increased the bonding surface area and provided mechanical retention. This could explain why adhesive failures, such as debonding, were not observed in this study.

In the present investigation, indirect restorations were found to have a smoother surface appearance than direct restorations. Depending on the material type, the first signs of surface texture deterioration could be observed already after the first year.[49] More commonly, however, the surface of

Table 5. Biological outcome

	All restorations	Endocrowns (GCE)		SFC restorations (SFCR)		P-value (between material)
		study teeth	control teeth	study teeth	control teeth	
Mean plaque index score	0.59	0.42	0.58	0.68	0.64	0.574
Mean BOP %	41.2%	33.3%	33.0 %	45.5%	47.0 %	0.346

Endocrowns: indirect restorations fabricated from leucite-reinforced glass-ceramic endocrowns (GCE group).
SFCR: direct restorations with SFC base.

Table 6. Reason for repair/replacement of direct composite restorations and ceramic endocrowns, with additional information on patients, teeth, restoration size and material used

Patient age (y)	Gender	Study tooth	Restoration size	Restoration type	Complications and maintenance / treatment measures	Complication type
28.7	F	16	MOB	SFCR	Overhanging and loss of proximal contact; repair	technical complication
37.2	M	46	MODBP	SFCR	Secondary caries; replacement	failure
61.6	F	17	MODBP	SFCR	Chipping at the distal surface; adjustment	technical complication
38.1	F	46	MODBL	SFCR	Secondary caries and loss of proximal contact; repair	biological/technical complication
24.9	F	16	MOB	SFCR	Rough buccal surface in need of a polishing; adjustment	technical complication
48.0	M	26	MODB	IPS Empress CAD	Apical periodontitis, tooth extraction	failure
38.5	M	16	MODBP	IPS Empress CAD	Occlusal adjustment	technical complication

F: female; M: male; SFC: SFC material used was everX Posterior; IPS Empress CAD: leucite-reinforced glass-ceramic.
MOB: mesio-occlusal-buccal; MODBP: mesio-occlusal-distal-buccal-palatinal; MODBL: mesio-occlusal-distal-buccal-lingual; MODB: mesio-occlusal-distal-buccal.
Endocrowns: indirect restorations fabricated from leucite-reinforced glass-ceramic endocrowns (GCE group).
SFCR: direct restorations with SFC base

various types of adhesive restorations could become slightly rough or pitted, on average, over 4 years of service time.[38,48,49] Rougher surfaces could explain the slightly higher BOP scores observed for the direct restorations in this investigation. Plaque accumulation in vivo has been found to correlate with the surface roughness of the material, with polished ceramic surface having the smoothest surface and lowest counts of adhered bacteria.[54] However, the surface texture of the SFCRs is dependent on the overlaying composite type and could be improved by selecting a veneering material with smaller filler size. Nonetheless, polished ceramic materials retain less plaque than other restorative materials[54] and this advantage of the ceramic materials has been observed also clinically in this and another study.[55] Comparison to other studies is limited, because cusp covering ceramic and resin composite restorations have never been compared in a controlled clinical trial. Until today, only a few studies have been conducted to compare ceramic and resin composite inlays[38,42,50] and the results are inconclusive. It should be mentioned, that surfaces that in this study were found rough, required only polishing.

Indirect restorations have superior esthetics and anatomic contours, including good proximal contacts. In this study, indirect restorations showed better anatomic morphology than direct restorations. A similar trend is observed in other studies comparing direct and indirect restorative approaches.[38,42] GCEs in the present study were fabricated utilizing CAD/CAM technology, which is known to reproduce restorations with superior anatomical contour.[56] Indirect manufacturing is also less technique sensitive as well as less dependent on operator skills and experience than the direct technique, particularly for large posterior restorations. The direct restorations scored lower for 'anatomic contour' most likely because of their size. Such extensive restorations as made in this study often require modified techniques for achieving good interproximal and interocclusal contacts, and also specific skills.[57-59] Although supervised and highly motivated, the restorations in the present study were made by undergraduate students. Whether the deficiencies in anatomic form increased the plaque retention of SFCRs contributing to secondary caries occurrence could only be speculated, but still not excluded.

The marginal adaptation, however, did not differ between the materials and slight margin discoloration was detected for both material types. Marginal area is probably the most difficult and critical part to be designed in the CAD software, and is also difficult to mill exactly as designed because it is very thin. Consequently, margins are prone to fracture either at the time of milling or at the cementation visit. Particularly this was the case for the technology available at the time when the present study was conducted, when both CAD/CAM technology and CAD/CAM materials were not as developed as they are today. Therefore, the study design was limited to the technology and materials available at that time. For direct SFCRs, polymerization shrinkage of the superficial (veneering) composite layer is a possible reason leading initially to marginal leakage at the interface of tooth and restoration, and later to secondary caries (material related factor). The plaque accumulation (observed in the higher BOP scores for this material group) and the poor oral hygiene (patient related factor) could have accelerated this process.

Concerning the amount of removed tissue during preparation, as subjectively reported by the investigators, direct restorations required minimal preparation technique (decay orientated) allowing undercuts. Measurements performed on the plaster models confirmed this, because the SFCR group had greater coronal tissue amount remaining after tooth preparation. Indirect restorations required more extensive preparation in terms of cusps' reduction (for providing sufficient and equal material thickness at the cusp tips) and undercut elimination. Consequently, it could be assumed that the direct technique is less invasive and could enable maximal tissue conservation. Within the limitations of this study, however, it cannot be speculated whether or how the additional loss of sound dental tissue for indirect restorations could have affected the survival rates.

Finally, fabrication of indirect restorations (GCEs) required always two appointments (preparation and cementation), whereas direct restorations (SFCRs) were made in one single appointment and in a few cases minor adjustments were made at the baseline investigation visit. Even with the maintenance appointments included, direct SFCRs required fewer visits during the 4-year follow-up. With a survival rate of 90.9%, direct SFCRs can be considered a cost-effective way to restore ETMs.

Limitations of the present study are small sample size and uneven distribution of the studied restoration types (11 SFCRs, 7 GCEs). One way of overcoming this limitation would have been recruiting more patients. However, this was not possible due to lack of resources. Having this in mind, attempts were made to reduce variability between the groups and improve the power by having a similar amount of remaining coronal tissue in both groups. The follow-up time in this study was relatively short, on average 4 years. Possible clinical failures will need a longer time to occur and it is undeniable that the results presented here can only be regarded as preliminary. However, the concept of using high aspect ratio SFC clinically is novel and thus also short-term clinical data can be considered to give valuable information. Moreover, cusp covering SFC restorations and ceramic restorations have not been investigated in the same patient population and randomized clinical trial before.

CONCLUSIONS

Within the limitations of this study it could be concluded that:

1. Both restorative techniques are viable therapeutic options for restoring non-vital molars.
2. Direct technique utilizing SFC was found to require fewer visits, but more maintenance than the indirect technique, which needed more (two) visits, but less maintenance.
3. Anatomical form and surface texture were better maintained by indirect endocrown restorations, whereas marginal integrity of restorations did not differ between the studied materials.

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