

Two-year clinical comparison of direct and indirect composite restorations in severely damaged molars: A split-mouth randomized clinical study

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ABSTRACT

Objectives: This randomized, split-mouth clinical study compared the clinical performance of direct restorations using a short fiber-reinforced composite veneered with a microhybrid composite and indirect CAD-CAM restorations fabricated from a hybrid CAD-CAM block in severely damaged molars.

Methods: One hundred restorations in 42 patients—50 direct short fiber-reinforced composite restorations veneered with a microhybrid composite and 50 indirect CAD-CAM nanoceramic composite restorations—were randomly assigned to severely damaged molars in a split-mouth design; all restorations involved reconstruction of at least one cusp. All restorations were performed by a single qualified operator, and two independent calibrated examiners evaluated the restorations at baseline, 6 months, 1 year and 2 years using modified USPHS criteria. Patient satisfaction was also assessed at each evaluation.

Results: After two years of follow-up, all restorations remained functional, resulting in a 100% survival rate. One indirect restoration experienced debonding one week after placement, which was successfully re-bonded and showed no further complications during follow-up. Both restorative approaches demonstrated excellent clinical performance across all USPHS criteria, with no significant differences between direct and indirect composite restorations.

Conclusions: Direct and indirect restorations showed high survival and success rates after 2 years. Patient satisfaction was high, with no significant difference between the two restorative approaches.

Clinical significance: At the 2-year follow-up, direct restorations based on short fiber-reinforced composite showed clinical results comparable to those of indirect CAD-CAM composite restorations in severely damaged molars.

1. Introduction

For decades, indirect restorations—particularly crowns—were considered the treatment of choice to achieve long-term durability, and even permanence [1]. The traditional approach consisted of removing or covering previous direct restorations, based on the assumption that indirect restorations ensured superior marginal adaptation, aesthetics and improved resistance to wear, fracture, and discoloration [1]. Nevertheless, indirect procedures involve multiple clinical appointments and are associated with higher material and laboratory costs compared to direct composite techniques [1–4]. This assumption is now regarded as outdated, since modern adhesive restorative materials show similar

clinical longevity whether applied through direct or indirect techniques [1,3,5–7]. Moreover, patient-related risk factors may outweigh material-related factors in unfavorable conditions [1,8,9]. Nowadays, the priority is the preservation of dental tissues and the maintenance of overall dentition function rather than the longevity of the restoration itself. Recent evidence indicates that both direct and indirect restorative approaches can provide reliable outcomes in the management of structurally compromised molars [2,5,6,10].

Direct composite restorations have several advantages. They do not require invasive preparations [11], have properties compatible with restorations of posterior teeth, can be completed in a single appointment and are less costly for the patient [5,12]. Extensive direct restorations in

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posterior teeth remain technically demanding and require procedures whose success depends closely on the clinician's expertise [13]. Proper anatomical and occlusal outcomes depend on advanced operator skills [14–16]. Moreover, the intrinsic polymerization shrinkage of resin-based composites introduces significant biomechanical challenges [16–19]. Shrinkage-induced stresses may impair the dentin–resin interface [16,17,20,21]. Moreover, when high-performance adhesive systems are employed, the resulting stress may instead manifest as cuspal deflection or enamel cracking at the base of the cusp [16,22,23].

Severely damaged molars represent a high-risk biomechanical situation. The extensive loss of coronal structure reduces cuspal rigidity and increases cuspal deflection under occlusal load, which favors crack initiation and fracture [24,25]. This fragility is further amplified in endodontically treated teeth [26]. Clinically, these factors justify the need for restorative approaches that can reinforce the remaining tooth structure [24].

Frequent bulk fractures and wear in posterior teeth raise concerns about the reliability of conventional composites in large cavities [13]. To overcome these limitations, short fiber-reinforced composites (SFRCs) have been developed. They improve crack resistance and stress distribution through fiber reinforcement [13,19,27,28]. *In vitro* studies show that short fiber-reinforced composites effectively strengthen structurally compromised teeth [29,30]. When used as dentin substitute beneath a conventional composite veneer, SFRCs increase fracture resistance, preserve residual tooth structure, and reduce catastrophic failures [16,21]; a cusp-supporting design further reinforces weakened cusps by limiting deflection and stress concentration [13]. Due to these dentin-like biomechanical properties, SFRCs have expanded their indications to both vital and endodontically treated teeth, even in extensive mesio-occluso-distal (MOD) cavities [29]. Although indirect restorations were traditionally considered the gold standard, recent advances suggest that direct alternatives may offer comparable reliability with greater efficiency [21,25].

Recent advances in dental materials have led to the development of new CAD-CAM options designed to combine the benefits of both composites and ceramics [31–34]. From a clinical perspective, dispersed particle-filled composites demonstrate survival rates ranging from 89.0% to 97.9% over observation periods of two to five years [34,35].

A key limitation identified in the literature is that, although several classifications have been proposed, none is universally accepted or consistently applied in clinical studies to describe severely damaged molars [36]. Most available clinical studies have focused on Class II restorations, often involving moderate tissue loss, without cuspal coverage and without clearly defining what constitutes a “damaged molar” [19,37]. As is common in studies assessing the longevity of composite restorations, most reported cases concern small to moderate defects [2]. However, the presence of a Class II cavity does not necessarily imply a severely damaged tooth. To better reflect clinical reality, this study aims to evaluate restorations placed in severely damaged molars with at least one missing cusp. A standardized classification scheme for structural loss would therefore be essential to properly characterize the extent of tissue destruction and to facilitate comparison across clinical studies [36,38].

However, despite the growing body of evidence supporting both direct and indirect restorative approaches, the optimal strategy for managing severely damaged molars with cuspal loss remains unclear. In such cases, clinicians face a clinical dilemma: indirect restorations are traditionally recommended but require more extensive tooth preparation, potentially leading to additional loss of sound dental tissue, whereas direct approaches allow for a more conservative management but their reliability in these high-risk biomechanical situations remains debated.

Therefore, there is a need for clinical studies comparing these approaches under standardized conditions to better document clinical decision-making within the framework of minimally invasive dentistry. The objective of this randomized clinical study was to compare direct

and indirect restorations in severely damaged molars in adult patients using both qualitative (patient- and operator-reported outcomes) and quantitative (USPHS criteria) assessment methods. The null hypothesis was that there would be no difference in clinical performance or patient satisfaction between direct short fiber-reinforced composite restorations and indirect composite overlay restorations placed in severely damaged molars.

2. Methods

2.1. Study characteristics and design

The reporting of this study adheres to the CONSORT checklist [39] and was conducted in accordance with the principles outlined in the Declaration of Helsinki for medical research involving human subjects. The study protocol was reviewed and approved by the Ethics Committee of the University Hospital of Liège (reference number: 2019/50). Written informed consent was obtained from all participants prior to their enrolment.

This split-mouth randomized clinical trial was conducted from April 2019 to April 2023 in the Department of Fixed Prosthodontics and Restorative Dentistry, School of Dental Medicine, University of Liège. At least 2 severely damaged molars, all characterized by advanced structural loss with at least one missing cusp, were restored in each participant with one direct short fiber-reinforced composite restoration (everX® Posterior, GC, Tokyo, Japan) and one indirect CAD-CAM composite restoration (Ceramart™ 270, GC Corp., Tokyo, Japan) on contralateral teeth, either within the same jaw or across different jaws. The random allocation sequence was generated using a computer-based randomization file (Microsoft Excel, Microsoft Corporation, Redmond, WA, USA), in which each eligible pair of severely damaged molars was randomly assigned to either the direct or the indirect restorative technique. Allocation concealment was ensured by preparing sealed envelopes based on this sequence, which were opened by the operator only at the time of the restorative procedure, after confirmation of eligibility. All restorations were placed by a single qualified operator with six years of clinical experience at study initiation in 2019, while two independent calibrated examiners performed the clinical evaluations. Paired restorations were not performed during the same appointment due to differences in clinical workflow between direct and indirect procedures.

2.2. Sample size calculation and participants

The primary end point of the trial was the 24-month clinical success rate according to the modified USPHS criteria. A restoration was considered successful if none of the following conditions were met: a score of B for USPHS 8 (secondary caries), a score of C for USPHS 10 (fracture), or a score of B for USPHS 11 (debonding). To determine the sample size, let P and Q denote for each patient the proportions of successful direct and indirect restorations over pairs of damaged molars. Then, at the patient population level, under the null hypothesis of equality between direct and indirect restorations, the mean of the difference $D = (P - Q)$ is expected to be 0; otherwise, it differs from 0 ($\Delta \neq 0$). Then, a power calculation showed that at least $N = 34$ patients were required to detect an effect size of 0.5 with a power of 80% and a critical level of 5% using a two-sided paired *t*-test.

Adult patients attending the Department of Fixed Prosthodontics and Restorative Dentistry of the University Hospital of Liège and requiring extensive restoration of severely damaged molars were included sequentially in the study provided they fulfilled inclusion criteria. Each patient contributed at least one pair of homologous molars. In cases where two eligible pairs were present, both pairs were included in the study. Eligibility criteria were respectively: age ≥ 18 years; presence of at least one pair of homologous molars (vital or endodontically treated) with severe structural loss, including at least one cusp requiring reconstruction, suitable for both tested strategies; occlusal stability allowing

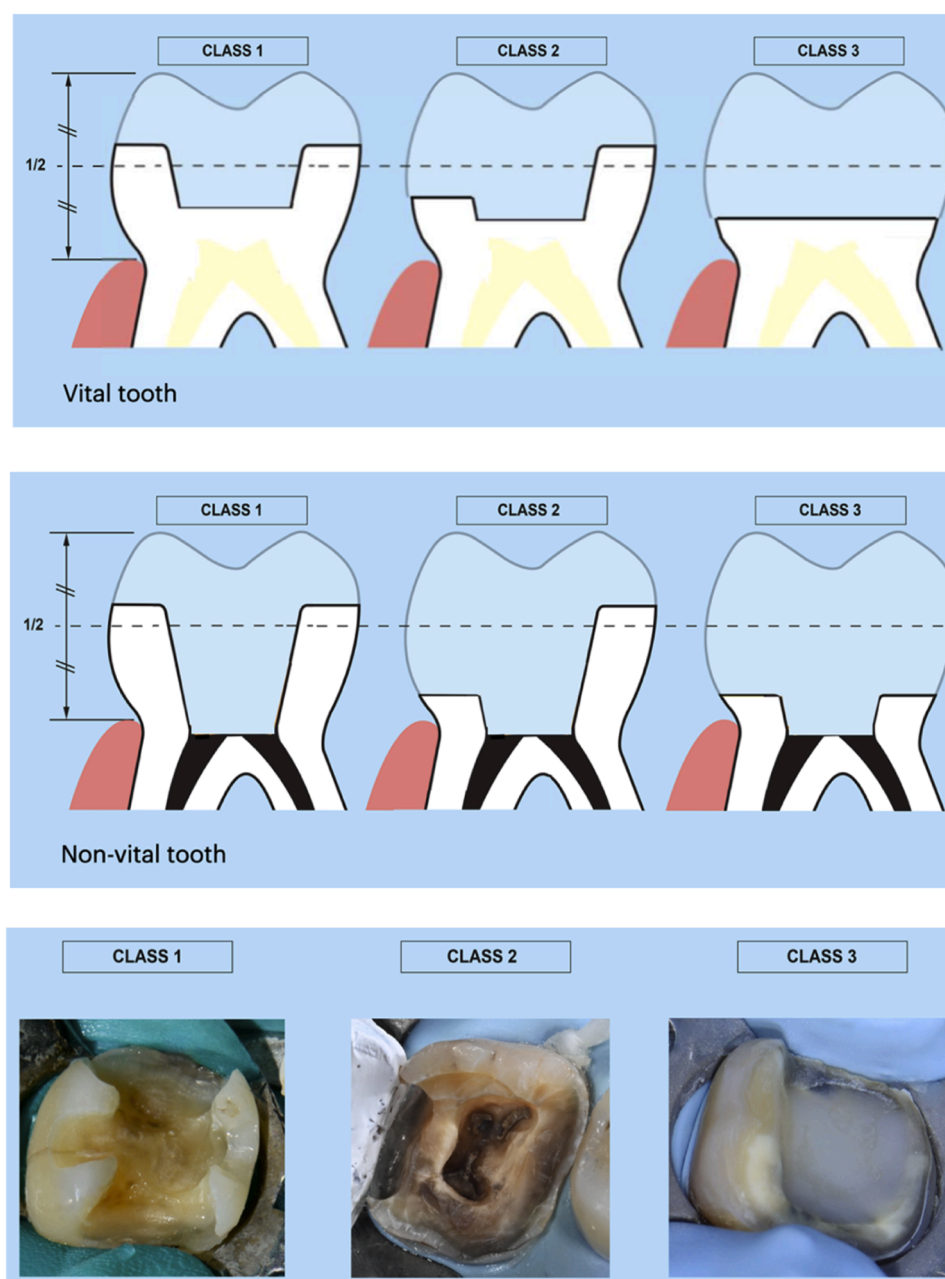


Fig. 1. Classification based on residual tooth tissue amount after preparation of both vital and non-vital teeth.

adhesive rehabilitation; and ability to provide informed consent and attend follow-up visits. Although pulp vitality may influence fracture behavior and long-term prognosis, the extent of residual coronal tissue loss was considered the main inclusion criterion in the present study, since all included molars exhibited severe structural compromise with cuspal loss. No exclusion criteria were applied regarding oral hygiene level, caries risk, or parafunctional habits (e.g., bruxism), to reflect routine clinical conditions and enhance external validity.

Randomization was performed within each eligible pair of molars using a computer-generated list (Excel, Microsoft Corporation, Redmond, WA, USA), allocating one tooth to the direct protocol and the contralateral tooth to the indirect protocol in a 1:1 ratio, following a split-mouth design. Treatment allocation was strictly randomized and independent of operator judgment, with no clinical selection based on tooth vitality or extent of damage.

2.3. Classification according to residual dental structures

For this trial, all included teeth exhibited severe structural loss before tooth preparation, with at least one cuspal wall requiring reconstruction. A classification was established according to the amount of residual dental structures after preparation [38]. Three categories were defined for vital and non-vital teeth, respectively: Class 1, when at least two cuspal walls preserved more than half of their original height; Class 2, when only one cuspal wall preserved more than half of its original height; and Class 3, when all cuspal walls were reduced by more than half of their original height (Fig. 1). Although residual cuspal thickness is also known to influence fracture risk, this parameter was not measured quantitatively, as treatment allocation was randomized and not based on structural parameters such as cuspal thickness.

2.4. Clinical procedures

2.4.1. Direct restorations

For direct restoration, rubber dam isolation was used in all cases. Cavities were prepared according to a minimally invasive approach, restricted to the removal of previous restorative materials and carious tissue. A total-etch procedure was performed with 37% phosphoric acid for 20 s on enamel and 15 s on dentin, followed by the application of a three-step etch-and-rinse adhesive system (OptiBond™ FL, Kerr, Bioggio, Switzerland) in accordance with the manufacturer’s instructions. The cavity was first transformed into a Class I using a circumferential matrix (Hawe Micro Thin Matrix, Kerr, Switzerland) and then filled with microhybrid composite (ELS®, Saremco Dental AG, Rebstein, Switzerland). Then a short fiber-reinforced composite (everX® Posterior, GC, Tokyo, Japan) was placed in bulk increments of up to 4 mm, sculpted to replace dentin, and light-cured for 40 s using a LED curing light (VALO™ Cordless; Ultradent Products, Inc., South Jordan, UT, USA). The occlusal surface was subsequently covered with a composite (ELS®, Saremco Dental AG, Rebstein, Switzerland) to reproduce the enamel occlusal morphology. No flowable composite liner was applied beneath the short fiber–reinforced composite and conventional resin composite was used as a superficial veneering layer with a standardized thickness of 2 mm. Restorations were finished and polished using dedicated polishing burs.

2.4.2. Indirect restorations

All indirect restorations performed in this study were overlays, characterized by cuspal coverage. All treatments were performed in two clinical appointments spaced one week apart. During the first appointment, rubber dam isolation was used for all clinical steps. Carious tissues and existing restorations were removed, preserving as much sound tooth structure as possible. In endodontically treated teeth, the pulp chamber was systematically filled with a short fiber–reinforced composite (everX® Posterior, GC, Tokyo, Japan). Immediate dentin sealing (IDS) was performed in all cases using a three-step etch-and-rinse adhesive (OptiBond™ FL, Kerr, Bioggio, Switzerland), applied according to the manufacturer’s instructions and light-cured immediately after preparation using a LED curing light (VALO™ Cordless; Ultradent Products, Inc., South Jordan, UT, USA). In some situations, undercut areas of the cavity were filled with a composite resin (ELS®, Saremco Dental AG, Rebstein, Switzerland) to avoid unnecessary removal of sound tissue and to obtain a non-retentive preparation. The cavity base was prepared with a flat configuration in all cases. Digital impressions were obtained using an intraoral scanner (Trios®, 3Shape, Copenhagen, Denmark). No provisional overlay was placed during the one-week interval. At the second appointment, the restorations—designed and milled using CAD-CAM technology from nanoceramic composite blocks (Cerasmart™ 270, GC Corp., Tokyo, Japan)—were bonded. Prior to luting, the intaglio surface of the restorations was air-abraded with 50 µm alumina and treated with a silane coupling agent (Monobond Plus; Ivoclar Vivadent, Schaan, Liechtenstein). After air abrasion of the IDS surface with CoJet™ (3 M, Saint Paul, MN, USA) and application of a dual-cure adhesive system (Excite® DSC, Ivoclar, Schaan, Liechtenstein), all restorations were luted using a resin cement (Variolink® II, Ivoclar, Schaan,

Liechtenstein) and light-cured using a LED curing light (VALO™ Cordless; Ultradent Products, Inc., South Jordan, UT, USA). Occlusion was carefully adjusted, and the restorations were finished and polished.

2.5. Evaluation

All restorations were evaluated at baseline, 6 months, 1 year, and 2 years by two independent examiners, not involved in the restorative procedures. Examiner calibration was performed prior to study initiation, and inter- and intra-examiner reliability were assessed using Cohen’s weighted kappa. The observed agreement was 86.7%, with all disagreements limited to adjacent categories (Alpha/Bravo), indicating a high level of examiner reliability. The examiners were blinded to randomization, treatment allocation, and previous evaluation scores; however, complete blinding to restoration type was not possible due to the inherent differences between the restorative approaches. Clinical evaluation followed the modified United States Public Health Service (USPHS) criteria, assessing anatomical form, interproximal contact points, surface texture, color match, marginal adaptation, marginal discoloration, gingival inflammation, secondary caries, postoperative sensitivity, fracture and debonding. Each criterion was scored on a four-point scale (Alpha, Bravo, Charlie, Delta), according to modified USPHS criteria reported in previous clinical studies. Alpha and Bravo scores were considered clinically acceptable for most criteria, except for secondary caries, fractures, and debonding, where only Alpha was considered acceptable. Charlie and Delta scores were always classified as failures, with Delta used to identify catastrophic failures or restorations requiring replacement. For each restoration, a periapical radiograph was obtained at every evaluation time point. Radiographs were taken by the examiners and used to assess marginal adaptation and the presence of secondary caries.

2.6. Patient satisfaction

Patients were asked to rate their satisfaction using a 5-point Likert scale (1 = very dissatisfied, 5 = very satisfied) immediately after restoration placement and at each follow-up visit (6 months, 1 year, and 2 years). Four domains were evaluated: aesthetics, treatment time, surface texture, and comfort. The use of a Likert scale was intended to provide a pragmatic assessment of subjective perceptions and should be interpreted as complementary to the objective clinical evaluation based on USPHS criteria.

2.7. Operator evaluation at baseline

At baseline, immediately after placement of the restorations, the operator performed an evaluation using a similar 5-point Likert scale (1 = very dissatisfied, 5 = very satisfied). The assessment covered aesthetics, treatment time, surface texture, and ease of procedure. These data provided complementary information on the operator’s perception of the clinical handling and immediate outcome of the two restorative strategies.

2.8. Statistical analysis

Results were summarized as mean and standard deviation (SD) for quantitative variables and scores while numbers (%) were used for binary and categorical variables. Direct and indirect restorations being applied in each patient, mean values were compared by the paired Student *t*-test and proportions by the McNemar test. The time evolution of scores between direct and indirect restoration procedures was compared by generalized linear mixed effects models (GLMM) to account for repeated assessment scores within patients and intra-patient correlation between direct and indirect teeth evaluations. Results were considered significant at the 5% critical level (*p* < 0.05). Statistical calculations and graphs were performed with SAS version 9.4 and R

Table 1
Patient characteristics (N = 42).

Variable	N	Number (%)
Age at first restoration (years)	42	53.1 ± 11.8*
Sex	42	
Female		26 (61.9)
Male		16 (38.1)
Number of pairs of molars restored per patient	42	
1		34 (81.0)
2		8 (19.0)

* Mean ± SD.

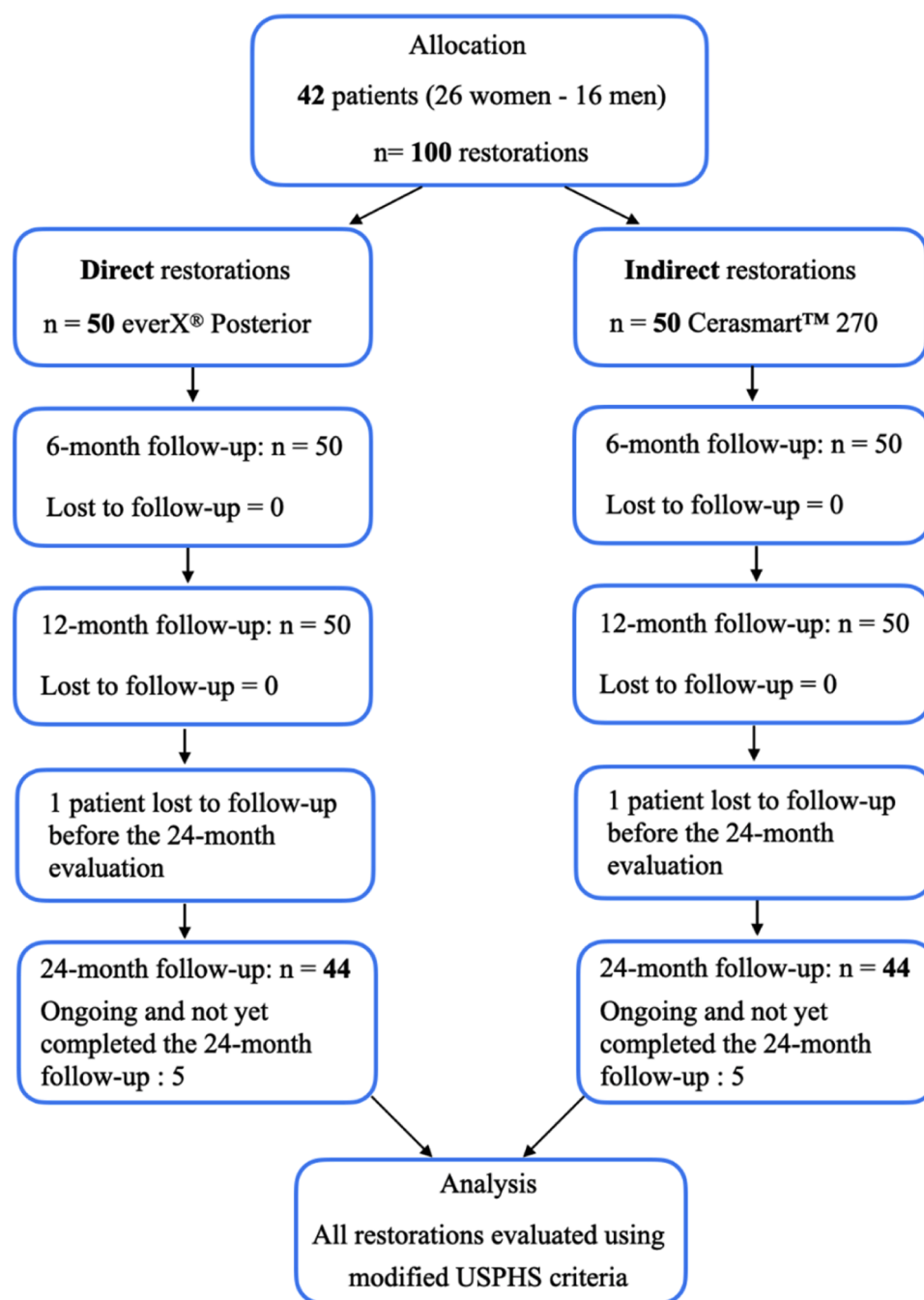


Fig. 2. CONSORT flow diagram of patient and tooth allocation.

version 4.4.1 programs.

3. Results

3.1. Patient characteristics

Forty-two patients (26 women and 16 men; mean age 53.1 ± 11.8 years, range 22–73 years) were included in the study for a total of 100 restorations, 50 direct short-fiber reinforced composite and 50 indirect CAD-CAM nanoceramic composite, respectively. Most patients (81%) received one pair of restorations, while 19% received two pairs (Table 1). At 24 months, 36 (85.7%) patients contributed to 44 pairs of restorations (88 teeth). One patient was lost to follow-up before the 24-month recall, and five patients had not yet reached this time point at

database lock (Fig. 2).

3.2. Classification according to residual dental structures

Among the 50 direct restorations, after preparation, 26 (52%) were classified Class 1, 15 (30%) Class 2 (30.0%), and 9 (18%) Class 3. In contrast, indirect restorations were associated with larger post-preparation cavities, with 47 (94%) assigned to Class 3, only 2 (4%) to Class 2, and 1 (2%) to Class 1 (Table 2). This difference in distribution was significant ($p < 0.0001$), indicating that the indirect restorative strategy resulted in greater post-preparation structural loss. It should be emphasized that this classification was established after tooth preparation and therefore does not represent a baseline characteristic; the observed distribution reflects intrinsic differences between restorative

Table 2

Tooth characteristics in direct and indirect restoration procedures (N = 50 pairs of teeth).

Variable	N	Direct restoration	Indirect restoration	P-value*
Location (N,%)	50			0.83
Maxillary		21 (42.0)	20 (40.0)	
Mandible		29 (58.0)	30 (60.0)	
Residual tooth structure class (N,%)	50			<0.0001
1		26 (52.0)	1 (2.0)	
2		15 (30.0)	2 (4.0)	
3		9 (18.0)	47 (94.0)	
Devitalized tooth (N,%)	50			0.0011
No		37 (74.0)	22 (44.0)	
Yes		13 (26.0)	28 (56.0)	
Patient evaluation score at the end of the restoration (mean $\pm$ SD)				
Aesthetic	50	4.9 $\pm$ 0.3	4.9 $\pm$ 0.3	0.77
Time	50	4.5 $\pm$ 0.7	4.5 $\pm$ 0.8	0.85
Texture	50	4.8 $\pm$ 0.5	4.8 $\pm$ 0.4	0.32
Comfort	50	4.7 $\pm$ 0.6	4.6 $\pm$ 0.8	0.50
Practitioner evaluation score at the end of the restoration (mean $\pm$ SD)				
Aesthetic	50	3.8 $\pm$ 0.4	4.3 $\pm$ 0.5	<0.0001
Time	50	4.0 $\pm$ 0.6	4.2 $\pm$ 0.6	0.078
Texture	50	3.9 $\pm$ 0.4	4.4 $\pm$ 0.5	<0.0001
Ease	50	3.9 $\pm$ 0.7	4.1 $\pm$ 0.7	0.16

* McNemar or paired Student *t*-test.

strategies and, more specifically, the associated preparation techniques.

3.3. Tooth characteristics

Among the 50 pairs of restored molars, 42% of the direct restorations and 40% of the indirect restorations were placed in the maxilla, while 58% and 60%, respectively, were placed in the mandible. Of the 100 restorations, 59% were performed on vital teeth and 41% on endodontically treated teeth (ETT). A higher proportion of endodontically treated teeth was observed in the indirect group, as detailed below. Based on residual tooth structure after preparation, a significant difference was observed between groups: indirect restorations resulted in larger post-preparation structural loss due to the more invasive preparation design (Fig. 1, class 3) than direct restorations (94%vs. 18%, $p < 0.0001$). Endodontically treated teeth were also more common in the indirect group than in the direct group (56%vs. 26%, $p = 0.0011$) (Table 2). Inclusion was based on the extent of coronal tissue loss rather than pulpal status; both vital and endodontically treated molars were therefore included, as severe structural compromise was considered the major biomechanical determinant. Accordingly, the higher proportion of endodontically treated teeth observed in the indirect group was not used as a selection criterion and resulted solely from the randomization process. This approach was intentionally chosen to reflect routine clinical conditions.

3.4. Patient and operator evaluation

Immediately after treatment, patients reported similarly high levels of satisfaction for both techniques regarding aesthetics (mean 4.9 ± 0.3 vs. 4.9 ± 0.3), treatment time (4.5 ± 0.7 vs. 4.5 ± 0.8), texture (4.8 ± 0.5 vs. 4.8 ± 0.4), and comfort (4.7 ± 0.6 vs. 4.6 ± 0.8), with no significant difference (Table 2). Patient-reported comfort improved

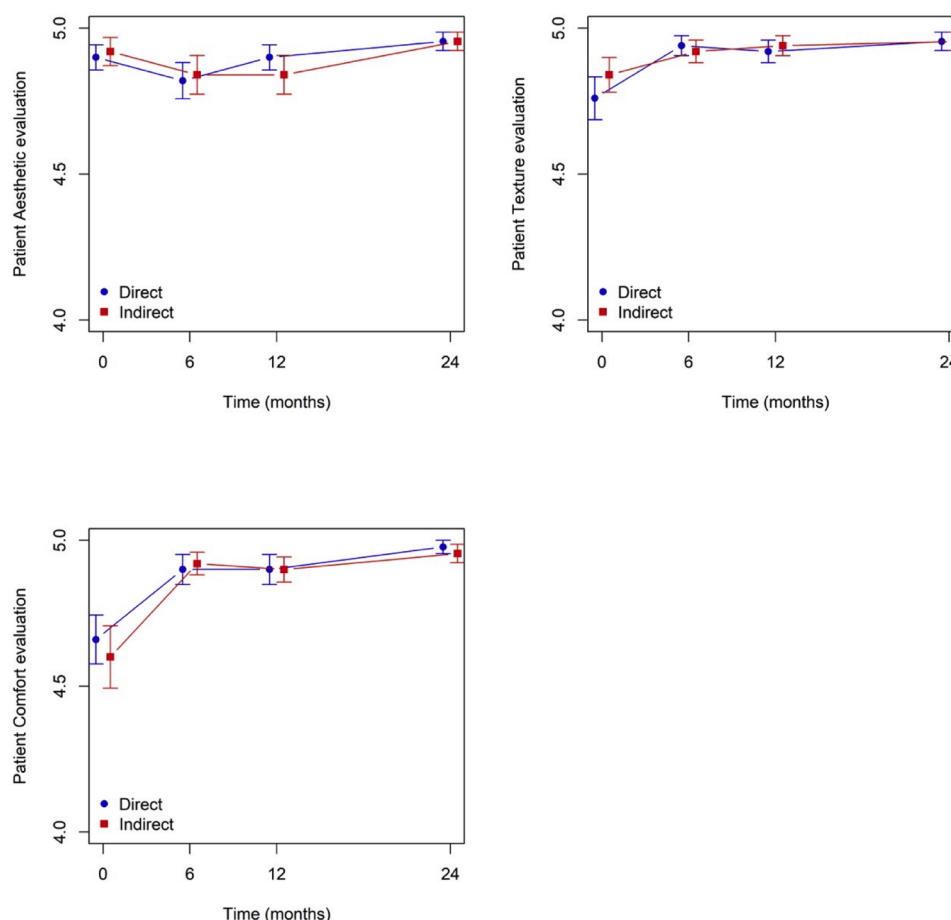


Fig. 3. Evolution of patient evaluation scores (esthetic, texture and comfort) during 24-month study period.

Table 3

Distribution (%) of modified USPHS scores for direct and indirect restorations at 6, 12, and 24 months of follow-up.

6 months ¹							
Variable	Direct restoration n=50 molars			Indirect restoration n=50 molars			
	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	
1. Anatomical form	88.0	12.0		90.0	10.0		
2. Interproximal contact points	98.0	2.0		98.0	2.0		
3. Surface texture	92.0	8.0		96.0	4.0		
4. Color match	68.0	32.0		66.0	34.0		
5. Marginal adaptation	94.0	6.0		76.0	20.0		4.0
6. Marginal discoloration	92.0	8.0		92.0	8.0		
7. Gingival inflammation	100.0			98.0	2.0		
8. Secondary caries	100.0			100.0			
9. Postoperative sensitivity	98.0	2.0		96.0	4.0		
10. Fracture	100.0			100.0			
11. Debonding	100.0			98.0	2.0		
12 months ²							
Variable	Direct restoration n=50 molars			Indirect restoration n=50 molars			
	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	
1. Anatomical form	90.0	10.0		90.0	10.0		
2. Interproximal contact points	98.0	2.0		98.0	2.0		
3. Surface texture	92.0	8.0		94.0	6.0		
4. Color match	56.0	44.0		68.0	32.0		
5. Marginal adaptation	90.0	10.0		68.0	28.0		4.0
6. Marginal discoloration	94.0	6.0		94.0	6.0		
7. Gingival inflammation	100.0			94.0	6.0		
8. Secondary caries	100.0			100.0			
9. Postoperative sensitivity	96.0	4.0		98.0	2.0		
10. Fracture	100.0			100.0			
11. Debonding	100.0			100.0			
24 months ³							
Variable	Direct restoration n=44 molars			Indirect restoration n=44 molars			P-value ⁴
	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	
1. Anatomical form	88.6	11.4		86.4	13.6		0.74
2. Interproximal contact points	97.7	2.3		100.0			0.32
3. Surface texture	84.1	15.9		93.2	6.8		0.10
4. Color match	52.3	47.7		63.6	36.4		0.20
5. Marginal adaptation	86.4	11.4	2.3	77.3	15.9	6.8	0.32
6. Marginal discoloration	93.2	6.8		84.1	15.9		0.16
7. Gingival inflammation	100.0			100.0			1.00
8. Secondary caries	100.0			100.0			1.00
9. Postoperative sensitivity	100.0			95.5	4.5		0.16
10. Fracture	100.0			100.0			1.00
11. Debonding	100.0			100.0			1.00

¹ N=42 patients (50 pairs of damaged molars)² N=42 patients (50 pairs of damaged molars)³ N=36 patients (44 pairs of damaged molars)⁴ McNemar test comparing proportions of "A" of modified USPHS success criteria

significantly over time ($p < 0.01$), reaching almost perfect scores at 24 months (Fig. 3). Operator assessment at completion revealed a significant preference for indirect restorations concerning aesthetics (4.3 ± 0.5 vs. 3.8 ± 0.4 ; $p < 0.0001$) and texture (4.4 ± 0.5 vs. 3.9 ± 0.4 ; $p < 0.0001$). Differences in treatment time and ease of procedure were not statistically significant. Practitioners were consistently more critical than patients at baseline, with mean differences ranging from 0.6 to 1.0 points across aesthetics, time, and texture (all $p < 0.001$).

3.5. Clinical performance

According to the modified USPHS criteria, the evolution of both groups was highly similar over time, as shown in Table 3. At the 24-month follow-up visit, 44 pairs of restorations (36 patients) were available for evaluation. According to the primary end point of the trial and the definition of success based on the three specific USPHS 8, 10 and

11 criteria, all 88 restorations were successful, and no difference was observed between direct and indirect restorations (100%vs. 100%, $P = 1.0$). Both groups demonstrated excellent performance with very high proportions of Alpha scores across most parameters (Table 3). No differences were observed between direct and indirect restorations for anatomical form (88.6%vs. 86.4%), interproximal contact points (97.7%vs. 100%), surface texture (84.1%vs. 93.2%), marginal adaptation (86.4%vs. 77.3%), or marginal discoloration (93.2%vs. 84.1%). Color match was slightly but not significantly higher for indirect restorations than for direct restorations (63.6% Alpha vs. 52.3%, $p = 0.20$). Both approaches also achieved 100% Alpha scores for gingival inflammation and secondary caries. Postoperative sensitivity was absent in all direct restorations and reported in only two indirect cases (95.5% Alpha). Median time from indirect preparation to bonding was 8 days. A single case of debonding occurred in an indirect restoration one week after placement. Following successful re-bonding, no further incidents of

fracture or debonding were reported throughout the observation period.

3.6. Survival and success

The overall two-year survival and success rates were 100% for both restorative techniques when considering the modified USPHS success criteria. One indirect restoration experienced an early debonding at one week, which was successfully re-bonded and showed no further complications.

4. Discussion

The present split-mouth randomized clinical study compared the 2-year performance of direct short-fiber reinforced composite restorations (everX® Posterior, GC, Tokyo, Japan) and indirect CAD-CAM nanoceramic composite blocks (Cerasmart™ 270, GC Corp., Tokyo, Japan) placed in severely damaged molars. Both restorative approaches showed excellent clinical outcomes, with high survival and success rates according to the modified USPHS criteria. These findings are consistent with previous systematic reviews and clinical trials showing that composite restorations, whether placed directly or indirectly, can achieve satisfactory outcomes in posterior teeth [1,3,5–7,10]. This corroborates the results of da Veiga et al. [5] and Incekara and Karadas [6], who reported no significant differences in survival between direct and indirect approaches in posterior teeth.

Patient satisfaction was high and comparable for both techniques. These findings are consistent with previous reports demonstrating satisfactory outcomes for both direct and indirect composite restorations when adhesive procedures are properly performed [1,5,6,10]. Aesthetic evaluation scores remained stable and favorable in both groups, with a slight initial advantage for indirect restorations that diminished over time, leading to comparable values at 24 months. Functional evaluation showed a steady improvement in both groups, with no significant differences between techniques. Comfort evaluation increased markedly during the first 6 months and remained consistently high thereafter, with no difference between techniques. Importantly, patient-reported outcomes are infrequently reported in clinical trials on direct and indirect restorations, which further strengthens the relevance of the present findings. Overall, these results suggest that, from the patient's perspective, both restorative strategies appear to provide comparable outcomes in terms of aesthetics, function, and comfort in the short to medium term. Operator assessment at completion favored indirect restorations in terms of aesthetics and surface texture, likely reflecting improved control of morphology and finishing [3,11].

At 24 months, both groups maintained very high proportions of Alpha scores across most USPHS parameters. The only minor event was a debonding in the indirect group, which occurred one week after placement and was successfully re-bonded, with no further complications. This finding supports the short-term reliability of both restorative protocols. Comparable results have been reported in studies evaluating large restorations restored with SFRCs or CAD-CAM composites [12,19,21,23,25,27,37].

A relevant question is whether a conventional direct resin composite restoration alone would have shown similar short-term performance, independently of the use of SFRC [19,37]. The present study was not designed to isolate the material-specific effect of SFRC, as no conventional direct composite control group was included. Instead, it compared two clinically relevant strategies for severely damaged molars: a minimally invasive direct approach based on SFRC to preserve and reinforce weakened cusps, and a more invasive indirect composite overlay approach. Given the relatively short follow-up, conventional composites may also exhibit acceptable performance at 2 years [37]. However, SFRC was selected to enhance internal reinforcement, limit cuspal deflection, and reduce fracture risk, particularly when cusp preservation is intended [27].

An important observation of this study is that indirect restorations

resulted in the largest post-preparation cavities, despite the random allocation of teeth. Treatment allocation was performed prior to preparation and was not based on tooth structure or cusp thickness. All included molars initially presented severe coronal destruction with at least one missing cusp requiring cuspal coverage, independently of the restorative strategy assigned after randomization. Pulpal status was not used as an inclusion criterion, as coronal tissue loss was considered the major biomechanical determinant. Although a higher proportion of non-vital teeth was observed in the indirect group, pulpal status alone should not be interpreted as a direct indicator of baseline defect severity in the present study population. The observed differences between groups can be explained by the fact that indirect restorations require greater tissue removal, as preparations must be free of undercuts and include cusp coverage, resulting in larger cavities. The higher proportion of Class III restorations in the indirect group therefore reflects the more invasive nature of indirect preparation rather than baseline differences. However, this also introduces a structural imbalance between groups after preparation, which should be considered when interpreting the results and may partly explain the observed comparability between the two techniques. These findings should therefore be interpreted with caution when directly comparing the two restorative approaches. Selective composite build-up prior to indirect restoration is increasingly used to limit unnecessary tissue removal. This approach helps preserve sound structure, which remains a key objective in restorative dentistry [40]. Indirect preparations remain more invasive due to cuspal coverage. In contrast, the direct SFRC approach allowed preservation of weakened cusps, even in severely compromised teeth. This conservative strategy was intentionally adopted to evaluate reinforcement under unfavorable biomechanical conditions.

In the present trial, a pragmatic classification (Fig. 1) was applied for inclusion purposes and performed after tooth preparation, based on two key criteria: the number of missing cusps and the height of the remaining walls, taking inspiration from the classification model proposed by Belleflamme et al. in 2017 [38]. The higher proportion of Class 1 restorations in the direct group therefore reflects differences between strategies rather than baseline selection bias. Direct SFRC restorations (everX® Posterior, GC, Tokyo, Japan), being less invasive and more cost-effective, may represent a reliable alternative to indirect CAD-CAM techniques [21,27], particularly when tooth structure preservation is prioritized. By eliminating laboratory steps and reducing the number of appointments, this approach lowers treatment costs and overall chair-side time [19,21]. Direct restorations are typically reimbursed, whereas indirect restorations often involve additional patient costs. Such efficiency may be particularly beneficial for patients with limited access to dental care, those with financial constraints, or when rapid treatment delivery is required. Consistently, Soares et al. (2018) demonstrated that in large MOD restorations, direct approaches incorporating a short fiber-reinforced composite base achieved mechanical performance and enamel crack resistance comparable to semi-direct and CAD-CAM inlays, further supporting the reliability of minimally invasive direct techniques [16].

This aligns with the biomimetic approach, which prioritizes tissue preservation and functional integration [41,42]. Acting as dentin substitute, SFRCs (everX® Posterior, GC, Tokyo, Japan) are aligned with this approach, combining adequate mechanical reinforcement with minimally invasive cavity preparation. Importantly, these minimally invasive approaches may also be especially relevant for high-carries-risk patients or those with parafunctional habits, where maintaining future treatment options is critical.

Another key finding concerns the role of SFRC as dentin substitute [21]. Owing to its fiber reinforcement and mechanical properties, SFRC provides internal support that closely mimics the biomechanical behavior of natural dentin [43]. This is particularly relevant in severely compromised molars, where residual walls are often thin and prone to fracture. By distributing occlusal forces and reducing cuspal deflection, SFRC helps lower fracture risk. Preserving coronal tissue is essential, as

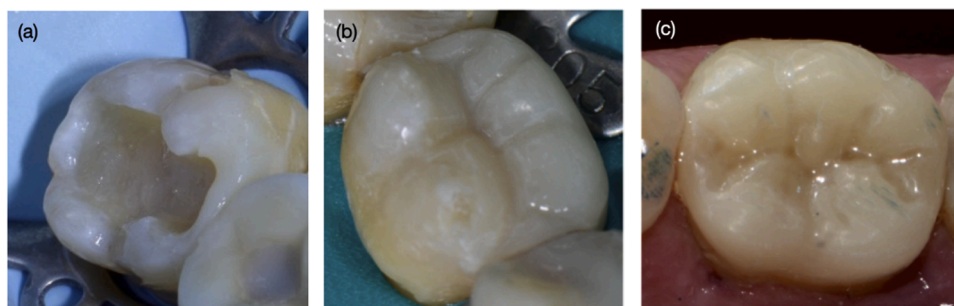


Fig. 4. Representative clinical examples of restorative approaches in severely damaged molars: (a) everX fiber-reinforced composite base, (b) direct restoration, and (c) indirect restoration.

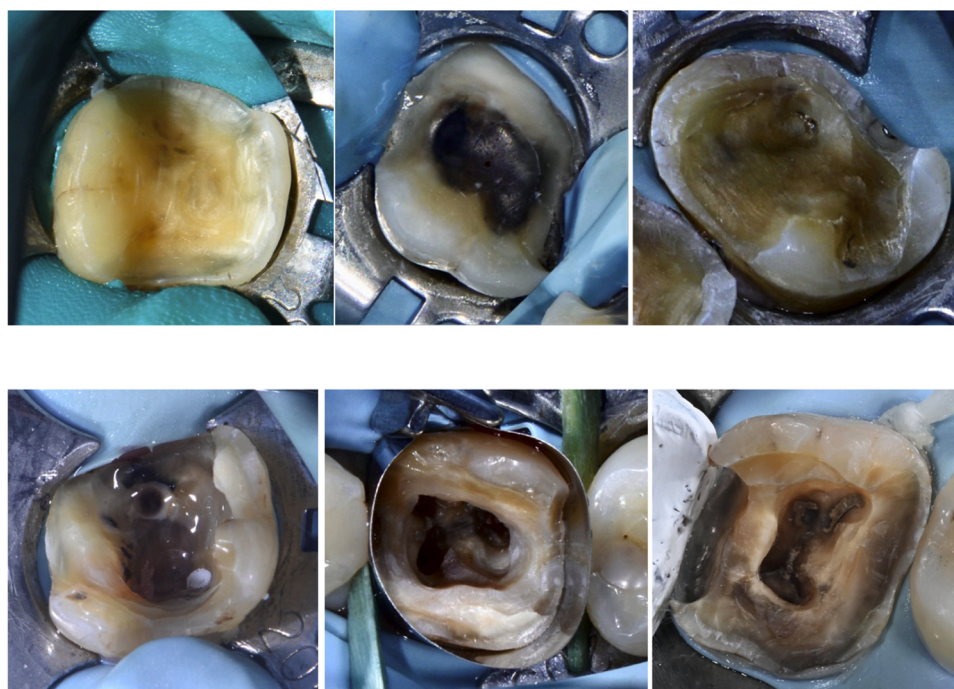


Fig. 5. Representative clinical examples showing that structural severity may not directly correlate with pulpal vitality status. Severely compromised vital molars (upper row) may present greater structural loss than certain endodontically treated molars (lower row), supporting the rationale for considering residual tooth structure as the major biomechanical inclusion criterion.

further removal would weaken the tooth [21]. Thus, SFRC serves both as a dentin substitute and a reinforcing material in such cases [24,29].

An important aspect of the present study is that all included molars were severely damaged, with at least one missing cusp. Despite the clinical complexity and unfavorable biomechanical conditions, both direct and indirect restorations demonstrated excellent short-term outcomes. These findings suggest that direct SFRC restorations (everX® Posterior, GC, Tokyo, Japan) can be a reliable treatment option even in structurally compromised molars, a clinical situation traditionally regarded as an indication for the indirect technique [21]. This highlights the potential of minimally invasive direct approaches to successfully manage advanced structural loss while preserving tooth tissue (Figs. 4 and 5).

The main limitation is the 2-year follow-up, which does not allow conclusions on long-term performance. Longer follow-up is required to assess restoration longevity and failure patterns. Furthermore, patient-related factors such as oral hygiene, caries risk, and parafunctional habits were not included in the present analysis and may have influenced the outcomes, which should be considered when interpreting the results. These parameters will be incorporated and analyzed in the planned 5-year follow-up. The study is ongoing with a planned 5-year

follow-up, which will provide additional insights.

5. Conclusion

Within the limitations of this split-mouth randomized clinical study, both direct short-fiber reinforced composite restorations and indirect CAD-CAM composite restorations demonstrated excellent survival and success rates (100%) after 2 years when placed on severely damaged molars. Patient satisfaction was high for both approaches. No significant differences in clinical performance were observed between groups according to the modified USPHS criteria. These findings suggest that direct short fiber-reinforced composites represent a minimally invasive and cost-effective alternative to indirect CAD-CAM restorations, with comparable outcomes over the short-term follow-up. Longer observation periods are warranted to confirm the durability of both restorative strategies.

Ethical approval

This study was approved by the Ethics Committee of the University Hospital of Liège (reference number: 2019/50) and conducted in

accordance with the Declaration of Helsinki.

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Data availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

CRediT authorship contribution statement

Marcia Belleflamme: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Laurance Seidel:** Writing – review & editing, Validation, Formal analysis. **Adelin Albert:** Writing – review & editing, Validation, Supervision, Formal analysis. **Amandine Bolette:** Investigation. **Audrey Guéders:** Writing – review & editing, Validation, Supervision, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this paper. No financial support, sponsorship, or material provision was received from the manufacturer of the materials used in this study. Although both materials evaluated originate from the same company, their selection was based solely on their clinical relevance and widespread use. The study was conducted independently, with no involvement of the manufacturer in the study design, data collection, analysis, or interpretation of the results.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.jdent.2026.106785](https://doi.org/10.1016/j.jdent.2026.106785).

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