

Clinical Evaluation of a Visible Light-Cured Indirect Composite for Long-Term Provisionalization

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Abstract

- **Objective:** To clinically evaluate a visible light-cured (VLC) resin composite system for long-term provisional and esthetic diagnostic restorations, fabricated using indirect techniques.
- **Methods:** One-hundred and nine teeth were restored in 31 patients. Preoperational impressions were used to create VLC resin composite restorations (Radica™) using indirect techniques. Restorations were relined as necessary and placed using various provisional cements at a follow-up appointment, subsequent to preparation of the teeth. Both fabricating laboratory technicians and placing dentists rated the restorations for acceptability in esthetics, marginal fit, occlusion, and functionality in various stages of provisionalization.
- **Results:** All restorations (100%) were rated acceptable for esthetics prior to relining. After relining, a majority (93–100%) of restorations were rated acceptable in esthetic and functional criteria. At the placement of the permanent restoration, a majority (96–100%) of restorations were rated acceptable in esthetic and functional criteria. Terms of service ranged from two to seventy-six days.
- **Conclusion:** In combination with *in vitro* results, the clinical performance of the Radica VLC system for provisionalization and esthetic diagnostic restorations was judged to be acceptable. The system offers esthetics that are superior to conventional provisional restorations, and should be a valuable option to practitioners considering longer-term provisionalization in complex cases.

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Introduction

The provisional restoration plays an important role in the fixed prosthodontic treatment sequences used for maintaining the esthetic and functional aspects of a patient's dental health. It has a significant impact on the final restoration placement as well. Specifically, the provisional restoration provides comfort and function, and improves esthetics during treatment. The popular use of implant therapy has significantly increased the service lifetime of provisional restorations, from the conventional one to two weeks, to six months and even longer-term use. Further, provisionals have multiple additional functions, such as preserving periodontal health, preventing movement of abutment teeth, or protecting pulpal tissue and teeth from caries. They have diagnostic functions as well, allowing practitioners to assess the patient's home dental care regimens, or helping to evaluate occlusal function, phonetics, and vertical dimensions. They may even be used as matrices to retain surgical dressings, or to provide anchorage for orthodontic brackets.¹⁻⁴

Most contemporary restoration systems have limitations of their wear characteristics in service, their load-bearing capability in the term of service, or in their esthetics.⁵⁻⁸ It is desirable that a provisional system be strong and durable, and adapts well to a tooth for marginal fit. The appliance needs to be comfortable to wear, and the esthetics need to be acceptable to the patient, at the very least. Color stability and translucency are important contributing factors. The material does need to be biocompatible, and nonirritating to pulp and other tissues. Low exothermicity is also desirable.

Materials and Methods

The Radica VLC Provisionalization System

The use of a composite material as a provisional is not novel in and of itself; however, the fabrication process is cumbersome, and involves layering buildups.⁹⁻¹¹ The Radica system (Radica™, Dentsply Prosthetics, York, PA, USA) offers a unique approach by using a shape-stable, visible light-cured composite material as a basis. The system offers physical properties approximating those of composite materials indicated for provisional or even permanent restorations (Table I).¹² Enhancement of flexural strength could provide a longer survival time and resistance to fracture in provisional restorations.¹³⁻¹⁶

To receive a customized provisional restoration, practitioners forward impressions of unprepared teeth, typically using VPS

Table I
Manufacturer's Data for *In Vitro* Properties of Radica Material

Property	ISO 10477 Requirement	Radica System Property
Biocompatibility	Biocompatibility	Non-cytotoxic (MEM elution) Non-irritating to mucous membrane, non-sensitizing Non-mutagenic (Ames test, Saline Extract)
Flex. Strength	≥ 50 MPa	160 MPa
Degree of Cure	≥ 70%	96% (comparative hardness ratio, bottom:top layer)
Water Sorption	≤ 40 µg/mm ³	10.9 µg/mm ³
Solubility	≤ 7.5 µg/mm ³	≤ 0.001 µg/mm ³
Color Stability	Slight	Very Slight

impression materials, to a trained dental laboratory. After preparing a model from this impression (Figure 1, Step 1), the laboratory creates a matrix out of quick-setting Radica matrix silicone. Next, warmed enamel resin is extruded into the incisal area. Warmed Radica dentin is then extruded into the dentin area of the matrix (Figure 1, Step 2). The matrix is now adapted to the model. The shape-stable composite cools into the exact contours determined by the lab (Figure 1, Step 3). This resin may be added to, adapted, tried in, or modified in its wax-like uncured state (Figure 1, Step 4).

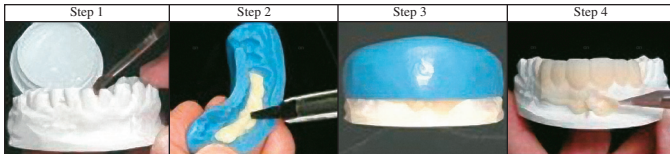


Figure 1. Radica provisional—laboratory process.

The resin is light- and heat-cured with a glaze-like sealer in one of three processing units (Eclipse®, Enterra™, or Triad®, Dentsply Prosthetics, York, PA, USA). The laboratory delivers the finished provisional to the dentist after custom characterization, as needed.

Upon receipt from the laboratory, the provisional restoration's internal surfaces are microetched. They can then be relined with a variety of materials, such as conventional acrylics or bis-acryl resins. When both patient and practitioner are satisfied, the restoration is luted in place with a provisional cement of choice. Because of the simplicity of the fabrication process, the system may also be used for creating esthetic diagnostic restorations

instead of the conventional wax restorations. Use of diagnostic restorations can enhance patient acceptance of treatment plans and offer esthetic expectations.¹⁴ Patient communication is significantly more meaningful using a tooth-colored diagnostic restoration. Upon acceptance of the treatment plan, the Radica diagnostic can double as the provisional itself (Figure 2).



Figure 2. Radica diagnostic (left) installed as a provisional (right).

Sample Size and Demographics

In this study, 109 teeth were replaced in 33 patients in four locations. Sixteen of the patients were male and seventeen were female. Inclusion criteria were limited to the patient being over 21 years of age, requiring definitive fixed prosthodontic restoration, available for the evaluation period, and capable of giving informed consent. All patients signed an informed consent form prior to inclusion in the study. Patients were excluded with symptoms of irreversible pulpitis, or with teeth not suitable to receive definitive fixed prosthodontic restorations. Teeth not suitable to receive definitive crown and bridge restorations included periodontally involved teeth, and cases with inadequate biological width.

Table II
Evaluation Criteria

Criteria	Acceptable Observations	Unacceptable Observations
Surface Reflection, Translucency and Shade Match	No mismatch in color shade and/or translucency between restoration and adjacent teeth Restoration surface smooth. No irritation of adjacent tissue Slight mismatch between shade of restoration and adjacent tooth Restoration surface slightly rough but can be polished	Grossly irregular surface not related to anatomy and not subject to collection of debris and/or stain Mismatch between restoration and adjacent tooth outside normal range of color, shade and/or translucency Gross porosities in crown material Shade in gross disharmony with adjacent teeth
Marginal Fit	No visible evidence of crevice along margin that explorer would penetrate. No evidence of ditching along margin. Visible evidence of slight marginal discrepancy with no evidence of decay, repair/reline possible but perhaps unnecessary. Explorer gets stuck in one direction. Discoloration of margin between restoration and tooth structure	Penetrating discoloration along margin of restoration in pulpal direction Retained excess cement Mobile restoration Fractured restoration Caries continuous with margin of restoration Fractured tooth structure
Proximal Contact and Occlusion	Restoration contour in functional harmony with adjacent teeth and soft tissues within good individual anatomic form Restoration slightly overcontoured Restoration slightly undercontoured Occlusion not completely functional Margin ridges slightly undercontoured Contact slightly open Facial flating present	Restoration grossly undercontoured Restoration grossly overcontoured Occlusion affected Contact faulty Margin overhand present Gross underocclusion Restoration caused unremitting pain in tooth or adjacent tissue Damage to tooth, soft tissue, or supporting bone
Gingival Health	Very good, good or clinically acceptable gingival response	Gingiva showing irritation, inflammation, or other clinically unacceptable reaction to provisional

Evaluation Criteria

Four operators, calibrated to the criteria described in Table II, placed all of the restorations. Calibration was completed through cross-evaluation of conventional bis-acryl provisional restorations and Radica provisional restorations. Consensus acceptability criteria were generated based on visual and tactile evaluations, as well as clinical examination post-placement.

No consensus standards, such as the Ryge criteria used to evaluate clinical dental restorative materials, exist to evaluate provisional restorations.¹⁷ Therefore, the following criteria were judged to be descriptive in evaluating this system, drawing from previous literature in this area.¹⁸ Fabricating laboratory technicians evaluated restorations based on acceptability of esthetics, fit to the model, and overall acceptability. Each crown/bridge was evaluated by the prescribing dentist prior to relining for surface reflectance or luster, esthetics or translucency, and shade match to the Vita® Lumin®-Vacuum Shade guide (Vita Zahnfabrik H. Rauter GmbH & Co. KG, Bad Sackingen, Germany). Surface reflectance or luster, esthetics or translucency, shade, fit to margin, proximal contact where possible, occlusion where possible, and contour were also evaluated after relining. At delivery of the final restoration(s), gingival tissue response was scored, as well as ease of removal/cement adherence.

For the purposes of this study, fractures of provisional restorations, as well as failure of the temporary cement to retain the provisional restoration were judged to constitute anticipated adverse events. Failure rates due to fracture or loosening from the prepared tooth were judged to be acceptable if equal to or less than 5% for all crowns and bridges in the study per two-week period of wear. This was based on a higher failure rate (18.75%), with a median time to failure rate of 12 days, recorded in a recent study in dental schools.¹⁹ Our stringent acceptance criteria were set based on the expectation of a higher strength material and use of experienced operators, resulting in a higher rate of success. Any other untoward responses to the provisional restorations constituted unanticipated adverse events which would necessitate immediate removal of test prosthesis and replacement.

Clinical Sequence

Preoperative impressions were taken of the patients, and dental casts were created. Using these casts, three trained dental laboratory sites fabricated provisional prostheses using the methods described above. Provisionals were returned to prescribing dentists, who then used the laboratory's tooth reduction on the diagnostic model as the initial clinical preparation guide. The internal aspect of each retainer was fitted to the prepared abutment tooth. Final fitting of the prefabricated provisional crown or bridge to the prepared teeth is accomplished by relining with commercially available PMMA or bis-acryl resins. After a final impression of the prepared tooth was captured, provisional crowns and bridges were provisionally cemented using commercially available temporary cements.

Removed provisionals were disinfected using a 10:1 dilution of bleach (0.5% solution of Clorox®, Harry J. Bosworth Inc., Skokie, IL, USA) for 30 minutes before rinsing, drying, labeling, and shipping to a central recovery and analysis site. Each

recovered provisional was examined for evidence of wear, solubility and disintegration, and cracks or fractures at 6× magnification.

Restorative Sites and Types of Restorations

Various types of provisional restorations were placed. These included fourteen veneers, sixteen single crowns, two 2-unit bridges, seven 3-unit bridges, eight 4-unit bridges, three 6-unit bridges, and a 9-unit bridge. Restorations keyed to Vita Lumin shades A2, A3.5, and B1 were placed. Of these, seventy-nine teeth were replaced with multi-unit fixed prosthodontic restorations. A description of the restorations by teeth replaced, as well as mean time in service, is given in Table III.

Table III
Summary Table of Restorations

Type	Teeth Replaced	Negative Comments	Days in Use
Veneers	12	None	20
Veneers	2	None	26
Crowns	2	None	21
Crown	1	None	31
Crown	2	None	21
Crown	1	None	16
Crown	1	None	7
Crown	1	None	2
Crown	4	None	17
Crown	4	None	34
9uB	9	None	49
6uB	6	None	65
6uB	6	None	33
6uB	6	None	58
4uB	4	None	26
4uB	4	None	22
4uB	4	None	26
4uB	4	None	41
4uB	4	None	41
4uB	1	None	34
4uB	4	None	37
4uB	4	None	40
3uB	2	None	16
3uB	3	Occlusion at reline unacceptable Translucency at removal unacceptable	68
3uB	3	None	21
3uB	3	None	22
3uB	2	None	22
3uB	3	None	36
3uB	3	None	33
2uB	2	Occlusion at reline unacceptable	21
2uB	2	None	76
Total = 109			Mean = 32 days

Results

Laboratory Technician Evaluations

All restorations were rated acceptable in terms of esthetics, fit to model, and overall acceptability prior to delivery to the prescribing dentists.

Evaluation Prior to Relining

Operators rated the following aspects of the restoration prior to relining or adjusting the restoration, to evaluate the quality of the as-received lab provisional. Results are expressed as a percentage of cases receiving acceptable ratings. All placed restorations were rated as acceptable in these attributes (Table IV).

Table IV
Evaluations Prior to Relining

Attribute	Percentage "YES"	Percentage "NO"
Surface Reflectance (Polished Luster) is Acceptable	100%	0%
Translucency is Acceptable	100%	0%
Shade Matching is Acceptable	100%	0%

Evaluations After Relining

Operators rated the following aspects of the restoration after relining or adjusting the restoration, to evaluate the quality of the as-received lab provisional. Results are expressed as a percentage of cases receiving acceptable ratings. Over 90% of all placed restorations were rated as acceptable in these attributes (Table V).

Table V
Evaluations After Relining

Attribute	Percentage "YES"	Percentage "NO"
Surface Reflectance (Polished Luster) is Acceptable	100%	0%
Translucency is Acceptable	96.7%	3.3%
Shade Match is Acceptable	100%	0%
Fit to Margin is Acceptable	100%	0%
Proximal Contact is Acceptable	100%	0%
Occlusion is Acceptable	93.3%	6.7%

Evaluations at Placement of Definitive Restoration

Operators rated the following aspects of the restoration as the provisional was removed and the definitive restoration was placed, to assess the performance of the restoration through its term of service. Results are expressed as a percentage of cases receiving acceptable ratings. No issues were reported with ease of removal and replacement with the definitive restoration. Over 90% of all placed restorations were rated as acceptable in these attributes (Table VI).

Table VI
Evaluations at Placement of Definitive Restoration

Attribute	Percentage "YES"	Percentage "NO"
Surface Reflectance (Polished Luster) is Acceptable	100%	0%
Translucency is Acceptable	96.7%	3.3%
Shade Match is Acceptable	100%	0%
Gingival Health is Acceptable	100%	0%

Adverse or Unexpected Events

As an anticipated adverse event, one bridge connector (Patient LHy, 3-unit posterior bridge, Nos. 13–15) was observed to fracture after 20 days. Visual inspection showed that this occurred due to undersized connector dimensions. The fractured restoration was replaced with another Radica provisional, designed with larger connectors. The case proceeded to a satisfactory completion with no attendant sequelae.

An unanticipated adverse event occurred in the case of one other patient (Patient KSe, single unit, No. 14). The surface luster of the provisional was lost after two days in service, and was reported by the patient. The restoration was otherwise func-

tional, and retained acceptable esthetics. In the interest of patient comfort, the restoration was replaced with a fresh Radica provisional restoration that was fabricated according to directions for use. This case proceeded to completion satisfactorily, with no attendant sequelae. With these exceptions, all other provisionals performed successfully through the term of service.

Discussion

The following clinical- and laboratory-related observations were made with regard to the investigational system, as supported by the acceptability responses. From a laboratory's perspective, the VLC shape stable nature of the material lent itself to convenient laboratory fabrication, and acceptable results to laboratory technicians. The Radica system appeared to accurately reproduce the main features of a natural tooth color, translucency, and texture which was esthetically acceptable to both patient and clinician. The restorations matched the prescribed Vita shades 100% of the time when returned from the laboratory. From a clinician's perspective, the dentin- and enamel-layering method of laboratory fabrication provided very good esthetic translucency. All (100%) of the restorations were rated as acceptable for esthetics at placement after relining, as well as at placement of the definitive restoration. While a limited range of dentin shades was available at the time of this study, the shades were high in chroma, lending vitality to the system. The capability to efficiently layer enamel and dentin materials, in combination with esthetic gingival and stain characterization, provided for excellent patient satisfaction when serving as both a diagnostic and a provisional restoration.

The observed gingival health, in combination with *in vitro* biocompatibility studies, suggests a tissue-friendly material. While the sealer contains methyl-methacrylate, the dentin and enamel materials do not. Accommodation for MMA-sensitive patients may be made by processing the restorations without the sealer layer, and using composite polishing techniques to achieve surface luster and gloss.

The choice of relining material has significant effects on the esthetics, and processing the material without relining could enhance both esthetics and resultant restoration strength. A wide variety of commercially available relining materials, including acrylics, bis-acryls, and VLC materials, were used successfully. A wide variety of commercially available provisional cements were also used successfully with the Radica system. Observations made on all of the recovered restorations confirmed that a range of provisional cements remain bonded to the crown/retainer interiors during use and removal. This was rated a positive attribute by operators because cement clean-up (removal of adherent debris from the cut dentin surfaces) was expedited. Also, there were no reports of Radica provisional restorations requiring re-cementation. This suggests that the provisional cements used in the clinical study have retained Radica restorations very well.

Marginal adaptation of the cemented crowns was 100% acceptable after relining. Ninety-three percent of restorations were rated acceptable for occlusion at placement, possibly due to the necessity of relining. This suggests that an indirect provisional procedure in the dental office, planned using the definitive prepa-

ration, could be a direction for improvement in technique with this product. There was only one clinical failure in a bridge restoration due to bulk fracture.

Overall, the evaluators agreed that the Radica system offered esthetic advantages, and was clinically viable. The smaller sample size and extent of longitudinal clinical observation limit the clinical conclusions that may be reached from this study alone.

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