



Radica® – Clinical Brochure

The highly durable, esthetic provisional and diagnostic restorations.

Over forty million teeth are restored indirectly in North America every year, all of which require provisionalization. The provisional restoration plays an important role in maintaining the esthetic and functional aspects of a patient's dental health, and has a significant impact on the final restoration placement, as well. Provisional restorations are also being used for longer service terms, as the use of implant therapy becomes more popular. Current options, direct and indirect, suffer from material and process limitations, giving rise to concerns about wear in service, durability, load-bearing capability, or esthetics. Radica® is a system for provisional and diagnostic restorations from Dentsply Prosthetics. Based on a visible light curing (VLC) composite platform, Radica has been developed to exceed the performance criteria of currently available restorations. It has been proven in clinical study. A simple lab process offers the dual benefits of using this system for a truly lifelike diagnostic system as well as a provisional restoration.

Fig. 1: A well-made provisional is the basis of successful restorative treatment.



Radica*
Diagnostic/Provisional



Esthetic
Smile Result

Functions and Limitations of Current Systems

Provisional restorations provide comfort and function, and improve 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 longer term use. In addition, provisionals have multiple other functions such as preserving periodontal health, preventing movement of abutment teeth, and protecting pulpal tissue and teeth from carious impairment. They have diagnostic functions as well, in allowing practitioners to assess the patient's personal dental care regimens, and helping in evaluating occlusal function, phonetics and vertical dimensions. They may even be used as matrices to retain surgical dressings, or to provide anchorage for orthodontic brackets¹⁻⁴.

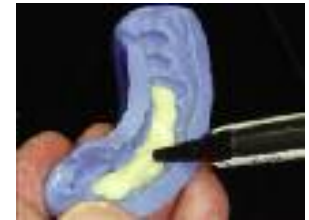
However, most contemporary restoration systems have limitations in terms of their wear characteristics in service, their load-bearing capability in the term of service, or in their esthetics⁵⁻⁸. It is most desirable that a provisional system is strong and durable, and adapts well to a tooth for marginal fit. The appliance needs to be comfortable to wear, and the esthetics need to be acceptable at the very least. Color stability and translucency are also important contributing factors. The material must be biocompatible, nonirritating to pulp and other tissues. Low exothermicity is also desirable. All of these ideas guided the design of Radica provisionals.

*Photograph courtesy of:
Functional Esthetics, Farmington, MO
Restoration designed by: Douglas J. Frye C.D.T.

Fig. 2:
Radica Provisional – Lab Process



Step 1



Step 2



Step 3



Step 4

Radica: An Efficient Indirect Provisional Process

The use of a composite material as a provisional is not novel in and of itself. However, the process to fabricate these is cumbersome, and involves layering build-ups⁹⁻¹¹. The Radica system offers a unique solution by using a shape stable visible light cured composite material as a basis.

To receive a customized provisional restoration, practitioners forward impressions of unprepared teeth to a trained dental laboratory, using VPS materials such as Aquasil Ultra Smart Wetting® Impression Material. After preparing a model from this impression (Fig. 2, Step 1), the laboratory creates a matrix out of quick-setting silicone. Next, warmed Radica enamel resin is extruded into the incisal area. Warmed Radica dentin is then extruded into the dentin area of the matrix (Fig. 2, Step 2). The matrix is now adapted to the model.

The shape-stable Radica resin cools into the exact contours determined by the lab (Fig. 2, Step 3). This resin may be added to, adapted, tried in or easily modified in its wax-like uncured state (Fig. 2, Step 4). The resin is light and heat-cured with a glaze-like sealer in a variety of processing units: the Eclipse®, the Enterra® or the Triad® 2000 VLC Light Curing Unit. The restoration may be characterized using effect dentins and stains. The laboratory delivers the finished provisional to the dentist.

Fig. 3:

Relined and tried-in Radica restorations



Fig. 4:

Radica bridges cemented in place



Radica: Clinical Usage and Recommendations

Upon receipt from the lab, the provisionals are microetched. They can then be relined with a variety of materials, including MMA acrylics and bis-GMAs (e.g. Integrity® Temporary Crown and Bridge Material). This provides for exactly adapted margins (Fig. 3). The Enhance® Finishing System and PoGo® One-Step Diamond Polishers are ideal for achieving a high gloss on composite surfaces. When both patient and practitioner are satisfied, the restoration is luted in place with a provisional cement (e.g. Integrity® TempGrip® from DENTSPLY Caulk (Fig. 4).

If in rare cases the restoration fractures in use, several repair methods are possible. The restoration may be repaired with the parent Radica material, after the fracture surfaces have been cleaned and roughened to remove any sealer. The repaired material is then cured using the curing units listed previously. Repairs may also be made using other composites. The surface needs to be cleaned and roughened. Next, Prime and Bond® NT™ priming agent is applied to surfaces. TPH®3 Micro Matrix Restorative is applied to the fracture surface and used to join the surfaces. The TPH®3 curing directions (with handheld lights) are followed.

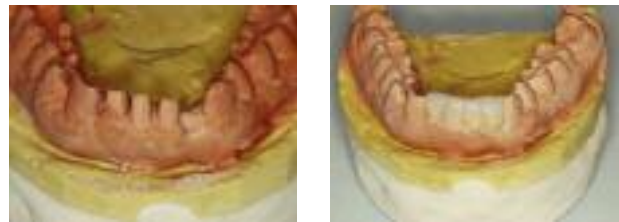
Fig. 5:

Radica Diagnostic Process



Step 1

Step 2



Step 3

Step 4

Radica: Use in Removable Applications

Adding denture teeth to a partial or full denture (conventional or VLC) is a challenging clinical/lab situation that can be made easier by the use of Radica.

The fully cured denture base is processed on a model to prevent distortion. The denture surface is prepared using a coarse carbide bur, steam cleaned to remove debris and dried thoroughly. Next, the surface is primed with a thin coat of the VLC sealer, which is bench set for 2 minutes. Radica is applied to the desired area and shaped to final contour. Following this, another layer of VLC sealer is applied and the assembly is cured following Radica directions. The denture is finished and polished along with the Radica restoration using a rag wheel with pumice and polishing compound.

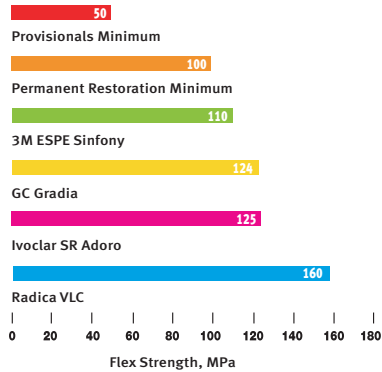
Fig. 6:

Adding Radica Teeth to a Denture Base (From L-R, applying sealer to denture base, shaping Radica tooth and finished denture).



Fig. 7:

Superior Strength (160 MPa)



Radica: Clinical and InVitro Studies

The Radica system has been extensively tested in-vitro and in-vivo, to ensure its performance.

Flexural Strength: The international standard ISO 10477, recognized by the USFDA, recommends a minimum strength of 50MPa (3 point bend, flexural strength) for provisional systems¹². Radica surpasses the strength of other material systems (Fig. 7) and approaches the strength of a permanent composite (Cristobal®+). Practitioners can use Radica confidently in both routine and long-term restoration cases.

Long-term Durability: Many materials are initially strong, but can lose load-bearing capability over time under the stress, thermal cycling and wear of the oral environment. A test developed independently by the University of Regensburg in Germany was used to evaluate durability of Radica restorations¹³. Three-unit bridges of Radica and acrylic (Jet) materials were fabricated to predetermined dimensions using a clear silicone matrix. A control fracture strength was obtained after water storage (14 days, 37°C). The bridges were then fatigued for a simulated two-year service term (TCML: 2,400x5°C/55°C, 2 min/cycle; 480,000x50N, 1.66Hz, human molar antagonist), and fracture tested again. The results are summarized in Fig. 4. Pair-wise parametric analysis reveals that Radica provisionals do not show a statistically significant loss of strength after two years of simulated service, while acrylics do. Based on in-vitro and clinical results, the Radica system's indications include up to 2 years in the mouth for all single unit restorations, inlays/onlays, and 3-unit bridges up to the second bicuspid. This provides patients with the assurance that Radica can withstand the test of time needed for a durable and dependable provisional.

Fig. 8:

Long-Term Durability¹³

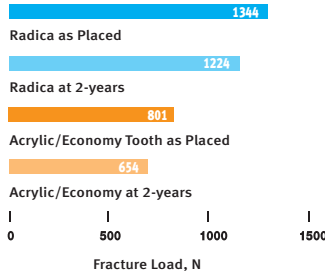
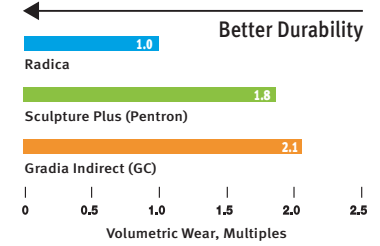


Fig. 9:

Superior Wear Resistance¹⁴



Wear Resistance: Wear during function is the leading concern with common temporary materials³⁻⁴. Radica is significantly more wear resistant than common temporary materials, as well as some permanent composites, in a three body wear test using a modified Leinfelder method (Fig. 9)¹⁴⁻¹⁶. Low wear greatly reduces the risk of provisional perforation, and the risk of saliva, bacteria and thermal irritants reaching the tooth, especially in longer term use.

Clinical Evaluation: Radica was also tested in a multi-center, multi-practitioner clinical evaluation by four clinicians¹⁷. Over a hundred teeth were restored in thirty patients. Over 80% of restorations placed were bridge units, to increase the severity of the test. The restorations ranged from laminate veneers and single crowns through three- and four-unit bridges, to even six- and nine-unit bridges. One bridge connector fractured after 20 days due to undersized connector dimensions. With that exception, all other provisionals performed successfully through the term of service. Evaluation criteria included surface luster, attainability and preservation of occlusal and proximal contacts, esthetic translucency, shade match, and marginal adaptations. Practitioner approval ratings were either 95% or more for each positive criterion. This excellent clinical result validated the use of Radica provisionals in real-life environments. Few provisional systems can show such a proven track record prior to commercialization. Radica has also been validated by field-testing in laboratories, with over 90% of evaluators expressing a preference for Radica over their current processes.

Shade and Material offering: Radica offers the full 16 A-D Dentin Shades; Two - Bleach Shades: i2, RD-001*; Three-Enamel Shades: Light, Medium & Translucent; Effect Dentins: Tissue Tint & Deep Red Tissue Tint and Stains: Brown, Blue, White, Orange & Olive. In addition, Radica's natural radiopacity allows for X-ray or CT scans chairside.

*Keyed to Vita® 3D Master® Shade OM1. Vita® and 3D-Master® are registered trademarks of Vita Zahnfabrik H. Rauter GmbH & Co.

Table 1:

Comparison of Radica to other Provisional Systems^{4, 18}

Property	MMA based, e.g. BioTemps*, Jet	EMA Based, e.g. Snap, Trim	bis-GMA based, e.g. Protemp	VLC Composite, Radica®
Strength	Good	Good	Very Good	Excellent
Wear	Moderate	Good	Very Good	Excellent
Color Stability	Good	Acceptable	Very Good	Excellent
Polishing/Repair	Good	Very Good	Acceptable	Excellent
Marginal Fit	Good	Acceptable	Very Good	Excellent
Pulp Irritation	Moderate	Good	Very Good	Excellent
Minimal Odor	Moderate	Acceptable	Very Good	Excellent
Stain Resistance	Good	Very Good	Moderate	Very Good
Oral exotherm	Acceptable	Good	Very Good	Excellent

* Note: Provisional restorations consisting of MMA backing with ground in economy denture teeth improve upon the esthetics of MMA alone. However, the performance parameters are unchanged.

Ongoing Developments with Radica:

Several recent works have examined the multiple applications of the Radica system. These applications include addition of teeth to removable prostheses²³, long term provisionals over implant abutments²⁴, and in complex and esthetic restorative protocols²⁵⁻²⁶.

In addition, independent evaluations of the physical properties of Radica in comparison to other provisional materials continue to confirm its superiority. As part of a Ph.D. dissertation at the Indiana University School of Dentistry, Radica was compared to competitive materials, and exhibited superior flexural strength and fracture toughness even after aging (Fig. 10-11). The author concluded that compared to the other materials tested, Radica is the most suitable for application with high biomechanical demands, such as long span temporary bridges²⁷. Work at the University of Iowa, evaluating flexural strength of interim fixed prosthesis materials after simulated function, came to a similar

conclusion. There, the author also concluded that Radica demonstrated significantly superior flexural strength over other materials tested²⁸.

Summary:

The advantages of Radica are clear in contrast to other systems. Radica provides enhanced strength, durability, and wear resistance, with a significant improvement in esthetics over current provisionals. The capability to efficiently layer enamel and dentin materials, in combination with characterization, provides for excellent patient satisfaction when serving as both a diagnostic and a provisional restoration¹⁹⁻²².

Table 1, adapted from previous works, compares classes of provisional materials, and their advantages and limitations. Radica is a best in class material for provisional restorations, and fulfills many characteristics of an ideal provisional material.

Fig. 10: Flexural Strength

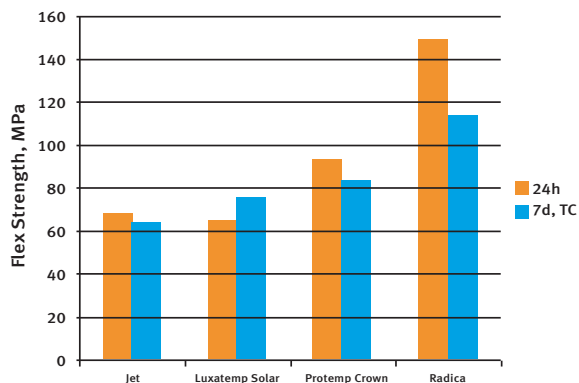
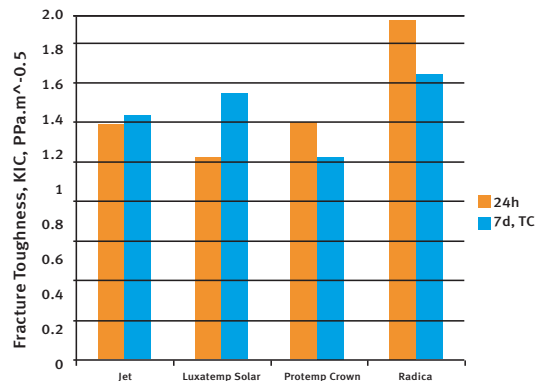


Fig. 11: Fracture Toughness



Suggestions for a Clinical Armamentarium:

- Impression Materials: Jeltrate® (alginate), Aquasil Ultra Smart Wetting® Impression Material (VPS), Dentsply Caulk
- Impression Tray: First Bite™ Impression Trays (Dentsply Caulk)
- Modeling Stone: ModelStone (Dentsply Prosthetics)
- Carbide Burs: #HP1558, 1mm (Midwest®, Dentsply Professional)
- Model Release Agent and Matrix Putty, VLC Resin, Sealer: Radica® System (Dentsply Prosthetics)
- Curing Lights: Triad®, Enterra®, Eclipse® Processing Unit (Dentsply Prosthetics)
- Reline Materials: Triad® VLC Provisional Material, Biolon® C&B Resin (Dentsply Prosthetics), Temporary Bridge Resin, Integrity® Temporary Crown and Bridge Material.
- Temporary Cements: NoGenol (GC America), IRM®, Integrity® TempGrip® (Dentsply Caulk).
- Polishing System: Enhance® Finishing System and PoGo® One-Step Diamond Polishers
- Repair Materials: Prime and Bond® NT Universal Adhesive System, TPH®3 MicroMatrix Restorative (Dentsply Caulk)


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Note: Jet, Luxatemp Solar, Protemp Crown, 3M ESPE Sinfony, Ivoclar SR Adoro, GC Gradia & Sculpture Plus (Pentron) are not registered trademarks of DENTSPLY International.

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