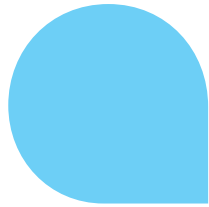


radicoTM
provisional & diagnostic resin



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 new system for provisional and diagnostic restorations from DENTSPLY Ceramco. 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

Image courtesy of Dr. Thanos Kristallis

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 the six months and longer term use. In addition, provisionals have multiple other functions such as preserving periodontal health, preventing movement of abutment teeth, or protecting pulpal tissue and teeth from carious impairment. They have diagnostic functions as well, in allowing practitioners to assess the patient's home dental care regimens, or 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.

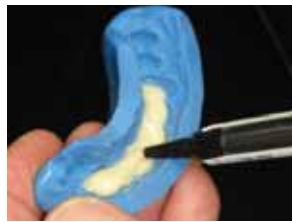
However, most contemporary restoration systems have limitations in terms of their wear characteristics in service, their load-bearing capability in the term of service, or in their esthetics⁵⁻⁸. It is desirable that a provisional system is strong and durable, and adapts well to a tooth for marginal fit.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

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 may create 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® VLC Light Curing Units. 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 (e.g. Biolon® Crown and Bridge Resin), 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 (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

Fig. 6:
Radica Diagnostic (left) installed as a Provisional (right)



Radica: Use As A Diagnostic Provisional

The shape stability and esthetics of Radica also lend themselves to use as a diagnostic system. Patient communication is significantly more impactful using a tooth colored diagnostic restoration that is simple to fabricate. Upon acceptance of the treatment plan, the Radica diagnostic can double as the provisional itself.

To use as a diagnostic, the desired final dental contours are created in wax, on the model of the patient's current oral situation (Fig. 5, Step 1). A silicone matrix is created of this ideal contour, (Fig. 5,

Step 2). Next, the model is prepared (Fig. 5, Step 3), to simulate the tooth reduction (1mm axial is typical). Warmed Radica enamel and dentin are placed appropriately in the matrix, and the diagnostic is created in a procedure identical to the provisional restoration fabrication (Fig. 5, Step 4).

The light-cured diagnostic, in dentin and enamel shades, enhances patient communications and establishes expectations for patient outcomes (Fig. 6).

Fig. 7:
ISO 10477 Flexural Strength Comparisons
of Radica with other Materials

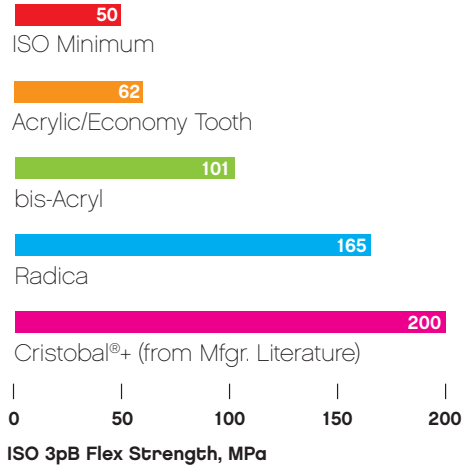
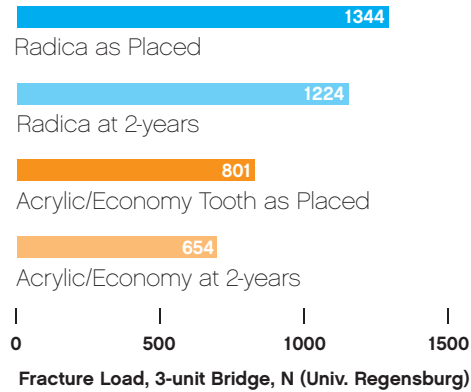


Fig. 8:
Long-term Durability of
Radica Restorations



Radica: Clinical and InVitro Studies

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

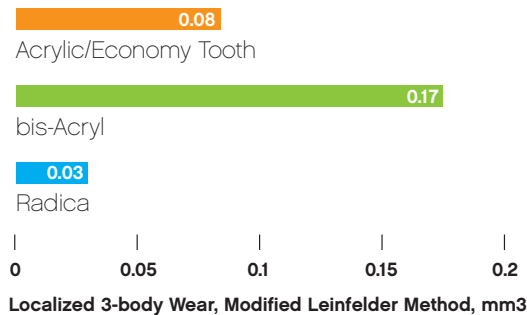
Flexural Strength: The international standard ISO 10477, recognized by the USFDA, recommends a minimum strength of 50MPa (3 point bend, flexural strength) for provisional systems¹². Flexural strength measurements showed that results obtaining composite systems for permanent restorations were obtained for Radica. This 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: 2400x5°C/55°C, 2 min/cycle; 480.000x50N, 1.66 Hz, 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. Even after the two-year term, Radica provisionals retain significantly more load-bearing capability than acrylics.

Fig. 9:

Radica Shows Very Low Wear
Against Antagonists



Wear Resistance: Wear during function is the leading concern with common temporary materials^{3,4}. Radica is significantly more wear resistant than common temporary materials, in a 3-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 clinicians. 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.

Table 1:Comparison of Radica to other Provisional Systems⁴¹⁸

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.

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 restoration¹⁷.

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.

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 Trubyte)
- Carbide Burs: #HP1558, 1mm (Midwest®, DENTSPLY Professional)
- Model Release Agent and Matrix Putty, VLC Resin, Sealer: Radica™ System (DENTSPLY Ceramco)
- Curing Lights: Triad®, Enterra™, Eclipse® Processing Unit (DENTSPLY Trubyte)
- Reline Materials: Triad® VLC Provisional Material, Biolon® C&B Resin (DENTSPLY Trubyte), Temporary Bridge Resin, Integrity™ Temporary Crown and Bridge Material.
- Temporary Cements: NoGenol (GC America), IRM®, Integrity™ TempGrip (in 2007, 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)

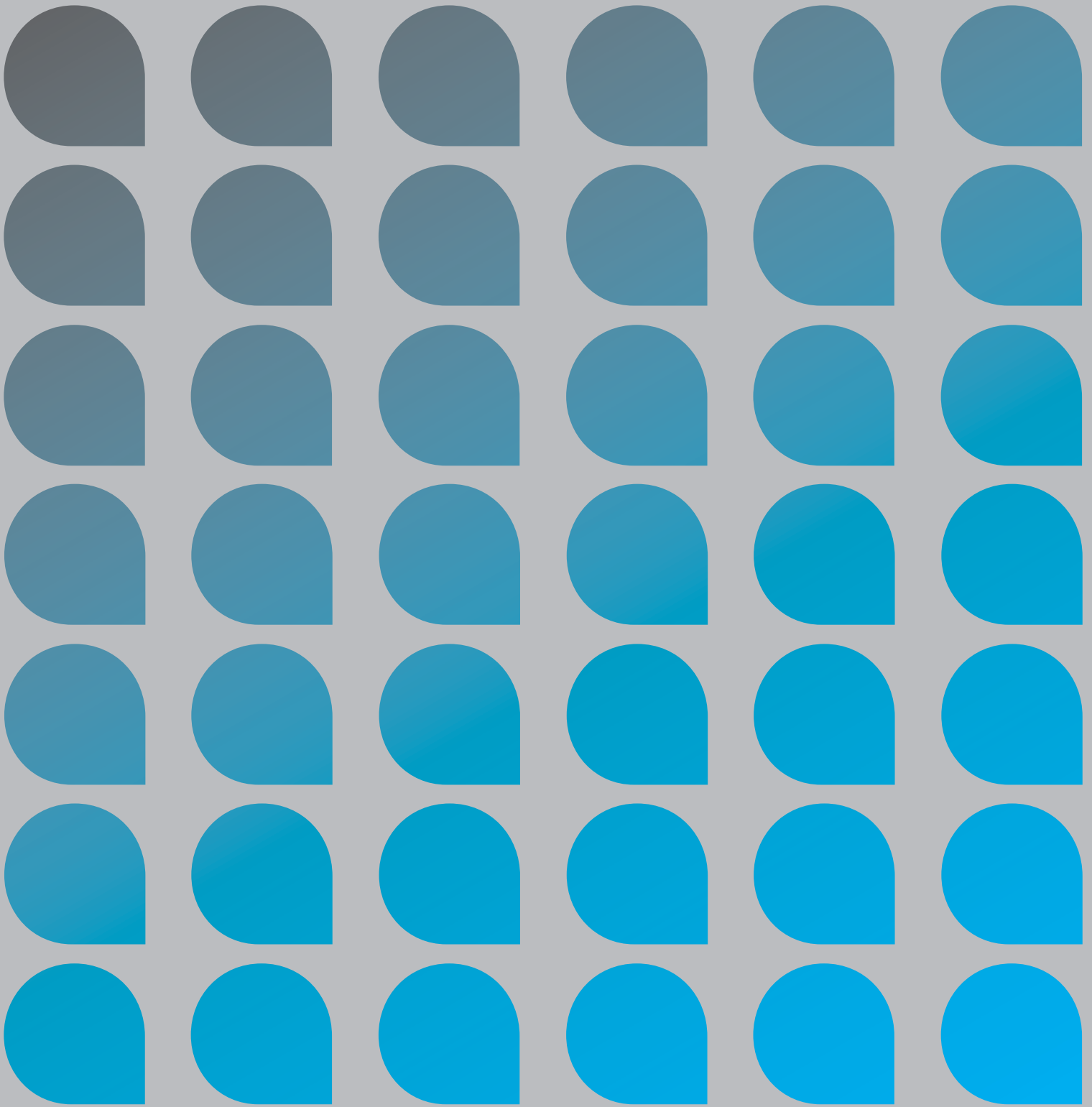
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Note: BioTemps, Alike, Jet, Snap, Trim, Luxatemp and ProTemp are not Trademarks of DENTSPLY International.

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