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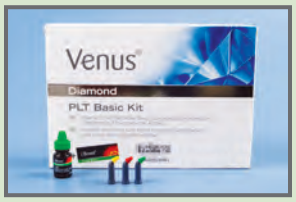
Class II Resins: Nanofill Brands as Group Show Best Performance Yet

Gordon's Clinical Bottom Line: Class II resin-based composite restorations remain the most placed restorative material in developed countries. Although these routine restorations are relatively difficult to place properly, they generate only minimal revenue for practices. In spite of this, patients expect these posterior restorations to last many years. Are composite brands equal in their ability to serve? What are the most frequent types of failures? Can longevity be improved? *TRAC Research, the long-term studies division of CR, has performed a clinical comparative study to try to answer these questions for you.*

TRAC RESEARCH

In CR/CRA's 37-year history of controlled clinical trials now involving over 100 different brands of resin-based composites, the nanofill resin brands tested showed best performance yet recorded at three years of service. Brand names of the three top performers are Venus Diamond, Esthet.X HD, and Herculite Ultra *(see images to right).* **This report shows results from this important study.**

Figure 1. Top performers in a 3-year practice-based controlled clinical study



Venus Diamond *(Kulzer)*

Esthet.X HD *(Dentsply)*

Herculite Ultra *(Kerr)*

1. METHODS: Practice-Based Controlled Clinical Trial

55 dentists from 24 U.S. states and Canada placed 386 large Class II restorations in molars in 198 patients. Performance was monitored annually using visual direct grading under 2–3x magnification clinically and indirect grading using high resolution dies at 10x, scanning electron microscope images, and full-color clinical images in the laboratory. 12 characteristics were graded, and grades were statistically analyzed by an off-site independent statistician's group to determine if performance differed from the Heliomolar control. Characteristics graded were:

- Caries
- Cracks
- Endodontic need
- Margin adaptation
- Sensitivity duration
- Wear of opposing dentition
- Chips and breaks
- Color match
- Interproximal contacts
- Post-op sensitivity
- Surface smoothness
- Wear of test material

2. DURABILITY: Ranking by problems that cause replacement *(cracks, chips, large breaks, and surface degradation)*

Many Class II resin restorations continue to serve even after they pass optimal condition. However, once they exhibit cracking and/or chips in critical locations, breaks involving 1/4 or more of the restoration, and/or severe surface crumbling, they become compromised to the point that replacement is necessary. ***In this study, material performance was ultimately ranked by the criteria that cause replacement since durability in posterior restorations is of primary importance to patients.*** Below is the listing of brands studied in order of frequency of occurrence of problems causing replacement.

Table 1: Repeated measures comparison of cracks, chips, large breaks, and surface degradation over 3 years

Brand Name	Estimated Mean *(score 1 best)*
Venus Diamond	1.762
Esthet.X HD	1.838
Herculite Ultra	1.913
Heliomolar* *(study control)*	3.036
Filtek Supreme Plus	3.062
Clearfil Majesty	3.170
N'Durance	3.280
Empress Direct	3.973

Brand names connected by a vertical solid bar are not statistically different from each other.

Bonferroni Multiple Comparisons were used.

**Heliomolar (study control) is a microfill*

Summary of Table 1 at left: Venus Diamond, Esthet.X HD, and Herculite Ultra were similar to each other and statistically superior to the other five materials in having the least problems with cracks, chips, large breaks, and surface degradation. Venus Diamond and Esthet.X HD best tolerated clinical problems and patient's habits. Herculite Ultra had the best combination of strength plus surface smoothness. The other five materials served well also, showing performance statistically the same as the study control, Heliomolar *(a microfill),* which has remained on the world market for over 30 years due to its reliable clinical performance. Based on results from this study, Empress Direct would serve best as an anterior restorative with its beautiful colors and smooth surface.

3. IMPROVEMENTS: Past problems *not seen* with formulations in this study

A. Wear. Past generations of Class II resins have shown loss of surface material described as wear. This was not exhibited by any of the eight materials in this study. All wore less or about the same as current generation Heliomolar, the microfill resin study control. *(See Table 2 at right for quantitative wear measurements.)*

B. Post-op sensitivity, open contacts, and caries reported in many past studies published internationally were not problems in this study. Newer techniques and products such as tooth preparation disinfection using 5% glutaraldehyde—35% HEMA *(See Clinicians Report, Nov. 2009, page 1)* and accessories for establishing contacts *(See Clinicians Report, April 2009, page 2)* assisted in solving these problems.

C. Surface Roughness. In all three years, Heliomolar, N'Durance, and Empress Direct had significantly smoother surfaces on average than most of the other materials. The roughest surfaces noted were with Clearfil Majesty and Venus Diamond, but they were noticeably smoother than past generation formulations. *(See images on following page.)*

Table 2: Quantitative wear measured by occlusal mapping of restoration surfaces at initial placement and after 3 years of service

Brand Name	Mean Wear Over 3 Years *(µm)*
Filtek Supreme Plus ✶	62
Clearfil Majesty	63
Herculite Ultra	75
Empress Direct	83
Esthet.X HD	89
Venus Diamond	91
Heliomolar *(study control)*	94
N'Durance	108

Solid bar indicates not statistically different

Current generation is Filtek Supreme Ultra ✶

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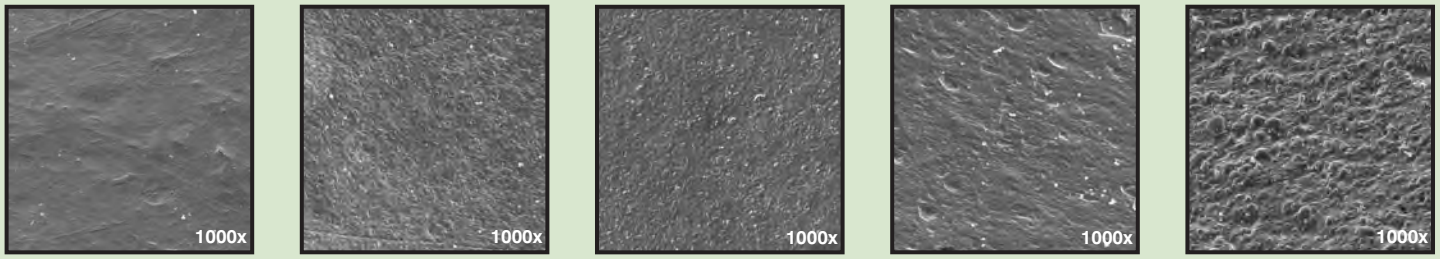
Figure 2: Scanning electron microscope images of representative brands of restoration surfaces in this study after 1 year of service intraorally



Heliomolar *(study control)* microfill | Herculite Ultra nano hybrid | Esthet.X HD nano hybrid | Venus Diamond nano hybrid | Clearfil Majesty nano hybrid

4. CLINICAL ERRORS: Two *common errors* that shorten Class II restoration life

A. Non-rounding of marginal ridges leads to chips that often compromise proximal contacts.

B. Heavy localized occlusion is not tolerated well by *any category* of current dental restorative materials. CR suggests checking occlusion at recare appointments, in addition to immediately after placement, to monitor occlusion as teeth shift. A future report will address special software/hardware that may help with this problem *(e.g., T-Scan by Tekscan).*

TRAC Conclusions:

This three-year practice-based controlled clinical trial of eight Class II resin-based composite materials showed clinically acceptable service of all materials tested, with Venus Diamond and Esthet.X HD best able to overcome clinical problems and patient habits and Herculite Ultra demonstrating the best combination of strength and surface smoothness over time. Some of the brands have been modified since the initiation of this study.

What is CR?

WHY CR?

CR was founded in 1976 by clinicians who believed practitioners could confirm efficacy and clinical usefulness of new products and avoid both the experimentation on patients and failures in the closet. With this purpose in mind, CR was organized as a unique volunteer purpose of testing all types of dental products and disseminating results to colleagues throughout the world.

WHO FUNDS CR?

Research funds come from subscriptions to the *Gordon J. Christensen Clinicians Report®*. Revenue from CR's "Dentistry Update®" courses support payroll for non-clinical staff. All Clinical Evaluators volunteer their time and expertise. CR is a non-profit, educational research institute. It is not owned in whole or in part by any individual, family, or group of investors. This system, free of outside funding, was designed to keep CR's research objective and candid.

HOW DOES CR FUNCTION?

Each year, CR tests in excess of 750 different product brands, performing about 20,000 field evaluations. CR tests all types of dental products, including materials, devices, and equipment, plus techniques. Worldwide, products are purchased from distributors, secured from companies, and sent to CR by clinicians, inventors, and patients. There is no charge to companies for product evaluations. Testing combines the efforts of 450 clinicians in 19 countries who volunteer their time and expertise, and 40 on-site scientists, engineers, and support staff. Products are subjected to at least two levels of CR's unique three-tiered evaluation process that consists of:

1. Clinical field trials where new products are incorporated into routine use in a variety of dental practices and compared by clinicians to products and methods they use routinely.
2. Controlled clinical tests where new products are used and compared under rigorously controlled conditions, and patients are paid for their time as study participants.
3. Laboratory tests where physical and chemical properties of new products are compared to standard products.

THE PROBLEM WITH NEW DENTAL PRODUCTS.

New dental products have always presented a challenge to clinicians because, with little more than promotional information to guide them, they must judge between those that are new and better, and those that are just new. Due to the industry's keen competition and rush to be first on the market, clinicians and their patients often become test data for new products.

Every clinician has, at one time or another, become a victim of this system. All own new products that did not meet expectations, but are stored in hope of some unknown future use, or thrown away at a considerable loss. To help clinicians make educated product purchases, CR tests new dental products and reports the results to the profession.

Clinical Success is the Final Test

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