1 Introduction

With the evolutionary development of filling materials, there is an ever increasing need for better tooth-coloured restorative materials to replace missing tooth structure and to modify tooth colour and contour, thus enhancing facial aesthetics.\(^1\) Polymeric restoratives have continued to evolve into the direct restorative materials of choice mainly because of their superior aesthetic characteristics. Development of composite restorative materials started in the late 1950’s. Many significant advances have been made since then in improving the properties of earlier resin based restoratives. Currently, composites are the most widely used materials in restorative dentistry with the widest range of indications.

The bond between resin-based restorative material and natural enamel was revolutionised when Buonocore introduced the enamel acid etch technique.\(^2\) Modern adhesives bond composite tenaciously to both enamel and dentine substrates in the oral environment, improving restoration retention and virtually eliminating postoperative sensitivity. Some of the most recent composites have been improved to be more wear resistant, stronger, and more colour stable.

Dentsply products have helped to shape the evolution of resin-based restorative materials: \(^3\)

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1949</td>
<td>Introduction of Kadon(^\circledast), DENTSPLY’s first direct plastic filling material.</td>
</tr>
<tr>
<td>1970</td>
<td>Adaptic(^\circledast) was launched as a chemically-curing conventional composite.</td>
</tr>
<tr>
<td>1973</td>
<td>Introduction of Nuva-Fil(^\text{TM}). The first command-set dental restorative, cured with UV light, was the first resin material commercially produced to be used with the acid etch technique developed by Buonocore in 1955.</td>
</tr>
<tr>
<td>1981</td>
<td>Introduction of Ful-Fil(^\circledast). The first visible-light-cured posterior composite accepted by the American Dental Association.</td>
</tr>
<tr>
<td>1988</td>
<td>Introduction of Prisma(^\circledast) AP.H(^\circledast), a fine-particle hybrid composite to be used in both anterior and posterior restorations.</td>
</tr>
<tr>
<td>1992</td>
<td>Introduction of Prisma(^\circledast) TPH(^\circledast) designed to be more wear-resistant in posterior teeth than Prisma APH. Furthermore, the material was made more polishable due the reduced mean particle size.</td>
</tr>
<tr>
<td>1993</td>
<td>Introduction of Dyract(^\circledast), the world's first compomer restorative, combining the favourable properties of glass-ionomers with those of composites.</td>
</tr>
</tbody>
</table>
1995 Introduction of **Spectrum™ TPH** restorative system, a clinically proven universal hybrid composite with simplified placement properties, and outstanding tooth and Vita¹ shade guided aesthetics.

1997 Introduction of **Dyract AP** the first compomer indicated for all cavity classes including posterior restorations in permanent dentition.

1998 Introduction of **SureFil™** High Density Posterior Restorative, an alternative to amalgam, with excellent physical properties, “packable” handling and bulk placement up to 5 mm.

In the 1980's, separately formulated composites were developed specifically for either highly aesthetic anterior restorations or stress bearing posterior restorations since there was no single material available that met both anterior and posterior restoration requirements. In the late 1980's, “Universal Hybrid” composites, indicated for both Anterior and Posterior restorations were developed (e.g. Prisma AP.H, and Prisma TPH). While combining aesthetics and strength it may be technically challenging to achieve the high lustre polish a highly aesthetic restoration demands with the traditional hybrid composites. Therefore, clinicians often used a weaker “microfilled” composite for anterior restorations due to its polishable aesthetic characteristics, and a hybrid composite for posterior restorations because of its high strength and wear resistance.

The following are key attributes that an ideal composite should provide:

- Durability
- Aesthetics
- Handling
- Polish
- Wear-Resistance
- Minimal Shrinkage
- Multiple Opacities
- Moderate Modulus
- Fluoride Release
- Radiopacity

¹ Vita® is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co, Bad Säckingen, Germany.
Anterior and posterior restoratives have different requirements. For anterior use, aesthetics, shades and polish are most important\(^2\), whereas wear resistance and durability should be considered first for posterior use. A single restorative material, to be considered for use in both anterior and posterior restorations, should meet these requirements, optimising the balance of strength and beauty for both anterior and posterior restoratives.

The anterior teeth characterise a person’s smile. In today’s health and beauty conscious societies world-wide, a highly aesthetic restoration that mimics the natural tooth aesthetics is demanded by both patients and clinicians. Dentists are demanding improved and more easily achieved aesthetics in anterior restorations than those offered by current universal composites, without sacrificing the strength.

To develop a new class of composite restorative possessing the “strength of a hybrid and the polish of a microfill, offering superior aesthetics with broad shade and opacity ranges”, Project “R-30” was initiated over two years ago and development objectives were set up as follows:

### 1.1 Project Development Objective

To develop an improved hybrid composite with ideal characteristics to perform highly aesthetic, durable anterior and posterior restorations

- Polish Comparable to a Microfill
- Maintenance of Polish in the Mouth
- Shade System to Enable Creating Restorations “from the inside out”
- Sculptable, Non-Sticky Handling
- Physical Properties equal or better than Spectrum\(^\text{TPH}\) Hybrid
- Excellent Resistance to Wear
- Fluoride Releasing

Following intensive research and development, clinical trials and clinician input, the product design specifications were met, creating a new class of restorative product, now identified as Esthet\(\text{X}\) Micro Matrix Restorative.

\(^2\) Data on File: Restorative Survey, 1998
1.2 EsthetX Micro Matrix Restorative
Performance Summary

- Superior Handling Characteristics
- Complete Aesthetic Shade Range
  - Opaque Dentine Shades
  - Regular Body Shades
  - Enamel/Translucent Shades
- Co-ordinated Opacity Across Shade Ranges
- Polish Comparable to Traditional Microfills
- Retention and Maintenance of Polish After Placement
- Wear Resistance Equal to or Greater Than Traditional Hybrids
- Improved Ambient Light Working Time

With EsthetX Micro Matrix Restorative composite and the advanced adhesive technology now available, dentists can create the restorations that not only preserve and reinforce tooth structure, but also produce durable, truly superb aesthetic results.
2 Esthet•X Micro Matrix Restorative Technology

2.1 Resin Matrix Chemistry

The resin matrix of Esthet•X Micro Matrix Restorative is based on that of Spectrum™ composite, a urethane modified BisGMA resin matrix system. This resin matrix is well known and documented with excellent clinically proven performance (strength and longevity). It consists mainly of the BisGMA-adduct, ethoxylated Bisphenol-A-dimethacrylate, and Triethylene glycol dimethacrylate (TEGDMA). The high molecular weight BisGMA-adduct (a major portion of the resin matrix) contains fewer C=C double bond per molecule, which contributes to less polymerisation shrinkage during polymerisation. The final resin composition was determined through the optimisation of physical properties, handling preference and aesthetic requirements.

Esthet•X Micro Matrix Restorative contains the DENTSPLY patented, highly efficient photoinitiation system. The matrix contains a combination of the diketone, Camphoroquinone (CQ), and the organic amine Ethyl-4-dimethylaminobenzoate (EDAB), which has been optimised to provide sufficient clinical working time (reduced sensitivity to ambient light). This unique initiator system enables Esthet•X Micro Matrix Restorative to demonstrate high curing efficiency and excellent physical properties (See Chapter 6 - Physical Properties).

2.2 Fillers

The filler component of Esthet•X Micro Matrix Restorative is a synergistic blend of a unique, proprietary inorganic bariumalumino fluoroborosilicate (BAFG) glass with nano-sized silicon dioxide particles. The BAFG glass possesses unique optical and mechanical properties that enable Esthet•X Micro Matrix Restorative to have natural, tooth-like appearance with exceptional polish, while at the same time maintaining all the mechanical strength of traditional hybrid restoratives.

The BAFG glass has an average filler particle size of 0.6 - 0.8 microns with a narrow particle size distributions of 0.02 - 2.5 microns. The silicon dioxide nanofiller is in the range of 10 to 20 nm. The total percentage by volume of inorganic fillers is ca. 60 vol.%; the percentage by
weight is ca.77 wt.%. Thus, Esthet•X Micro Matrix Restorative has both the ideal anterior restorative attributes of superior, non-slumping handling, high polishability and optical aesthetics AND the ideal posterior composite attributes of wear resistance, sculptability, excellent strength, and low post cure shrinkage.

![Figure 1](image.png)

**Figure 1** SEM of Esthet•X Micro Matrix Restorative Filler Particles (courtesy of Dr. M. Vargas)  
(Note: After polymerisation, the surface of this sample was treated with reagents to remove surface resin and expose the underlying filler particles.)

<table>
<thead>
<tr>
<th>New Proprietary Glass</th>
<th>Silica Nanosized Fillers</th>
<th>Proprietary Processing of Fillers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique Properties:</td>
<td></td>
<td>Sculptable Handling</td>
</tr>
<tr>
<td>Polish</td>
<td></td>
<td>Polish of a Microfil/Properties</td>
</tr>
<tr>
<td>Optical</td>
<td></td>
<td>and Matrix of an Advanced Hybrid</td>
</tr>
<tr>
<td>Wear</td>
<td></td>
<td>Coordinated Opacities that</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Replicate Natural Teeth</td>
</tr>
</tbody>
</table>

6
3 Product Description

Esthet•X Micro Matrix Restorative is an aesthetic, visible-light cured, radiopaque, micro-hybrid composite restorative material designed specifically for use in all cavity classes in both anterior and posterior restorations. It is to be used with a dental adhesive system, such as Prime&Bond® NT Universal Light Cured Dental Adhesive. This one-component composite is packaged in pre-dosed Compules® Tips and syringes. The regular body shades are optimised to match the Vita System and offer a chameleon effect.

In addition to regular body shades, opaque dentine and translucent enamel shades are available for aesthetically demanding applications beyond the traditional Vita System. Each shade range possesses its own unique opacity characteristics. Custom blending of these three opacity ranges allow the clinician to create restorations possessing natural aesthetic beauty.

A custom blended shade guide is available to guide the clinician in shade selection and blending technique.

Currently, there are thirty-one shades available in the Esthet•X System:

**Opaque Dentine, Regular Body** (Dentine) and **Translucent Enamel** series.

<table>
<thead>
<tr>
<th>Opaque Dentine Shades</th>
<th>Regular Body Shades</th>
<th>Translucent Enamel Shades</th>
</tr>
</thead>
<tbody>
<tr>
<td>White-O = W-O</td>
<td>White = W</td>
<td>Clear Enamel = CE</td>
</tr>
<tr>
<td>A2-O</td>
<td>Extra Light = XL</td>
<td>White Enamel = WE</td>
</tr>
<tr>
<td>A4-O</td>
<td>A1</td>
<td>Yellow Enamel = YE</td>
</tr>
<tr>
<td>B2-O</td>
<td>A2</td>
<td>Amber Enamel = AE</td>
</tr>
<tr>
<td>C1-O</td>
<td>A3</td>
<td>Grey Enamel = GE</td>
</tr>
<tr>
<td>C4-O</td>
<td>A3.5</td>
<td></td>
</tr>
<tr>
<td>D3-O</td>
<td>A4</td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dark Yellow/B5 = B5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Esthet•X Micro Matrix Restorative offers a durable, high surface lustre commonly seen in traditional microfill materials, with the patented hybrid resin matrix and a unique particle distribution that offers superior strength, durability, and fracture toughness, too.

Esthet•X Micro Matrix Restorative is incrementally placed (up to 2.0 mm for each layer), and each layer is cured for 20 Seconds.

Esthet•X Micro Matrix Restorative is an advanced hybrid aesthetic composite possessing physical properties that rivals typical hybrid restoratives (e.g. SpectrumTPH, Herculite™ XRV, etc.). Inherent Esthet•X Micro Matrix Restorative are those desirable features of high polishability (ease of polish, as well as longevity), superior handling (non-sticky, “sculptable”, slump-resistant), and a complete shade system with a broad range of shades having multiple opacities. Being incrementally placed and cured (up to 2 mm for each layer), Esthet•X Micro Matrix Restorative enables the clinician to build a tooth “from inside out”, similar to natural dentition, to create the natural beauty of vital teeth.

<table>
<thead>
<tr>
<th>Characteristics of Ideal Anterior and Posterior Composites</th>
<th>Esthet•X</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Polish (ease, and longevity)</td>
<td>✔</td>
</tr>
<tr>
<td>Aesthetics (broad shades with multiple opacities)</td>
<td>✔</td>
</tr>
<tr>
<td>Non-Sticky, “Sculptable,” Slump-resistant Handling</td>
<td>✔</td>
</tr>
<tr>
<td>Superior Physical Properties</td>
<td>✔</td>
</tr>
<tr>
<td>Low Wear (Equal to Amalgam/Close to Enamel)</td>
<td>✔</td>
</tr>
</tbody>
</table>
4 Indication for Use

Esthet•X Micro Matrix Restorative is indicated for use in the following types of restorations:

1. Esthet•X Micro Matrix Restorative is indicated as a direct restorative for ALL cavity classes in anterior and posterior teeth.

2. Esthet•X Micro Matrix Restorative is indicated as a direct aesthetic veneering material and for use in cosmetic reshaping (e.g. diastema closure, incisal lengthening).

3. Esthet•X Micro Matrix Restorative is indicated for the indirect fabrication of inlays, onlays and veneers.
5 Esthet•X Micro Matrix Restorative Shade Guide

A custom blended Esthet•X Micro Matrix Restorative shade guide is available to guide the clinician in shade selection and blending technique.

SHADE GUIDE CONCEPT

Esthet•X Micro Matrix Restorative TruMatch™ Shade Guide
The goal of the Esthet•X Micro Matrix Restorative system is to enable clinicians to achieve the most natural “tooth-like” restorations. In order to facilitate this, the TruMatch shade guide for Esthet•X Micro Matrix Restorative was designed to guide creation of the restoration “from the inside-out” by an “Incremental Technique.” That is, each shade tooth of the shade guide is constructed by blending three different shaded layers, representing the opaque dentine, regular body and translucent enamel portions.

To use the shade guide, the clinician selects the appropriate tab to predict the desired final restoration aesthetic. Once selected, the shade tab handle and the reverse side of the shade guide both outline the “recipe” used to create that particular shade tooth. By selecting the corresponding shades of Esthet•X Micro Matrix Restorative and layering the shades sequentially into the cavity preparation, the clinician can achieve the desired result exactly portrayed by the shade tab. For example, to create a final restoration of “A3.5”, first a foundation layer of A2-O (opaque dentine) shade is placed, followed by A3.5 body (regular body) shade and finally covered with YE (translucent enamel) shade. The following table illustrates the recipes provided on the shade guide.
Both colour (shade) and translucency (contrast ratio) determine the aesthetic quality of a composite restoration. Colour is important because the shade match between the restoration and its surrounding teeth must be indistinguishable. Translucency of a restorative will provide the added “life-like” vitality and natural appearance of the completed restoration.
Translucency may be measured as contrast ratio, wherein a material becomes less translucent (more opaque) as the contrast ratio increases. The translucency range of Esthet•X Micro Matrix Restorative was developed to match that of human enamel and dentine. The translucency (contrast ratio) of Esthet•X Micro Matrix Restorative spans from ca. 40% in Translucent Enamel Shades to ca. 80% in Opaque Dentine Shades (see Figure 3).

Custom blending of these three differing opacities allows the clinician to create restorations possessing natural aesthetic beauty. The customised translucency gradient of Esthet•X Micro Matrix Shades creates a “chameleon effect.” That is, the restoration acquires the appearance of its surroundings, making it “invisible” within the tooth and the adjacent arch. The combination (over-layering) of the selected Opaque Dentine/Regular Body/Translucent Enamel shades with the customised translucency gradient makes Esthet•X Micro Matrix Restorative the most complete Aesthetic Restoration System. Use of the TruMatch blended shade guide eliminates the “guess work” of blending shades, making custom shade blending for the ultimate aesthetic restoration an easy, predictable procedure.

Figure 3  Esthet•X Shade Opacity
6 Physical Properties of Esthet•X

6.1 Materials Evaluated

The following composite materials were selected in our extensive in-vitro competitive property evaluations:

<table>
<thead>
<tr>
<th>Material Designation</th>
<th>Product</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esthet•X</td>
<td>Esthet•X Restorative</td>
<td>DENTSPLY</td>
</tr>
<tr>
<td>XRV</td>
<td>Herculite XRV</td>
<td>Kerr</td>
</tr>
<tr>
<td>Vitalescence</td>
<td>Vitalescence³</td>
<td>Ultradent</td>
</tr>
<tr>
<td>Z250</td>
<td>Filtek™ Z250</td>
<td>3M™</td>
</tr>
<tr>
<td>Silux+</td>
<td>Silux Plus</td>
<td>3M™</td>
</tr>
<tr>
<td>Tetric Ceram</td>
<td>Tetric Ceram™</td>
<td>Vivadent</td>
</tr>
<tr>
<td>SpectrumTPH</td>
<td>SpectrumTPH</td>
<td>DENTSPLY</td>
</tr>
<tr>
<td>Z100</td>
<td>Z100™ Restorative</td>
<td>3M™</td>
</tr>
<tr>
<td>Prodigy</td>
<td>Prodigy</td>
<td>Kerr</td>
</tr>
<tr>
<td>Charisma</td>
<td>Charisma</td>
<td>Kulzer</td>
</tr>
<tr>
<td>Renamel</td>
<td>Renamel Microfil</td>
<td>Cosmedent</td>
</tr>
<tr>
<td>Synergy</td>
<td>Synergy</td>
<td>Coltene</td>
</tr>
</tbody>
</table>

6.2 Polishability (Surface Roughness and Gloss)

Clinical Relevance: Polish is one of the most important material attributes for aesthetic restoratives. Polish can be viewed in three stages: the ease of which the polish is obtained, the actual polish results obtained, and the longevity of the polish during the lifetime of the restorative. In order to create or replicate natural tooth beauty, a restorative material must be polishable to the extent that its lustre is equivalent to that of enamel. To retain that vitality, it must retain a highly lustrous polish over the restoration lifespan.

³ In some countries available as Enamel Plus / Enamel Plus HFO
The ability of a composite restorative material to achieve enamel-like surface lustre is called the “polishability.” Due to its unique optimised filler system comprising of narrow-distributed very fine (sub-micron) BAFG glass filler coupled with nano-sized silica, Esthet•X Micro Matrix Restorative demonstrates exceptional polishability (ease of polish, polish obtained, and retention of the high polish) using Enhance® polishing system. After polishing, Esthet•X Micro Matrix Restorative has a surface roughness that is equivalent to a typical microfill composite, comparing more favourably than other leading hybrid composite brands. More significantly, once achieved, the high polish of Esthet•X Micro Matrix Restorative endures. Its exceptional hardness and wear resistance prevents the surface from dulling due to mastication and toothbrush abrasion. As “proven” in both the following in-vitro study (e.g. Tooth Abrasion Study at University of Montreal) and the in-vivo multiple-site clinical study (see Chapter 8, for details), Esthet•X Micro Matrix Restorative exhibited a high polish feature, contributing to its exceptional aesthetic restoration quality.

6.2.1 In-vitro Toothbrush-dentifrice Abrasion of Esthet•X Composite

Study Site
Dr. Daniel J. Fortin, et al (The University of Montreal, Canada)

Toothbrush-dentifrice abrasion can take place on all restoration surfaces. However, it is more commonly seen on restorations in anterior teeth and in cervical erosion abrasion lesions. Unfortunately, wear is one of the least understood properties of restorative materials because it can involve different processes such as abrasion, adhesion, fatigue, and erosion, all of which may not be independent of each other. For the type of non-standardised testing used here, the inclusion of a control material (3M™ Silux Plus microfill and Kerr Herculite™ XRV Hybrid composite resin) are essential in order to enable sensible comparisons to be made.

The objective of this study was to compare the rate of abrasive wear change in surface roughness of Esthet•X Micro Matrix Restorative when subjected to toothbrush dentifrice abrasion.

Three composite restoratives, i.e. Esthet•X Micro Matrix Restorative (Shade A1 [Regular body] and Y-E [Translucent Enamel]), Silux Plus Microfil (Shade Light), and Herculite XRV hybrid (Shade A1), were used. Sample size n = 5. All the composite block samples (dimension 18 x 9 x 2 mm) were made in a Teflon mould and cured. The flat surface of the cured composite samples were polished (sanded) using a Buchler Polishing system (Buchler Ltd., IL) through a polishing sequence of 600, 1200, 2400, 4000 grit polishing media and finished with 0.05 micron diamond polishing paste. The surface profiles and surface
roughness of the pre-test and post-test samples in this study were analysed (scanned area 8 x 5 mm, with 50 µm intervals x 250 scans) using the Form Talysurf Series 2 profilometry measuring device (Rank Taylor Robson Ltd, England). The obtained surface mapping profiles of both pre-test and post-test specimens were further analysed using Talymap Software (Rank Taylor Robson Ltd.) from which the surface roughness ($S_{Ra}$) and surface topography of pre- and post-test samples were obtained.

Specimens of each material were subjected to toothbrush abrasion using 56,000 strokes of brushing (brushing twice a day, 56,000 strokes would be equivalent to approximately 5 years of normal home care). The tooth-brushing device consisted of five heads to hold the toothbrushes, each with an opposing specimen holder connected to a camshaft driven by a motor/gearbox system, and control unit. A toothbrush with medium bristles was fitted into each head, and the specimens were mounted in the opposing specimen holders. Care was taken that the filaments in each tuft of the brush were perpendicular to the surface of the material and touched the surface evenly without bending. Toothbrush holders reciprocated a distance of 5mm at a speed of 50 cycles/min up to 56,000 cycles, during which a 55 gram load was applied to the toothbrush. The dentifrice, used in this experiment was of a low abrasivity. The dentifrice was placed between the brush and the surface of the material to maintain a constant supply of abrasive during brushing. After the test, the surface was rinsed with tap water, gently air-dried, and profiled. The surface roughness of post abrasion test was determined in the same manor as described for pre-abrasion test.

**Results and Conclusions**

Surface roughness values ($S_{Ra}$) of pre-abrasion test and post abrasion test for all the materials evaluated are given in Figure 4. As can be seen from the Figure 4, initial roughness of all specimens was not significantly different. All materials exhibited a smooth surface immediately after polish. However, post-abrasion data showed significant difference in surface roughness among different materials. After brushing, the roughness of Herculite XRV (group 3) was significantly higher than that of Esthet•X Micro Matrix Restorative (Shade A1, and Y-E) and Silux Plus (One-way ANOVA for group effect $p = 0.008$ and Tukey pairwise mean comparison $p < 0.03$). Esthet•X Micro Matrix Restorative (Shade A1, and Y-E) {group (1) and (2)}) were not significantly different from Silux Plus (group 4). The new Esteht•X Micro Matrix Restorative demonstrated pre-and post-toothbrush abrasion wear results similar to that of a traditional microfill.
Esthet• X™: Tooth Brush Abrasion Test

University of Montreal

![Graph showing toothbrush abrasion results](image)

**Figure 4** Surface Roughness (SRa) of Esthet•X vs. Others (Pre-abrasion and Post-abrasion Results)

In addition, as shown in Figure 5 and Figure 6 from another external independent study (Atomic Force Micrography), Esthet•X Micro Matrix Restorative has twice the surface smoothness ($S_{Ra} = 30.1$ nm, $Z$ range = 387.8 nm) than that of another hybrid composite Filtek™ Z250 ($S_{Ra} = 62.0$ nm, $Z$ range = 708.3 nm) after the clinical polishing steps.

### 6.2.2 Surface Roughness ($S_{Ra}$) of Clinically Polished Esthet•X vs. Filtek Z 250

(AFM Analysis, Dr. M. Vargas)

<table>
<thead>
<tr>
<th>Composite</th>
<th>$S_{Ra}$ (nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esthet•X</td>
<td>30.1</td>
</tr>
<tr>
<td>Z 250</td>
<td>62.0</td>
</tr>
</tbody>
</table>
Clinical Significance

It is sometimes difficult to predict the in-vivo performance of a material from the results of in-vitro experiments. However, reflecting on the in-vitro resistance to toothbrush-dentifrice abrasion, the new Esthet•X Micro Matrix Restorative composite resin demonstrates better surface characteristic compared to a regular hybrid composite and similar surface characteristics compared to a microfill composite resin.
6.2.3 Surface Roughness Evaluation of Composite Resins

J.C. Ramos, A. Vinagre, P. Nicolau, J. Paulo (Coimbra Medical and Dental School, University of Coimbra, Portugal), (IADR 2000)

Proper finishing and polishing of tooth-coloured restorations enhance the aesthetics and longevity of restored teeth. Plaque retention, surface discoloration and wear of the restoration have been related to the smoothness of the restoration surface. The aim of this study was to compare the surface roughness of various composite resins. Four samples with 12 x 12 x 2 mm were made for each group using polyethylene moulds. The samples were polymerised with a visible light-curing unit during 60 s on each side. One sample of each group was polymerised against a celluloid matrix and was not polished. The other samples were polished with Enhance Composite Finishing & Polishing System according manufacturer instructions. After polishing, the samples were stored 48 hours in distilled water at 37°C and then measured by non-contact laser stylus tracing (Perthometer S8P-Feinpruf Perthen GmbH, Gottingen, Germany), with a spot size of 1µm. Six standard crossed measurements were made for each sample. Although surface topography is generally correlated with (Ra) values, in order to better describe the surface texture, other parameters were registered, too (Table 1). Data were analysed using ANOVA and Student's t-test (p ≤ 0.005). The results are summarised in Figure 7. For qualitative analysis the samples were sputter-coated with Au and observed by SEM (JEOL, JSM-5310, Japan) at 25 kV (see Figure 8).

<table>
<thead>
<tr>
<th>Results (µm ± SD)</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ra</td>
<td>R-30 (Esthet•X)</td>
</tr>
<tr>
<td></td>
<td>0.27 ± 0.04</td>
</tr>
<tr>
<td>Rz</td>
<td>3.17 ± 0.91</td>
</tr>
<tr>
<td>Rp</td>
<td>0.98 ± 0.37</td>
</tr>
</tbody>
</table>

Table 1 Various values for surface roughness
Figure 7  
Surface roughness: $R_a$-value

a) 

b)
6.3 Wear Resistance

While Esthet•X Micro Matrix Restorative is regarded as an exceptional anterior restorative due to its multiple shades and aesthetics, the product was designed to function in all cavity classes and locations in the mouth. Therefore, resistance to wear under strong occlusal loading is an important feature.

Clinical Relevance: Since restorations, especially in posterior teeth, are subject to severe abrasion from the opposing enamel cusps, the wear resistance of a restorative material correlates to its longevity.

The in-vitro wear resistance of Esthet•X Micro Matrix Restorative was determined by means of the methodology and apparatus designed by Dr. Karl Leinfelder formerly of the University of Alabama, which has been acknowledged as the industry standard. Cylindrical specimens were prepared and subjected to simulated cuspal occlusal wear forces. The cured test material specimen was abraded using a three body, cyclic, abrasion-wearing simulation. The composite restoration represents the 1st body worn against a Stainless Steel Stylus (2nd body), with abrasive slurry of PMMA (3rd body) representing a food bolus. This closely simulates the mastication effects of teeth under occlusal load. After being subjected to 400,000 abrasion cycles (which approximates three years of clinical use), the test specimen exhibits a distinct material volume loss at the abraded location. The volume loss of the worn area is measured using a Rank-Taylor Hobson Profilometer/Surface Analyser system. The profilometer employs a transversing stylus to construct a three-dimensional map.
of the worn area by means of an electronic interface unit linked to a host computer. The surface analyser program installed in the host computer graphically depicts the worn area, as shown in the following pictorial diagram (Figure 10), and calculates its volume. This volume, expressed in cubic millimetres, is regarded as the standard “mean volume loss” of the material. The higher the mean volume loss, the greater the wear.

As shown in Figure 9, Esthet•X Micro Matrix Restorative possesses a very low mean volume loss (0.02 mm$^3$) compared to most currently marketed hybrid composites and amalgams (Dispersalloy® 0.024 mm$^3$). In addition, the quality of the marginal interface between the restorative and the enamel was also evaluated and found to have “gap free” marginal structural integrity following the 400,000 cyclic fatigue loading.
6.4 Polymerisation Shrinkage

Clinical Relevance: Excessive post-cure polymerisation shrinkage of a composite is a major contributor to the stress-induced marginal microleakage and its concomitant post-operative sensitivity.

Polymerisation shrinkage was determined on an instrument designed and fabricated by the National Institute of Standards and Technology (NIST). The NIST instrument employs dilatometric measurements to determine the volumetric contraction (i.e. shrinkage) of a light cured composite material due to polymerisation of its resin component. The quantitative difference between pre-cure and post-cure volumes of the material is measured by means of a linear volume displacement transducer (LVDT) using mercury as the displacing medium.
An interfacing computer program records and calculates the percent volumetric polymerisation contraction of the test material.

The measured shrinkage of various composites was shown in Figure 11. As can be seen from the Figure 11, the volumetric polymerisation shrinkage of Esthet•X Micro Matrix Restorative is approximately 2.3%, which is similar to Herculite XRV, Spectrum™, Z100, Silux Plus and Synergy, but statistically lower than Vitalescence, Tetric Ceram, Charisma, Prodigy, and Renamel Microfill.

![Figure 11](image)

**Figure 11**  Polymerisation Shrinkage ($\Delta V/V\%$)

### 6.5 Depth of Cure

**Clinical Relevance:** The depth of cure value reflects the conversion (degree of polymerisation) of a material. Sufficient depth of cure values are desirable to assure that the composite placed in 2mm increments has optimal mechanical properties.

Esthet•X Micro Matrix Restorative was formulated to provide the optimum physical properties as well as aesthetics. To assure optimal curing of the material, the recommended increment to be placed using a 20-second visible light exposure, is 2.0 mm. That is, the restoration will be optimally cured with each increment of 2.0 mm with a single 20-second exposure using a visible light curing device ($300+ \text{ mW/cm}^2$) such as the Spectrum® 800 Curing Light.

### 6.6 Compressive Strength and Diametral Tensile Strength

**Clinical Relevance:** Compressive strength (CS) of a composite is particularly important in withstanding the chewing forces to which it may be subjected. The compressive strength of a
composite should approximate that of enamel to withstand compressive occlusal forces during mastication.

The compression strength of a composite restorative is determined by subjecting a 6 mm diameter by 12 mm long sample of the material to an increasing compressive force along its longitudinal axis until fracture failure occurs. The sample failure is a result of shear and tensile force. An Instron Universal Testing Machine (UTM) measures the compressive force at fracture. This force, divided by the sample cross-sectional area, is deemed the compressive strength of the material.

The compressive strengths of various materials are shown in Figure 12. As shown in Figure 12, Esthet•X Micro Matrix Restorative displayed higher CS than Tetric Ceram, Vitalescence, Charisma, Silux Plus, Renamel, but was not significantly different from Herculite XRV, Z250, SpectrumTPH, etc.

The Diametral Tensile Strength (DTS) of a composite restorative is determined using a similar apparatus. A 6 mm diameter by 3 mm long sample is subjected to an increasing compressive force along its transverse axis until fracture failure occurs. An Instron UTM measures the compressive force at fracture. This force, divided by the sample cross-sectional area, is deemed the DTS of the material.
The Diametral Tensile strengths of various materials are shown in Figure 13. As shown in the Figure 13, Esthet•X Micro Matrix Restorative displayed a higher DTS than Vitalescence, Tetric Ceram, Silux Plus, and Renamel, but was not significantly different from Herculite XRV, Z250, etc.

6.7 Flexural Strength and Flexural Modulus

Clinical Relevance: To minimise marginal degradation due to fatigue induced fracture, a composite restorative material must possess the proper combination of flexural strength and flexural modulus.

Flexural strength measures the ability of a material to resist fracture under bending loads. This is particularly critical where the restorative is in thin layers such as margins where the mastication forces are particularly severe. Related to flexural strength is flexural modulus, a measure of the elasticity of the material (the amount of unit stress to produce a unit strain). It measures the brittleness of a material and also denotes the tendency of a material to fracture. A very high modulus indicates the material is brittle and likely to fracture. A low modulus indicates a flexible material. A high flexural strength coupled with a moderate flexural modulus provides the best combination of strength and elasticity for a restorative composite.
Both flexural strength and flexural modulus are determined as per ISO 4049 by subjecting a 2 mm by 2 mm by 25 mm bar sample of the material to three point bending. Using an Instron UTM, a compressive force is applied and measured at the center of the bar whose ends are positioned on two upright supports. The bending action of the bar induces a compression stress at its top surface and a tensile stress at its bottom surface. This dual stress condition closely simulates the stress distribution exerted on restoration margins.

The flexural strength and flexural modulus of various composites are shown in Figure 14 and Figure 15. As shown in these figures, the flexural strength and flexural modulus of Esthet•X Micro Matrix Restorative demonstrates the proper degree of strength and toughness without exhibiting brittleness. The combined values of flexural strength and flexural modulus for Esthet•X Micro Matrix Restorative provide the necessary robustness to minimise marginal degradation due to mastication cyclic fatigue.

![Figure 14](image1.png)  24 Hour Flexural (Transverse) Strength

![Figure 15](image2.png)  24 Hour Flexural Modulus
Figure 16 and Figure 17 shows the flexural strength and flexural modulus data from an independent study that again confirmed the good flexural property of Esthet•X Micro Matrix Restorative composite.

![Figure 16](image1.png)

**Figure 16** 24 Hour Flexural (Transverse) Strength (Loma Linda University, Dr. C. Munoz)

![Figure 17](image2.png)

**Figure 17** 24 Hour Flexural Modulus (Loma Linda University, Dr. C. Munoz)

### 6.8 Fracture Toughness

**Clinical Relevance:** The fracture toughness of a restoration describes its ability to resist catastrophic propagation of cracks under applied mastication stresses. A higher fracture toughness implies a lower rate of marginal degradation.

Fracture toughness ($K_{IC}$) is a measure of a material’s ability to resist the propagation of a fracture crack. Essentially, it is the amount of energy needed to continue the propagation of a crack caused by an inherent flaw within the material until fracture occurs. Fracture toughness ($K_{IC}$) is a critical property with regard to the restoration marginal edges where surface flaws are usually prevalent. A material having high fracture toughness is generally considered strong, while a strong material is not necessarily tough. Fracture toughness ($K_{IC}$) was
determined by using the notchless triangular prism (NTP) specimen method developed by N. D. Ruse. The method uses the Instron UTM and a special test fixture to apply and measure the force required to initiate and propagate a fracture crack in the test material. The measured force, flaw depth and specimen dimensional parameters are calculated in determining the fracture toughness value.

![Figure 18](image)

**Figure 18** Fracture Toughness ($K_{IC}$)

The fracture toughness ($K_{IC}$) of various composite materials is shown in Figure 18. As can be seen from Figure 18, the fracture toughness of Esthet•X Micro Matrix Restorative is much greater than that of most currently marketed restorative composites. This is ideal for Class IV restorations.

### 6.9 Hardness

**Clinical Relevance:** The hardness of a restorative material measures its resistance to surface indentation and scratching. The value correlates, to certain extent, to wear resistance.

The pure abrasive wear of a material is correlated with its surface hardness. There are several standard methods and scales to measure hardness, but one common method is known as the barcol hardness. This method consists of forcing a carbide steel pin into the material under a specific force loading. The depth to which the pin penetrates the material indicates its hardness.

The surface barcol hardness (hard scale) of various composite materials is shown in Figure 19. As can be seen from Figure 19, Esthet•X Micro Matrix Restorative has higher surface hardness value than most of the other composites.
Clinical Relevance: Radiopacity is an important property of any composite restorative material. Its radiopacity must exceed that of the enamel/dentine structure to be visible with standard X-ray procedures. To routinely examine the condition of a restored tooth, it is essential that the restorative material be adequately radiopaque and discernable from tooth structure.

Radiopacity is determined as per ISO 4049 method by exposing a 1.0 mm thick material sample and the 1.0 mm aluminium stepped interval standard to 2.3 mAs on standard x-ray film. The density of the film at the sample location is compared to those of the aluminium stepped standard. The density equivalent to the specific aluminium thickness step is deemed its radiopacity.

The radiopacity of various composite materials is shown in Figure 20. As can be seen from Figure 20, Esthet•X Micro Matrix Restorative has a high radiopacity of 2.39 mm, i.e. Esthet•X Micro Matrix Restorative is approximately 2½ times as opaque to X-rays as dentine. Its high radiopacity is due to the high density of bariumalumino fluoroborosilicate glass (BAFG), which comprises a significant proportion of the filler component.
Clinical Relevance: Long term fluoride ion release is a desired attribute of a superior composite restorative material, potentially contributing to the inhibition of bacterial colonisation and prevention of recurrent caries and thus prolonging restoration longevity.

Cumulative fluoride ion release is determined using the Orion pH/Ion meter equipped with a fluoride ion electrode. Disc samples of the test material, 1 mm thick by 20 mm in diameter, are immersed in 20 ml of deionised water for one-week intervals. The fluoride ion content of the solution is determined and added to that of the previous week for a total of 52 weeks.

Esthet•X Micro Matrix Restorative continuously releases fluoride ions after placement. Figure 21 depicts the in-vitro cumulative fluoride ion release for 52 weeks. Even after one year, fluoride ions are still being released (see Figure 22).
6.12 Adhesion

**Clinical Relevance:** The strong adhesion of a restorative material to tooth structure is essential to prevent the “gap formation” causing microleakage and postoperative sensitivity, and thus promotes restoration longevity.

With the advance of adhesive dentistry, restorative materials now can be tenaciously attached to tooth structure without degradation during its restoration lifespan. Use of adhesives with restorative materials means that undercuts can be minimised and in most cases totally eliminated, allowing minimum preparation and maximum conservation of a tooth. The shear bond strength (SBS) between a restorative material and human tooth substrates (Enamel or Dentine) was determined by bonding a 4.5 mm diameter rod of testing material to enamel or dentine with appropriate adhesive system applied per its Direction For Use. The SBS samples were immersed in distilled water for 24 hours at 37 °C, and then subjected the bond to compressive shear stress using an Instron UTM. The load at fracture divided by the contact area is the adhesive bond strength.

A particularly effective adhesive is Prime&Bond NT from DENTSPLY. The excellent bond strength values, obtained with the Esthet•X Micro Matrix Restorative/Prime&Bond NT adhesive, to etched and non-etched dentine and enamel are shown in the data Table 2 and Figure 23 below. These results showed that strong and durable adhesion can be achieved between Esthet•X restorative and tooth structure when using Prime&Bond NT adhesive system with simple “One-Coat/One Cure” Technique.
Figure 23  Shear Bond Strength of Esthet•X Micro Matrix Restorative to Human Tooth Structure (Using Prime&Bond NT adhesive with “One-Coat/One Cure” Technique)

<table>
<thead>
<tr>
<th>Composite/Adhesive System</th>
<th>Adhesion Substrate</th>
<th>Bond Strength [MPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esthet•X/Prime&amp;Bond NT</td>
<td>Enamel (Etched)</td>
<td>26.0 (±7.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100% Cohesive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enamel Failures</td>
</tr>
<tr>
<td>Esthet•X/Prime&amp;Bond NT</td>
<td>Dentine (Etched)</td>
<td>20.0 (±3.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100% Cohesive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dentine Failures</td>
</tr>
<tr>
<td>Esthet•X/Prime&amp;Bond NT</td>
<td>Dentine (Unetched)</td>
<td>19.9 (±2.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80% Cohesive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dentine Failures</td>
</tr>
</tbody>
</table>

Table 2  Shear Bond Strength of Esthet•X to Human Tooth Structure (Using Prime&Bond NT adhesive with “One-Coat/One Cure” Technique)

6.13 Colour Stability

Clinical Relevance: The colour stability of a restorative material in oral environment is very important to retain its natural appearance with surrounding tooth structure over the restoration’s lifespan.

The colour stability of a restorative material is its resistance to a shade shift once it is placed and cured. All currently available tooth-coloured composite restoratives shift slightly upon curing, with the shift being more notable in the lighter shades compared to the darker shades. Once cured, there should be minimal shade shift of the restoration in the mouth over time.
The “colour” or shade of any material can be defined through the use of a colour co-ordinate system known as CIELAB (see Figure 24). The colour of an object is defined by the colour co-ordinates of lightness (e.g. white/black or “L*”), red/green (e.g. “a*”) and yellow/blue (e.g. “b*”). As the shade (or colour) of an object changes over time, the corresponding changes in L*, a*, and/or b* can be measured and compared to the original colour co-ordinates.

The magnitude of the change in shade is known as $\Delta E$ (a measurement of colour difference), and is calculated using the following equation:

$$\Delta E = \left\{ (\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2 \right\}^{1/2}$$

where the prefix “ $\Delta$ ” represents “the change in”. The greater the $\Delta E$ value, the greater the shade shift. A $\Delta E$ value of less than about 1.5, although measurable using a colour spectrophotometer, usually can not be detected by the human eye. Upon direct viewing of a sample, a person trained in colour recognition may be able to detect a $\Delta E$ value of 1.5 - 2.5 units, while a person with average colour matching ability will be able to recognise a shift of $\Delta E$ of 2.5 - 3.5 units.

In order to predict the colour stability of various composites, an accelerated ageing study following ISO 7491 was conducted. Nine different composites, i.e. Esthet•X Micro Matrix Restorative, Z250, Z100, Prodigy, Vitalescence, Herculite XRV, Tetric Ceram, and Spectrum$^{TPH}$ were evaluated at 60 °C in water for more than three weeks. For each product, three composite disks of 1 mm thickness by 30 mm in diameter were prepared and cured prior to immersing in 60 °C water. The colour (L*, a*, b* values) of all the samples at each time interval (weekly) was measured in the CIEL*A*B* system on a reflection
spectrophotometer (Macbeth Colour Eye). The colour change or shade shift ($\Delta E$) was determined by comparing the $L^*$, $a^*$, $b^*$ values immediately upon curing and then at each weekly interval after immersion in water at 60°C. Colour change ($\Delta E$) of each product during the stability testing period is graphically shown in the Figure 25. As can be seen from the Figure 25, Esthet•X Micro Matrix Restorative is one of the most “Shade Stable” materials, showing a total $\Delta E$ of less than 0.6. This value was significantly lower than that of Z250 ($\Delta E = 1.31$, lighter), Vitalescence ($\Delta E = 1.30$, more yellow), Prodigy ($\Delta E = 1.43$, more yellow) and Charisma ($\Delta E = 1.04$, more yellow) over the colour stability testing period.

![Figure 25](image-url)  
**Figure 25**  
Esthet•X Colour Stability

### 6.14 Stain Resistance Study

**Clinical Relevance:** The stain-resistance of a restorative in the oral environment is very important to retain its natural appearance with surrounding tooth structure over the restoration’s lifespan.

The stain resistance of a restorative material can be measured in a manor similar to that described for colour stability. Resistance to staining effects caused by staining media (such as coffee, tea, juice, etc.), are expressed in $\Delta E$ units, with the lower values indicating less staining. Ten different composite restoratives (i.e. Esthet•X, Spectrum$^\text{TPH}$, Z100, Tetric Ceram, Herculite XRV, Silux Plus, Vitalescence, Prodigy, Z250, and Charisma) were evaluated for stain resistance at 37 °C over 28 days. The samples were immersed in Coffee, Tea, and Water (used as a control media) at 37 °C. For each product, three disks of 1 mm thickness by 20 mm in diameter were prepared and cured prior to immersing in the media. The colour ($L^*$, $a^*$, $b^*$ values) of all the samples at each time interval was measured in the CIEL*A*B* system on a reflection spectrophotometer (Macbeth Colour Eye). The colour
change (or shade shift, ΔE) was determined by comparing the L*, a*, b* values immediately upon curing and at each interval after immersion in media.

Colour change (ΔE) of each product during the testing period in coffee and tea is graphically shown in Figure 26 and Figure 27, respectively. After being immersed in either coffee or tea, all the products become darker, redder and more yellow. As can be seen from Figure 26, after 14 days immersed in Coffee at 37 °C, Esthet•X Micro Matrix Restorative exhibited much less colour change (ΔE = 3.22) than that of Z250 (ΔE = 3.64), Z100 (ΔE = 8.32), Vitalescence (ΔE = 5.26), Tetric Ceram (ΔE = 4.89), Silux Plus (ΔE = 5.00), Herculite XRV (ΔE = 4.42), and Charisma (ΔE = 6.39), while demonstrating equivalent colour stability compared to SpectrumTPH (ΔE = 2.55).

![Figure 26](image)

**Figure 26** Coffee-Staining Resistance Comparative Study

Figure 27 records the colour change of various composites when immersed in Tea. As can be seen from Figure 27, after 14 days immersed in Tea at 37 °C, Esthet•X Micro Matrix Restorative exhibited significantly less magnitude of colour change (ΔE = 2.15) than that of Z100 (ΔE = 2.82), Vitalescence (ΔE = 3.96), Tetric Ceram (ΔE = 3.61), Silux Plus (ΔE = 3.35), Herculite XRV (ΔE = 2.67), and Charisma (ΔE = 3.34).
Clinical Relevance: Adequate ambient working time of a composite restorative in the dental operatory environment is very important to enable dentists having enough working time to finish the restoration procedures.

The ambient working time of a composite restorative was measured according to ISO/FDIS 4049 (2000) where the minimum 60 seconds at 8000 Lux light intensity was specified for a composite material. Different composite restoratives including Esthet•X (C-E, A1, B2), Herculite XRV (E-A2), Vitalescence (T1), Z250 (A1, B2), Silux Plus (U), Tetric Ceram (T), SpectrumTPH (A1), Z100 (A1), and Renamel (C), were evaluated for their ambient working time under 8000 lux light exposure. Figure 28 shows the ambient working time of various composites. As can be seen from Figure 28 (although not all tested shades of Esthet•X Micro Matrix Restorative were listed), Esthet•X Micro Matrix Restorative has the working time (75-90 seconds, depends upon the shades) exceeding the minimum 60 seconds requirement as per ISO/FDIS 4049 (2000).
Figure 28  Ambient Working Time

6.16 Fluorescence

Under extreme light conditions like 'black light' in clubs or on a very clear midsummer day the ability of a restorative material to change ultra violet light into visible light may effect the aesthetic outcome of the restoration.

As can be seen in Figure 29, Esthet•X offers a fluorescence that is neither too low nor too high.

Figure 29  Fluorescence
7 Esthet•X Customer Evaluation (User Study)

During 1999, a large scale User Evaluation was conducted to evaluate various characteristics of Esthet•X Micro Matrix Restorative (formerly called R-30). Nearly 300 kits were mailed to clinicians consisting of groups of composite restorative users of Tetric Ceram, Z100, Herculite XRV and SpectrumTPH. Of those clinicians responding, 84% indicated their desire to purchase the Esthet•X material. Among the various user groups, 87% of the TPH composite users, 92% of the Z100 users, 93% of the Herculite XRV users and 87% of the Tetric Ceram users indicated they were likely to purchase the Esthet•X product.

7.1 Esthet•X User Evaluation Highlights

4213 Total Restorations placed with Esthet•X

- 1750 (42%) Posterior Restorations
  - 925 Class I, 825 Class II

- 2463 (58%) Anterior Restorations
  - 1009 Class III, 335 Class IV
  - 133 Recontouring, 225 Direct Veneers
  - 761 Class V

"Esthet•X was much better or better than their current restorative in regards to the following":

- Ease of Finish/Polish 91%
- Final Surface Finish/Polish 90%
- Overall Aesthetic Result 88%
- Surface Smoothness 88%
- Sculptability 87%
- Stickiness 82%
- Handling 81%
8 Clinical Investigations

8.1 Overview

Protocol
The design of the clinical studies is in compliance with but not restricted to the Revised Guidelines for Submission of Composite Resin Materials published by the American Dental Association (1989)[11]. These studies were designed to evaluate clinical performance of Esthet•X Micro Matrix restorative material in all cavity classes, with emphasis on the aesthetically demanding Class III, IV and Direct-Placement Full Facial Veneer restorations. Both the informed consent form and these research protocols were reviewed and approved by an Institutional Review Board at respective universities.

The investigations are longitudinal trials, with 3 month, and 1 year recalls planned, with recall extension to 24 months, 36 months and 4 years. The performance of restorations will be assessed at baseline and for designated recall intervals. The quality of the restorations is assessed for direct and indirect clinical evaluation according to the clinical evaluation criteria of Cvar and Ryge (USPHS, 1973)[12] for the following parameters:

Direct Evaluation Parameters

- Maintenance of anatomic form or contour (wear)
- Maintenance of acceptable colour (match or stability)
- Marginal adaptation or integrity
- Marginal leakage or discoloration (interfacial staining)
- Recurrent or secondary caries
- Surface Polish
- Interproximal contact (maintenance of interproximal contour)
- Surface texture
- Surface staining
- Post operative sensitivity
In summary, the recalled restorations in the clinical study must demonstrate “no greater incidence” of clinical failures than the limits listed:

<table>
<thead>
<tr>
<th>Acceptance Criteria</th>
<th>2 years</th>
<th>4 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of Colour</td>
<td>&lt;10% Charlie</td>
<td>&lt;10% Charlie</td>
</tr>
<tr>
<td>Marginal Discoloration</td>
<td>&lt;10% Charlie</td>
<td>&lt;10% Charlie</td>
</tr>
<tr>
<td>Marginal Integrity</td>
<td>&lt;5% Charlie</td>
<td>&lt;10% Charlie</td>
</tr>
<tr>
<td>Maintenance of Interproximal Contact</td>
<td>&lt;5% Charlie</td>
<td>&lt;10% broadening</td>
</tr>
</tbody>
</table>

As of October 25, 1999, over 147 restorations have been placed at four university centers. There are no reports of persistent postoperative sensitivity. All restorations, placed to date, are clinically satisfactory.

Study Sites
- Creighton University, School of Dentistry, Omaha, NE
- Loma Linda University, School of Dentistry, Loma Linda, CA
- Tufts University, School of Dental Medicine, Boston, MA
- University of Maryland, College Park, MD

8.1.1 Creighton University

Investigation Title
“Clinical Evaluation of a New Polishable Hybrid Composite Resin”

Study Site
Creighton University, School of Dentistry
Omaha, Nebraska

Principal Investigator
Mark A. Latta, D.M.D., M.S.
Associate Dean for Research

Investigators
Wayne W. Barkmeier, D.D.S., M.S. / Dean
W. Thomas Cavel, D.D.S.
R.S. Shaddy, D.D.S.
Scott DiLorenzo, D.D.S., M.S.
**Objective**

The purpose of the investigation is to evaluate the clinical performance of a new composite resin formulation with the mechanical properties of a hybrid composite and the aesthetics and high polishability of a microfil when used for restorations in Class I, II, III, IV, V cavities, and facial veneers.

**Design**

The protocol is a longitudinal trial. The study is designed in compliance with the ADA Guidelines for Submission of Composite Resin Materials (1989). The study included permanent anterior, canine, premolar and molar teeth. This study included full facial veneer restorations, too.

**Results**

This study was initiated in January 1999. Baseline clinical photographs and preoperative documentation were evaluated. All insertions are completed. 61 restorations were inserted on 36 patients, including 12 Class II, 12 Class III, 17 Class IV and Full Veneer, and 20 Class V.

Three-month recall: “No evidence of post-operative sensitivity has been reported at baseline and recall. The three-month recall results were excellent. No significant changes in colour were observed. Marginal integrity was excellent and the tissue compatibility was also excellent. Of significance was the maintenance of polish. Most hybrid restoratives even if polished to a “Alfa” lustre at baseline will at follow-up be less shiny. The new composite (Esthet•X Micro Matrix Restorative) appeared to hold a high lustre even after three months. This was especially noted in the large Class IV and veneer restorations where surface finish degradation is obvious and impacts the acceptance of the restorations by the patient. The three month observations with respect to polish suggest that the limitation of surface finish is dictated by the skill of operator and the use of a suitable polishing system at the baseline placement and finishing of the material.”

Twelve-month recall: All parameters maintained the reported excellent levels from the 3-month evaluation.

**8.1.2 Loma Linda University**

**Investigation Title**

“Clinical Evaluation of a New Composite Resin Formulation In Class I, Class II, Class III, Class IV, Class V and facial veneers”

**Study Site**

Loma Linda University School of Dentistry  
Center for Dental Research  
Loma Linda, California
Principal Investigator
James Dunn, D.D.S.
Associate Professor, Department of Restorative Dentistry

Investigators
Carlos Munoz, D.D.S., M.S.D. / Director of the Center for Dental Research
Robert Kinzer, D.D.S. / Professor and Chairman, Department of Restorative Dentistry
Jenny Sy-Munoz, D.D.S., M.S.D. / Assistant Professor, Department of Restorative Dentistry
Daniel Tan, D.D.S. / Associate Professor, Department of Restorative Dentistry

Objective
The purpose of the investigation is to evaluate the clinical performance of a new composite resin formulation when used for restorations of all cavity classes on permanent anterior, canine, premolar and molar teeth.

Design
The protocol is a longitudinal trial. The study is designed in compliance with the ADA Guidelines for Submission of Composite Resin Materials (1989). This study included large complex Class IV and direct-placement facial veneer restorations. The study strictly adhered to ADA and ICH Guidelines for Good Clinical Practices (GCP).

Results 12-month recall
This study was initiated in January 1999. All 43 insertions were completed between March 18, 1999 and April 29, 1999, to include 5 Class I, 6 Class II, 7 Class III, 15 Class IV and Full Veneer, and 10 Class V. “None of the subjects reported sensitivity related to restoration.” “At baseline and 3 month recall, all restorations are reported to be satisfactory for clinical evaluation criteria.” At baseline, 21 of 43 restorations rated Alpha for polishability. At 3 months, 24 of 36 rated Alpha, leading investigators to state: “As the (Esthet•X) restoration ages there seems to be an auto-polishing effect as the number of Alpha restorations increased in smoothness and shiny appearance.”
At 12 months 38 restorations were evaluated. All restorations had excellent marginal adaptation, and only one restoration was judged to have poor colour match and poor marginal discoloration.
The surface polish of the restorations seems to have increased over the first 6 months and did not change until 12 months. Two restorations had unacceptable polish, which was probably due to the initially chosen polishing technique.

8.1.3 Tufts University

Investigation Title
“Clinical Evaluation of a New Polishable Hybrid Composite Resin”

Study Site
Tufts University School of Dental Medicine
Medford, MA

Principal Investigator
Ronald Perry, D.M.D., M.S.
Director, Gavel Center for Restorative Dental Research
Assistant Clinical Professor

Investigators
Gerald Kugel D.M.D., M.S/Assistant Dean for Research
Head, Division of Advanced Clinical Restorative Dentistry
Samer Kastali D.D.S., M.S./Assistant Professor
Director, High Technical Center
Assistant Director of Post Graduate Aesthetic Dentistry
Aikaterini Papathanasiou D.D.S./Assistant Clinical Professor
Clinical Co-ordinator of Post Graduate Aesthetic Dentistry

Objective
The purpose of the investigation is to evaluate the clinical performance of a new composite resin formulation with the mechanical properties of a hybrid composite and the aesthetics and high polishability of a microfill when used for restorations in Class I, II, III, IV, V cavities and facial veneers.

Design
The protocol is a longitudinal trial. The study is designed in compliance with the ADA Guidelines for Submission of Composite Resin Materials (1989).[12] The study included permanent anterior, canine, premolar and molar teeth. This study included full facial veneer restorations. Distribution will be approximately 33% Class III and V, 40% Class IV and Facial Veneers, and 27% Class I and II.
Results
This study was initiated in June 1999. Baseline clinical photographs and preoperative documentation were evaluated. All insertions are completed. 27 restorations were inserted without any complications. One-month recall is partially completed. As of this writing, 19 restorations have been re-evaluated, all graded Alpha, zero changes, no inflammation.

“Based upon the initial placement and one month recalls, this material (Esthet•X) has easy placement, handling and polishability. It displays clinical efficacy in all parameters assessed.”

8.1.4 University of Maryland

Investigation Title
“A Clinical Evaluation of R-30 Composite Restorative Material”

Study Site
The University of Maryland
Baltimore College of Dental Surgery
Baltimore, Maryland

Principal Investigator
David L. George, DDS, FAGD
Assistant Director Advanced General Dentistry
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Director/Associate Professor Advanced General Dentistry

Co-Investigators
James C. Gingell, DDS, MS
Associate Professor Associate Director Advanced General Dentistry

Objective
The purpose of the investigation is to evaluate the clinical performance of a new composite resin restorative material in Class I, II, III, IV, V cavities and facial veneers.

Design
The protocol is a longitudinal trial. Thirty patients were enrolled. Treatment was done according to the directions for use.

Distribution was 36.7% Class III and V, 36.7% Class IV and Facial Veneers, and 26.6% Class I and II.

Results
Twenty-nine of thirty patients have been recalled through 6 months. All evaluated restorations showed perfect results after this short period of usage.
Regarding surface polish 55% of the fillings were rated Alpha (smooth and highly shiny, similar to enamel) and all remaining 45% were rated Bravo A (smooth and satin, highly reflective).

The preliminary clinical findings of R-30 appear to indicate that this new composite restorative material shows promise especially with respect to aesthetic qualities.
9 Summary and Conclusions

Esthet•X Micro Matrix Restorative Summary

- Polish Comparable to a Microfill
- Maintenance of Polish in the Mouth
- Shade System (Broad Range of Shades and Opacities) to Enable Creating Restorations “from the inside out”
- Superior Handling (Non-Sticky, Scuptable, and Slump-resistant)
- Physical Properties of a hybrid composite
- Excellent Resistance to Wear
10 Questions and Answers

What is the difference between Esthet\textbullet{}X and Spectrum\textsuperscript{TPH}? 

There are some similarities between Esthet\textbullet{}X Micro Matrix Restorative and Spectrum\textsuperscript{TPH}, but they are different in handling, composition, and performance. The first difference is in the glass, wherein Esthet\textbullet{}X Micro Matrix Restorative uses a proprietary fluoride-releasing Bariumalumino fluoroborosilicate (BAFG) glass and Spectrum\textsuperscript{TPH} uses a Bariumalumino borosilicate (BABG) glass. Secondly, the particle size and particle size distribution (PSD), as well as the glass optical characteristics between Esthet\textbullet{}X Micro Matrix Restorative and Spectrum\textsuperscript{TPH} glass are different. The filler particle size of Esthet\textbullet{}X Micro Matrix Restorative is much smaller (sub-micron filler, with a mean particle size of 0.6-0.8 $\mu$m) and the PSD (Particle Size Distribution) is much narrower than that of Spectrum\textsuperscript{TPH}. Thirdly, Esthet\textbullet{}X resin matrix is also modified allowing Esthet\textbullet{}X Micro Matrix Restorative to have a longer ambient light working time than Spectrum\textsuperscript{TPH}. Additionally, Esthet\textbullet{}X Micro Matrix Restorative offers the most complete shading system that includes Translucent Enamel shades, regular Body shades, and Opaque Dentine shades in a total of 31 shades with a wide range of opacity. As a result of the composition difference, Esthet\textbullet{}X Micro Matrix Restorative demonstrates some "unique" properties as highlighted below:

- High polish (ease of and retained polish)
- Complete shade system (shades and opacity selection) that enables dentists to rebuild tooth structure "from inside out"
- Sculptaple, non-sticky, slump-resistant handling
- Superior physical properties
- Excellent resistance to wear
- Esthet\textbullet{}X Micro Matrix Restorative has sculptable handling, while Spectrum\textsuperscript{TPH} has a creamier, spreadable handling
What is Esthet•X Micro Matrix Restorative?

Esthet•X Micro Matrix Restorative provides the polish of a microfill in a resin matrix of an advanced hybrid resin. Esthet•X Micro Matrix Restorative offers a durable, high surface lustre commonly seen in traditional microfil materials. Through its patented resin matrix and a unique particle distribution, it offers superior strength, durability, and fracture toughness, too. Esthet•X Micro Matrix Restorative is an aesthetic, visible-light cured, radiopaque, micro-hybrid composite restorative material designed specifically for use in both anterior and posterior restorations. It is to be used with a dental adhesive system, such as Prime&Bond NT Universal Light Cured Dental Adhesive. Esthet•X Micro Matrix Restorative is a complete aesthetic restorative system meeting dentists' needs of high aesthetics (patient satisfaction) and restoration longevity.

How many shades are available from Esthet•X Micro Matrix Restorative and what is their opacity range?

Currently, there are total 31 shades available for Esthet•X composites, which includes 5 Translucent Enamel Shades (White Enamel, Clear Enamel, Yellow Enamel, Amber Enamel, and Gary Enamel), 19 Body Shades (W, XL; A1, A2, A3, A3.5, A4; B1, B2, B3, B5/DY; C1, C2, C3, C4, C5/XGB; D2, D3, and U), and 7 Opaque Dentine Shades (W-O, A2-O, A4-O, B2-O, C1-O, C4-O and D3-O). The opacity (contrast ratio) range of Esthet•X spans from ca. 40% (or 60% translucency, designed to mimic natural human enamel) for the Translucent Enamel shades and ca. 57-61% (or 39 to 43% translucency designed to mimic human dentine) for regular Body shades and ca. 80% for the Opaque Dentine shades. The wide range opacities enable dentist to "rebuild the tooth structure from inside out" replicating the tooth natural beauty.

What is the filler level of Esthet•X Micro Matrix Restorative and particle size?

The filler loading in Esthet•X is approximately 77-78% by weight (about 60% by volume). The primary particles in Esthet•X are within the range of submicron to a top end of about 1.5 to 2.5 microns. The average particle size is about 0.6 to 0.8 microns and the material also contains functionalised silica nano-sized fillers (10-20 nm).
What are the indications for use of Esthet•X Micro Matrix Restorative? Can Esthet•X be used as both Anterior and Posterior restorations?

Esthet•X Micro Matrix Restorative is indicated for the following restorations:

- Direct restorations of all cavity classes in anterior and posterior teeth
- Direct aesthetic veneers and cosmetic reshaping (e.g., diastema closure, incisal lengthening).
- Indirect fabrication of inlays, onlays and veneers.

Yes, Esthet•X Micro Matrix Restorative can be used in both Anterior AND Posterior restorations as indicated. As shown in the Clinical Investigations and Physical Property Studies, Esthet•X Micro Matrix Restorative is fully qualified for both Anterior and Posterior applications providing the high aesthetics and restoration longevity.

What is wear rate of Esthet•X Micro Matrix Restorative?

Esthet•X micro matrix restorative is a very wear-resistant composite. As shown in the in-vitro wear study, Esthet•X typically exhibited a volume loss of $2 \times 10^{-2}$ mm$^3$ after 400,000 wear cycle (corresponding to a simulated 3 year clinical period). Please refer to the Wear Section (6.3) in the manual for detail.

Should Esthet•X Micro Matrix Restorative be placed in Incremental or Bulk? What is the placement depth and cure time?

As indicated in its Direction For Use, Esthet•X Micro Matrix Restorative is placed in increments up to 2.0 mm. For each incremental placement, a visible light cure time of 20" is recommended using a typical tungsten/halogen dental curing unit of at least 300 mW/cm$^2$ light intensity. The reason for recommending the "Incremental Placement up to 2.0 mm" is due to the following reason:

- In order to replicate or create the natural tooth beauty, Esthet•X Micro Matrix Restorative was designed to rebuild tooth structure from "inside out" using incremental layers of material, each having its own unique characteristics (enamel shade layers overlays the regular body [dentine] layer, which overlays the opaque dentine). This typically is accomplished by using up to 2 mm for each material.
How do I use the Esthet•X Micro Matrix Restorative TruMatch Shade Guide?
The Esthet•X Micro Matrix Restorative TruMatch Shade Guide provides a tool for clinicians using a “3-D shade recipe” (the recommended combination of Esthet•X shades to create the desired final shade restoration). For example,
A1 = A2-O + A1 + C-E; U = D3-O + U + C-E.

Please refer to the corresponding section (5) in the manual for further details.

Is Esthet•X Micro Matrix Restorative available in both Compules Tips and Syringes?
Yes, Esthet•X Micro Matrix Restorative composite is packaged in pre-dosed Compules Tips (0.25 g) and Syringes (3 g).
11 Directions for Use

**Esthet•X** is a visible light cured, radiopaque, composite restorative material for anterior and posterior restorations of primary and permanent teeth. It is to be used with Prime&Bond NT adhesive system.

**Esthet•X** offers superior strength, durability, and fracture toughness through its patented resin matrix. This matrix is combined with a unique particle distribution that offers a durable, high surface lustre commonly seen in traditional microfil materials.

This one-component, visible light cured composite restorative is available in predosed Compules Tips and syringes. The regular body shades are optimised to match the Vita System and offer a chameleon effect. Additional regular body, opaque dentine and translucent enamel shades are available for aesthetically demanding applications existing beyond the traditional Vita System. Custom blending of these three opacities allow the clinician to create restorations possessing natural aesthetic beauty. A custom blended shade guide is available to guide the clinician in shade selection and blending technique.

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<tr>
<th>Opaque</th>
<th>Regular</th>
<th>Translucent</th>
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<tr>
<td>Dentine Shades</td>
<td>Body Shades</td>
<td>Enamel Shades</td>
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<tr>
<td>White-O = W-O</td>
<td>White = W</td>
<td>Clear Enamel = CE</td>
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<tr>
<td>A2-O</td>
<td>Extra Light = XL</td>
<td>White Enamel = WE</td>
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<td>A4-O</td>
<td>A1</td>
<td>Yellow Enamel = YE</td>
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<td>B2-O</td>
<td>A2</td>
<td>Amber Enamel = AE</td>
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<td>C1-O</td>
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<td>Grey Enamel = GE</td>
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**DeTrey Conditioner 36** - the easiest and most efficient way to etch enamel, to remove the smear layer, and to condition dentine in a one-step procedure.

**Prime&Bond NT** is a universal self-priming dental adhesive designed to bond composite and Dyract compomer materials to enamel and dentine as well as to metals and ceramic. **Prime&Bond NT** combines primer and adhesive in a single bottle. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage.
HANDLING

Esthet•X micro matrix restorative is a “sculptable,” non sticky, material that resists slumping and allows the operator to create precise anatomical form. When using Esthet•X, it is best not to “spread” the material, but to “push” or “sculpt” the material.

POLISHING

Esthet•X micro matrix restorative was developed to provide the highest surface lustre in order to replicate natural enamel. To achieve maximum polish and maintenance it is highly recommended to fully complete the polish of Esthet•X material with Prisma Gloss polishing pastes.

Caution: For dental use only.

11.1 Composition

DeTreyConditioner 36
Phosphoric acid
Highly dispersed silicon dioxide
Detergent
Pigment
Water

Prime&Bond NT
Di- and trimethacrylate resins
Functionaized amorphous silica
PENTA (dipentaerythritol penta acrylate monophosphate)
Photoinitiators
Stabilisers
Cetylamine hydrofluoride
Acetone

Esthet•X
Bis-GMA-adduct (adduct of 2,2-Bis[4-(2-hydroxy-3-methacryloyloxypropoxy)-phenyl]propane with hexamethylene diisocyanate)
Bis-EMA (2,2-Bis[4-(2-methacryloyloxyethoxy)-phenyl]propane)
TEGDMA (triethylene glycol dimethacrylate)
Photoinitiators
Stabilisers
Barium fluoro alumino boro silicate (mean particle size < 1 µm)
Highly dispersed silicon dioxide (particle size 0.04 µm)
The percentage by volume of total inorganic fillers is 60%, the percentage by weight is 77%.

11.2 Indications

1. Esthet•X material is indicated as a direct restorative for all cavity classes in anterior and posterior teeth.
2. Esthet•X material is indicated as a direct aesthetic veneering material and for cosmetic reshaping (e.g. diastema closure, incisal lengthening).
3. Esthet•X material is indicated for the indirect fabrication of inlays, onlays and veneers.

11.3 Contraindications

DeTrey Conditioner 36
For use on soft tissue including oral mucosa, skin, eyes and dental pulp tissue.

Prime&Bond NT
For direct application to dental pulp tissue (direct pulp capping).

Esthet•X / Prime&Bond NT
If skin sensitisation occurs or if a known allergy to methacrylate resin exists

11.4 Adverse Reactions

Prime&Bond NT
The following adverse reaction has been associated with the use of acetone solutions and acrylate monomers:
- Reversible inflammatory changes of the oral mucosa after accidental contact.

Esthet•X
The following adverse reaction has been associated with the use of polymerisable monomers:
- Skin sensitisation (allergic contact dermatitis).

11.5 Warnings

1. DeTrey Conditioner 36 contains 36% phosphoric acid which can cause burns of soft tissue. Avoid contact with oral tissues, eyes, and skin. If accidental contact occurs immediately rinse with plenty of water and seek medical attention. Do not take internally.

2. Esthet•X and Prime&Bond NT contains methacrylates which may be irritating to skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of soap and water Do not take internally.

3. Prime&Bond NT contains acetone. Acetone is highly flammable. Keep away from sources of ignition - no smoking. Do not breathe vapour. Take precautionary measures against static discharges.

4. Esthet•X and Prime&Bond NT contains polymerisable monomers which may cause skin sensitisation (allergic contact dermatitis) in susceptible persons. Wash thoroughly with soap and water after contact. If skin sensitisation occurs, or if a known allergy to methacrylate resin exists, discontinue use.
11.6 Precautions

1. DeTrey Conditioner 36 gel should extrude easily: DO NOT USE EXCESSIVE FORCE. Replace original cap of DeTrey Conditioner 36 tightly after each use to avoid evaporation. Discard needle after use, as needles may clog if gel is allowed to dry inside.

2. Avoid Prime&Bond NT saturating gingival retraction cord. If Prime&Bond NT soaks into the cord, it may set hard and bond the cord to the underlying tooth surface making removal difficult.

3. Use a gentle, even motion when exerting pressure on the Compules tip applicator gun. Use of excessive force or sudden movement could create a potential hazard with extrusion.

11.7 Interactions with other materials

DeTrey Conditioner 36
Some liners and bases may be etched by phosphoric acid. In general, this does not impair their barrier function.

Prime&Bond NT
If H₂O₂ has been used to clean the cavity, proper rinsing is essential. Higher concentration H₂O₂ may interfere with the setting of polymerisable material and should not be used prior to the application of Prime&Bond NT.

Prolonged and intensive contact with acetone-containing products may lead to minute dissolution of the outermost surface of calcium hydroxide materials. This has no detrimental effect on the adhesion to the cavity walls.

Prime&Bond NT / Esthet•X
Eugenol containing dental materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.

11.8 Step-by-Step Instructions

Shade Selection
Shade selection should be made prior to the restorative procedure while the teeth are hydrated. Prophy with pumice and water to remove any extraneous plaque or surface stain. Use the Esthet•X guide provided. After selection of the best matching shade guide tooth refer to the back of the shade guide holder and see the 'recipe' of the three opacities used for this specific tooth (Figure 29).
The opacity of Esthet•X body shades have been designed to scientifically allow the tooth structure enamel and dentine to blend together with the composite with a life-like translucent result. Additional opaque dentine and translucent enamel shades allow replacement of each component of lost tooth structure (see Figure 30). Layering opacities form a restoration with natural vitality and translucence.

The final shade will ultimately result from an interaction of the thickness of the layer(s) of restorative composite and surrounding tooth structure (enamel and/or dentine). The intensity of the shade is related to the thickness or thinness of opaque, body and/or translucent shade layers of the Esthet•X restorative material used.
**Technique Tip:**
The use of a mock-up is an excellent method for shade verification. The technique includes the use of the shade that has been selected in the thickness to approximate that of the final Esthet\(\text{X}\) restoration. The material is placed on the clean, hydrated unetched tooth in the area of the cavity or restoration on the tooth. The composite so applied without etch or bonding agent is then cured thoroughly. Layering and/or altering shades in varying thickness will allow trial customisation of the final shade. The dentist, patient and ancillary dental support personnel can co-jointly view the shade selection result. After viewing, the composite material can be removed by the use of a dental explorer or scaler.

Be aware of room and ambient light effects on shade selection. Incandescent versus fluorescent lighting versus natural daylight (ideal light is northern exposure/outdoors/overcast).

Room accessories can influence shade selection as with coloured walls/wallpaper reflection. Also, the patient dental napkin should be removed. Observe tooth shades for short periods of time, use grey-blue background to neutralise the effect of extended shade viewing comparisons. Viewing a grey-blue background will have a relaxing effect on the viewing operators photo/colour optic discrimination. Eyes should be rested. It is useful to have ancillary corroboration on shade selection by dental personnel as well as by the patient.

**Cavity Preparation**

**Anterior Restorations.** Use conservative cavity preparations for all Class III, IV and Class V restorations. Refinement of the cavo-surface margin (bevelling) for enhancement of acid-etching, enamel bonding, and aesthetic results is recommended.

**Technique Tip:** Aesthetic masking of underlying intrinsic staining may require deeper preparation, allowing for adequate restorative material blending.

**Posterior Restorations.** Cavity design requirements are essentially a conventional preparation with refinement of cavo-surface margins for enhancement of acid-etching. No residual amalgam or other base material should be left on the internal surfaces of the preparation which would interfere with light transmission and the hardening of the restorative.

Clean uninstrumented enamel and dentine with a rubber cup and pumice or a non-fluoride cleaning paste such as Nupro prophylaxis paste. Wash thoroughly with water spray and air dry.

Clean freshly instrumented enamel and dentine with water spray and then air dry.

**Moisture Control**
Surface cleanliness is paramount for the development of adhesion. Isolate prepared tooth from contamination with saliva, sulcus fluid, or blood with adequate measures (rubberdam).

**Pulp Protection and Base**
In deep cavities cover the dentine close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (DYCAL\(^*\)) leaving the rest of the cavity surface free for bonding with Prime&Bond NT.

**Placement of the Matrix**
Use a matrix system, preferably a transparent one, with proper wedging for proximal contacts. PRE-WEDGING IS ADVOCATED TO ACHIEVE SLIGHT SEPARATION AND FACILITATE OPTIMAL PROXIMAL CONTACT.
In class II cavities the use of a deadsoft, thin matrix band and subsequent burnishing of the matrix band will improve final interproximal contact and contour.

**Acid Conditioning of Enamel and Dentine (Total Etch Technique)**

1. **Application of DeTrey Conditioner 36**
   - Attach disposable needle to end of syringe. Needle tip may be bent for easy access.
   - Gently extrude DeTrey Conditioner 36 gel (36 % phosphoric acid) to the cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentine for 15 seconds or less.

2. **Rinsing and Drying**
   - Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 15 seconds.
   - Remove excess water from the rinsed cavity with a soft blow of air. Avoid desiccating the dentine, leave a moist surface.

   Properly etched enamel has a dull, frosty-white appearance. If this is not the case, re-etch enamel, rinse, and dry as described above.

   Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with vigorous water-spray, dry, and repeat conditioning procedure of enamel for 5 seconds only. Rinse and dry as described above.

**Application of Prime&Bond NT**

One layer of Prime&Bond NT is applied:

1. Dispense Prime&Bond NT directly onto a fresh Applicator Tip or onto a disposable brush. Alternatively, dispense into a fresh DENTSPLY Applicator Dish or standard dappen dish.

2. Immediately apply ample amounts of Prime&Bond NT to thoroughly wet all tooth surfaces. This surface should be saturated which may necessitate additional application of Prime&Bond NT.

3. Leave the surface undisturbed for 20 seconds.

4. Remove solvent by blowing gently with air from a dental syringe for at least 5 seconds. Surface should have a uniform, glossy appearance. If not, repeat steps 2 to 4.

5. Light-cure for a minimum of 10 seconds. Ensure uniform exposure of all cavity surfaces.

6. Immediately place composite restorative over the cured Prime&Bond NT.

**Placement of Esthet•X**

Using Compules Tips

Insert Compules tip into the notched opening of the applicator gun barrel. Be certain that the collar on the Compules tip is inserted first. Remove the coloured cap from the Compules tip. The Compules tip may be rotated to gain the proper angle of entrance into the cavity. To dispense the material, use a slow, steady pressure. Excessive force is not necessary. Dispense Esthet•X directly into the cavity.

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4 Alternatively to the Total Etch Technique, the conventional Enamel Etch Technique can be followed. In this case, the enamel margins only are treated with DeTrey® Conditioner 36 for at least 15 seconds. Then rinse and dry as described below.

5 DENTSPLY Applicator Dish and Applicator Tips are available from your dental dealer.

6 Check curing light for minimum curing output of at least 300 mW/cm².
Using syringes
Dispense the necessary amount of Esthet•X restorative material from the Syringe onto a mixing pad by turning the handle slowly in a clockwise direction. To prevent oozing of the material when dispensing is completed, point the front tip of the syringe upwards and turn the handle anti-clockwise. Immediately re-close the syringe with the respective cap.
Place Esthet•X in increments into the cavity and protect remaining material against light.

**Anterior Placement**
Contour and shape with appropriate composite instruments. Material may be placed and light cured in increments up to 2mm.

**Technique Tip:** For aesthetic blending of shades, shade layers may be individually cured 20 seconds\(^6\) to form a foundation for subsequent shade placement.

**Posterior Placement**
A flowable restorative (Dyract flow) might be used in a thin layer as liner to best wet the cavity floor.

A) **Class I and V:** Esthet•X may be placed in 2mm increments, light curing each increment for 20 seconds\(^6\).
B) **Class II:** Beginning in the proximal box, firmly adapt a thin increment of material to cavity walls and stabilise matrix band by stepping a clean non-serrated condenser (plunger) from middle to edges, reducing incorporated air and eliminating voids. Light cure for 20 seconds\(^6\). The remainder of the preparation may be filled in up to 2mm increments, each followed by 20 seconds\(^6\) light cure.

Prior to final light curing, contour and shape the final increment with the operator's choice of clean carving and burnishing instruments.

**Technique Tip:** To minimise finishing time, contour marginal ridge first before occlusal anatomy. Carve margins and anatomy to final form. Esthet•X resists slumping, allowing carving of the majority of anatomical form prior to Visible Light Curing.

**Curing**
Expose each area of the restoration surface to a VLC polymerisation unit (e.g. DENTSPLY Spectrum 800 or QHL75) for at least 20 seconds\(^6\). The Esthet•X material should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal.

**Finishing and Polishing**
STEP1: Begin finishing immediately after curing. For removal of gross excess and contouring finishing burs or diamonds may be used.

Additional finishing and polishing is obtained by using Enhance Finishing Discs, Cups or Points. Alternatively, other standard aluminium oxide disc series may be used.

STEP 2: Insert an Enhance Finishing Disc, Cup or Point into a latch conventional speed contra-angled handpiece and continue finishing. The aggressiveness of the Enhance Disc is controlled by the pressure applied to the surface of the composite. The greater the pressure, the more material is removed; lighter pressure leaves a smooth surface without removing bulk, and begins the polishing sequence.
To achieve a very high lustre on Esthet•X restorative, it is necessary to apply Prisma®-Gloss™ regular paste followed by Prisma-Gloss ExtraFine polishing paste with Enhance polishing foam cups. Once polished with both Prisma-Gloss pastes, Esthet•X material will maintain its high surface gloss due to its micro matrix technology.

STEP 3: Attach an Enhance Foam Polishing Cup to the provided metal mandrel by inserting the bayonet end of the mandrel into the opening on the narrow end of the disposable cup. Rotating the mandrel 1/4 turn makes insertion easier. Make sure the mandrel inserts fully into the foam cup. Insert the mandrel into a conventional speed contra-angled handpiece.

STEP 4: Apply a small amount of Prisma-Gloss Material to the surface of the Enhance Foam Polishing Cup. Work the surface of the restoration, dry initially, at moderate speed and pressure. Use flat end and corner edge of cup.

STEP 5: To increase surface lustre, ADD WATER IN SMALL AMOUNTS (i.e. dropwise) to dilute the paste using a light circular buffing motion. Repeat as needed to produce a smooth surface.

STEP 6: Rinse Prisma-Gloss from the tooth surface and Enhance Foam Polishing Cup. Apply Prisma-Gloss Extrafine Paste to the Enhance Foam Polishing Cup as described in STEP 4 and polish the surfaces dry at first, then adding increasing amounts of water for 15-30 seconds for final lustre. The Enhance Cup should be discarded after use.

Technique Tip:
1. Polishing efficiency is greatly increased and splatter of Prisma-Gloss is greatly reduced by rubbing paste into the surface of the Enhance Foam Polishing Cup before use. This procedure leaves a thin, adherent surface film of paste in the cup surface. Use the paste impregnated cup dry at low speed; after 30-60 seconds, apply a small amount of water to the tooth and cup. Use again at low speed for another 30-60 seconds to achieve high surface lustre.
2. As with any rotary instrument, heat will build up when using the Enhance Finishing Disc, Cup or Point with prolonged contact. Use intermittent pressure.
3. Use the flat end and corner edge of the Enhance Foam Polishing Cup. Excessive lateral pressure may dislodge cup from mandrel.

CLEANING THE COMPULES TIP APPLICATOR GUN
The applicator gun is sterilisable by autoclave or cold sterilisation solution following the manufacturers' instructions.
It is recommended that the applicator gun be disassembled for assured sterilisation. Partially close the applicator gun and place thumb under the rear portion of the hinge. Push upward and lift hinge separating the applicator gun, exposing the plunger. Remove residual composite with a soft paper tissue and a suitable solvent (70 % alcohol).
To reassemble, insert plunger into applicator gun barrel, press components together and snap hinge mechanism in place.

STORAGE
All products: Keep out of sunlight. Not to be stored at temperatures exceeding 24 °C.
DeTrey Conditioner 36: Replace cap immediately after use.
Prime&Bond NT: The Prime&Bond NT bottle should be tightly closed immediately after use. Keep in a well ventilated place.
Esthet•X: Replace cap upon extrusion of composite.
BATCH NUMBER AND EXPIRY DATE
Do not use after expiry date.
The batch number should be quoted in all correspondence which requires identification of the product.

If you have any questions, please contact:
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11.9 Picture DFU
12 References


