Dyract® AP

The Compomer with Advanced Performance

Individual Attention Only

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1 Introduction

Dyract® was introduced in 1993 as the first of a new class of material combining some of the best properties of composites and glass ionomers. The material was classed a Compomer, a term derived by combining parts of the two words COMPOsite and ionoMER, and intended to suggest a combination of composite and glass ionomer technology. The material was immediately widely accepted and used because of its unique combination of ease of use, aesthetics, physical properties, and fluoride release. As the first representative of its class these properties are quite outstanding, but as with any product there is always room for improvement.

Many of these points have become apparent over the years of clinical use of Dyract® and have been brought to our attention by dentists from all over the world.

Dyract® AP breaks fresh ground in dentistry by combining all the aesthetic and handling properties of original Dyract® with still higher strength, lower wear, and more fluoride. This enables its use in a still wider range of indications including all cavity classes, posterior as well as anterior. Dyract® AP is the first compomer specifically recommended for use in stress bearing occlusal surfaces.

2 What is a Compomer?

In order to fully appreciate the wide range of uses and indications for which Dyract® AP is suitable, it is helpful to have some insight into the makeup and mechanism of the compomer system, and how this differs from composites and glass ionomers. Uncured composites consist essentially of a mixture of a resinous monomer and an inert glass powder. Since the glass is inert, it is normally coated with a reactive, polymerizable layer to enable it to become chemically part of the cured composite. Curing the composite then simply joins the monomer molecules as depicted in Figure 1 into one cross-linked network, with the glass acting as a reinforcer. A cured composite therefore consists of an inert glass in a matrix of organic polymer as shown schematically in Figure 2.
On the other hand, a glass ionomer comprises an aqueous solution of an acidic polymer and a reactive, acid soluble glass. In this case the polymer is already formed but not cross-linked. When the glass ionomer is mixed, the glass starts to dissolve in the acidic solution thereby releasing fluoride ions, metal ions and silica. The polymer becomes cross-linked by the metal ions, causing the mixture to harden. This setting mechanism is demonstrated in Figure 3.
For Dyract®, a totally new monomer was developed which contains both the polymerizable groups of a composite resin and the acidic groups of a glass ionomer polymer, as shown in Figure 4. The initial hardening reaction occurs, as in a composite, by light initiated polymerisation of the monomer via its methacrylate groups. In the presence of water from the environment, a glass ionomer reaction is also able to take place, leading to fluoride release and further cross-linking of the polymer. Evidence for the acid-base reaction in Dyract® has been obtained through two different techniques. Firstly, a study using 100nm thick samples of the water saturated cured material showed strontium ions to be present throughout the resin matrix as well as in the glass. Secondly, an FTIR study (Kakaboura, Eliades and Palaghias, 1995) showed a change of the unionised carboxyl groups in the anhydrous material to metal carboxylates in the water saturated material. This ionic reaction confirms the hybrid character of Dyract® and supports use of the term "Compomer" as the correct generic description.
3 What is new in Dyract® AP?

In order to improve Dyract® further, several ingredients needed to be optimised. Firstly, the mean particle size of the glass in Dyract® AP has been reduced 0.8 microns. This brings greater strength, lower wear, higher fluoride release, and the ability to take - and retain - a better polish. The organic matrix has also been modified by adding a small amount of a highly cross-linking monomer. Although a small change, this brings an enormous increase in the hardness and strength of the matrix. Finally, the photoinitiator system was newly optimised, so that further increases in strength were obtained. The overall result is a new compomer with increased fluoride release, with the strength, aesthetics and low wear of a composite, but still retaining the ease of use that has become associated with Dyract®. These improvements are described in detail later.

4 What has not changed?

The excellent aesthetic and handling properties of Dyract® have not changed, and these are retained in Dyract® AP.
5 Physical Properties of Dyract® AP

5.1 Compressive and Flexural Strength

A filling material intended for long-term use needs to have high compressive and flexural strength, since these are important factors which determine how well a material can withstand chewing forces in the mouth. The compressive strength has been measured for Dyract® AP, and compared to that of normal Dyract® as well as the composite material Spectrum and several competitive materials. Measurements were made at times of twenty-four hours and one month after curing, and all samples were stored in water at 37°C until they were measured. From Figure 5 it is seen that twenty-four hours after curing Dyract® AP has a compressive strength almost equal to that of the composite, and considerably higher than original Dyract®. After one month storage in water the compressive strength has risen to equal that of the composite material. It is interesting that some competitive materials appear to decrease in strength as water is absorbed. Similarly, the flexural strength of Dyract® AP is compared to that of other materials in Figure 6. The flexural strength measures the resistance of a material to resist fracture under bending loads, and is particularly important where the restorative is used in a thin layer. The flexural strength of Dyract® AP is seen to be equal to that of the composite material Spectrum.

![Figure 5](image1)

![Figure 6](image2)

The elastic modulus of Dyract® and Dyract® AP measured after 24 h storage in water at 37°C is 7500 ± 500 MPa and 9000 ± 500 MPa respectively. This compares with an elastic modulus of 10500 ± 560 MPa for Spectrum.
5.2 Hardness

The pure abrasive wear of a material is correlated with its surface hardness, and this is therefore another important factor in determining how well a material performs in the mouth. There are several standard methods and scales for measuring hardness, but one common method is known as the Vickers Hardness. This consists essentially of forcing a diamond pyramid into the surface of the material with a known load, and measuring how far the diamond is able to penetrate. This test has been carried out for a range of materials, and results are presented in Figure 7.

![Vickers hardness chart]

**Figure 7**

It can be seen that the hardness of Dyract® AP is similar to that of the composite, and significantly higher than that of normal Dyract®. This is a consequence of both the smaller glass particles and the more tightly cross-linked resin matrix in Dyract® AP. In the pure abrasive mode of wear, Dyract® AP is therefore expected to perform at least as well as a composite material. Clinically, wear seems to be a complex mixture of several mechanisms however, and pure abrasion is only part of the story. A tooth filling material also needs to be able to withstand wear due to impact fractures with resultant loss of matrix and filler particles, for instance. Over the years, many methods to try to assess the overall wear of tooth filling materials have been suggested. Most methods attempt to combine several different modes of wear, and each test combines these modes in different proportions. Since results from the different test methods are therefore not directly comparable, the wear resistance of Dyract® AP was tested using several different methods.
5.3 Wear

The wear of Dyract® AP was first assessed at Dentsply using a device designed by Dr. C. Leinfelder (Leinfelder et al. 1989). In this, samples of the material are subjected to a repeated twisting load of 17 lb. (about 7.7 kg) in the presence of water and polymethylmethacrylate beads with a mean diameter of 44 microns. These beads act as a mild abrasive to simulate chewing food. After two hundred and fifty thousand cycles, the depth of the worn area was measured using a profilometer. A second test was carried out at the Academic Centre for Dentistry Amsterdam (ACTA), using the method designed there (De Gee et al. 1994). In this method, a wheel having ten samples around its circumference is rotated against an antagonist wheel in a stirred slurry of rice and millet seed shells, again simulating food mastication. The two wheels are pressed together with a force of 15 N, and turn at different speeds with the slip rate at their circumference adjusted to 15%. After a set number of revolutions of the primary wheel the wear in the samples is measured, again using a profilometer. Finally, the wear was also tested at the Zentrum für Zahn-, Mund- und Kieferheilkunde at the University of Zurich. Here, a chewing simulator was used in which the material under investigation were subjected to 1.2 million chewing actions in water using enamel cut from an extracted tooth as antagonist. Simultaneously, the samples were thermocycled three thousand times between 5 and 50 °C. At the end of all this, the vertical material loss was measured with a three dimensional scanner, and the areas of wear assessed by electron microscopy (Krejci and Lutz, 1997). A similar test was also performed at the University of Munich (Kunzelmann, 1997). In such tests the variations in results are naturally quite large, but it is highly significant that in all tests Dyract® AP exhibited a wear rate similar to that of the composite. The results are summarised in Figure 8. Note that in this Figure the Zurich values have been adjusted so that the wear rate of Dyract® equals one hundred, and the wear rate of Dyract® AP is shown relative to this. Other values are as measured.
5.4 Fluoride Release

The strength and wear properties of Dyract® have therefore been improved to equal or exceed those of composite materials, but Dyract® AP still has at least one further major advantage over these materials - fluoride release. It might be expected that an improvement in the physical properties could only be gained at the expense of lower fluoride release rates. As demonstrated in Figure 9, however, the rate of release of fluoride from Dyract® AP is actually higher than that from Dyract®. This is partly due to the finer particle size of the fluoride glass contained in Dyract® AP. In the Figure, the non cumulative release rates are also compared with those for another material.
It is generally accepted that fluoride ions are absorbed into tooth substance, helping to harden this and protect it from decay.

5.5 Adhesion

Modern restorative dentistry relies ever more heavily on the adhesion of filling materials to tooth substance. Use of an adhesive filling material means that undercuts can be minimised and in most cases totally dispensed with, allowing minimal preparation and maximum conservation of a tooth. This important concept has been considerably advanced in the last few years by the introduction of highly effective bonding agents. The Dyract® system broke new ground in dentistry with the introduction of Dyract®-PSA, the first effective "one bottle bond". This successfully combined into one solution the separate primer and adhesive which were conventional at the time, allowing high, long lasting bond strengths to be achieved simply. Although the original PSA was a breakthrough in its time, further improvements are always possible, and continued research and development resulted in Prime & Bond® 2.0, Prime & Bond® 2.1 and now Prime & Bond NT.

With Prime & Bond NT we achieved a significant further progress in simplifying the bonding procedure as- contrary to the previous adhesives- it can be used in a one-coat technique. This is achieved by inclusion of a nanoscale filler into the formulation. This inorganic nanofiller strengthens the hybrid layer and the adhesive layer, making these interfaces more compatible with both the tooth structure (containing inorganic calcium apatite) and the
compomer material (containing inorganic glass filler). Furthermore, the viscosity of Prime & Bond NT has not increased significantly, allowing deep penetration of the bonding agent into the dentine.

Another step towards simplification of the bonding procedure was taken with the introduction of NRC, the first non-rinse conditioner. The NRC is an alternative to conventional phosphoric acid etching. It is only to be employed in situations where extra adhesion to enamel is required, i.e. in large stress-bearing class I and II situations, in class IV cavities and whenever bevelled margins are preferred (see section 7, Directions for Use, for detailed indications). Previously, in these situations phosphoric acid etching was recommended. NRC treatment is more convenient than acid etching as the NRC can simply be dried off and a rising step is not needed. The complete scheme of how the NRC saves time and simplifies the adhesive procedure is shown in the figure below.

![Diagram showing bonding procedure with NRC]

**Figure 10:** Comparison of NRC and phosphoric acid conditioning. Note that in most clinical situations, with Dyract® AP neither NRC nor phosphoric acid conditioning are required.

Bond strengths have been measured to both conditioned and non-conditioned dentine and enamel, and as seen in the table below, superior adhesion to dentine and to conditioned enamel is provided with Dyract® AP. The table also shows that for clinical situations where bonding to mostly enamel is required (e.g. large stress-bearing class I and II cavities, class IV cavities), an enamel conditioning procedure is recommended.
### Table 1: Adhesion of Prime&Bond® NT and Dyract® AP to enamel and dentine

<table>
<thead>
<tr>
<th>Substrate</th>
<th>Pre-treatment</th>
<th>Bond Strength, MPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>dentine</td>
<td>not conditioned</td>
<td>19.2 ± 3.8</td>
</tr>
<tr>
<td>dentine</td>
<td>conditioned with NRC</td>
<td>20.8 ± 2.3</td>
</tr>
<tr>
<td>dentine</td>
<td>conditioned with phosphoric acid gel</td>
<td>21.9 ± 3.1</td>
</tr>
<tr>
<td>enamel</td>
<td>not conditioned</td>
<td>11.4 ± 3.3</td>
</tr>
<tr>
<td>enamel</td>
<td>conditioned with NRC</td>
<td>19.1 ± 5.5</td>
</tr>
<tr>
<td>enamel</td>
<td>conditioned with phosphoric acid gel</td>
<td>23.0 ± 3.0</td>
</tr>
</tbody>
</table>

### 5.6 Fracture Toughness

The fracture toughness of Dyract® AP has been measured as 1.28 MPa.m$^{0.5}$ (Watts, D.C., Manchester) and this compares favourable to that of a composite. For instance Spectrum has a fracture toughness of 1.75 MPa.m$^{0.5}$ while a typical value for a glass ionomer is around 0.5 MPa.m$^{0.5}$.

### 5.7 Creep

The creep strain and creep recovery was measured on samples which had been stored in water at 37°C for one month. A load of 32 MPa was applied to each specimen for 8 hours and the compression of the samples measured. After removal of the load their recovery was measured over a further 2 hours. Results are shown Table 2. The creep strain represents the amount of initial compression in the material, while the creep recovery measures how well the material returns to its original shape when the load is removed.

<table>
<thead>
<tr>
<th>Material</th>
<th>Dyract®</th>
<th>Dyract® AP</th>
<th>Spectrum®</th>
<th>Dentine</th>
<th>ChemFil Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creep strain %</td>
<td>0.71</td>
<td>0.68</td>
<td>0.67</td>
<td>0.64</td>
<td>0.72</td>
</tr>
<tr>
<td>Creep recovery %</td>
<td>92.8</td>
<td>96.8</td>
<td>86.5</td>
<td>48</td>
<td>74.1</td>
</tr>
</tbody>
</table>

*Table 2: The close match of the creep strain of Dyract® and Dyract® AP to that of human dentine may be one reason for their clinical success.*

### 5.8 Aesthetics

The aesthetic qualities of a material are determined by two main factors, namely its colour and its opacity. The colour is obviously important in that there must be a near overall match.
of a filling to its surroundings if the material is to look at all natural. Less obvious is that the opacity must also be correct, for while a totally opaque colour will only match an exactly similar totally opaque colour, a more translucent material tends to take up the colour of its surroundings. This is the so called "chameleon effect", and therefore allows an acceptable match even if the colours are not exactly the same. At the other extreme, a material that is too translucent suffers from a dark background showing through, lacks intensity, and in situations where a background is totally missing also looks too dark. There is therefore an optimum range for the opacity of about 40 to 45 percent, and this is achieved in Dyract® AP as well as in Dyract® and most composite materials. The opacity of a material is easily measured, and typical values for representative materials are given in Table 3. On this scale, materials with an opacity of 50 or more would be classified as opaque.

<table>
<thead>
<tr>
<th>Material</th>
<th>Opacity % for A2 shade or near equivalent a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectrum TPH</td>
<td>42</td>
</tr>
<tr>
<td>Dyract§</td>
<td>41</td>
</tr>
<tr>
<td>Dyract® AP</td>
<td>41</td>
</tr>
<tr>
<td>ChemFil Superior</td>
<td>65</td>
</tr>
</tbody>
</table>

Table 3

This data was measured at Dentsply Konstanz using a Langer LUCI 100 photometer. Opacities were calculated using the relationship opacity = \( \frac{R_b}{R_w} \times 100 \), where \( R_b \) is the light reflected from a 1 mm thick sample with a black background (\( R = 4.5 \)), and \( R_w \) is the light reflected from the sample with a white background (\( R = 95 \)).

It is not only important that the initial opacity and colours are correct, but also that these do not change appreciably. In order to test this, the colour and opacity of several batches of Dyract® AP were measured, then the samples were stored in water at 37°C and remeasured periodically. The delta E value, which is a measure of the overall colour change, is calculated from Equation 1.

\[
\Delta E = \sqrt{(L - L')^2 + (a - a')^2 + (b - b')^2}
\]

where \( L, a, b = \) the initial values, \( L', a', b' = \) the values after storage.

Equation 1

A delta E value of around 1 is barely visible. Results available so far are given in Table 4 and illustrate the excellent colour stability that is achieved with Dyract® AP.
<table>
<thead>
<tr>
<th>Storage Times (weeks)</th>
<th>A2</th>
<th>A3</th>
<th>A4</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>0.6</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>4</td>
<td>0.5</td>
<td>1.0</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Table 4

5.9 Radiopacity

It is important that dental restoratives are radiopaque, particularly if they are to be used in posterior restorations. The radiopacity of Dyract® AP is, like original Dyract®, approximately two and one half times as opaque to X-rays as dentine.

5.10 Polishability

Healthy enamel has a highly glossy surface, and for optimum aesthetics a dental restorative should be able to mimic this. This property is commonly called the "polishability", and it can be assessed in a number of ways. The polishability of Dyract® AP and comparative materials was measured directly using apparatus able to measure the surface roughness (Watts, 1997). Samples of each material were prepared, and polished according to the manufacturers instructions before the surface roughness was measured.

Naturally it is not only important that a material is able to be highly polished, but also that it maintains this high polish. The samples were therefore next abraded with a toothbrush and toothpaste before the surface roughness was remeasured. Data is presented in Figure 11 and confirms the excellent results that may be achieved with Dyract® AP.
After polishing, Dyract® AP had a surface roughness of 0.15 microns, and this rose to about 0.3 microns after being abraded with toothpaste. This compares very favourably with a top class composite such as Spectrum, which in this test had an initial and abraded roughness of about 0.4 microns. Both materials are therefore fully acceptable, though due to its finer glass particle size Dyract® AP is able to take a better initial polish. The same is not true for either the light cured glass-ionomer or the conventional glass-ionomer. Although both of these can be polished quite well to a surface roughness of about 0.6 microns, after toothpaste abrasion both are left with a relatively rough surface (1.5 to 2 microns). This manifests itself clinically by a rough feeling to the tongue and increased staining. Once again therefore, the excellence of Dyract® AP is demonstrated, as well as its equality to a top composite and its superiority over either the light cured or conventional glass-ionomer.

![Figure 11: Roughness after polishing and abrasion](image)

5.11 Filler Content

The filler content of Dyract® AP is about 73 % by weight. With the particular resin blend and glass used, this gives a filler content of about 47 % by volume. These are average values and may vary by up to about 1 %.
5.12 Shrinkage and Expansion

An inherent problem common to all light cured materials including composites is the shrinkage due to polymerisation of the monomers.

All restorative materials that are cured by polymerisation shrink during the curing process. Modern medium viscous composites typically exhibit a volume shrinkage of about 2.5 – 4 %, whereas so called packable composites demonstrate a volume change of 1.8 – 2.2 % due to their higher filler content.

With Dyract AP the pathway to overcome or diminish this clinically detrimental effect has been to allow controlled hydrophilic expansion through water up-take. As water is taken up from the saliva into the restorative material (Martin et al., 1998), it starts to expand slightly. At the same time the acid-base reaction proceeds, leading to the release of fluoride ions. Although water is being taken up, the mechanical strength is being retained (Cattani-Lorente et al., 1999) due to the acid-base reaction.

The degree of expansion of Dyract AP was carefully adjusted by the chemical nature of the TCB-resin and the TCB-resin volume percentage of the compomer formulation. Due to the controlled hydroscopic expansion, a Dyract AP filling returns to almost exactly the size it had before curing. In other words, the initial shrinkage is almost completely compensated for, resulting in the net volume change for the Dyract AP material being merely 0.5 % versus about typically 2 % of a composite.

Figure 12 shows the time-dependent dimensional behaviour of Dyract AP compared to that of a typical composite material. The exact rate of expansion in the clinical situation depends on the size and shape of the filling.
Figure 12: Shrinkage and Expansion behaviour of Dyract AP and a typical composite material

It is obvious that while the composite material essentially only displays an initial shrinkage, both a shrinkage and a subsequent expansion can be observed for the compomer Dyract AP. The reason lies in the chemical nature of the compomer: it combines properties of both the composite and the glass ionomer. Figure 13 gives a summary of the causes for the volume changes in Dyract AP.

Figure 13: Volume change of Dyract AP and compomer chemistry

- **Composite properties lead to initial shrinkage:**
  New bonds are formed from methacrylate double bonds.

- **Glass ionomer properties lead to reexpansion:**
  Acidic groups in the compomer lead to higher hydrophilicity, which in turn leads to water uptake and re-expansion.

- **The combination of composite properties (methacrylate groups) and glass ionomer properties (acidic groups) leads to the shrinkage compensation observed in Dyract AP.**
A consequence of the shrinkage compensation of Dyract AP should be a better marginal integrity of Dyract AP restorations compared to conventional composite restorations. Initial polymerisation stresses working on the cavity walls decrease with the gradual water uptake of the compomer in the cavity, preventing gap formation.

Indeed, two recent in-vitro studies show that stress-relaxing effects may indeed explain part of the clinical success of Dyract AP.

Haller et al (1998) at the University of Ulm found that due to hydrophilic expansion, dentine margins of Dyract AP were intact after 6 months of water storage and thermocycling, while under identical conditions polymerisation stress resulted in marginal gap formation for all investigated composite systems. Figure 14 and Figure 15 compare the margins of Dyract and a composite before ageing and after 6 months of water storage.

![Figure 14](image)

**Figure 14:** Margin between Dyract AP and dentine before and after water storage. No gaps are visible, indicating a perfect margin.
Figure 15: Margin between a typical composite and dentine before and after water storage. Gaps are clearly visible.

In another, as yet unpublished study by Pioch (1999) of the University of Heidelberg, class I cavities were prepared in human dentine. Eugenol was applied to parts of the cavity wall to artificially create gaps (the eugenol prevents curing of the adhesive). The cavities were then restored with either Prime&Bond NT/ Dyract AP (compomer material) or with Prime&Bond NT/ TPH Spectrum (composite material). The Prime&Bond NT had previously been marked with a dye to make it visible on the subsequently taken photos. A schematic description of the experiment is shown in Figure 16.
After defined intervals of water storage, CLSM (confocal laser scanning microscopy) photos were taken below the surface of the cavity. On these CLSM photos, the Prime&Bond NT is clearly visible due to its dye content, allowing determination of the gap width. Typical photos for Dyract AP are shown in and Figure 18. The gap width clearly decreases with the time of water storage, indicating shrinkage compensation of the Dyract AP.
Figure 17: CLSM photo of artificial gaps in Dyract AP restorations. Gap width is reduced after 2 weeks of water storage.

Figure 18: CLSM photo of artificial gaps in Dyract AP restorations. Gap width is further reduced after 7 weeks of water storage.

The identical experiments with a composite restorative material (TPH Spectrum) did not show any change in gap width with time of water storage. This is in accordance with the volume behaviour of composites described in Figure 12 of this section. Figure 19 and Figure 20 summarise the study run by Pioch. While gap width clearly decreases for the compomer, no such change can be observed for the composite material.
In summary, recent studies have shown that there is a clear difference in dimensional behaviour of compomers and composites. The shrinkage compensation observed for the compomer Dyract AP may be an explanation for the widespread clinical success observed for the material.
6 Clinical Investigations

Long-term clinical data obtained with the original Dyract® formulation together with the results of comprehensive ex-vitro investigations of Dyract® AP already allow a good prediction of the clinical performance of Dyract® AP.

However, for assessment of the performance of Dyract® AP in the extended indications and in particular when used for large occlusal stress bearing class II and I restorations, clinical data on the present formula were obtained prior to launch of the product.

Presently, DENTSPLY DeTrey is involved in clinical investigations on Dyract® AP at 10 trial centres (Table 5).

- Creighton University (investigations of class V and II restorations)
- Livorno Research Centre for Dentistry (investigations for core build-up for full ceramic restorations and of class V restorations)
- The University of Hong Kong (investigation of class II restorations)
- The University of Liverpool (investigations of class V and class II restorations)
- The University of Malaya (investigation of class II restorations)
- The University of Michigan (investigation of class V restorations)
- The University of Munich (investigation of class II restorations)
- The University of Nijmegen (investigation for deciduous molars)
- The University of Singapore (investigation of class IV restorations)
- The University of Ulm (investigation of class V restorations)

Table 5

The majority of these trials investigate the safety and efficacy of Dyract® AP for large occlusal stress bearing class I and II restorations (chapter 6.1). 2-year data from two investigations are now available from two sites and are of particular interest as they clearly show that the product behaves very satisfactorily in this demanding situation.
Since Dyract® AP is part of an adhesive restorative system, clinical investigations on Dyract® AP have to also include an assessment of its retentive properties. Therefore, investigations on the use of Dyract® AP in wedge-formed class V lesions are conducted (chapter 6.3).

**Figure 21:** Dyract AP, Clinical Trial Sites

6.1 Clinical Investigation on the Use of Dyract® AP for load-bearing Class I and II Restorations in permanent posterior Teeth

The physical properties of Dyract AP and data on abrasion resistance presented by three different investigators for these second generation compomers suggest that its clinical performance should be equivalent to a modern fine particle hybrid composite when used for the restoration of occlusal stress-bearing class I and II cavities in permanent posterior teeth.

All the clinical data accumulated at the 2-year recall of clinical investigations undertaken at the renowned Schools of Dentistry of the Universities of Liverpool and Munich continue to support the suitability of Dyract AP as an easy-to-apply amalgam alternative.
Design of Investigations

The Revised (1989) Guidelines for submission of Composite Resin Materials for Posterior Restorations published by the American Dental Association were found to be a suitable basis for the protocol of the clinical investigations carried out in Liverpool and Munich with modifications only regarding the width of the cavity which in the case of Dyract® AP is limited to 2/3 of the intercuspal distance. Patient numbers and requirements regarding teeth and type of cavity are given in Table 6.

<table>
<thead>
<tr>
<th>Patients and Restorations for Clinical Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
</tr>
<tr>
<td>≥ 30 at baseline</td>
</tr>
<tr>
<td>≥ 25 at 2 years</td>
</tr>
<tr>
<td>≥ 20 at 4 years</td>
</tr>
<tr>
<td><strong>Teeth</strong></td>
</tr>
<tr>
<td>First or second molars</td>
</tr>
<tr>
<td>Must be in Occlusion</td>
</tr>
<tr>
<td><strong>Cavity Class</strong></td>
</tr>
<tr>
<td>≥ 75 % Class II</td>
</tr>
<tr>
<td><strong>Cavity Size</strong></td>
</tr>
<tr>
<td>≥ 1/3 ≤ 2/3 intercuspal distance</td>
</tr>
<tr>
<td><strong>Cavity Type</strong></td>
</tr>
<tr>
<td>≥ 10 complex restorations</td>
</tr>
</tbody>
</table>

Table 6: Patient numbers and restorations for class II clinical investigations

Performance Criteria

Evaluation is conducted according to USPHS (Ryge) criteria including retention, colour match, visual and tactile margin integrity, secondary caries, and post-operative sensitivity.

*By direct Evaluation:*

a) Maintenance of anatomic form
b) Maintenance of approximate contour
c) Maintenance of acceptable colour (match or stability)
d) Marginal discoloration
e) Caries
f) Fracture (localised or bulk)
g) Post-operative sensitivity.

*By indirect Evaluation:*
a) Wear (measuring wear between 6 months and 2 years and between 6 months and 4 years)
b) Maintenance of interproximal occlusal embrasure form (if using casts for evaluation)
c) Fracture (if using casts for evaluation)

Radiography
Radiographs are taken preoperatively where clinically indicated and when judged clinically appropriate, at least at the 2 recalls.

Success Criteria

Acceptance Criteria
The recalled restorations in the clinical study must demonstrate "no greater incidence" of clinical failures for the different test parameters than the limits listed in Table 7:


<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; 15% Charlie</td>
</tr>
<tr>
<td>• Marginal integrity</td>
<td>&lt; 5% Charlie</td>
<td>&lt; 10% Charlie</td>
</tr>
<tr>
<td>• Caries-recurrent or marginal</td>
<td>&lt; 5% Charlie</td>
<td>&lt; 10% Charlie</td>
</tr>
<tr>
<td>• Maintenance of interproximal contact</td>
<td>&lt; 5% observable broadening</td>
<td>&lt; 10% observable broadening</td>
</tr>
</tbody>
</table>

Table 7: Clinical success criteria for posterior composite restorations

Wear
The required wear resistance to comply with the ADA submission guidelines are given in Table 8.
Required Wear Resistance

<table>
<thead>
<tr>
<th>Wear Measurement</th>
<th>Maximum Allowed Wear (MW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricted Category</td>
<td>6M-2Y</td>
</tr>
<tr>
<td>Unrestricted Category</td>
<td>6M-2Y</td>
</tr>
</tbody>
</table>

| Average for restoration | 125 | 200 | 75 | 150 |
| Local (occlusal contact) | 400 |

**Table 8:** Required wear resistance for class II clinical investigations

**Cumulative Failures**

In addition, the total of failures resulting from marginal integrity, caries, wear, and replacements must demonstrate no greater incidence than listed in Table 9.
6.1.1 Clinical Investigation of the Compomer Restorative Material K95-9608086 for Class II and I Cavities of permanent posterior Teeth at The University of Munich (Project # 4.403)

Investigators
Benz, Ch.; Gust, C.; Folwaczny, M.; Benz, B.; Hickel, R.

Design
The investigation is a longitudinal trial.
44 class I and II restorations were placed in posterior teeth of 36 patients.
Dyract® AP was placed with cotton roll isolation and wedged metal matrix without any acid conditioning. Prime&Bond 2.1 dentine and enamel adhesive was used in a two-layer-two-cure technique.
Assessments are made at baseline, 6 months, 12 months and 2 years.
In addition, wear is measured with a laser 3-D analysing system using replica.

24-Month Results
Patients and Restorations: 40 Dyract® restorations in 32 patients were available for the recall examination.
Caries: Caries in proximity to the restorations was not observed.
Fractures: 1 fracture of a restoration was observed at 24 months on a restoration of which the opposing tooth had received a crown between the 12-month and the 24-month recalls.
Anatomic Form: Changes of anatomic form due to wear of the occlusal surface was observed with two restorations in one patient. The restorations received a Bravo rating due to the wear facets observed. The dentition of this patient showed signs of bruxism. In addition a posterior bridge was placed 6 months before the recall in a quadrant different to the one where the restorations were situated; this could also have contributed to the wear of the restorations.
Approximal Contact: Ideal approximal contacts could not be achieved for all restorations at placement, but over the 24-month observation period no changes occurred due to approximal wear.
Marginal Adaptation/Staining: Over the 24 months in service, five restorations changed from an Alpha to a Bravo rating and one changed from Bravo to Charlie. The latter was possibly caused by the removal of the adjacent wisdom teeth.
**Colour Stability:** In two cases, a shift was observed from Alpha to Bravo. In both cases with smokers. The superficial staining was removed by polishing.

**Post-Operative Sensitivity:** At 24 months, none of the restored teeth exhibited pain or hypersensitivity. No signs of pulp necrosis were observed.

**Conclusions:**
Under the conditions of this clinical investigation, Dyract AP was found to be a safe and efficient material for the restoration of class I and II cavities in permanent posterior teeth.

Provided that the indirect determination of wear by laser measurement confirms the clinical findings of only irrelevant amounts of wear, Dyract AP is considered to be an easy-to-place amalgam alternative.

At this stage in this investigation, Dyract AP meets the requirements of the Guidelines of the ADA for a posterior composite material for unrestricted use.

Summary by DENTSPLY DeTrey.

6.1.2 **Clinical Investigation of the experimental Compomer K95-KL18-158-2 for Class II and I Restorations at The University of Liverpool (Project # 4.404)**

**Investigators**
Jedynakiewicz, M. N.; Martin, N.

**Design**
The investigation is a longitudinal uncontrolled trial.
A total of 41 restorations was placed in 31 patients in load-bearing class II and I cavities in permanent teeth.

**Application**
Rubber dam was used to isolate the tooth in all placements. No acid-conditioning of enamel or dentine was used. No lining was placed under the restorations with the exception of one tooth where pulp-capping was performed with a calcium-hydroxide liner. Prime&Bond 2.1 dentine and enamel adhesive was used in a two-layer-two-cure technique.
24-Month Results

Patient response to recall
Of the 42 restorations placed in 31 patients, 25 restorations of 20 patients were examined directly for the two-year interim report.

Retention/Fractures
100% retention was recorded for the restorations. Although one tooth suffered cuspal fracture, the restoration was retained in its entirety.
The fractured tooth had been restored with a class I restoration of moderate volume. Some undermining of the mesiobuccal cusp was evident from examination of the fractured surface. The cusp was a supporting cusp and under moderate occlusal load. There is no doubt that the cuspal tissue was weakened at the time of the restoration.

Colour Match
Colour match remained acceptable in all restorations with all restorations scoring Alpha. This category requires that the restorations were invisible at normal conversational distance. Many of the restorations went much further than the Alpha of evaluation indicates and were invisible to all but the closest clinical examination.

Surface Texture
All restorations were recorded as texture grade A at baseline and retained this status at the 6-month recall, at the one-year recall and at the two-year recall.

Marginal Discoloration
The marginal discoloration was scored as Alpha for all retained restorations at the two-year review. Because the original placement protocol did not include any conditioning of the enamel or dentine surfaces prior to the placement of the adhesive, the category of evidence "Marginal discoloration" was again examined with especial vigour. No evidence of marginal percolation was noted. Beyond the level of sensitivity of the Ryge criteria used, no subjective discrimination suggested that the margin seal was in any way different to a conventional etch-bonded composite margin.

Marginal Integrity
Marginal integrity remained at grade A for all retained restorations with the exception of the tooth that suffered cuspal fracture.
Recurrent Caries
No recurrent caries was recorded in any case.

Surface Contour (Wear)
All restorations rated as grade A surface contour at two years.

Pulp Status
All teeth in the trial remained asymptomatic. Upon interrogation, no patient reported hypersensitivity to thermal or osmotic changes. No other symptoms were reported.

Conclusions
At two years, the trial continues to support the use of Dyract AP in combination with the single-component adhesive Prime&Bond 2.1 for use in the restoration of load-bearing posterior restorations that do involve cusp replacement.

Summary by DENTSPLY DeTrey.

6.1.3 Summary of the Liverpool and Munich Trials

The clinical data obtained at the 2-year recall (Table 10, Table 11) of the class I, II investigations in Liverpool and Munich show that Dyract AP is a safe and efficient material for occlusal stress-bearing restorations of permanent posterior teeth. At 2 years, Dyract AP fulfils the performance criteria stipulated by the ADA for composite resin materials for unrestricted use in posterior teeth (an alternative to dental amalgam) with exception of the indirect wear measurements which are in progress.
### Performance at 2 years

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Liverpool</th>
<th>Munich</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A B C</td>
<td>A B C</td>
</tr>
<tr>
<td>Wear*</td>
<td>100 0 0</td>
<td>93 7 0</td>
</tr>
<tr>
<td>Colour match</td>
<td>100 0 0</td>
<td>95 5 0</td>
</tr>
<tr>
<td>Marginal discolouration</td>
<td>100 0 0</td>
<td>85 13 3</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>96 0 4**</td>
<td>97 0 3#</td>
</tr>
<tr>
<td>Caries</td>
<td>100 0 0</td>
<td>100 0 0</td>
</tr>
<tr>
<td>Approx. Contact*</td>
<td>100 0 0</td>
<td>100 0 0</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>100 0 0</td>
<td>100 0 0</td>
</tr>
</tbody>
</table>

* of Alpha teeth at baseline only  ** cusp fracture  # bulk fracture

**Table 10:** Summary of 2-year results of class I, II investigations in Liverpool and Munich

### Cumulative failures at 2-year recall

Cumulative failures = Marginal integrity failures + caries + wear failures + replacements + fractures

<table>
<thead>
<tr>
<th>ADA category</th>
<th>ADA requirement</th>
<th>Liverpool</th>
<th>Munich</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricted use</td>
<td>≤ 8</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Unrestricted use</td>
<td>≤ 5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 11:** Cumulative failure at 2 years of the clinical investigations in Liverpool and Munich
6.2 Clinical Investigation of the K 95 Compomer Restorative Material for Class I and II Cavities of deciduous Molars at the Pedodontic Clinic "Beuningen" in Co-operation with The University of Nijmegen (Project # 4.405)

Investigators
Roeters, F. J. M.; Frankenmolen, F. W. A.; Hooiveld, Ch.; Smale, I.; Kusters-Visseren, L.

Objective
It is the purpose of this trial to evaluate the efficacy and safety of Dyract® AP when used for restorations of class I and II cavities of deciduous molars.

Design
The trial is a longitudinal study taking into consideration the ADA Guidelines for Submission of Composite Resin Materials for Posterior Restorations (11-1-89) where applicable for the assessment of deciduous teeth.
The performance of 35 restorations in 31 patients is assessed at baseline, 6-month and the 1-year recalls.
The quality of the completed restorations is assessed by direct clinical evaluation using the well-established rating system of Ryge. At the recalls, the restorations are evaluated clinically and by interview (sensitivity). The status of the gingiva adjacent to the restorations is assessed preoperatively and at the recalls.

At the 12-month recall, 32 restorations in 30 patients were available for inspection, since three teeth were exfoliated and one patient did not show up for the recall. No post-operative sensitivity was recorded. Marginal integrity and marginal discoloration showed only minor fluctuations in time. No recurrent caries occurred.
Comparing the results for Dyract AP to the one-year results for Dyract, marginal integrity and anatomic form are even better maintained in Dyract AP. The authors conclude that the scores for the anatomic form and marginal integrity indicate that Dyract AP wears less than Dyract.
The data continue to support the use of compomer restorative materials as the material of choice for restoration of deciduous molars.

Summary by DENTSPLY DeTrey.
6.3 Clinical investigations on the use of Dyract® AP for class V restorations

The restoration of class V carious lesions and abrasion/erosion or abfraction lesions is an important indication for compomer restorative materials.

Caries-free class V lesions, without cavity preparation and macro-mechanical retention, are routinely used to determine the safety and performance (efficacy) of dental adhesive materials for providing retention and resistance to micro-leakage.

Design of the Investigations

The requirements stipulated by the American Dental Association for this kind of test are summarised in Table 12, Table 13, and Table 14. The clinical investigations on Dyract® for class V cavities are carried out according to these recommendations.


Tooth/ Cavity Selection

- Caries-free class V lesions
- No cavity preparation or bevelling
- No macro-mechanical retention
- Margins primarily in dentine

Table 12: Requirements of the ADA Protocol Guidelines for Dentin and Enamel Adhesive Materials (1994)

Clinical Evaluation

2 studies at least, each with:
- A minimum of 30 restorations
- At least 25 patients at baseline
- 20 patients at 6-month recall
- 15 patients at 18-month recall
- Balance in age groups: 20-39, 40-59, > 60


Acceptance Criteria

<table>
<thead>
<tr>
<th>Retention Failure</th>
<th>Marginal Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>baseline</td>
<td>0% Charlie</td>
</tr>
<tr>
<td>6 months</td>
<td>&lt; 5% Charlie</td>
</tr>
<tr>
<td>18 months</td>
<td>&lt; 10% Charlie</td>
</tr>
</tbody>
</table>

\[
\text{failure} [%] = \frac{100 \times \text{previous failure + new failure}}{\text{previous failure + recalled restorations}}
\]

Table 14: Requirements of the ADA Protocol Guidelines for Dentin and Enamel Adhesive Materials (1994)
6.3.1 Clinical Investigation of the experimental Compomer K95-9608086 for Class V Restorations at The University of Liverpool (Project # 4.401)

Investigators:
Jedynakiewicz, M. N.; Martin, N.

Design
This investigation is a longitudinal, uncontrolled trial according to the ADA Protocol Guidelines for Dentin and Enamel Adhesive Materials (1994).
64 class V Dyract® AP restorations were placed in 37 patients in non-retentive cervical cavities in permanent teeth. They are assessed at baseline and at the 6-month, 12-month, and 18-month recalls.

Application
Dyract® AP was used in combination with Prime&Bond® 2.1. No acid-conditioning of the cavity surface was performed.

24-Month (final) Results
As two restorations were not retained and one tooth was lost due to periodontitis, 59 restorations could be rated according to the criteria established by Ryge. No recurrent caries was recorded in any case. Marginal integrity remained at grade A for 56 restorations with three restorations scored as B. Marginal discoloration remained at grade A for all restorations at the two-year review except one with distinct discoloration which was scored B. 59 restorations were retained. A previous loss at one year was replaced following the last recall. This replacement restoration was also lost. The patient clearly experienced bruxism and the occlusal loading upon the tooth was high. All restorations rated as grade A surface contour at the two-year recall. All restorations were recorded as texture grade A at baseline and retained this status at the two-year recall. Colour match remained acceptable in all restorations with all the restorations scoring Alpha. Measurements of the gingival status were recorded according to the trial protocol. No significant changes were observed from the recordings made at baseline. A summary is given in Table 15.
**Conclusions**

The investigation supports the continued use of Dyract AP as an effective restorative material for the restoration of non-carious cervical lesions in permanent teeth. These data may also be used to support issues relating to the efficacy of the adhesive bond achieved by the adhesive Prime&Bond 2.1 and derivatives in combination with the compomer restorative material when used without prior etching of the tooth surface.

In this clinical investigation, Dyract AP used in combination with Prime&Bond 2.1 has met the requirements of the ADA Guidelines for Dentin and Enamel Adhesive Materials.

Summary by DENTSPLY DeTrey.
Clinical Investigation of the Non-Rinse Conditioner NRC used in combination with the adhesive Prime&Bond® 2.1, the composite resin SpectrumTPH, or the compomer Dyract® AP at Livorno Research Centre for Dentistry (Project # 4.805)

Investigator: Ferrari, Marco

Design
This investigation is a longitudinal, uncontrolled trial according to the ADA Protocol Guidelines for Dentin and Enamel Adhesive Materials (1994). Class V Dyract® AP and SpectrumTPH restorations were placed in non-retentive cervical cavities in permanent teeth. They are assessed at baseline and at the 6-month, 12-month, and 18-month recalls.

Application
Dyract® AP was used in combination with Prime&Bond® 2.1. Acid-conditioning of the cavity surface was performed with NRC™. SpectrumTPH was used in combination with Prime&Bond® 2.1. Acid-conditioning of the cavity surface was performed with NRC.

18-Month (final) Results of the Dyract® AP Group
All 30 restorations placed were examined in the 18-month recall. 29 (97%) of the restorations were retained and were scored according to Ryge criteria. A summary is given in Table 16.

One tooth remained hypersensitive but to a degree which is considered clinically acceptable and not requiring any treatment.
**Table 16**

**Conclusions**
In this investigation, Dyract AP used in combination with NRC™ and Prime&Bond 2.1 has met the requirements of the ADA Guidelines for Enamel and Dentin Adhesive Materials.

Summary by DENTSPLY DeTrey.

**6.3.3 Clinical Evaluation of the Prime&Bond® 2.1 Restorative System, Creighton University**
*(Project # 4.402)*

**Investigators**
Latta, M.; Barkmeier, W. D.

**Design**
This investigation is a longitudinal, uncontrolled trial according to the ADA Protocol Guidelines for Dentin and Enamel Adhesive Materials (1994).
48 class V Dyract® AP restorations were placed in 37 patients.
They are assessed at baseline and at the 6-month, 12-month, and 18-month recalls.
Application
Dyract® AP was used in combination with Prime&Bond® 2.1. No acid-conditioning of the cavity surface was performed.

6-Month Results
At the 6-month recall 39 restorations were available for evaluation. All recalled restorations were in situ. No post-operative sensitivity was reported, and no recurrent decay (secondary caries) was noted. At 6 months, the evaluated parameters generally showed good to excellent performance. However, other than in the Liverpool study, where marginal integrity for all restorations was rated Alpha, in this study 33 per cent of the restorations received a Bravo rating. Different interpretation of the Ryge criteria by the investigators in Liverpool and at Creighten is a possible explanation for this discrepancy.

6.4 Clinical evaluation of K 95 compomer to build up abutments for indirect porcelain restorations at Livorno Research Centre for Dentistry
(Project # 4.407)

Investigator: Ferrari, Marco

Objectives
The objective of this investigation is to determine the safety and efficacy of Dyract® AP as a direct build-up material of abutments for indirect tooth-coloured restorations.

Design
This investigation is a longitudinal, uncontrolled trial. The restorations of 40 patients will be assessed over at least 1 year.

Application
Dyract® AP was used in combination with Prime&Bond® 2.1 after acid-conditioning for build-up of tooth substance prior to (crown, inlay, or onlay) preparation. Ceramic restorations (Empress crowns, inlays, onlays) were luted using Dyract® Cem and Prime&Bond® 2.1.
12-Month Results

Post-Operative Sensitivity
One restoration showed post-operative sensitivity at the 1-week recall. The sensitivity disappeared spontaneously after 3 to 4 weeks. At the 6-month and 12-month recalls, all restorations were asymptomatic.

Retention
No partial or complete loss of restorations was reported at 12 months.

Marginal Quality
92 per cent of the restorations were rated Alpha regarding marginal leakage. 8 per cent showed a moderate discoloration at the interface. The same restorations showed a Bravo score for marginal integrity.

Surface Crazing
Surface crazing of ceramic restorations was detected in 2 per cent, but the restorations did not require replacement.

Conclusions
The investigator concluded that based on the 12-month data Dyract® AP is suitable for building up abutments for indirect porcelain restorations.

Note by the Manufacturer
In spite of these promising data, Dyract® AP is at present not indicated as a core build-up material for full ceramic crowns until additional clinical data support the safety and efficacy of Dyract® AP for this indication.
7 Directions for Use

Dyract® AP
Advanced Performance Compomer Restorative

Dyract® AP is a universal compomer-based restorative material suitable for cavities in anterior and posterior teeth.

Dyract® AP exhibits advanced performance regarding physical strength and abrasion resistance which is of special importance for occlusal stress-bearing restorations.

Dyract® AP allows a simplified and fast application technique and combines fluoride-releasing glass-ionomer chemistry with the strength and aesthetics of a composite.

Dyract® AP, pre-dosed in Compules® tips for direct intra-oral application, is available in 12 Vita shades and one extra light (XL) shade.

Dyract® AP is used following application of Prime&Bond® NT, a universal self-priming dental adhesive designed to bond the restorative to enamel and dentine.

Caution: For dental use only.

COMPOSITION
Dyract® AP
Polymerisable resins
TCB resin
Strontium-fluoro-silicate glass
Strontium fluoride
Photo initiators
Stabilisers
NRC™ Non-Rinse Conditioner
Organic acids/monomers in aqueous solution.

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

**INDICATIONS**
Dyract® AP is indicated for all cavity classes in anterior and posterior teeth.

Until the results of continuing studies confirm the unrestricted use of Dyract AP in posterior teeth the width of class I and II cavities must be less than 2/3 of the intercuspal distance.

**CONTRAINDICATIONS**
- Direct or indirect pulp capping.
- Core build-up for full ceramic crowns.
- Use in patients with a known allergy to dimethacrylate resins.
- When contamination with saliva, blood, etc. cannot be avoided.

**WARNINGS**
1. NRC™ contains organic acids which may cause burns. Avoid contact with oral tissues, eyes and skin. If accidental contact occurs, flush affected area with copious amounts of water. In case of contact with the eyes, immediately rinse with plenty of water and seek medical attention.
2. 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. The product may cause sensitisation by skin contact in susceptible persons. If skin sensitisation occurs discontinue use.
3. Avoid contact of Prime&Bond® NT with mucous membranes. After accidental contact, wash and rinse with plenty of water.
4. 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.

5. Dyract® AP light cured compomer restorative 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.
   The product may cause sensitisation by skin contact in susceptible persons. If skin sensitisation occurs discontinue use.

PRECAUTIONS
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.

INTERACTIONS WITH DENTAL MATERIALS
Some liners and bases may be etched superficially by NRC™. In general, this does not impair their barrier function.

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.

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.

ADVERSE REACTIONS
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.
STEP-BY-STEP INSTRUCTIONS

1. Shade Selection
Shade selection should be made prior to the restorative procedure whilst the teeth are hydrated. Remove any extraneous plaque or surface stain. Use the Dyract® AP shade guide provided which contains samples of original Dyract® AP restorative. The colour coding dot on the shade guide matches the coloured cap on the Compules tip.

Alternatively, a Vita Lumin® Vacuum shade guide may be used. The Dyract® AP shade corresponds to the central part of the respective Vita® tooth.

2. Cavity Preparation
In all classes of cavity this may be kept to the minimum required for caries removal.

3. Cleaning
Cavity cleanliness is paramount for the development of adhesion.

In cases where no cavity preparation has been made, clean the tooth surface with a rubber cup and pumice or a prophy-paste like Nupro®. Preparing a fresh surface with a finishing bur will significantly increase bond strength to enamel. Wash surface thoroughly with air/water spray. Remove rinsing water by blowing gently with an air syringe or blot-dry with a cotton pellet. Do not desiccate the dentine structure.

4. Pulp Protection
For direct or indirect pulp-capping protect the dentine close to the pulp (< 1mm) with a hard-setting calcium hydroxide liner (e. g. DYCAL®), leaving the remaining cavity surface free for bonding with Prime&Bond® NT.

Conditioning of dentine and enamel
For most restorative procedures with Dyract AP it is not necessary to condition the prepared tooth. In this case, proceed to step 6.
In the case of stress-bearing class I and II permanent restorations - as well as for class IV restorations and in situations where for cosmetic reasons bevelled enamel margins are preferred - conditioning with NRC™ Non-Rinse Conditioner is recommended:

5. Application of NRC™
1. Dispense NRC™ into a DENTSPLY ApliDish or standard dappen dish.
2. Apply sufficient amounts of NRC™ with an Applicator Tip or disposable brush to enamel and dentine. Leave undisturbed for 20 seconds. Do not rinse.
3. Remove excess NRC™ by blowing gently with an air syringe or blot dry with a cotton pellet. Do not desiccate the dentine structure.

Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with forceful water-spray and repeat the application of NRC™.

Alternatively to NRC™, conditioning with DeTrey® Conditioner 36 as described for composite restorations, may be applied.

6. 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 ApliDish 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 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 Dyract® compomer over the cured Prime&Bond® NT.

7. Placement of Dyract® AP
Insert Compules tip into the notched opening of the applicator gun barrel. Dispense Dyract® AP directly into the cavity preparation. In deep cavities, incremental placement and curing (in 3 mm layers or less) is recommended to minimise polymerisation shrinkage.
8. Curing
Cure each increment separately with a VLC dental polymerisation unit for at least 40 seconds or according to the table below. The tip of the light guide should be held as close as possible to the restoration during curing.
Important: Be sure to expose each area of the entire restoration to the curing light. Additionally, the restoration should be cured through lingual or buccal enamel walls.

<table>
<thead>
<tr>
<th>Shade</th>
<th>Light Curing Time</th>
<th>Curing Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1,XL, I-B1</td>
<td>20</td>
<td>3</td>
</tr>
<tr>
<td>A2,A3,C2,C3</td>
<td>30</td>
<td>3</td>
</tr>
<tr>
<td>A3.5, A4,B3,C4,O-A2,O-B3</td>
<td>40</td>
<td>3</td>
</tr>
</tbody>
</table>

9. Finishing
Begin finishing immediately after curing. Gross excess material may be removed with fluted finishing burs or diamonds. Finishing is best achieved by using Enhance™ Finishing and Polishing Discs and interproximal finishing and polishing strips. A high final lustre can be obtained by applying Prisma® Gloss and Prisma® Gloss Extra-Fine Polishing Pastes.

MAINTENANCE OF 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 compomer 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
The Prime&Bond® NT bottle and Dyract® AP Compules tips should be tightly closed immediately after use.
Keep out of sunlight.
Not to be stored at temperatures exceeding 25 °C.
Keep Prime&Bond® NT in a well ventilated place.
Humidity can adversely affect the properties of unsealed Compules tips. Therefore keep Compules tips sealed in their blister pack until use. Under normal ambient conditions, unsealed Compules tips stay usable for about 4 weeks.

**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:

**DENTSPLY DeTrey GmbH (Manufacturer), De Trey-Straße 1, D-78467 Konstanz,**
Phone 0 75 31/5 83-0

**DENTSPLY United Kingdom, Hamm Moor Lane, Addlestone, Weybridge,**
Surrey KT15 2SE, England, Phone 01932-853422

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8 References


9. Roeters FJM, Frankenmolen FWA, Hooiveld Ch, Smale I, Kusters-Visseren L (1997). Clinical investigation of the K 95 compomer restorative material for class I and II cavities of deciduous molars at the Pedodontic Clinic "Beuningen" in cooperation with The University of Nijmegen. Interim Report. Summary by DENTSPLY.⁴


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