Dyract® Seal

Compomer pit and fissure sealant for the Total-Seal™ technique
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1 Dyract Seal - A new concept for pit and fissure sealing

Prevention is the most distinguished mission of modern dentistry. Fissure sealing is a well-proven method of caries prevention. With more than 17 years of experience with fissure sealing materials, DENTSPLY has long been on the forefront of preventive dentistry.

Compomer Technology

DENTSPLY is not only an innovation leader in the field of preventive dentistry, but also with regard to restorative materials. The DeTrey Division of DENTSPLY developed Dyract®, the first compomer restorative material, back in 1993. This material comprises a reactive fluoride-containing glass and monomers containing polymerisable groups and carboxylic groups. Compomers combine the advantageous properties of both composites and glass ionomers, such as good mechanical and optical properties and fluoride release.

Based on the successful compomer concept, DENTSPLY has now developed the light-curing pit and fissure sealant Dyract Seal. By introducing compomer technology into fissure sealing, fluoride release as another effective way of caries prevention is added to the concept of preventing caries by mechanical sealing of fissures.

Non-rinse conditioning

With NRC™ Non-Rinse Conditioner, DENTSPLY has introduced an innovative acid-conditioning procedure for Dyract® compomer materials. NRC is applied for 20 seconds to the surface to be conditioned. Afterwards, remaining material is removed with the air syringe. Due to the non-rinsing procedure, the change of cotton rolls has become obsolete. Sealing without rinsing enhances acceptance of the treatment procedure particularly with small children.

The Total-Seal technique

The application of Prime&Bond® NT, a low-viscous acetone-based adhesive, prior to application of the sealant, ensures deep penetration of resin into the most narrow fissures. On top, Dyract Seal provides a tight and abrasion-resistant sealing.
This Technical Manual describes the innovative properties of Dyract Seal as well as of the new Total-Seal treatment concept.

2 The Dyract Seal system

Dyract Seal is a restorative system composed of a number of elements designed for optimum interaction. In analogy to Dyract and Dyract AP, Dyract Seal is a light-curing, self-adhesive compomer. The active ingredients of Dyract Seal (Table 1) in combination with the filler result in extraordinary properties of the material.

Dyract Seal is a one-component compomer. It combines total sealing ability, high abrasion resistance, excellent mechanical properties, and long-term fluoride release.

The subsequent chapters describe the chemical principles of Dyract Seal as well as the most important properties of the new Total-Seal system.

2.1 Composition of Dyract Seal

The components of the Dyract Seal paste are listed in Table 1.

The paste contains two patented resins, aminopenta and the macromonomer M-1A-BSA (Figure 1). It also contains an initiator system for the photopolymerisation and a strontium-aluminium-fluorosilicate glass.

The reactive silicate glass is an important component as the amount of fluoride released is mainly dependent on the glass filler. Furthermore, the sealing ability of the restoration and the viscosity of the restorative material depend on the filler. Therefore, a fine glass with an average particle size of 0.8 µm and a high fluoride content is used for Dyract Seal. Such a reactive glass is a component of conventional glass ionomer cements and is successfully used in the DENTSPLY products BaseLine and Dyract.
The macromonomer resin is a substance that fulfils the characteristics of the new materials
class of compomers: after the initial light-curing, it can further react with the glass filler.

As shown in Figure 1, each molecule of the patented macromonomer contains two
methacrylate groups as well as at least four carboxylic groups (COOH). The methacrylate
groups enable the macromonomer to take part in radical polymerisation. If water is present,
the carboxylic groups of the macromonomer can undergo an acid-base reaction with metal
ions of the glass filler, leading to the formation of carboxylate salts.

The structural design of the aminopenta molecule, as also depicted in Figure 1, is based on
the concept of hydrophobic and hydrophilic groups contained in the same molecule. The
partly hydrophilic properties imposed by the presence of the phosphate groups of
aminopenta are required in order to achieve good wettability of the largely moist tooth
substrate. Moreover, the phosphate groups act as adhesion promoters which are thought to
interact with the calcium ions of the hydroxyapatite. The presence of five methacrylate
groups per molecule also enables aminopenta to function as a powerful cross-linking
monomer. In addition, the more hydrophobic methacrylate groups provide good chemical
compatibility with the macromonomer.
2.2 Reactions in Dyract Seal

Dyract Seal is a one-component system that is cured by irradiation with visible light. The mechanism is that of a photochemically initiated radical polymerisation. In order to understand the mechanism of this type of polymerisation one should notice that the only difference between a thermally initiated and a photochemically initiated polymerisation is the initiation step. In the case of a thermally initiated reaction, the radical polymerisation is started by heat, in the case of a photochemically initiated polymerisation by irradiation with light. Both polymerisations then continue as radical polymerisations without the need of further energy supply (both in the form of light or heat). In the case of the photochemically initiated polymerisation this is described as the subsequent dark reaction that leads to a further polymerisation and thus to a higher degree of conversion of double bonds.

The photochemically induced polymerisation mechanism is the same for light-curing composite materials (e.g. SpectrumTph) as well as for compomer materials (e.g. Dyract AP). The molecules aminopenta, macromonomer and DGDMA polymerise with each other, forming a three-dimensional network that incorporates the filler particles. The polymeric network is mechanically stable in itself, but it is further strengthened by the filler.

The kinetics of the subsequent acid-base reaction of Dyract Seal are different from those of glass ionomer cements. The latter hardens instantly once exposed to moisture. With Dyract Seal, the acid-base reaction cannot occur instantly as the material initially does not contain water. Therefore, the carboxylic groups of Dyract Seal remain inactive at this first stage. Only after water uptake, which continues over several weeks, the carboxylic salts are formed which simultaneously is accompanied by the release of fluoride ions.

Hence, with Dyract Seal there are two curing reactions occurring: the quick photoinitiated polymerisation and the subsequent slow acid-base reaction. The latter forms the basis of the continuous release of fluoride ions which is an important property of Dyract Seal. This is described in detail in the fluoride release chapter of this manual.
3 Polymerisation properties of Dyract Seal

3.1 Depth of cure

The depth of cure of a fissure sealant is important for the long-lasting success of the sealing. As the geometry of the fissures may vary considerably, the depth of cure has to be sufficient to guarantee complete polymerisation of the sealant even in deep fissures.

Assuming that the opacity of the material is paramount for the amount of light passing through (and thus paramount for the polymerisation of the underlying adhesive layer), the depth of cure for the two different shades of Dyract Seal was determined. The depth of cure is as least 5 mm for the translucent and 3 mm for the opaque shade.

Thus the depth of cure of 1.5 mm that is demanded in ISO norm 6874 is exceeded considerably.

3.2 The unpolymerised layer

It is well-known that the radical polymerisation of methacrylates is influenced by a large number of factors. Among these are reactions that terminate the radical chain leading to chain transfers. Oxygen plays an important role in the polymerisation and the formation of an oxygen-inhibited unpolymerised layer on the surface of the material.

For Dyract Seal the thickness of the unpolymerised layer was determined to be about 40 µm which is well below the maximum thickness of 100 µm required in ISO norm 6874.

3.3 Light sensitivity

Depending on the shade the light sensitivity of Dyract Seal is between 2 and 3 minutes. Not only is this far above the minimum value of ISO norm 6874 (25 s); it also is by far higher than
that of any other competitive product, making Dyract Seal the least light-sensitive sealant of all products examined.

4 Adhesive properties of Dyract Seal

The newly developed monomers of Dyract Seal contribute to the self-adhesive properties of Dyract Seal.

Every molecule of the macromonomer contains at least 4 carboxylate groups (COOH, see Fig. 1). Every molecule of aminopenta contains 5 polymerisable methacrylate groups and one phosphate group. The hydrophilic carboxylate and phosphate groups of the monomers are responsible for the good wetting ability of the compomer.

The adhesion achieved with the Total-Seal technique was compared (s. Table 2) to that of the conventional procedure comprising the enamel pretreatment with phosphoric acid followed directly by the application of the sealant.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Pretreatment</th>
<th>Adhesion (24 h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Nupro Medium, r, d, NRC (20&quot;), d, P&amp;B NT (20&quot;), DS</td>
<td>11.1 ± 2.4</td>
</tr>
<tr>
<td>B</td>
<td>Nupro Medium, r, d, Etching gel (20&quot;), r, d, DS</td>
<td>12.9 ± 1.4</td>
</tr>
</tbody>
</table>

r = rinsing, d = drying, DS = Dyract Seal

Table 2 Initial adhesion of Dyract Seal to enamel, with different pre-treatments, with and without Prime&Bond NT

Within the precision of the adhesion method both results are equal indicating that with both pre-treatments Dyract Seal has sufficiently high adhesion to enamel.

5 Initial physical properties of Dyract Seal (24 h)

The mechanical properties of a fissure sealant play an important role in its clinical success. Therefore a number of initial mechanical properties of Dyract Seal such as compressive strength and yield strength were determined after 24 h storage in water
The initial data regarding polymerisation behaviour, adhesion, and solubility are summarised separately in sections 3, 4, and 7.

5.1 Compressive strength

From Figure 2 it is evident that Dyract Seal exhibits one of the highest compressive strengths of the examined materials.

![Figure 2](image-url)

**Figure 2** Compressive strength of fissure sealants after 24 h water storage at 37°C

5.2 Yield Strength

Pit and fissure sealants are subjected to mechanical stress due to mastication forces. In order to be able to predict the clinical performance it is of interest to examine the behaviour of the bulk material under mechanical stress. Materials show a permanent deformation (which should be avoided) only beyond a certain stress. This stress is called yield stress or yield strength. Figure 3 shows the yield strength of Dyract Seal compared to other pit and fissure sealants.
As can be seen Dyract Seal has one of the highest yield strength and should be less prone to plastic deformation compared to other competitive products.

### 5.3 Resilience modulus

As can be expected from the high yield strength of Dyract Seal, the material has an extraordinarily high resilience modulus of 7 MPa (Figure 4). All other examined materials do have a significantly lower resilience. A high resilience indicates the ability of the material to absorb energy when it is stressed, up to its limit of elasticity.
5.4 Surface hardness

Surface hardness is related to abrasion resistance. A high surface hardness indicates a high abrasion resistance. Dyract Seal (26.77 ± 0.33), Helioseal (25.33 ± 0.24) and FluroShield (29.80 ± 0.24) have the highest Vickers hardness (Figure 5). The surface hardness of all other materials is significantly lower: Delton Plus 18.13 ± 0.12, Concise 18.27 ± 0.31, Fissurit F 20.63 ± 0.33 and Ionosit-Seal 22.37 ± 0.21.

![Figure 5](image_url)

**Figure 5**  Vickers hardness of selected fissure sealants

5.5 Radiopacity

The radiopacity of Dyract Seal is as high as that of enamel (2 mm Al).

5.6 Opacity

Dyract Seal is available in two opacities: a translucent material with an opacity of $c_{0.7} < 15\%$, and an opaque shade of 70-75 %.

5.7 Colour Stability

The colour stability of Dyract Seal (7.2%) is comparable to that of FluroShield, Concise, and Ionosit-Seal and much better than the colour stability of Delton Plus (17.2%), Helioseal F (15.8%), Fissurit F (16.4%).
6 Dimensional changes

To achieve the total-sealing ability and the high fluoride release rate (see section 2 and 3), the Dyract Seal matrix is composed of molecules with relatively polar groups (carboxyl- and phosphatester- groups). These polar groups are capable of interaction with other polar substances such as water (hydrogen bonds). Therefore, water uptake and dimensional changes have to be considered.

Figure 6 shows that Dyract Seal linearly expands by about 0.9 % within the first 4 weeks of water storage at 37 °C. This is due to the water uptake. Under these conditions further water storage does not lead to additional expansion.

The other examined sealants display linear expansions between 0.4 and 0.7%. However, for two products, a linear expansion above 1% was found.

7 Solubility

The ionic structures of Dyract Seal (as described in the previous sections) give the material a certain affinity towards water (section 10). Furthermore, fluoride release is guaranteed due to the incorporation of a special fluoride-containing glass (section 4.5). Both properties obviously lead to a certain solubility of the material. With $2.71 \pm 0.42 \, \mu g/mm^3$ the solubility of Dyract Seal is not significantly higher than that of FluroShield ($2.23 \pm 0.01$) or Delton (1.56). However, the solubility is well below the limit of 7.5 $\mu g/mm^3$ given in the ISO norm.
This is also true for water absorption of Dyract Seal. It is $81.68 \pm 0.77 \mu g/mm^3$, which is somewhat higher than for composite-based materials, due to the polarity of the monomers of the Dyract Seal matrix.

8 Wear resistance

Fissure sealants are subjected to abrasive conditions within the mouth, particularly during food intake and tooth cleaning. Even though fissure sealants are not constantly exposed to occlusal forces, the abrasion resistance of these materials can determine the tightness of the sealing and thus its clinical efficacy.

In this regard Dyract Seal was subjected to a strict examination by established methods. The details of the abrasion measurement according to the ACTA method can be found in the literature (De Gee et al., 1994).

The data given in Figure 7 show that Dyract Seal has a significantly higher wear resistance than conventional fissure sealants such as Concise or Delton Plus.

![Figure 7](image)

**Figure 7**  Wear resistance of Dyract Seal and other fissure sealants (200000 cycles at 15 N and 15% slip)
Similar abrasion resistance tests were carried out at the Poliklinik für Zahnerhaltung und Paradontologie in Erlangen/ Germany. For these tests, samples made from Empress ceramic were furnished with a fissure of about 1 mm width. These artificial fissures were treated with various fissure sealants. Under these test conditions no significant differences in the abrasion resistance of the examined materials could be detected (Figure 8).

9 Penetration behaviour and tightness of sealing

9.1 Penetration behaviour and tightness of sealing (N. Krämer, University of Erlangen)

The penetration behaviour of fissure sealants and the tightness of the sealing are the main criteria for its long-term efficacy. Therefore, corresponding tests were run at the Poliklinik für Zahnerhaltung und Parodontologie (Erlangen). After 4 weeks storage in thymol solution sealed molars were subjected to dye penetration. Cross-sections were examined for tightness and depth of penetration (completeness).
No statistically significant differences between conventional fissure sealants and the compomer sealant Dyract Seal were found.

In experiments carried out at DENTSPLY Konstanz, teeth were cleaned with Nupro. Afterwards, the fissures were either sealed directly with Dyract Seal or treated according to the novel Total-Seal™ technique: applying NRC first, followed by one coat of Prime&Bond NT and then sealed with Dyract Seal (Figure 9).

While the conventional sealing technique only leads to a partial complete sealing the Total-Seal technique leads to a complete filling and perfect sealing of the fissures.

<table>
<thead>
<tr>
<th></th>
<th>Tightness of sealing</th>
<th>Completeness of sealing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Helioseal</td>
<td>100</td>
<td>83</td>
</tr>
<tr>
<td>Visio Seal</td>
<td>100</td>
<td>63</td>
</tr>
<tr>
<td>Delton Plus</td>
<td>100</td>
<td>77</td>
</tr>
<tr>
<td>Ionosit Seal</td>
<td>100</td>
<td>67</td>
</tr>
<tr>
<td>Deguseal mineral</td>
<td>100</td>
<td>63</td>
</tr>
<tr>
<td>Dyract Seal</td>
<td>100</td>
<td>89</td>
</tr>
</tbody>
</table>

Table 3 Sealing properties of Dyract Seal and other products
9.2 Microleakage of Dyract Seal (W. Barkmeier, M. A. Latta, Creighton)

Dyract Seal was tested for microleakage both after pretreatment with either DeTrey Conditioner 36 or NRC followed by one coat of Prime&Bond NT (Total-Seal technique). Afterwards the teeth were thermocycled (24 h between 5°C and 55°C) and stored in silver nitrate solution. The teeth were then irradiated with light and cross-sectioned. Both groups showed complete sealing (100%). Furthermore, it could be shown that a separate light-curing of the adhesive Prime&Bond NT was not necessary. The adhesive could be light-cured in one step together with Dyract Seal.

10 Fluoride release

As described in section 2, Dyract Seal contains a strontium-aluminium-fluorosilicate glass with a high fluoride content.

This glass has been patented by DENTSPLY and has been successfully used in DENTSPLY products for some time. Up to now in-vitro data on the continuous fluoride release of Dyract Seal are available over a course of one year. Figure 10 shows that after an initial release of about 2.0 µg/cm², an almost constant fluoride release of about 1.4 µg/cm² is reached.

For Dyract Cem, a product with a closely related chemistry, a continuous fluoride release of 2 µg/cm² per week was found over the course of 3 years. Therefore, a similar long-term behaviour is to be expected for Dyract Seal.

Furthermore, six other fissure sealants were examined. Though some of the materials showed a higher initial fluoride release than Dyract Seal, this release decreased below the level of Dyract Seal within 5 weeks. After 10 weeks the fluoride release of Helioseal and Fissurit F was almost below detection level.
In conclusion the in-vitro results for Dyract Seal indicate that long-term clinical success can be expected.

11 Clinical investigations

At present two clinical investigations are carried out, one at the University of Umeå in Sweden with Dr. Jan W. V. van Dijken, Associate Professor and Clinical Director, as the main investigator. The other investigation is carried out at the University of Valencia in Spain under the management of Professor Dr. Agustín Pascual Moscardó. The study design is identical in both studies and the protocols are the same regarding the method of application and evaluation.

11.1 Objectives

The objective of the two clinical investigations is to determine the safety and efficacy of the new fissure sealant Dyract Seal used in combination with non-rinse conditioner NRC and the adhesive Prime&Bond NT in an application procedure described by DENTSPLY as the Total-Seal technique.
11.2 Design

Both studies are longitudinal, controlled, double-blind trials.

The control is Delton® Plus Opaque fissure sealant used in combination with DeTrey® Conditioner 36, a phosphoric acid conditioner.

The fissures are randomly assigned to receive either the test or the control material. The sealants are placed according to a strict clinical protocol.

In each study, the sealings of at least 30 patients are observed for at least twelve months.

11.2.1 Performance criteria

The following parameters are to be evaluated at each recall: presence of caries, retention of the sealants as total retention, partial loss, or complete loss, and marginal discoloration with an expanded score scale of the USPHS criteria.

11.2.2 Success criteria

The recalled sealings with the test material in the clinical study must demonstrate no greater incidence of clinical failure than those with the control material.

11.2.3 Patients

At the begin of the study, patients are to be aged between 6 and 14 years. There have to be close to equal numbers of boys and girls in the study.

It is a requirement that the number of subjects (sample size) may not be less than 30 patients at baseline, 3 months, and 12 months, 20 patients at 24 months, and 15 patients at 48 months.

11.2.4 Test teeth

Efficacy is to be demonstrated on caries-free permanent molars in which no restorative or sealant have been placed and which are erupted to such a degree that the fissures to be treated are uncovered by periodontal tissue and that gingival fluid cannot contaminate the tooth during the application procedure.

Teeth with just initial signs of decalcification may be included.
Teeth with severe gingival inflammation or other clinical conditions which do not allow for a
dry working field are to be excluded.

11.2.5 Sealing numbers

At least 76 sealings are to be included in the study with a minimum of one sealing with
Dyract Seal and one control sealing per patient.

11.3 Method of reporting

Reports are written on the basis of the baseline, 3- and 6-month, and 12-and 24-month data.

11.4 Results up-to-date

From both studies, an interim report is available on the first 30 patients treated with sealings
in situ for more than 3 months. Application properties and patient acceptance were rated very
favourably. No retention losses or adverse events have been reported, and the performance
of both Dyract Seal and the control (Delton Plus Opaque) is efficient and without any
deficiencies. Both materials are considered to be safe and efficient for the given indications.

12 Directions for use

12.1 Indications

Preventive sealing of pits and fissures in the primary and secondary dentition.
12.2 Contraindications

Known allergy to dimethacrylate resins and other components of the material to be used in case of caries.

12.3 Step-by-step instructions for the Total-Seal technique

1. Cleaning
Clean surfaces to be sealed with an oil free paste such as NUPRO® Prophy Paste. Rinse well with water.

2. Isolating
Isolate the teeth to be sealed with rubber dam or cotton rolls and dry each tooth with air, free of oil or water contamination.

3. Application of NRC Non-Rinse Conditioner

![Application of NRC in the Total-Seal technique with Dyract Seal](image)

**Figure 11** Application of NRC in the Total-Seal technique with Dyract Seal

1. Dispense NRC into a DENTSPLY Applicator Dish or standard dappen dish.
2. Apply 1 drop of NRC with an Applicator Tip or disposable brush to the fissure. Leave undisturbed for 20 seconds. **Do not rinse.**
3. Remove excess NRC by blowing gently with an air syringe.

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1 Alternatively to NRC, a conventional phosphoric acid conditioning procedure may be performed.
Once the fissure has been properly treated, it must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with forceful water-spray and repeat the application of NRC.

4. Application of Prime&Bond NT

![Diagram of Prime&Bond NT application]

Figure 12  Application of Prime&Bond NT in the Total-Seal technique with Dyract Seal

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 1 drop of Prime&Bond NT to the fissure.
3. Leave undisturbed for 20 seconds.
4. Remove solvent by blowing gently with air from a dental syringe for at least 5 seconds.
5. Immediately place Dyract Seal.

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2 DENTSPLY Applicator Dish and Applicator Tips are available from your dental dealer.
3 DENTSPLY Applicator Dish and Applicator Tips are available from your dental dealer.
5. Application of Dyract Seal Compomer Pit and Fissure Sealant

Dyract® Seal

Application of Dyract® Seal

Dispense Dyract® Seal directly into the fissure
Light cure
Discard needle immediately after use

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Figure 13 Application of Dyract Seal in the Total-Seal technique

1. Remove cap from the end of the syringe. To assure free flow of material from syringe, express a small amount onto pad.
2. Attach disposable needle tip to end of the syringe. **Turn tip clockwise ¼ to ½ turn to assure that it is fully seated.** Tug on tip to be sure that it is locked into the collar of the syringe.
3. Dyract Seal should flow freely with gentle pressure. Do not use excessive force. If more than gentle pressure is required, remove from patient field and check for obstruction.
4. Dispense Dyract Seal directly into the fissure.
5. Discard needle immediately after use. Replace original cap. Do not store syringe with dispensing tip in place. Store only with original cap.
6. It is recommended to pull back slightly on the syringe plunger after use to prevent excessive flow of material.

6. Curing

Cure for at least 20 seconds with a dental polymerisation unit (e. g. Spectrum™, ProLite™) keeping the tip of the light guide as near as possible to the tooth without touching it.
Remove soft (oxygen-inhibited) surface layer after light-curing with cotton pellets or cotton rolls.

Retention and occlusion control

Check with an explorer for complete coverage and retention. Check with articulating paper for premature occlusal contacts and correct, if necessary, with a finishing bur.
13 References


