

DENTSPLY
DeTrey

Dyract® XTRA

THE EVIDENCE-BASED RESTORATIVE



*„For my patients
who need
eXtra care!“*

2003-06-16 (Individual Attention Only)

With the compliments of

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SCIENTIFIC COMPENDIUM



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1 Introduction

Dental composites have been developing since the early 1970's, when the first materials of this class were introduced. Until this time, fillings had been based on silver-mercury amalgams, mixtures of acid leachable glass with phosphoric acid known as "silicate cements", or unfilled polymerisable resins. Each class of material has certain strengths, but also weaknesses which provide the impetus for the development of new materials. For instance, amalgams are generally considered to be cheap, easy to use, and to have a long lifetime. However disadvantages of amalgam are toxicity of the mercury and the black colour of the filling. Silicate fillings were approximately tooth coloured and released fluoride into the tooth to help prevent a recurrence of decay. However they tended to dissolve quickly, are weak, and are essentially no longer used. Unfilled resins, introduced in the 1950's brought advantages of toughness, convenience, and aesthetics. However they were still weak, limiting their use to areas of low stress such as anterior teeth. These unfilled resins also have a high volume shrinkage, usually at least 5%. This leads in turn to formation of gaps between the filling and the tooth, and subsequent recurring decay of the tooth around and underneath the restoration. The introduction of composite materials brought improvements in surface hardness, higher physical strengths, good aesthetics, lower shrinkage, and also higher resistance to wear. In an attempt to improve the characteristics of the silicate cements, the phosphoric acid was replaced by polycarboxylic acid to give what are now known as glass-ionomers or glass polyalkenoates. These have a disadvantage of being visually rather opaque, and also very brittle. However they have advantages over composites in being easy to use with low technique sensitivity, and also releasing fluoride ions. In an attempt to combine the best properties of composites and glass-ionomers, a new class of material, the compomer, was introduced by DENTSPLY in 1993. The new material, Dyract, was an immediate success and it continues to be widely used ten years later.

To overcome the indication limitations of the first generation, DENTSPLY introduced the 2nd generation of Dyract[®] under the brand name Dyract[®] AP in 1997. Dyract AP was designed to allow its application in situations where abrasive resistance and enhanced mechanical strength are of primary importance. The improved mechanical strength of Dyract AP was achieved by optimising the monomer composition and by incorporating a sub-micron filler. The latter contributes also to the excellent polishability of Dyract AP.

The second generation, Dyract AP, brought higher strength and lower wear, and this allowed its use in limited class 1 and 2 cavities. Dyract AP has now been in the market for five years, and its excellent clinical performance is widely appreciated and acknowledged.

1.1 Project Development Objectives

The main objectives behind the development of the 3rd generation, Dyract eXtra was

- » to adjust the consistency of Dyract eXtra to that of the 1st generation of Dyract which had a slightly softer consistency than Dyract AP
- » to allow a 10 s cure for 2 mm layers of all shades using a high power halogen curing light such as DENTSPLY's Spectrum 800 lamp
- » to provide sufficient working time

1.2 Dyract eXtra Restorative Technology

1.2.1 Resin Matrix Chemistry

The Dyract eXtra resin matrix comprises a mixture of several well known and well tried methacrylate resins including ethoxylated Bisphenol-A-dimethacrylate, urethane resin, triethylene glycol dimethacrylate (TEGDMA), and trimethylolpropane trimethacrylate (TMPTMA). TCB resin is also included, and this serves to give the resin mixture a high cohesion, reduces its hydrophobicity, and increases the rate of fluoride release. These help to give Dyract eXtra its combination of excellent properties. The matrix also contains a combination of the photoinitiator camphoroquinone and the accelerator dimethylaminobenzoic acid ethyl ester, and the concentrations of these have been carefully optimised to provide a long clinical working time (reduced sensitivity to ambient light) as well as high depth of cure.

1.2.2 Fillers

The filler component of Dyract eXtra is the same well-tried and tested strontium fluoride glass that is used in both Dyract and Dyract AP. The glass has a mean particle size of 0.8 μm , meaning that a high polish is easily obtained. The particle size distribution, as measured by a Malvern laser Mastersizer, is shown below in Figure 1.

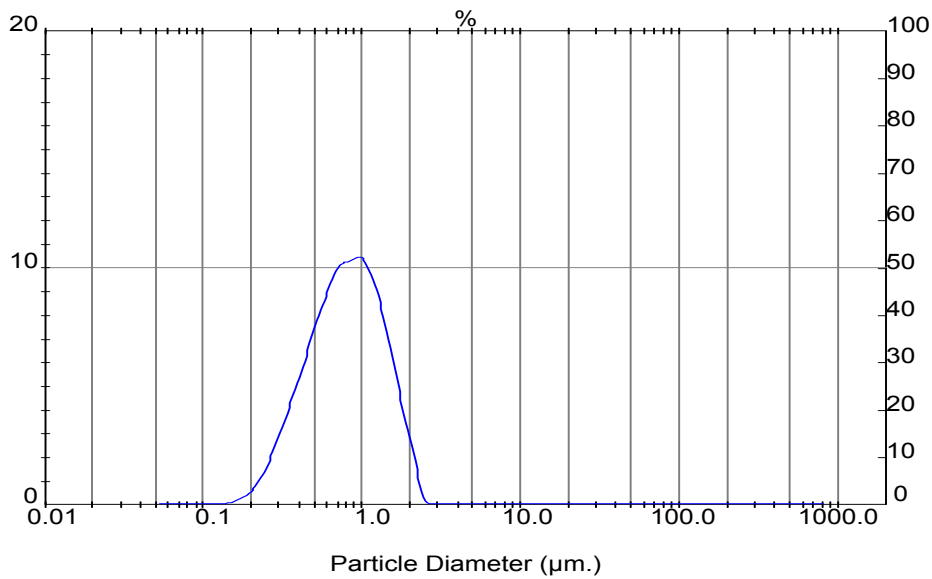


Figure 1 Particle Size Distribution of the Dyract eXtra Filler

1.2.3 Compomer Chemistry

The name compomer was derived by combining parts of the two words COMPOsite and ionoMER to suggest the combination of composite and glass-ionomer technology that characterises Dyract. The essential features of each class of material are summarised in the table below.

| Material class | 1st feature | 2nd feature | 3rd feature |
|-----------------------|--|-------------------------------|-------------------------------|
| Glass ionomer | <u>reactive</u> fluoride releasing glass | polyacid | water |
| Composite | <u>non-reactive</u> glass | monomer | |
| Compomer | <u>reactive</u> fluoride releasing glass | acidic monomer | water from the environment |

Table 1 Essential Features

A compomer is therefore a cross between a glass-ionomer and composite in that it contains a reactive fluoride glass and an acid as well as a monomer. A major and important difference between glass-ionomers and compomers is that in the glass-ionomer the acid is present as a polymer, while in the compomer the acid is present as a monomer and the polymer is formed by polymerisation of the monomers in the restorative during curing. A further difference is that the compomer contains no water, and reaction between the glass and the acidic monomer only takes place as the compomer takes up water from the environment. A misunderstanding about compomers arose early on because some people expected Dyract to have principally glass-ionomer like properties. However, inspection of the above table shows that this cannot be the case, and in fact the glass ionomer properties develop only slowly AFTER the material has first been used and cured like a composite.

2 Product Description

Dyract eXtra is a visible-light cured, radiopaque, compomer restorative material designed for use in all classes of restoration. It is to be used with a self-etch adhesive system such as Xeno[®] III or a total-etch adhesive like Prime&Bond[®] NT. The composite is packaged in pre-dosed Compules[®] Tips, and is available in ten shades.

Dyract eXtra may be cured in layers of 2 mm, and each layer should be cured for 10 seconds using a high power halogen curing light such as DENTSPLY's Spectrum 800 lamp. Physical properties of Dyract eXtra improve upon those of Dyract AP as well as those of many of the most widely used composites.

2.1 Indications for Use

Dyract eXtra restorative is indicated for use as a direct restorative for all cavity classes.

3 Physical Properties of Dyract eXtra

3.1 Materials Evaluated

The following restorative materials were selected in our *in-vitro* competitive property evaluations:

| Material Designation | Product | Batch | Manufacturer |
|----------------------|---------------|---------|--------------|
| Dyract AP | Dyract AP | various | DENTSPLY |
| Z250 | Filtek™ Z250 | OEF | 3M™ |
| Tetric Ceram | Tetric® Ceram | C16365 | Vivadent |

Table 2 Restorative Materials selected for *in-vitro* Competitive Property Evaluation

3.2 Yield and Compressive Strengths

3.2.1 Yield Strength

Clinical Relevance: The yield strength of a dental restorative is especially important, because this indicates the force that the material can withstand before damage occurs. The yield and compressive strengths are given together because they are measured in the same test.

The yield strength of a material is defined as the load at which the stress-strain relationship of the material becomes non-linear. Because the non-linear behaviour is due to plastic flow or crack formation within the material, the yield strength is also the highest load to which a material can be subjected before a permanent change in shape and structural damage occurs. This is a very important property for dental materials, since neither flow nor crack formation are desirable in a filling material, and it is important to know the load at which these

start, rather than when they catastrophically end as measured by the compressive strength. It is therefore clear that the yield strength of a material should be higher than the loads applied during use, and that the compressive strength is only of secondary importance.

From Figure 2, the yield strength of Dyract eXtra is 28% higher than that of Tetric Ceram, but there is no significant difference to the yield strengths of Filtec Z250 or Dyract AP.

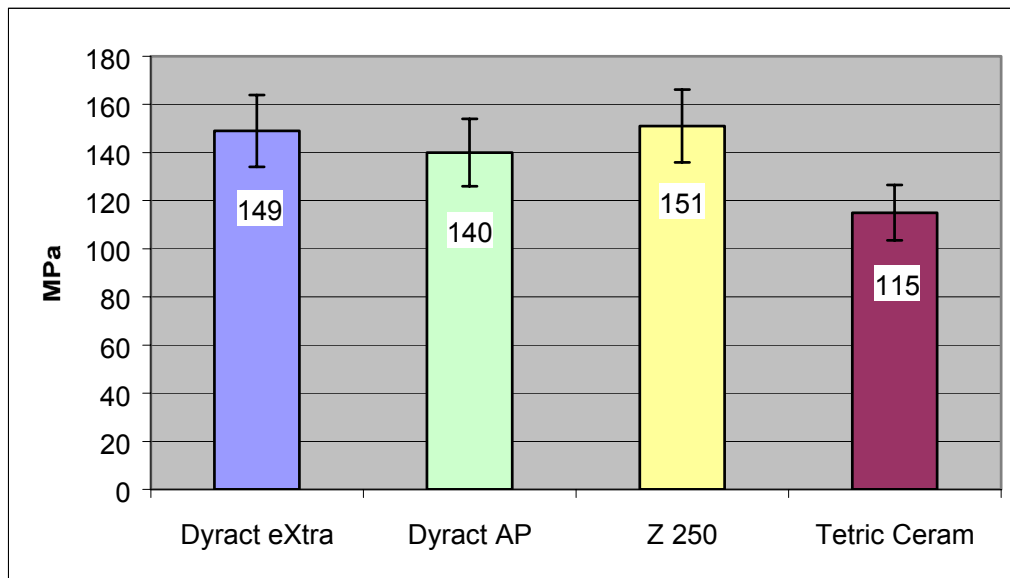


Figure 2 Yield Strengths

3.2.2 Compressive Strength

Clinical Relevance: The clinical relevance of the compressive strength is debated and values can be misleading if no account is taken of material flow.

The compressive strength of a material is the compressive load at which the material catastrophically fails. It has long been recognised that dental composites do not fail clinically in compression mode¹ (see for example Brosh T, Ganor Y, Belov I, Pilo R, Dent Mater. 1999 May;15(3):174-9), and the compressive strength test is not part of the ISO 4049 specification for composites. However the compressive strength measurement is often used as an easy control to check whether the glass filler is correctly silanated, and whether the paste is uniform and free from air bubbles or other imperfections. The mean compressive strength of different batches of Dyract eXtra has been found to vary between about 320 MPa and 340 MPa, a variation of about 6%.

Compressive strengths for various dental composites vary between about 250 MPa and 400 MPa (not taking account of material flow) and that of Dyract eXtra comes within this range.

The diameter of a composite compressive strength specimen increases during the test, but this is normally ignored. Values calculated using the initial sample diameter are:

| | | |
|--------------|--------------|-----------|
| Dyract eXtra | 339 ± 20 MPa | COV=6% |
| Dyract AP | 326 ± 15 MPa | COV=3.6 |
| Tetric Ceram | 360 ± 15 MPa | COV=4.2% |
| Filtek Z250 | 380 ± 45 MPa | COV=11.8% |

It should be emphasised again however, that these compressive strength values serve only to check whether the strength of a particular batch of a material comes in the normal range for that material. Because no account is taken of material flow, values should not be compared between materials.

3.3 Flexural Strength and Modulus

3.3.1 Flexural Strength

Clinical Relevance: The flexural strength of a dental material is an important property since materials may be used in thin layers or in poorly supported edges where flexural forces occur.

The flexural strength was measured according to ISO 4049 using samples nominally 2 mm square and 25 mm long. However due to the need to remove excess material by sanding, scratches and malformations are introduced which can lead to false values and high variations. Therefore the flexural strength was also measured according to a literature technique in which the samples are formed in 3 mm diameter glass tubes ². In this case cylindrical samples free of any defects are produced, and the values found by this method are therefore slightly higher with lower variation than those found by the ISO method.

However as shown in Figure 3, with neither method is there a statistically significant difference between the flexural strengths of Dyract eXtra, Dyract AP, and Tetric Ceram, while the flexural strength of Z250 is perhaps marginally higher. However all values are in the normal range expected for dental composite materials, and all materials easily pass the ISO limit of 80 MPa.

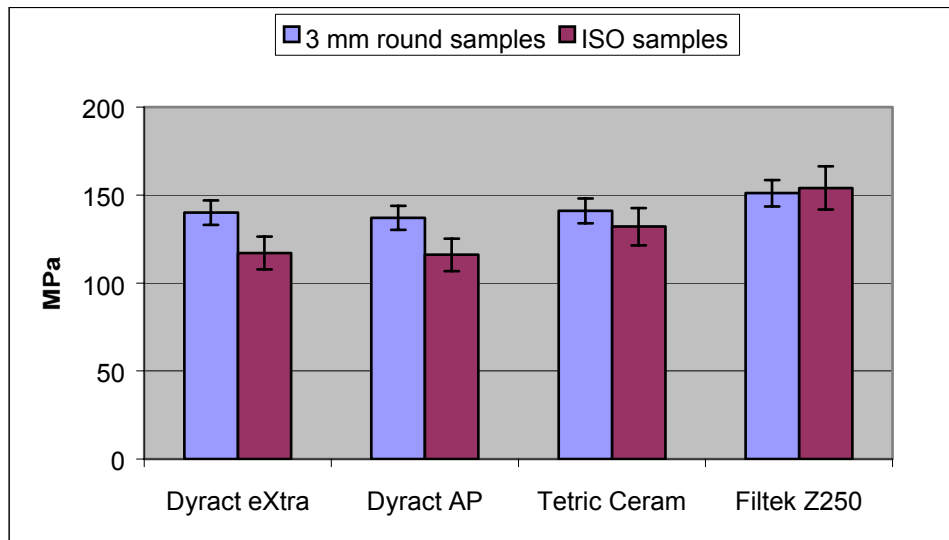


Figure 3 Flexural Strengths

3.3.2 Flexural Modulus

Clinical Relevance: Materials with too high a flexural modulus tend to be brittle, whereas those with too low a modulus are too flexible.

The flexural modulus, also known as Young's modulus, is a measure of the elasticity of a material. It is an important measurement because a dental filling material should neither be too elastic nor too rigid, and experience has shown that filling materials with a flexural modulus in the range 6000 to 12000 MPa perform satisfactorily. A flexural modulus over about 15000 MPa on the other hand leads to materials which are too brittle.

The values below were determined in DENTSPLY Konstanz.

| Material | Elastic Modulus MPa | Standard deviation MPa | Coefficient of variation % |
|-----------------|--------------------------------|-----------------------------------|---------------------------------------|
| Dyract eXtra | 7676 | 118 MPa | 1.5 |
| Dyract AP | 7094 | 300 MPa | 4.2 |
| Tetric Ceram | 9067 | 517 MPa | 5.7 |
| Filtek Z250 | 10308 | 254 MPa | 2.4 |

Table 3 Flexural Modulus

All of the above materials therefore have a flexural modulus in the useful and acceptable range.

3.4 Resilience Modulus

Clinical Relevance: The resilience modulus of a material is a measure of the amount of energy that the material can absorb before its elastic limit is exceeded and damage occurs (see for example “The Science of Dental Materials” by Skinner and Phillips). The resilience modulus should be as high as possible.

Perhaps the most useful aspects of the yield strength and elastic modulus are that they allow the resilience modulus to be calculated using the formula below.

Resilience modulus = (Yield strength)² / (2 x Elastic modulus)

Using the values given in the preceding pages, the resilience modulus values below are obtained for each material.

| Material | Resilience Modulus |
|-----------------|---------------------------|
| Dyract eXtra | 1.43 |
| Dyract AP | 1.38 |
| Tetric Ceram | 0.73 |
| Z250 | 1.11 |

Table 4 Resilience Modulus

The coefficients of variation for the resilience can be calculated from those of the yield strength and elastic modulus. With the assumption that these measurements are independent and that any errors in the measurements are random, a mean overall coefficient of variation of about 8% is obtained.

The resilience modulus of Dyract eXtra is therefore significantly higher than that of either Tetric Ceram or Z250, and this is expected to lead to longer clinical lifetimes.

3.5 Polymerisation Shrinkage

Investigators: Watts, University of Manchester

Clinical Relevance: Excessive post-cure polymerisation shrinkage of a restorative material contributes to the marginal microleakage of a restoration, and also to stress on the tooth cusps. Both of these can lead to post-operative sensitivity, and in extreme cases build-up of stress can lead to fracture of the tooth.

The polymerisation shrinkage of dental composite materials is easily measured and several methods are employed³⁻⁸. The shrinkage of Dyract eXtra was measured by Watts who used the bonded disc method developed in Manchester, as well as at DENTSPLY DeTrey using a method based on the Archimedes principal.

| | Watts, Manchester | DENTSPLY DeTrey | Literature values⁸ |
|--------------|--------------------------|------------------------|--------------------------------------|
| Dyract eXtra | 2.48 (0.06) % | 2.65 (0.05) % | |
| Dyract AP | | 2.79 (0.08) % | |
| Tetric Ceram | 2.66 (0.2) % | 2.75 (0.05) % | 2.9 % |
| Filtek Z250 | | 2.00 (0.05) % | 2.2 % |

Table 5 Shrinkage Values

For the literature values quoted, a quite different method involving a laser interferometer was used (E. A. Fogleman et al., Dental Materials 18 (2002) 324-330⁸). A shrinkage around 2.5 to 3.5% is common for restoratives with the normal filler load of about 50% by volume, and the above materials are not exceptional in this respect. There is very close agreement between the values measured in DENTSPLY DeTrey using the Archimedes method and those measured externally, indicating that the values are reliable and correct.

3.6 Expansion in Water

Clinical Relevance: Although a small degree of expansion can be useful in that it helps provide polymerisation stress relaxation, too great an expansion can lead to an outwards force on the tooth cusps with concomitant post-operative pain.

It is well known that composites shrink on curing but perhaps less well known that they also show varying degrees of expansion due to absorption of water^{7,8}. The ISO 4049 7.12 specification refers to a “water uptake” measurement, but the direct measurement of expansion is probably a more relevant and useful test.

The expansion values below were measured in DENTSPLY DeTrey using a laser micrometer to measure the diameter of a disc in a slight modification of the method described by Martin and Jedynakiewicz⁹. Discs of the material 25 mm diameter and 1 mm thick were made and a small hole was bored approximately in the centre to allow the disc to be held in the micrometer. The discs were then stored dry for 24 hours to allow post cure to occur. The diameters of the discs were next measured at one hundred points around the circumference using the laser micrometer fitted with a stepping motor to rotate the disc in known increments.

Finally the discs were stored in water at 37°C and the diameters of the discs were re-measured at suitable intervals until no further change in diameter took place. The linear expansion was then calculated and converted to volume expansion.



Figure 4 An Expansion Disc being measured with a Laser Micrometer

| Material | Volume expansion % in water |
|-----------------|------------------------------------|
| Dyract eXtra | 1.20 (0.05) |
| Tetric Ceram | 1.00 (0.05) |
| Filtek Z250 | 0.99 (0.05) |

Table 6 Volume Expansion

3.7 Depth of Cure

Clinical Relevance: The layer technique is now commonly used in the filling of cavities, and an incremental layer thickness of 2 mm has become the standard recommendation.

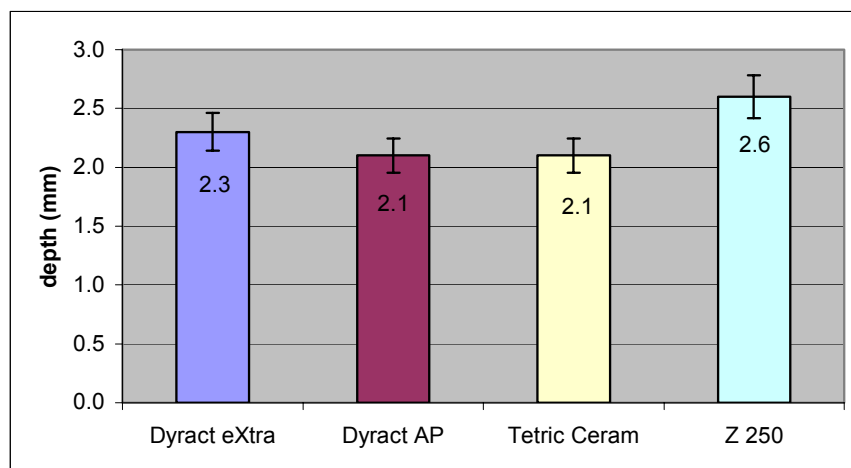


Figure 5 Depth of Cure (ISO 4049) with 800 mW/cm² /10 seconds cure time

The A2 shades of all three filling materials above may be cured to at least a depth of 2 mm after 10 seconds curing time, and therefore fulfil the requirements in this respect of a modern composite restorative. With Dyract eXtra the improvement in the depth of cure was taken a step further and ALL normal shades may be cured to a depth of at least 2 mm with 10 seconds cure, using a lamp with an output over 500 mW/cm². The two opaque shades need a 20 seconds cure time. The cure times of Dyract eXtra are compared to those of Dyract AP Figure 6 below, which shows the vast improvements made.

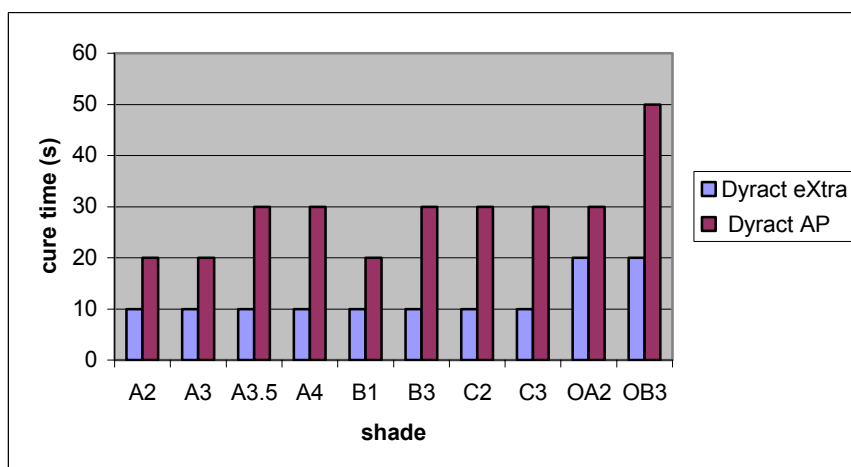


Figure 6 Cure Times of Dyract etXtra / Dyract AP

3.8 Wear Resistance

Investigator: DeGee, ACTA, Amsterdam

Clinical Relevance: A low wear rate means that enamel-restorative margins and contact points remain at the correct level, and that gross loss of material does not occur. It goes without saying that a low wear rate is a prerequisite for a modern composite.

The wear rate of Dyract eXtra has been measured at ACTA using the method developed there¹⁰, and also at DENTSPLY DeTrey using a slight variation of the method developed by Leinfelder.

3.8.1 The ACTA Wear Test

With the ACTA test, materials are set in a wheel which is rotated against an antagonist wheel at a speed of one revolution per second in the presence of a slurry of ground rice and poppy seeds. The pressure between the two wheels is adjusted to 15 Newtons, and the slip rate between the wheel containing the test material and the antagonist wheel is set to 15%. In this way, the organic material is drawn between the two wheels and acts as an abrasive. The material loss is measured with a profilometer at intervals of 200,000 cycles, and at time intervals of 1 day to 1 month after specimen preparation (i.e. polymerisation).

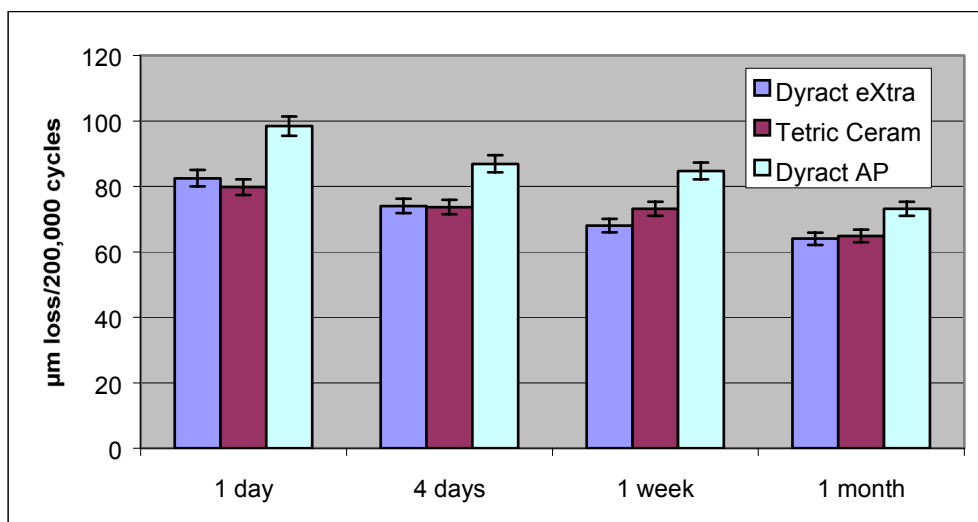


Figure 7 Wear measured at ACTA

As seen from Figure 7, the wear rate for the compomer Dyract eXtra is not significantly different to that of Tetric Ceram. As also seen, the wear rate of Dyract eXtra has been further reduced compared to the second generation compomer Dyract AP.

3.8.2 Leinfelder Wear Test

A slight modification of the wear test developed by Leinfelder¹¹ was used in DENTSPLY De-Trey to assess the wear rate of Dyract eXtra and to compare it with that of Tetric Ceram and Filtek Z250. In the test, the composite materials are first set in a hard silicon putty. After ageing the samples in water for one week, they are placed under steel pistons in a slurry of polymer beads. The pistons are driven up and down with a twisting action, so that the overall effect is an initial percussion followed by a grinding action between the test material and the steel piston, with the beads acting as food substitute. The force applied by the piston is accurately regulated to between 115 N and 120 N, and 200000 cycles are normally carried out. Several methods can be used to assess the resulting wear, and the results given below are the average diameter of the depression produced in the specimen after 200000 cycles.

| Material | Diameter of wear depression |
|-----------------|------------------------------------|
| Dyract eXtra | 1.19 (0.03) mm |
| Dyract AP | 1.30 (0.04) mm |
| Tetric Ceram | 1.21 (0.05) mm |
| Filtek Z250 | 0.98 (0.05) mm |

Table 7 Diameter of Wear Depression

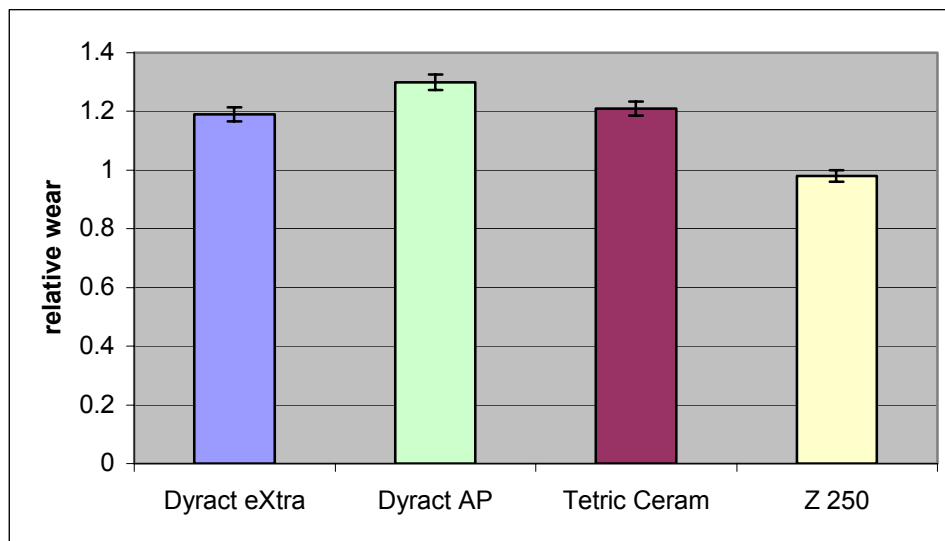


Figure 8 Relative Wear Rates from the Leinfelder Test

The Leinfelder test carried out in DENTSPLY DeTrey therefore shows that the wear rate of Dyract eXtra is not significantly different to that of Tetric Ceram and is also lower than that of Dyract AP, thus confirming the results from ACTA. The wear rate of Z250 is, however, still slightly lower than that of either Dyract eXtra or Tetric Ceram.

3.9 Surface Hardness

Clinical Relevance: Although the exact clinical meaning of surface hardness is difficult to define, it is clear that a hard surface will suffer less abrasive wear than a soft surface, and that other things being equal, a composite with a hard surface is therefore better than a composite with a soft surface.

Several methods are used for measuring the surface hardness of a material, and each has advantages in some circumstances. Perhaps the simplest method is known as the Barcol hardness, which involves pushing a needle under spring loading into the material to be tested. The hardness of the material is proportional to the depth of penetration of the needle and can be read directly from a dial. Although this method is very quick, the readings can be variable for composite materials if the size of the point is similar to or smaller than that of the filler particles. This problem is largely overcome by the Vickers hardness method in which a diamond pyramid is pushed into the surface of the test material under a known load. The size of the resulting depression is measured and is converted to hardness values with the use of tables. The Vickers hardness method was therefore used in DENTSPLY Konstanz.

The hardness values given below were measured with a load of five kilograms (49.03 Newtons) and by convention are referred to as the “HV5 value”. The error in each case is in the order of 1 unit.

| Material | Vickers HV5 value |
|-----------------|--------------------------|
| Dyract eXtra | 64.1 |
| Dyract AP | 56.5 |
| Tetric Ceram | 62.0 |
| Filtek Z250 | 95.0 |

Table 8 Vickers HV5 Value

The Vickers hardness of Dyract eXtra is therefore in the same region as that of Tetric Ceram, but both have a lower hardness than Filtek Z250. The surface hardness of Dyract eXtra is increased by about 14% compared to that of Dyract AP.

3.10 Polishability

Investigator: Watts, University of Manchester, England

Clinical Relevance: The surface roughness of a restoration is important since it affects not only the appearance of the restoration but is also related to how easily plaque adheres to the surface. In addition, and very importantly, a restoration with insufficient surface smoothness can feel rough to the tongue with discomfort to the patient.

Samples of each test material were first hardened for 40 seconds at 600 mW/cm² in Teflon moulds. The surface of some specimens were then lightly ground with an extra fine burr (Hi-Di 651XF) before being polished using the Enhance system, while other samples were left untreated. After storage in water for twenty four hours, the surface roughness of each specimen was measured using a profilometer. Each specimen was then subjected to 14000 strokes using a toothbrush and toothpaste before the surface roughness was re-measured. Results are tabulated below, where R_a is the average roughness in μm , and R_{max} is the maximum roughness measured.

| Material | R_a before finishing with a burr | R_a after finishing with a burr | R_a after finishing with a burr and toothbrush abrasion | R_{max} after finishing with a burr and toothbrush abrasion |
|--------------|------------------------------------|-----------------------------------|---|---|
| Dyract eXtra | 0.09 (0.02) | 0.06 (0.02) | 0.13 (0.05) | 1.53 (0.94) |
| Dyract AP | 0.11 (0.03) | 0.06 (0.01) | 0.13 (0.04) | 2.70 (0.97) |
| Tetric Ceram | 0.87 (0.02) | 0.14 (0.03) | 0.21 (0.09) | 4.20 (2.80) |

Table 9 R_a and R_{max} Roughness Values

From Table 9 it is clear that both Dyract eXtra and Dyract AP have much smoother surfaces than Tetric Ceram under all treatment conditions. Although Dyract eXtra and Dyract AP have a similar average smoothness after finishing, the effect of the tougher Dyract eXtra resin matrix becomes evident after toothbrush abrasion. After 14000 brush strokes, the maximum roughness of Dyract eXtra is still only 1.53 μm while that of Dyract AP is 2.7 μm . Under the same conditions, the maximum roughness of Tetric Ceram increased to 4.2 μm .

3.11 Radiopacity

Clinical Relevance: The radiopacity of a restorative has to exceed that of the enamel and dentine in order to be visible with standard X-ray procedures. In general, the higher the radiopacity of a restorative, the more easily discernible it is.

The radiopacity of Dyract eXtra and the competitive materials was measured relative to aluminium according to ISO 4049 section 7.14. The transmission of each region of the exposed and developed film was measured at 500 nm using a visible spectrometer, and the radiopacity of each material was calculated from the resulting calibration line.

The radiopacity of Dyract eXtra is equivalent to 3 mm of Al, which is similar to that of Tetric Ceram, and is sufficient to ensure visibility in X-rays. In contrast, the radiopacity of Z250 at just over 2 mm is very similar to that of enamel.

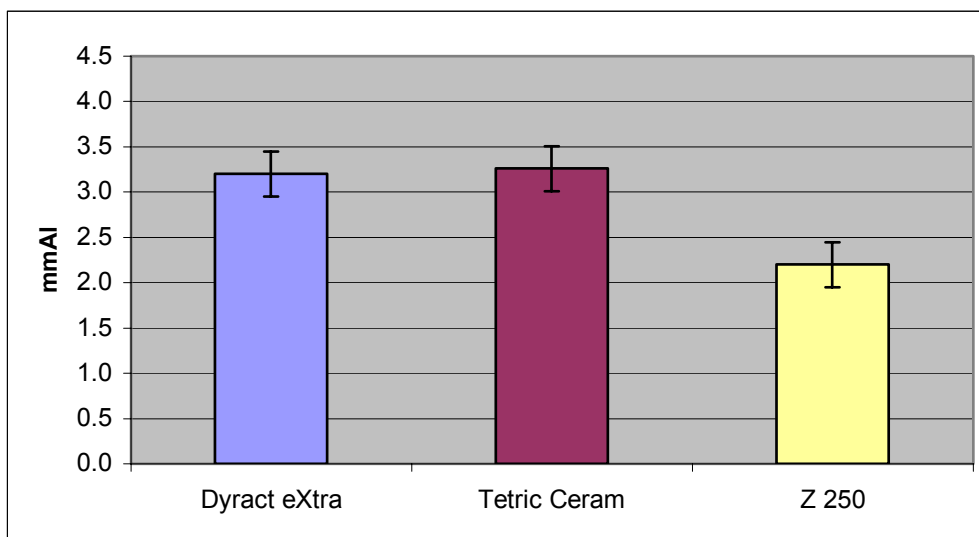


Figure 9 Radiopacity

3.12 Fluoride Release

Clinical Relevance: Long term fluoride ion release is desirable because of the potential for inhibition of bacterial growth, absorption into tooth substance, and reduction or prevention of recurrent caries.

The fluoride release from Dyract eXtra and competitive materials was measured using discs of material 25 mm in diameter and 1 mm thick. The discs were stored in 25 ml of deionised water at 37°C which was withdrawn and replaced weekly. The fluoride content of the water was then measured in the presence of TISAB IV buffer using a selective fluoride ion electrode.

The Figure 10 shows that up to at least 20 weeks, Dyract eXtra has an almost linear release rate of about 0.8 µg fluoride/cm² per week. This compares with 0.3 fluoride/cm² per week for Tetric Ceram, and 0.06 fluoride/cm² per week for Z250.

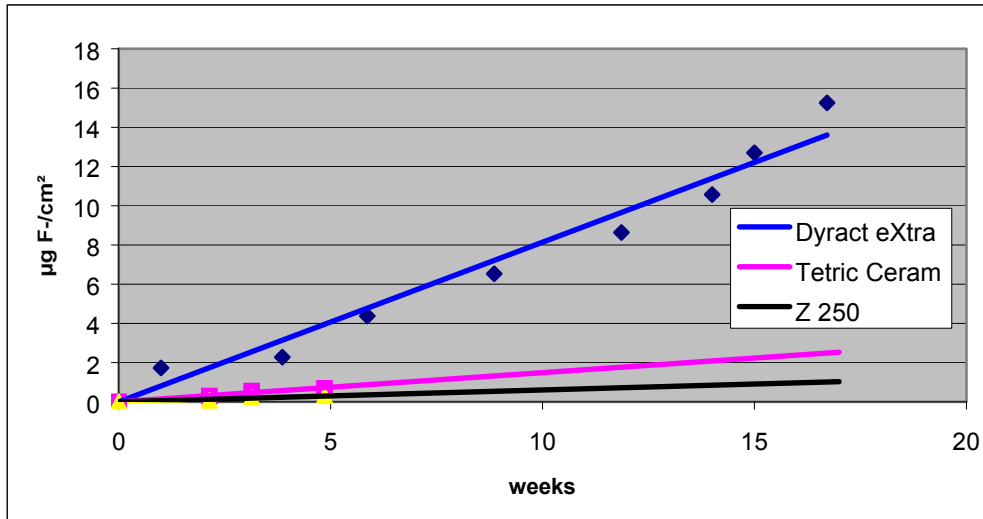


Figure 10 Fluoride Release

3.13 Adhesion

Clinical Relevance: Strong adhesion to tooth substrate is needed to prevent microleakage, and in today's climate of conservative dentistry, to hold the restorative in place in the absence of mechanical interlocking.

Adhesion samples were prepared using Dyract eXtra and Xeno III or Prime&Bond NT following the instructions in the respective DFUs. After preparation, the samples were stored overnight in water at 37°C before being thermocycled 1800 times between 5 and 55°C.

| | Xeno III | Prime&Bond NT |
|--------|----------------|----------------|
| Dentin | 16.4 (1.3) MPa | 15.6 (2.3) MPa |
| Enamel | 19.8 (2.0) MPa | 26.6 (3.6) MPa |

Table 10 Adhesion of Dyract eXtra

The adhesion to both dentin and enamel is satisfactory using both adhesive systems.

3.14 Working Time

The lifetime of a light cured dental filling material refers to the time that the material is likely to remain workable under the lighting conditions in a dental surgery. A standard brightness of 10000 lux was initially chosen for the method developed for ISO 4049, though this has since been reduced to 8000 lux. Materials in this report were tested under the harsher conditions of 10000 lux.

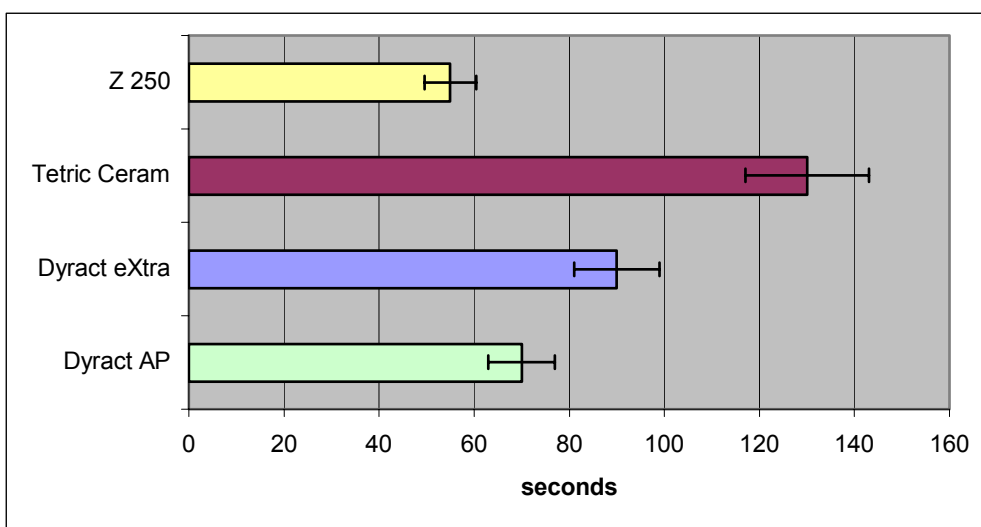


Figure 11 Working Time at 10000 lux

While a lifetime sufficiently long to allow the dentist time to place and form the filling is needed, an excessively long lifetime serves no useful purpose. The ISO 4049 specifies 60 seconds at 8000 lux as the minimum permissible lifetime, although a slightly longer lifetime is desirable to ensure that a sufficiently long working time is also available under stronger lighting conditions. Both Dyract eXtra and Tetric Ceram therefore have a sufficiently long lifetime, while that of Filtek Z250 is rather short. The working time of Dyract eXtra is also clearly improved over that of Dyract AP, giving about 25 seconds extra working time with these batches.

The improvement in the working time of Dyract eXtra over that of Dyract AP is further illustrated in the next graph. Note that Dyract eXtra has an increased working time AS WELL AS an increased depth of cure as given in Section 3.7, even though these two objectives normally have directly opposing requirements. This was made possible only by the use of specialised optimisation techniques. There is naturally some batch to batch variation, and the figures given should be regarded as a range rather than as fixed numbers.

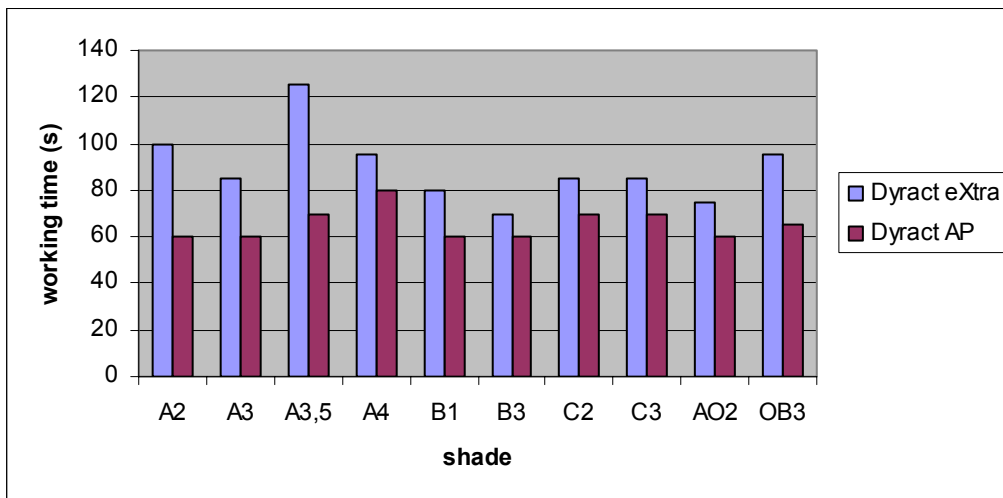


Figure 12 Working time of Dyract eXtra and Dyract AP with 10000 lux ambient light

3.15 Flexural Fatigue Limit

Investigator: Braem, Antwerp

Clinical Relevance: Many tests, such as compressive or flexural strength, involve simply increasing a load on a test specimen until failure occurs. However the high forces often reached in the laboratory rarely occur clinically, and it is more relevant to know how the material behaves under repeated loads that are less than those needed to produce instant catastrophic failure. The fatigue limit is such a test, and is a measure of a materials resistance to fracture through repeated stress at levels that do not lead to immediate fracture.

Method: The fatigue resistance of a material can essentially be determined in two modes. In the first mode, samples of the material are repeatedly subjected to a fixed load until failure of the specimen occurs. In order to obtain statistically significant results however a large number of specimens is required, and depending on the force chosen and the fatigue resistance of the material it is possible that a large number of cycles will also be needed. In the second method, the number of load cycles for each experimental series is fixed, and the load is increased in successive experiments until 50% of the specimens under test fail within the chosen number of cycles. This second method was used in the present test, and the specimens were subjected to 10,000 cycles at various loads.

Test Details: The fatigue specimens comprised beams of material 1.2 mm deep, 5 mm wide and 40 mm long. These were kept in water at 37°C for 30 ± 2 days before being tested and were also kept wet at 37°C during the test. For testing, the specimens were clamped between parallel supports 30 mm apart, and a bi-directional loading force was supplied by electromagnets attached to the centre of the beam. The load was applied at a frequency of 2 Hz until breakage occurred or 10,000 load cycles had been completed. If less than 50% of the specimens broke during this time, the test was repeated with the load increased by 4%.

| Material | Flexural fatigue limit MPa |
|-----------------|---------------------------------------|
| Dyract eXtra | 70.8 (11.7) |
| Dyract AP | 67.2 (5.1) |
| Tetric Ceram | 64.6 (3.7) |
| Silux Plus | 54.6 (3.4) |

Table 11 Results Flexural Fatigue Limit

The results above show that the flexural fatigue limit for Dyract eXtra is at least as high as that of Dyract AP and Tetric Ceram. The higher standard deviation for Dyract eXtra is due to air which was accidentally incorporated into the Dyract eXtra syringes during hand packing. In the absence of air bubbles, an even higher flexural fatigue limit can be expected.

3.16 Microleakage in Class V cavities

Investigator: Rosales, University of Granada, Spain

Clinical Relevance: Tight sealing of the restorative with the cavity margins is important, since leakage can lead to ingress of destructive fluids and bacteria, which in turn lead to secondary caries. The ability of Dyract eXtra to form a tight seal in both occlusal and gingival margins was investigated by Rosales using four different dental adhesives. The desired criterion was that the margins should not be worse than were obtained with Esthet-X, which was therefore used as the reference material.

The adhesive systems used are given in the table below. Forty teeth were prepared, each with two cavities covering both gingival and occlusal areas. On each tooth, one cavity was then restored with Dyract eXtra, and the other with Esthet-X.

| Adhesive | Manufacturer | batch |
|-------------------|--------------|-----------|
| Xeno III | DENTSPLY | 359-004 |
| Prompt L_Pop | Espe | L6 121222 |
| Clearfill SE Bond | Kuraray | 00236A |
| Prime&Bond NT | DENTSPLY | 0112142 |

Table 12 Adhesive Systems

Method

All materials were used according to the respective directions for use, and phosphoric acid etching was used only with Prime&Bond NT. In each tooth, two cavities were prepared each 3x2x2 mm deep, and with a 1 mm 45° bevel. Diamond coated #330 burs were used under water cooling to prepare the cavities, which were filled with restorative in two increments. After storage at 37°C in water for 24 hours, the filled teeth were thermocycled 250 times between 5 and 55°C with a dwell time in each bath of 30 seconds. Leakage was made visible by storage of the thermocycled teeth in 0.5% basic fuchsin for 24 hours, and the teeth were then sectioned. The aim is always to have perfect margins with no leakage at all, since once even slight leakage has occurred, the margin becomes clinically visible. Therefore although the specimens were carefully graded for the degree of leakage, the following analysis considers only those specimens which showed no leakage, or put the other way around, 100% perfect margins.

Analysis

| Filling material | Cavity wall | Adhesive | | | | mean score for cavity type | mean score for restorative |
|------------------|-------------------------|----------|--------------|------------------|---------------|----------------------------|----------------------------|
| | | Xeno III | Prompt L-Pop | Clearfil SE Bond | Prime&Bond NT | | |
| Esthet-X | Occlusal | 6 | 6 | 8 | 10 | 7.5 | 11.5 |
| | Gingival | 7 | 0 | 6 | 3 | 4.0 | |
| K-0134 | Occlusal | 8 | 5 | 9 | 10 | 8.0 | 13.25 |
| | Gingival | 7 | 2 | 7 | 5 | 5.25 | |
| | mean score for adhesive | 7.0 | 3.25 | 7.5 | 7.0 | | |

Table 13 Number of restorations out of 10 showing 100% perfect margins after thermo-cycling

An Analysis of Variance (ANOVA) shows that the adhesive used and cavity type had significant effects on the number of restorations with perfect margins ($p < 0.05$). However although Dyract eXtra tendentially gave a higher number of perfect margins than did EsthetX, this difference was not statistically significant. The aim that Dyract eXtra performs at least as well as EsthetX with regard to microleakage has therefore been achieved.

ANOVA results

| Effect | p-value |
|------------------|---------|
| Adhesive | 0.0127 |
| cavity type | 0.0029 |
| restorative type | 0.2999 |

This ranking order can also be seen by looking at the mean scores in Table 13. It is also easily seen and interesting to note that the three adhesive systems Xeno III, Clearfil SE and Prime&Bond NT produced equivalent results, while Prompt L-Pop produced significantly worse results than the other three ($p < 0.05$).

4 Summary and Conclusions

The original Dyract was introduced in 1993 and brought with it many interesting new properties and application possibilities. That the original Dyract is still widely used ten years after its introduction is proof of the confidence practitioners have in the product. The original Dyract has found particular use in children's teeth due to the easy handling, fluoride release, and the wear rate which closely matches that of enamel in children's teeth.

Naturally a material cannot be perfect in its first generation, and DENTSPLY continued to work to improve Dyract. The second generation, Dyract AP, brought higher strength and lower wear, and this allowed its use in limited class 1 and 2 cavities. Dyract AP has now been in the market for five years, and its excellent clinical performance is widely appreciated and acknowledged.

In spite of this wide use and the improvements with Dyract AP, some criticism was still heard based mainly on a comparison of handling properties with those of the first Dyract generation.

DENTSPLY listened and continued to work on improvements. In conclusion Dyract eXtra has

- » The same creamy consistency as original Dyract (ease of handling)
- » Fast curing combined with sufficient working time
- » Ease of polishability as with Dyract AP
- » Improved wear and tooth brush abrasion resistance compared to Dyract AP
- » The physical properties of a good composite.

5 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 eXtra shade guide provided which contains samples of original Dyract eXtra 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 eXtra 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 prophylaxis-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 the adhesive.

5. Conditioning and application of adhesive

Prior to the application of Dyract eXtra the cavity has to be conditioned and/or treated with XENO[®] III - Single Step Self-Etching Dental Adhesive or Prime&Bond NT - Nano-Technology Dental Adhesive. For application see Figure 13 and 14.

DENTSPLY
DETREY

Dyract[®]eXTRA and **X^en^o[®] III**

THE Evidence-Based Restorative

Preparation:

- Clean unprepared surfaces with rubber cup and cleaning paste
- Clean freshly cut surfaces with water spray
- Remove excess water
- **Do not desiccate**

Handling of bottles

Liquid A
Shake bottle two to three times. Incline. If liquid does not drop, squeeze.

Liquid B
Incline bottle; wait for approx. 2 sec. Squeeze until liquid drops.

CE 0123

Consult directions prior to use

Dosage
Dispense equal amounts of liquids A and B into the CLIXdish™ Light-Protective Dispensing Dish.

Mixing
Mix for approx. 5 sec.

Figure 13

Etch, Prime, and Bond Apply generous amounts onto cavity surfaces. Leave for at least 20 sec.

X^en^o[®] III and **Dyract[®]eXTRA**

Uniformly spread adhesive by a gentle stream of air pressure until there is no more flow.

Cure for at least 10 sec.

Six for ALL

| | |
|-------------|----------|
| B1 | ≈ A1, B2 |
| A2 | ≈ C1, D2 |
| C2 | ≈ D4 |
| A3 | ≈ D3 |
| A3.5 | ≈ B3, B4 |
| A4 | ≈ C3, C4 |

Also available:

| | |
|-----------|--------|
| B3 | ≈ O-A2 |
| C3 | ≈ O-B3 |

* For light output of at least 500mW/cm² only. 20 sec for O-A2 and O-B3.

K106053-02

Figure 14

6. Placement of Dyract eXtra

Insert Compules tip into the notched opening of the applicator gun barrel.

Dispense Dyract eXtra directly into the cavity preparation. In deep cavities, incremental placement and curing is recommended to minimise polymerisation shrinkage.

7. Curing

Cure each increment separately with a light curing unit¹ 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.

| Shade | Light Curing Time in seconds for minimum 500 mW/cm ² light output and 2mm layers |
|-------------------------------------|---|
| A2, A3, A3,5, A4, B1, B3, C2, C3 | 10 |
| O-A2, O-B3 | 20 |

8. 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. In patients with an adequate oral hygiene, the high final lustre of the restoration comes with use.

¹ Check curing light for minimum curing output of at least 500 mW/cm².

6 Summary of Clinical Studies

6.1 Clinical Investigation of the self-etching adhesive K-0139 for Class V Dyract eXtra and Esthet X restorations at the University of Liverpool

Objectives: The purpose of this investigation is to determine the safety and efficacy of Dyract eXtra applied in combination with the self-etching adhesive Xeno III for providing retention resistance to microleakage.

Design

(see Figures 15-17)

Prospective, longitudinal, controlled Clinical Investigation according to ADA Guidelines for Dentine and Enamel Adhesive Materials (2001).

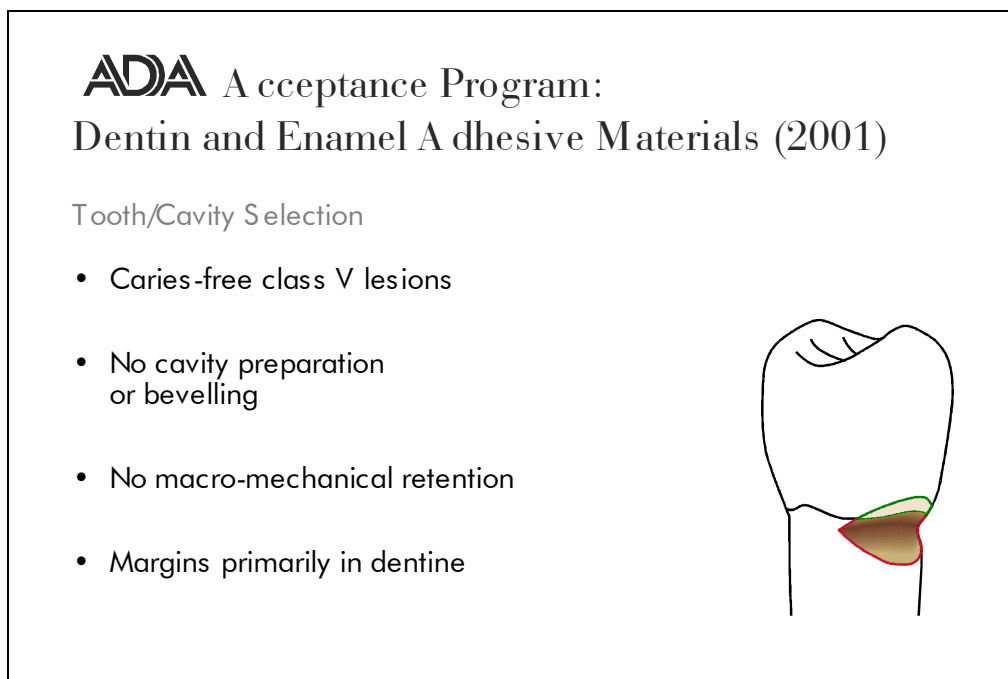


Figure 15

ADA Acceptance Program:
Dentin and Enamel Adhesive Materials (2001)

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

Figure 16

ADA Acceptance Program:
Dentin and Enamel Adhesive Materials (2001)

Acceptance Criteria

| | Retention Failure | Marginal Failure |
|-----------|-------------------|------------------|
| Baseline | 0% Charlie | 0% Charlie |
| 6 months | <5% Charlie | <5% Charlie |
| 18 months | <10% Charlie | <10% Charlie |

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

Figure 17

Modifications with Regard to ADA Guideline Higher number of patients and restorations. Finishing of margins. Beveling of coronal part of margins, if appropriate (cosmetics).

Investigator/s Dr. Nicolas M. Jedynakiewicz, Dr. Nicolas Martin

Number of Patients 40 at recalls.

| | |
|--|---|
| Number of Restorations | 40 at recalls |
| Acid Conditioner/s | None as a self conditioning adhesive is used |
| Adhesive/s | Xeno III single step self-etching dental adhesive |
| Control Material/s | Esthet X, fine particle hybrid composite |
| Method of Evaluation | Clinical examination, rating according to Cvar and Ryge |
| Recall Periods (those reported on are printed in bold) | Baseline, 3- , 6- and 18 months |
| Success Criteria | According to ADA Acceptance Criteria, with the understanding that for the 3-month recall the incidence of failures may not exceed 2.5%. |
| Summary of 3-Month Results (see Table 14) | In the 3-Month Report, 33 restorations with K-0134 and 33 restorations with the control (Esthet-X) were reviewed. All restorations were in place and retained. No patient reported post-operative hypersensitivity. All restorations are recorded as Alpha in all Ryge criteria investigated. |

| Clinical Investigation Class V Liverpool 3-Month Data | |
|--|--------------------------|
| Ryge (USPHS) Criteria | Alpha Ratings (%) |
| • Retention | 100 |
| • Margin adaptation | 100 |
| • Margin discolouration | 100 |
| • Recurrent caries | 100 |
| • Anatomic form | 100 |
| • Surface texture | 100 |
| • Colour match | 100 |

Interim Report by N. M. Jedynakiewicz 2002-11-19 on 30 restorations in 30 patients

Dyract[®] **EXTRA**

Table 14

Conclusions by the investigators

The test restorations maintained the high standard that was recorded after placement.

There are no adverse events or negative results to report.

At three month this trial supports the use of the non compomer Dyract eXtra in combination with the self-etching adhesive Xeno III for use in the restoration of non-retentive cervical lesions.

6.2 Clinical Investigation of the restorative system K-0134 (Dyract eXtra) and Xeno III for Class I and II restorations at the University of Munich

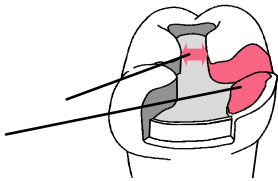
Objectives: Demonstration of the product's safety and efficacy regarding is unrestricted use in posterior teeth for all Class I and II restorations (an alternative for dental amalgam). Criteria to evaluate were pulp and gingival compatibility, marginal quality (sealing properties), retention, surface quality, resistance to occlusal stress and wear, shade match and colour stability.

Design

(see Figures 18-21)

Prospective, longitudinal, controlled Clinical Investigation according to Revised (1989) ADA Guidelines for Composite Resin Materials for Posterior Restorations.

| | |
|---|--|
| Revised ADA Clinical Protocol Guidelines for submission of Composite Resin Materials for Posterior Restorations (1989) | |
| Patients and Restorations for Clinical Investigations | |
| Patients | ≥ 30 at baseline ≥ 25 at 2 years ≥ 20 at 4 years |
| Teeth | First or second molars Must be in occlusion |
| Cavity Class | ≥ 75 % Class II |
| Cavity Size | ≥ 1/3 intercuspal distance |
| Cavity Type | ≥ 10 complex restorations |



The diagram shows a cross-section of a tooth with a Class II cavity. A red composite resin restoration is placed in the cavity. Two lines point from the text 'Cavity Size' and 'Cavity Type' in the table to the restoration, indicating the measurement of the intercuspal distance and the complexity of the restoration.

Figure 18

Revised **ADA** clinical Protocol Guidelines
for submission of Composite Resin Materials
for Posterior Restorations (1989)

| Acceptance Criteria | 2 years | 4 years |
|--------------------------------------|-------------------------------|--------------------------------|
| Maintenance of colour | < 10% Charlie | < 10% Charlie |
| Marginal discoloration | < 10% Charlie | < 15% Charlie |
| Marginal integrity | < 5% Charlie | < 10% Charlie |
| Caries - recurrent or marginal | < 5% Charlie | < 10% Charlie |
| Maintenance of interproximal contact | < 5% observable broadening | < 10% observable broadening |

No more than 5% Delta (bulk fracture) at any time.

Figure 19

ADA Posterior Composites Acceptance Program

Required Wear Resistance

| Wear Measurement | Maximum Allowed Wear (MW) | | | |
|--------------------------|----------------------------|-------|------------------------------|-------|
| | <i>Restricted Category</i> | | <i>Unrestricted Category</i> | |
| | 6M-2Y | 6M-4Y | 6M-2Y | 6M-4Y |
| Average for restoration | 125 | 200 | 75 | 150 |
| Local (occlusal contact) | 400 | | | |

Figure 20

ADA Posterior Composites Acceptance Program

Cumulative Failures:

Marginal Integrity Failures + Caries + Wear Failures + Replacements

| Indication | Maximum Allowed Cumulative Failures | |
|------------------|-------------------------------------|------------|
| | at 2 years | at 4 years |
| Restricted Use | 8 % | 15 % |
| Unrestricted Use | 5 % | 10 % |

Figure 21

| | |
|--|--|
| Modifications with Regard to ADA Guidelines: | Higher number of patients and restorations. Inclusion of a reference material. |
| Investigator/s | Prof. Dr. Reinhard Hickel, Dr. Jürgen Manhart, Dr. Lidka-Karin Thiele, Dr. Petra Neuerer |
| Number of Patients | 40 at recalls. |
| Number of Restorations | 40 at recalls |
| Acid Conditioner/s | None as a self conditioning adhesive is used |
| Adhesive/s | Xeno III single step self-etching dental adhesive |
| Control Material/s | Tetric ceram, Syntac classic |
| Method of Evaluation | Clinical examination, rating according to Cvar and Ryge, indirect evaluation of selected cases for wear. |
| Recall Periods (those reported on are printed in bold) | Baseline, 3-, 6- and 12, 24, 48 month |
| Success Criteria | According to ADA Acceptance Criteria, with the understanding that for the 3, 6 and 12-month recalls the incidence of failures may at the most be half of what is accepted for the 24-month recall. |

6-Month Results

(see Table 15)

In the Preliminary 6-Month Report of March 17, 2003, Manhart reports that 46 restorations in 30 patients were in situ and functional. There was no statistically significant difference in the performance of the test material and the control (a conventional fine-particle hybrid composite placed in combination with a multi-bottle bonding system and phosphoric acid conditioning).

| Clinical Investigation Class I, II Munich and 6-mth Data | | | | |
|---|------------|-------|--------|-------|
| Ryge (USPHS) Criteria 6-mth | Scores (%) | | | |
| | Alpha | Bravo | Charly | Delta |
| • Margin integrity | 100 | 0 | 0 | 0 |
| • Margin discolouration | 94 | 6 | 0 | n.a. |
| • Recurrent caries | 100 | 0 | n.a. | n.a. |
| • Anatomic form | 100 | 0 | 0 | n.a. |
| • Surface texture | 97 | 3 | 0 | n.a. |
| • Colour match | 100 | 0 | 0 | n.a. |

Interim 6-mth Report by J. Manhart 2003-03-17 on 35 restorations


Dyract 

Table 15

Conclusions by the investigators

With no failures at 6 months, K-0134 meets the success criteria stipulated.

6.3 Clinical Investigation of the restorative system k-0134 (Dyract eXtra) and Xeno III for Class I and II restorations of the University of Hong Kong

Objectives: Demonstration of the product's safety and efficacy regarding its unrestricted use in posterior teeth for all Class I and II restorations (an alternative for dental amalgam). Criteria to evaluate were pulp and gingival compatibility, marginal quality (sealing properties), retention, surface quality, resistance to occlusal stress and wear, shade match and colour stability.

Design (see Figures 18-21) Prospective, longitudinal, uncontrolled Clinical Investigation according to Revised (1989) ADA Guidelines for Composite Resin Materials for Posterior Restorations

Modifications with Regard to ADA Higher number of patients and restorations.

Guidelines:

Investigator/s Dr. Gary S.P. Cheung, Dr. Edward Lo.

Number of Patients 30 at recalls.

Number of Restorations 30 at recalls

Acid Conditioner/s None as a self conditioning adhesive was used

Adhesive/s Xeno III, single step self-etching dental adhesive

Method of Evaluation Clinical examination, rating according to Cvar and Ryge. Indirect evaluation of selected cases for wear.

Recall Periods Baseline, 3-, **6-** and 12, 24, 48 month
(those reported on are printed in bold)

Success Criteria According to ADA Acceptance Criteria, with the understanding that for the 3, 6 and 12-month recalls the incidence of failures may at the most be half of what is accepted for the 24-month recall.

6-Month Results (see Table 16) In the 6-month Report (Annex III) provided on 19 March 2003, data on 30 restorations were provided. The failure rate of 3% remained unchanged.

Clinical Investigation Class I, II Hong Kong and 6-mth Data

| Ryge (USPHS) Criteria 6-mth | Scores (%) | | | |
|-----------------------------|------------|-------|--------|-------|
| | Alpha | Bravo | Charly | Delta |
| • Restorations infunction | 97 | 3 | n.a. | n.a. |
| • Margin integrity | 93 | 7 | 0 | 0 |
| • Margin discolouration | 90 | 10 | 0 | n.a. |
| • Recurrent caries | 100 | 0 | n.a. | n.a. |
| • Anatomic form | 100 | 0 | 0 | n.a. |
| • Surface texture | 97 | 3 | 0 | n.a. |
| • Colour match | 100 | 0 | 0 | n.a. |
| • Hypersensitivity | 97 | 3 | n.a. | n.a. |

Interim 6-mth Report by G.S. Cheung 2003-03-24 on 30 restorations

Dyract[®] **eXTRA**

Table 16

Conclusions by the investigators With one failure at 6 months, K-0134 is considered to meet the success criteria stipulated.

6.4 Practitioner Product Assessment Dyract eXtra restorations

Objectives: Monitoring of the product's safety and efficacy regarding pulp and gingival compatibility, marginal quality (sealing properties), retention, surface quality, resistance to toothbrush abrasion, shade match and colour stability under the conditions of daily practice.

Design (see also Figures 15-17) Design according to ADA Guidelines for Dentine and Enamel Adhesive Materials (1994), where applicable

Modifications with Regard to ADA Guideline Higher number of patients and restorations. Finishing of margins. Beveling of coronal part of margins, if appropriate (cosmetics).

Investigator/s Kopp (organisation), Hellwig (scientific consultant), 22 general dental practitioners.

Number of Patients 196

Number of Restorations 219

Acid Conditioner/s None as a self conditioning adhesive was used

| | |
|--|--|
| Adhesive/s | Xeno III, single step self-etching dental adhesive |
| Method of Evaluation | Clinical examination, rating, and documentation guided by questionnaires. |
| Recall Periods | No fixed recalls. Restorations will be evaluated during routine appointments. Data consolidations for restorations becoming available for inspection being in situ for 2 - 4 months, 5 - 8 months, and 16 - 20 months. |
| Success Criteria | n/a |
| 3-Month Results (see Table 17) | In his report of 2003-02-11, Markus Kopp reports on the recalls of 170 of the 219 restorations placed. Of the subgroup of restorations 3 months (83 to 101 days) in situ (see Table 2 of Annex VIII), all observed restorations were retained in situ. All restorations were classified as functional. |

| Results for 209 examined restorations being in situ between 64 and 282 days (mean 154 days). | | |
|--|------------|------|
| | Scores (%) | |
| Results | Yes | No |
| • Restoration furthermore functional | 99 | 1 |
| • Restoration retained | 99 | 1 |
| • Margin discolouration* | 5.8 | 94.2 |
| • Marginal crevice* | 7.2 | 92.8 |
| • Secondary caries | 0 | 100 |
| • Mismatch in color between restoration / adjacent tooth substance* | 6.8 | 93.2 |
| • Signs of material loss of restoration (abrasion)* | 2.4 | 97.6 |
| • Post-operative hypersensitivities | 0.5 | 99.5 |
| • Indication for endodontic treatment | 0 | 100 |
| • Sensitivity or alteration of gingival | 2.4 | 97.6 |

*changes clinically acceptable


Dyract  **EXTRA**

Table 17

Conclusions by the investigators Under consideration of the high number of restorations established under the conditions of private practice and with no failures in the 3-month group, it is concluded that K-0134 is suitable for the restoration of Class V defects.

7 References

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