DENTSPLY

Dyract® eXTRA

THE *EVIDENCE-BASED* RESTORATIVE

With the compliments of

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SCIENTIFIC COMPENDIUM

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1 Introduction

Dyract eXtra is the 3rd generation of compomer restorative materials developed by DENTSPLY. Long-term fluoride release is characteristic for this product group. The clinical significance of this feature has been discussed controversially for a long time. Today with more than 250 full papers listed in PubMed on fluoride releasing restoratives (Wiegand et al., 2007) it can be concluded that both glass-ionomers and DENTSPLY compomers show cariostatic properties under simulated cariogenic conditions in vitro. In addition, a recent in-situ study undertaken by Lennon et al. (2007) proves that Dyract eXtra provides a caries-preventive effect on approximal surfaces.

The 1st generation of Dyract, introduced in 1993, was developed in an attempt to combine the best properties of composites and glass-ionomers. Composites offer surface hardness, physical strength, low shrinkage and resistance to wear, while glass-ionomers (glass polyalkenoates) offer low technique sensitivity and release fluoride ions but have the disadvantage of being rather opaque and very brittle.

The 1st generation Dyract was an immediate success and continues to be widely used. It is however only indicated for non-occlusal stress-bearing situations.

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 restoration of occlusal stress-bearing situations. 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 3rd generation, Dyract eXtra, was introduced in 2003 with the objectives:

» to adjust the consistency of Dyract eXtra to that of the 1st generation of Dyract which had a slightly softer consistency than Dyract AP and was preferred by the majority of users

» to allow a 10 s cure for 2 mm layers of all shades using a high power curing light such as DENTSPLY SmartLite LED curing lamps

» to provide prolonged working time

In the following chapters, detailed information on the chemical, physical, and clinical properties of Dyract eXtra is given.

2 Dyract eXtra Restorative Technology

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 (Figure 1) 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.

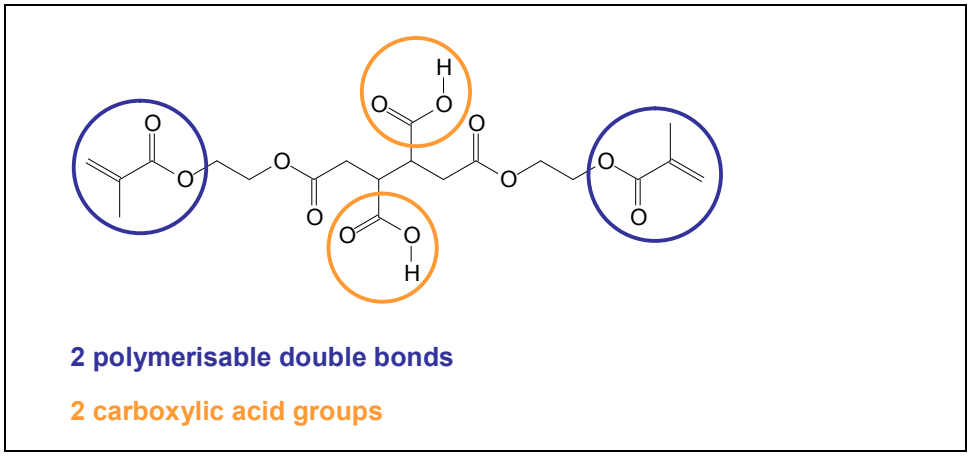


Figure 1 TCB: Butane-1,2,3,4-tetracarboxylic acid, bis-2-hydroxyethylmethacrylate ester

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 2.

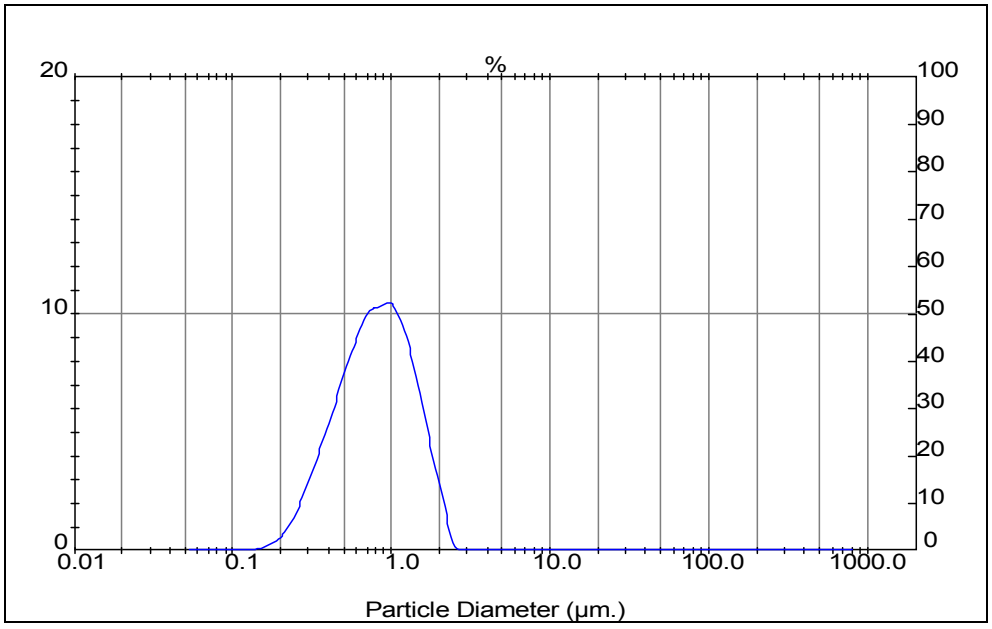


Figure 2 Particle Size Distribution of the Dyract eXtra Filler

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	reactive fluoride releasing glass	polyacid	water
Composite	non-reactive glass	monomer	
Compomer	reactive 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.

3 Clinical Features

Dyract eXtra is a light-curing restorative material for all cavity classes in anterior teeth and posterior teeth with cavities the widths of which are not more than 2/3 of the intercuspal distance.

Dyract eXtra restorative material is pre-dosed in Compules® tips for direct intra-oral application.

The special properties of Dyract eXtra are due to the combination of fluoridated glass fillers with acid-modified monomers patented by DENTSPLY. Dyract eXtra fillings release fluoride ions continually and function as acid-buffers along the interface with the tooth structure.

Dyract eXtra restorative can be used very successfully even with the latest and fastest adhesives such as Xeno self-etching adhesives.

The optimal handling properties of Dyract result in the best possible application and finishing efficiency.

With only 6 shades, chosen for their relevance (SIX for ALL), the complete shade range of the Vita®[1] shade range can be restored satisfactorily. Dyract eXtra restoratives only need extremely short curing times.

Dyract eXtra restorative material is particularly recommended for the treatment of children, adolescents and elderly and other patients with an increased risk of caries. As the oral hygiene in elderly patients and other risk groups is often uncertain and compliance is low, choosing Dyract eXtra for filling therapy is a logical addition to the appropriate prophylactic measures for these groups.

With more than 170 million Compules® tips sold, Dyract is one of the most widely used filling materials in the world. 45 clinical studies, more than 440 scientific publications and 13 years of successful use in dental practice make Dyract an example for evidence-based dentistry.

Dyract eXtra should not be used:

- with patients who have a history of severe allergic reaction to dimethacrylate resins or any other of the components.
- for direct application to dental pulp (direct pulp capping).
- for Class I and II cavities the width of which exceeds 2/3 of the intercuspal distance.
- as core build-up for full ceramic crowns.

The current version of the Directions for Use is available under www.dentsply.de.
Consult Directions for Use prior to clinical application.

[1] Vitapan® classical shades of Vita®,Vita® and Vitapan® are a registered trademark of Vita Zahnfabrik

4 Physical Properties of Dyract eXtra

4.1 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 ESPE
Tetric Ceram	Tetric® Ceram	C16365	Vivadent

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

4.2 Yield and Compressive Strength

4.2.1 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 3, 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.

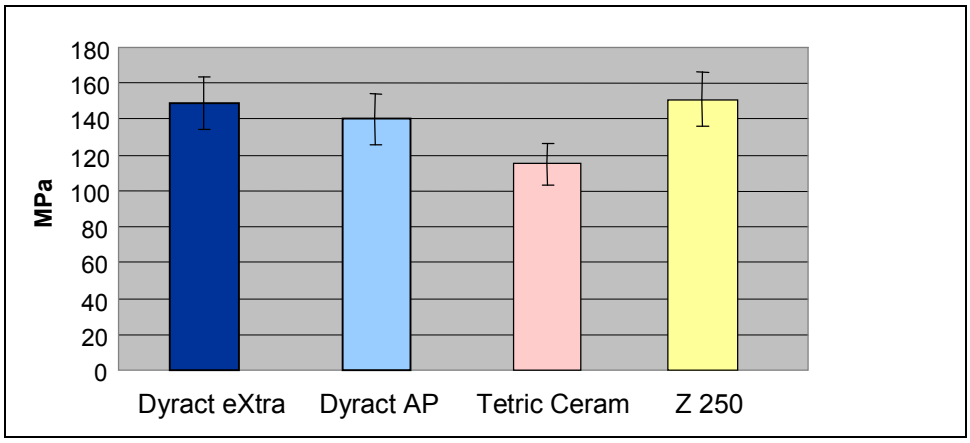


Figure 3 Yield Strengths

4.2.2 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 mode (Brosh et al., 1999), and the compressive strength test is not part of the ISO 4049[2] 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.

[2] ISO 4049:2000, Dentistry -- Polymer-based filling, restorative and luting materials

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.

4.3 Flexural Strength and Modulus

4.3.1 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 (Blackwell et al., 1998) 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 4, 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.

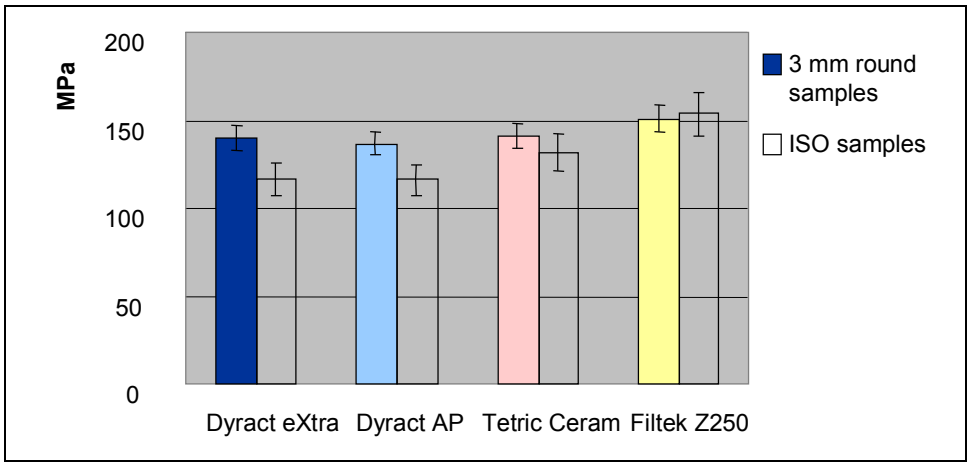


Figure 4 Flexural Strength measured according ISO and using 3 mm round samples

4.3.2 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 Youngs 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 6,000 to 12,000 MPa perform satisfactorily. A flexural modulus over about 15,000 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	7,676	118 MPa	1.5
Dyract AP	7,094	300 MPa	4.2
Tetric Ceram	9,067	517 MPa	5.7
Filtek Z250	10,308	254 MPa	2.4

Table 3 Flexural Modulus

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

4.4 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.

4.5 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 employed (Attin et al., 1995; Feilzer et al., 1988, 1995; Fogleman et al., 2002; McConnell et al. 1994; Soltész et al., 1993). 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 values**
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 (standard deviation)

For the literature values quoted, a quite different method involving a laser inferometer was used (Fogleman et al., 2002). 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.

4.6 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 (Attin et al., 1995; Fogleman et al., 2002). 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 Jedynakiewicz, 1995. 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 5 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

4.7 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.

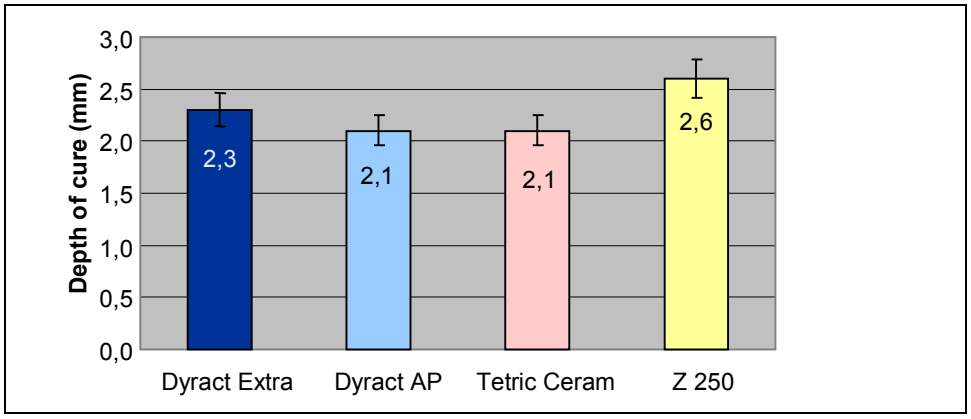


Figure 6 Depth of Cure (ISO 4049) with 10 seconds cure time at 800 mW/cm²

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 7 below, which shows the vast improvements made.

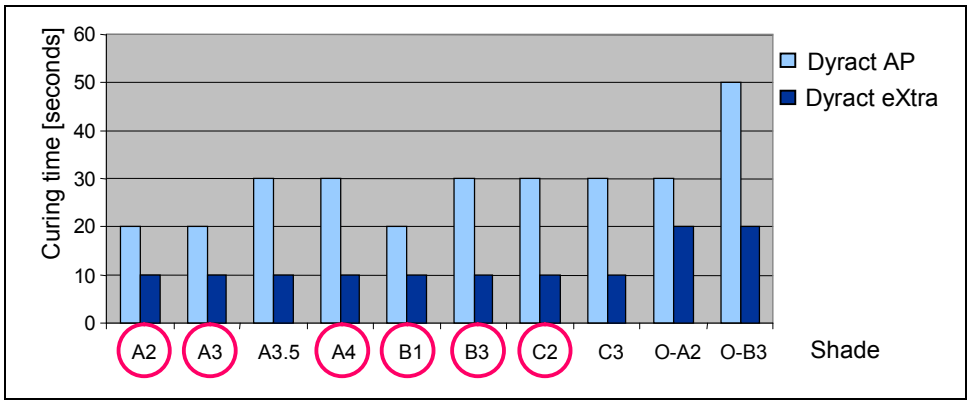


Figure 7 Cure Times of Dyract eXtra / Dyract AP
(Depth of Cure > 2 mm according to ISO 4049 at 500mW/cm².
Circled Shades = "Six for All")

4.8 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 by de Gee et al., 1994, and also at DENTSPLY DeTrey using a slight variation of the method developed by Leinfelder.

4.8.1 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).

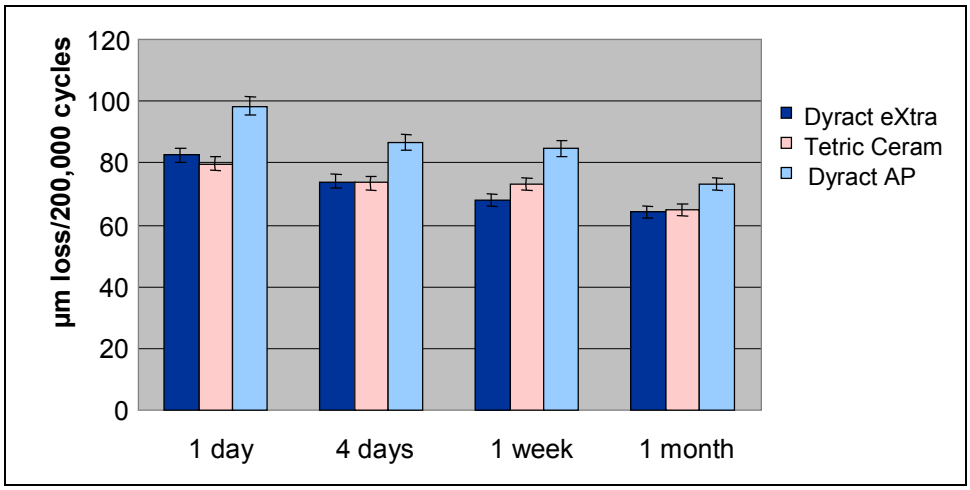


Figure 8 Wear measured at ACTA after different storage times

As seen from Figure 8, 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 Dyract AP.

4.8.2 Leinfelder Wear Test

A slight modification of the wear test developed by Leinfelder was used in DENTSPLY DeTrey 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 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 200,000 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 200,000 cycles.

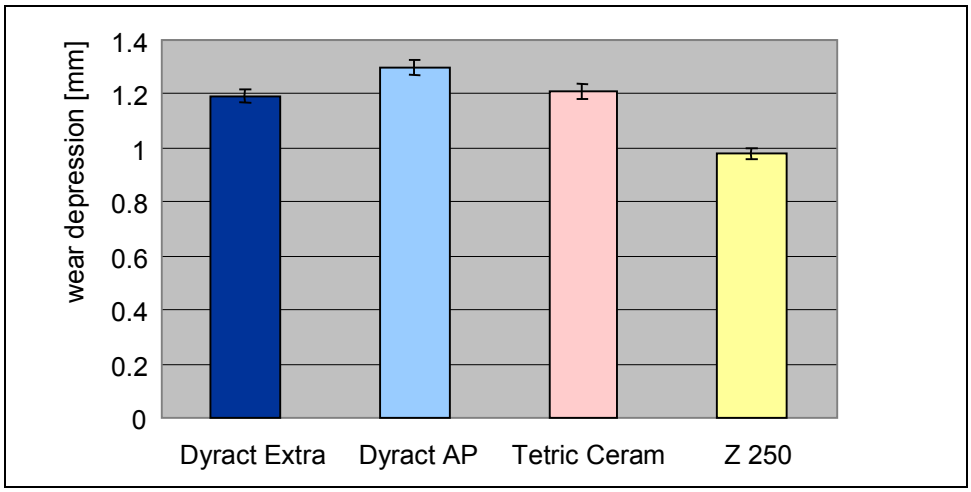


Figure 9 Wear Depression from modified Leinfelder Test at DENTSPLY DeTrey

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.

4.9 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 7 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.

4.10 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 14,000 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 8 R_a and R_{max} Roughness Values

From Table 8 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 14,000 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.

4.11 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.

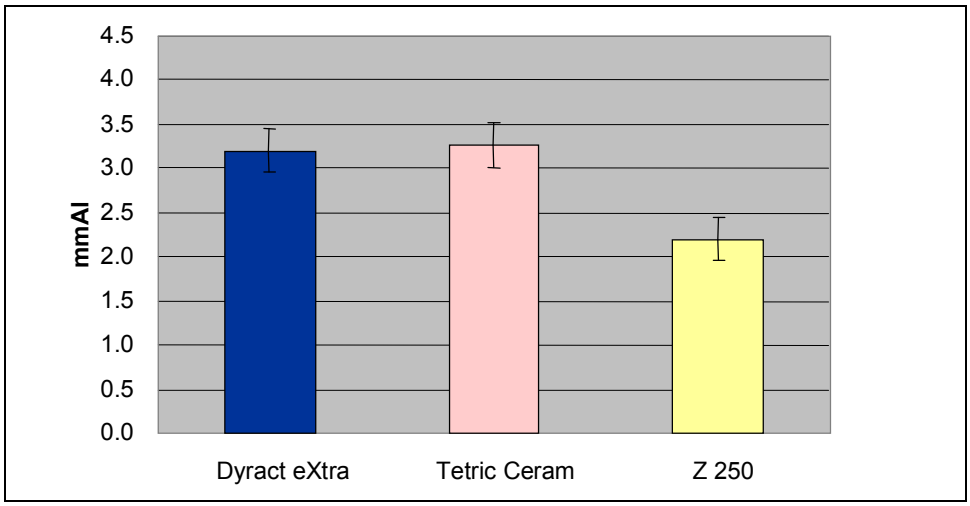


Figure 10 Radiopacity

4.12 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 11 shows that up to at least 20 weeks, Dyract eXtra has an almost linear release rate of about 1.5 µg fluoride/cm² per week. This compares with 0.16 µg fluoride/cm² per week for Tetric Ceram, and 0.06 µg fluoride/cm² per week for Z250.

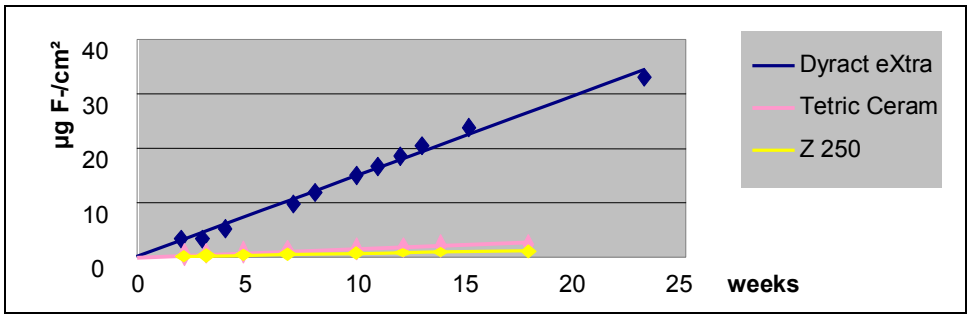


Figure 11 Fluoride Release

4.13 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 1,800 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 9 Adhesion of Dyract eXtra

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

4.14 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 10,000 lux was initially chosen for the method developed for ISO 4049, though this has

since been reduced to 8,000 lux. Materials in this report where tested under the harsher conditions of 10,000 lux.

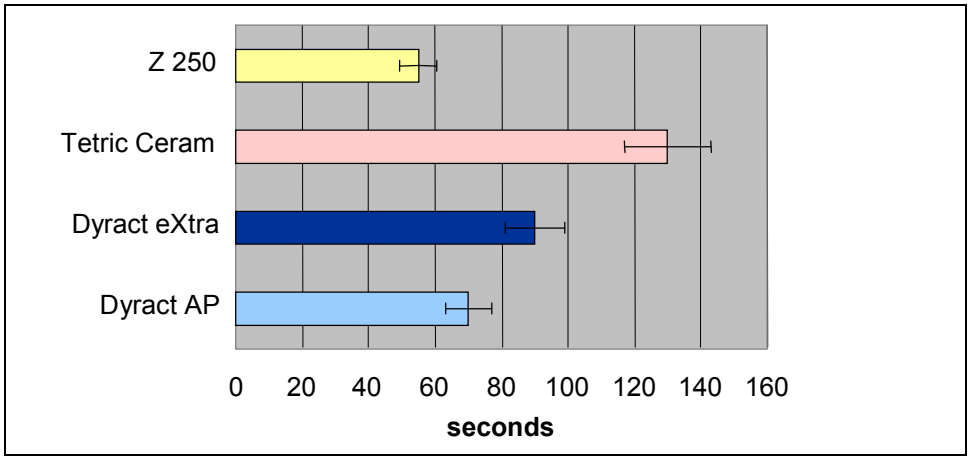


Figure 12 Working Time at 10,000 lux

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 8,000 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 4.7, 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.

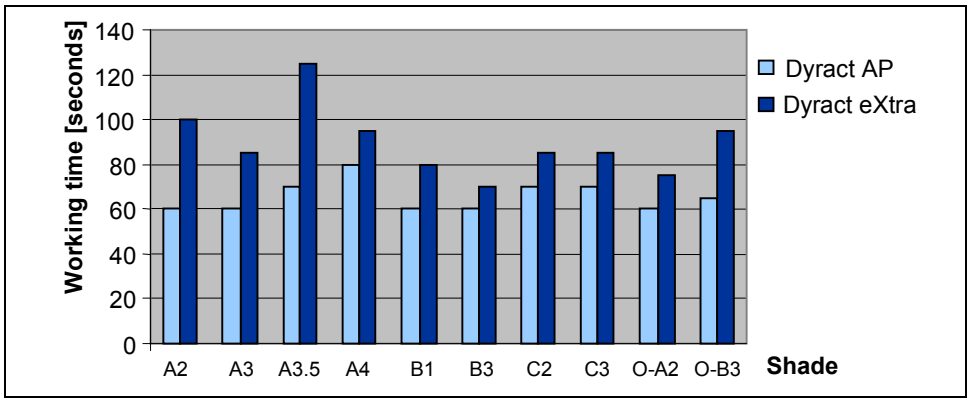


Figure 13 Working times of Dyract eXtra and Dyract AP with 10,000 lux ambient light

4.15 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 10 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.

4.16 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	3M ESPE	L6 121222
Clearfil SE Bond	Kuraray	00236A
Prime&Bond NT	DENTSPLY	0112142

Table 11 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 fuchsine 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

		Adhesive					
Filling material	**Cavity wall**	**Xeno III**	**Prompt L-Pop**	**Clearfil SE Bond**	**Prime&Bond NT**	mean score for cavity type	mean score for restorative
Esthet•X	**Occlusal**	6	6	8	10	7.5	11.5
	Gingival	7	0	6	3	4.0	
Dyract eXtra	**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 12 Number of restorations out of 10 showing 100% perfect margins after thermocycling

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 Esthet•X, this difference was not statistically significant. The aim that Dyract eXtra performs at least as well as Esthet•X 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 12. 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 ($p<0.05$).

4.17 In-situ study on caries preventive effect on approximal contact areas

Background

Restorative treatment of the posterior teeth is still one of the most common procedures in the dental office despite the increasing emphasis on prophylaxis – whether through regular professional prophylaxis or education in better oral hygiene and improved tooth-protective diet.

If a Class II cavity bordering approximally on an intact tooth surface must be treated (Figure 14), the question arises whether in addition to prophylactic measures, such as the use of floss and interdental brushes, the choice of filling material can also have an effect on the potential for developing caries on this approximal surface.

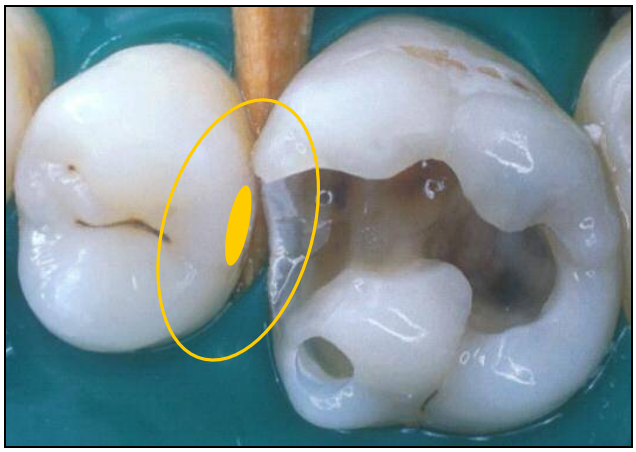


Figure 14 Intact approximal surface adjacent to a Class II cavity

An extensive literature review (Wiegand et al., 2006) has indicated that glass ionomers and their modified forms and compomers may have a potential caries-protective effect.

Unlike glass ionomers and conventional compomers, the compomer Dyract eXtra is indicated for occlusal stress-bearing posterior restorations. Benz et al. (2005) reported that the predecessor product Dyract AP demonstrated results after 4 years that were equivalent to those of a fine hybrid composite in a clinical study at the University of Munich.

Aim of investigation

Lennon et al. (2007) investigated the effect of the filling material on the development of enamel caries on approximal surfaces in a volunteer study in situ.

Method

To simulate the approximal contact, flat enamel specimens on the one hand and hemispheric specimens with flattened contact surfaces on the other were prepared from two filling materials (Dyract eXtra and a non-fluoride releasing composite restorative); enamel controls were also prepared. A flat intact enamel surface was placed in contact with a test specimen or a control sample made of enamel as shown in Figure 15.

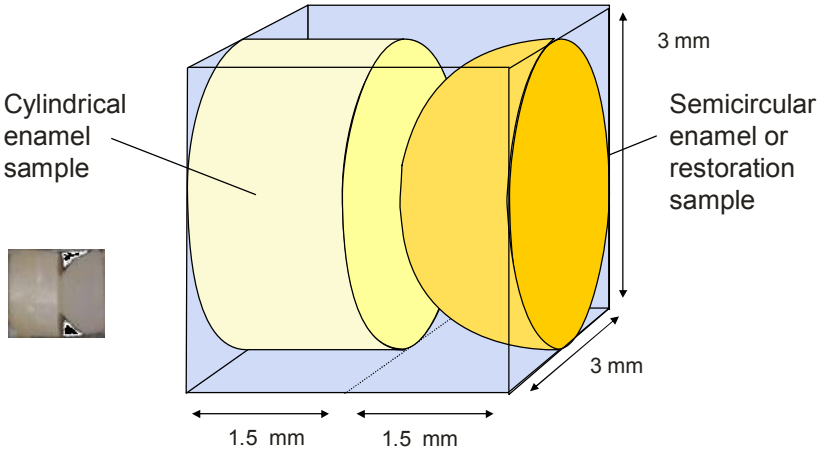


Figure 15 Relationship of cylindrical to semi-circular sample

An intra-oral appliance with a total of eight test chambers (four on each side) was used to submit the samples to intra-oral conditions in situ (Figure 16). One side was used for Dyract eXtra and the other for the non-fluoride releasing composite restorative.

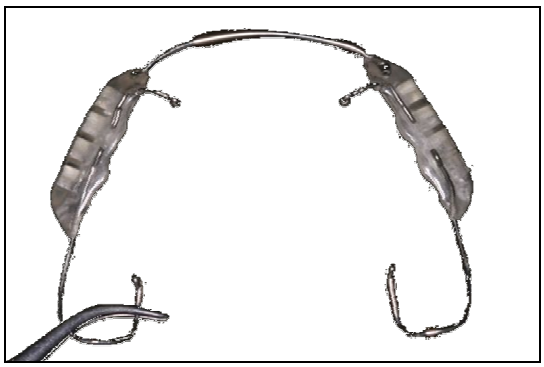


Figure 16 Intra-oral appliance with four chambers to hold sample pairs on each side

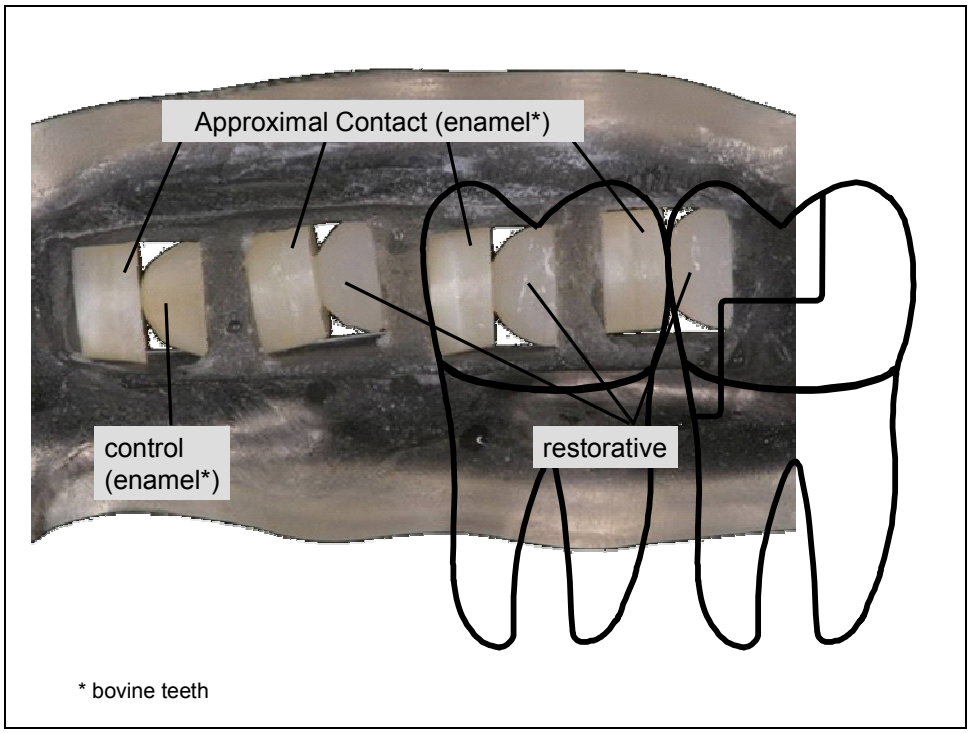


Figure 17 Three test chambers and one control chamber simulating approximal contacts in Class II restorations

Figure 17 shows how the flat enamel surface and the hemispheric sample simulate approximal contacts. The restorative material was applied in three chambers. The fourth chamber was given a control specimen (enamel-on-enamel) in alternating positions.

To test whether the effect of the filling material would potentially be overruled through regular use of fluoridated toothpaste, all specimens were treated twice daily for a period of 4 weeks with a slurry of fluoridated toothpaste before the start of the in-situ phase.
Then 20 volunteer subjects wore the prepared intra-oral appliances for four weeks. Twice a day they removed the appliances for tooth brushing for 2 minutes. When tooth brushing was finished, they reinserted the appliance and rinsed it with the fluoridated toothpaste foam for 30 seconds before spitting it out. This simulated regular teeth cleaning without interproximal hygiene.

In addition, the intra-oral appliances were placed five times per day in a 10% sucrose solution to simulate meal times and provide appropriate nutrition for the attached plaque.

The test enamel surfaces were analyzed before and after by quantitative light-induced fluorescence (QLF™). This method permits changes in the enamel, such as one finds in initial enamel lesions, to be captured optically (Figure 18) and quantitatively.

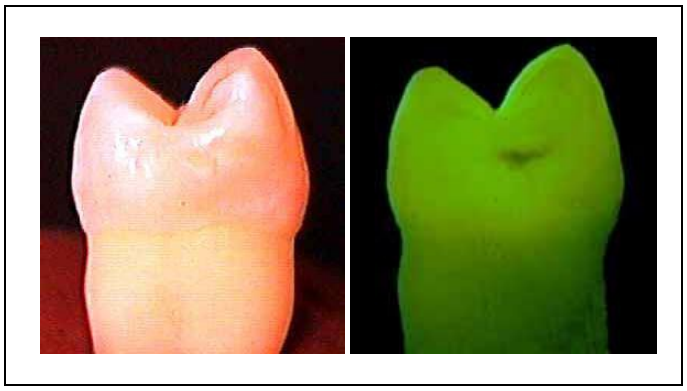


Figure 18 Initial enamel lesion: visible light and induced fluorescence www.inspektor.nl

The ΔQ (surface x mean fluorescence loss [% mm²]) was determined as a measure of carious activity.

Figure 19 shows by way of example the comparison between Dyract eXtra and the composite. In the composite (lower row) there is an evident loss of fluorescence (changes in the enamel).

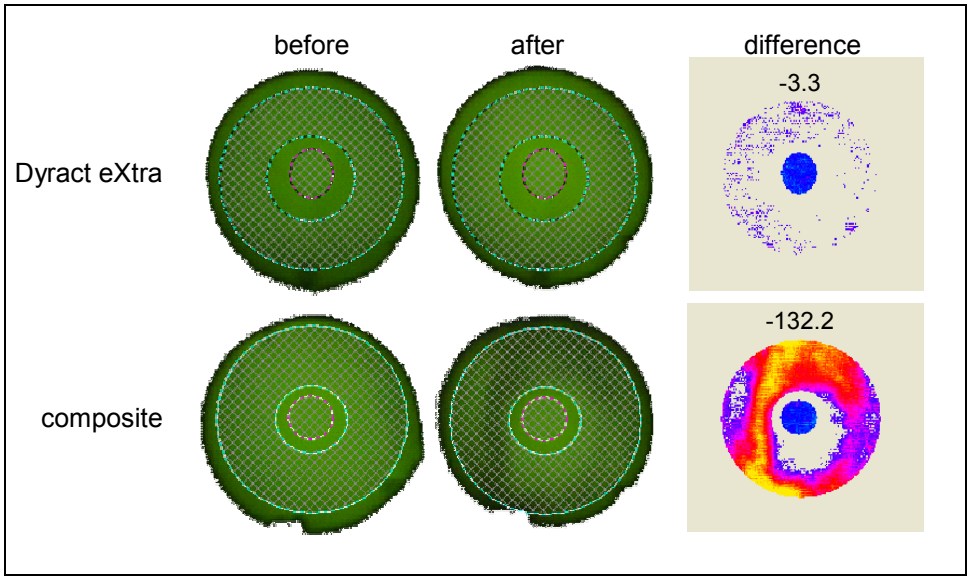


Figure 19 Dyract eXtra (above) and composite: before (left column) and after the in-situ phase. Pseudocolor images (right column) make changes clearly visible (Lennon et al., 2007)

Results

The statistical analysis of the results indicated that:

- Dyract eXtra effectively supported the prevention of initial caries lesions in approximal contact areas
- this effect was particularly remarkable in 50% of the test subjects with the highest carious activity (defined as high risk patients)
- even the control specimens (adjacent teeth) on the Dyract eXtra side displayed a trend ($p = 0.051$) toward fewer enamel changes than those on the composite side
- the protective effect of Dyract eXtra was evident when fluoridated toothpaste was used
- the composite showed no protective effect.

Therefore the choice of filling materials does influence the development of enamel lesions on approximal contact surfaces.

The choice of Dyract eXtra in restorative treatment for Class II cavities in patients prone to risk of caries is therefore advisable as extra care against the onset of new approximal caries.

4.18 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 thirteen 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 eight 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

» A caries protective effect on approximal contact areas

5 Summary of Clinical Studies

An overview on the current state of scientific knowledge regarding compomers in general and the Dyract restorative family in particular can be found in the excellent literature reviews presented by Norbert Krämer/Roland Frankenberger and Annette Wiegand, Wolfgang Buchalla and Thomas Attin.

13 years of clinical testing have resulted in numerous papers which report on the outcome of clinical investigations on Dyract, Dyract AP, and Dyract eXtra.

With regard to Dyract eXtra, clinical data are available from:

- Two investigations on occlusal load-bearing Class I and II restorations:
  - by Prof. R. Hickel at the University of Munich and
  - by Dr. G. S. P. Cheung at the University of Hong Kong,
- A field monitoring study under the scientific guidance of Prof. E. Hellwig in Germany.

The results up to date “demonstrate the safety, efficacy and utility of Dyract eXtra with regard to the intended indications” (Gary S.P. Cheung, Hong Kong). “Dyract eXtra showed very good clinical results” (Reinhard Hickel, Munich). In this controlled investigation, no statistically significant difference could be found in comparison to the control material, a conventional fine-particle hybrid composite. Regarding the restoration of Class V cavities under the conditions of daily practice, Elmar Hellwig and Markus Kopp concluded “that Dyract eXtra in combination with Xeno III has proven its suitability” in the post-marketing surveillance study conducted in Germany.

5.1 Clinical Investigation of the restorative system Dyract eXtra and Xeno III for Class I and II restorations at the University of Munich

Objectives:

Demonstration of product safety and efficacy regarding 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 **Figure 20** to **Figure 23**)	Prospective, longitudinal and controlled clinical investigation according to Revised (1989) ADA Guidelines for Composite Resin Materials for Posterior Restorations.

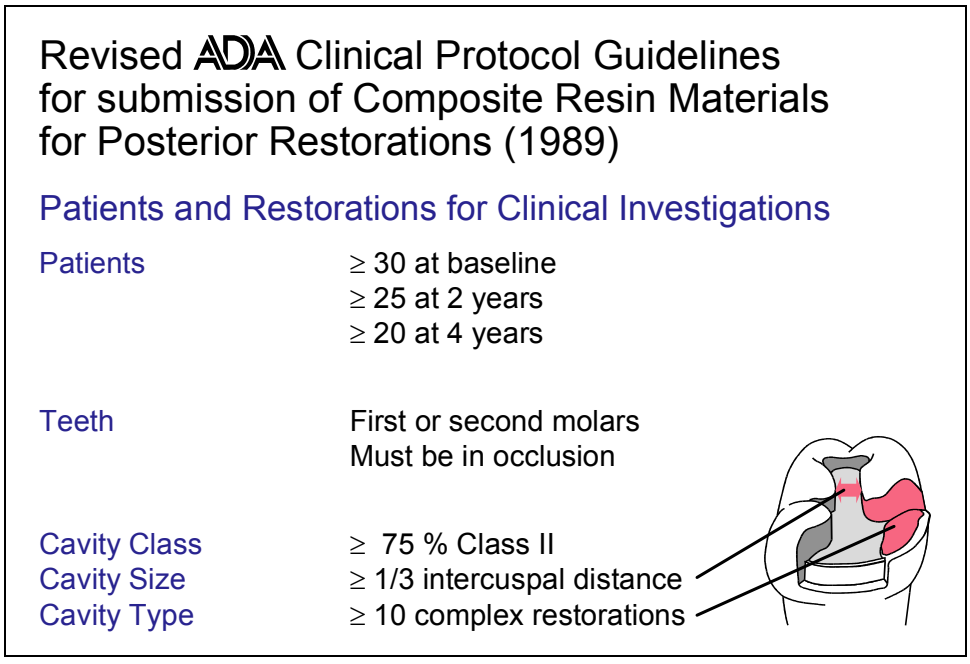


Figure 20 Patient, tooth, and cavity selection criteria according to ADA

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.

Dyract eXtra

Figure 21 Acceptance Criteria for posterior restorations by ADA

ADA Posterior Composites Acceptance Program

Required Wear Resistance

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

Figure 22 Accepted wear for posterior restorations by ADA

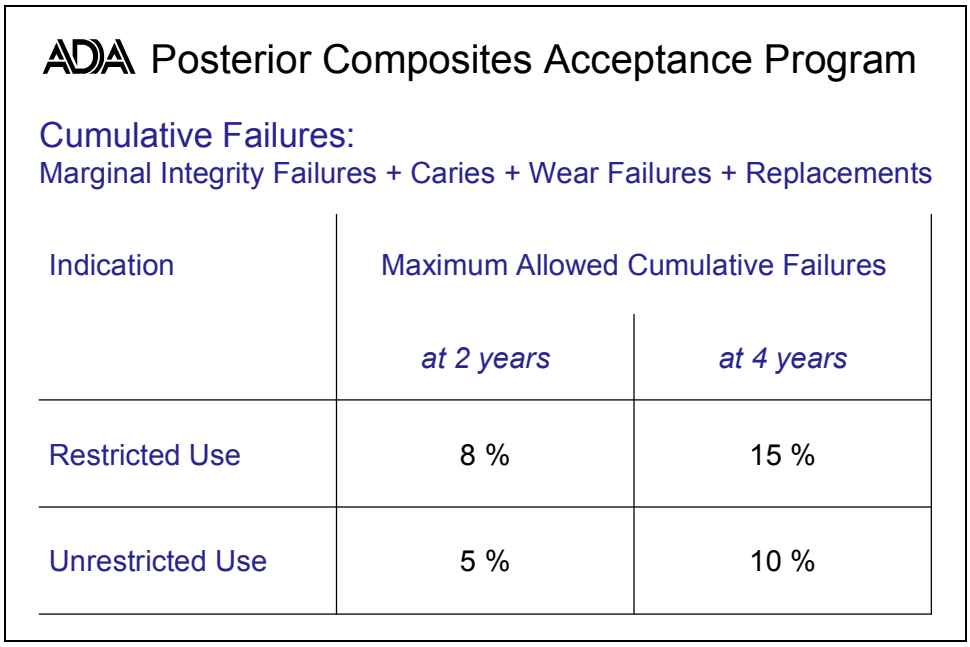


Figure 23 Accepted cumulative failure rates by ADA

Modifications with Regard to ADA Guidelines:	Higher number of patients and restorations. Inclusion of a reference material.
Investigator/s	Prof. Dr. Reinhard Hickel, OA Priv.-Doz. 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-**,** 18-, 36-, and **48 months**

Summary of results at 48 months (Table 13):

In the 48-Month Report dated July 18, 2007, data on 38 restorations in 33 patients were provided.

Alpha-Ratings:

- Retention, sensitivity, colour match, recurrent caries, anatomic form: 100%
- Surface texture: 94.7%
- Margin adaptation: 97.4%
- Margin discolouration: 71.1%

Cumulative failure rate: 2.6% (1 failure due to pulpitis)

No statistically significant differences to control material.

Dyract eXtra meets the success criteria defined by the ADA Acceptance Program for posterior composites.

Clinical Investigation Class I/II
Munich, 48-Month Data

Ryge (USPHS) Criteria	Alpha (%)	Beta (%)
Retention	100	0
Sensitivity	100	0
Margin adaptation	97.4	2.6
Margin discolouration	71.1	28.9
Recurrent caries	100	0
Anatomic form	100	0
Surface texture	94.7	5.3
Colour match	100	0

48-mth Report by J. Manhart 2007-07-18 on 38 restorations in 33 patients,
Cumulative failure rate: 2.6%, (One failure due to pulpitis)

Dyract eXtra

Table 13 Results for Dyract eXtra after 48 months

Relevant quotes and remarks by the Investigator/s at 48 months:

Very good clinical results.

Predominantly Alpha ratings.

Conclusions by DENTSPLY De Trey Clinical Research on the 48-month report:
With an overall success rate of 97.4% (1 failure due to pulpitis), Dyract extra by far exceeds the performance criteria of the Revised (1989) ADA Guidelines for Composite Resin Materials for Posterior Restorations. The 48-month recall confirms the suitability of Dyract eXtra used in combination with Xeno III for occlusal stress-bearing posterior restorations.
Criteria of special importance for the use in occlusal stress-bearing situations, such as anatomical form and marginal integrity, received high Alpha ratings (≥ 97.4%) and no Charlie ratings. The Investigators were impressed by the very good clinical performance. For all criteria investigated, Dyract eXtra performed equally well as the control, a conventional fine-particle hybrid composite used with a multi-bottle adhesive system. Other than a conventional composite, Dyract extra offers cariostatic properties by long-term fluoride release, which makes it the material of choice for patients with low compliance (children, senior citizens).

5.2 Clinical Investigation of the restorative system Dyract eXtra and Xeno III for Class I and II restorations at the University of Hong Kong

Objectives:

Demonstration of product safety and efficacy regarding 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 **Figure 20** to **Figure 23**)	Prospective, longitudinal and uncontrolled clinical investigation according to Revised (1989) ADA Guidelines for Composite Resin Materials for Posterior Restorations.
Modifications with regard to ADA Guidelines:	Higher number of patients and restorations
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 (those reported on are printed in bold)	Baseline, 3-, 6-, 12-, 18-, and **48-month**
Success Criteria	According to ADA Acceptance Criteria

Summary of results at 48 months (Table 14):

In the Draft 48-Month Report dated June 15, 2007 data on 17 restorations in 17 patients were provided.

- Retention: 100% Alpha

All other criteria: Alpha, Beta and Charlie ratings

- Recurrent caries: 94.1% Alpha, 5.9% Beta
- Colour match: 52.9% Alpha, 41.2% Beta, 5.9% Charlie
- Marginal discolouration: 47.1% Alpha, 47.1% Beta, 5.9% Charlie
- Marginal integrity: 58.8% Alpha, 35.3% Beta, 5.9% Charlie
- Anatomic form: 82.4% Alpha, 11.8% Beta, 5.9% Charlie
- Surface texture: 88.2% Alpha, 5.9% Beta, 5.9% Charlie

Overall failure rate: 15%; cumulated no. of failures: 3 (pulpal symptoms).

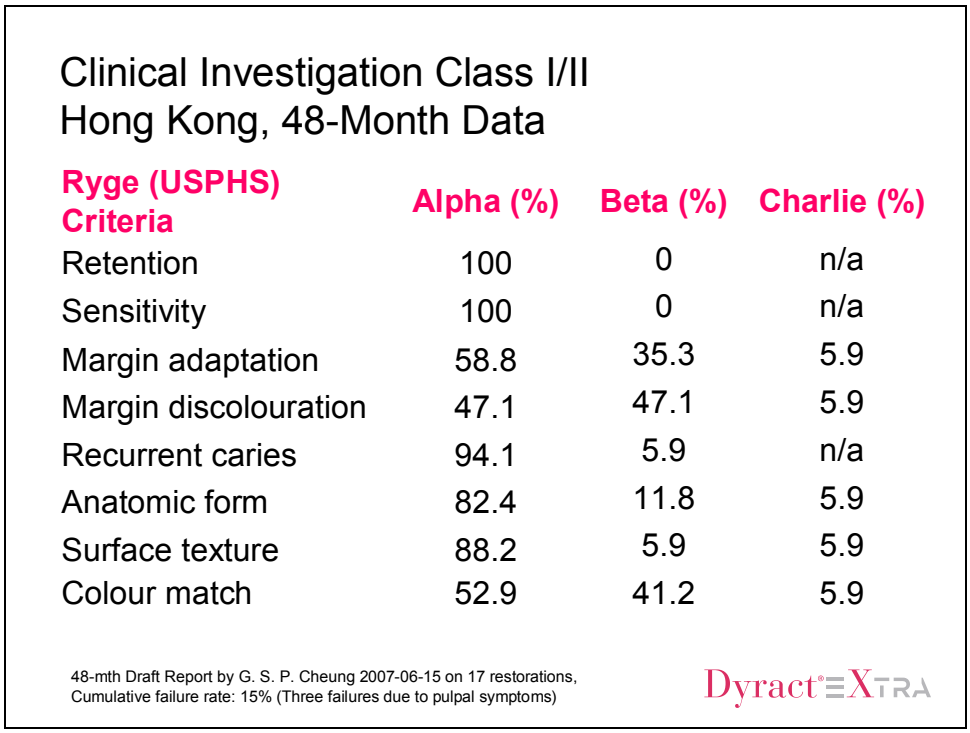


Table 14 Results of Dyract eXtra after 48 months

Relevant quotes and remarks by the Investigator/s at 48 months:

No new failure was noted at the 48-month review, thus giving a total of 3 restorations that had failed over four years of observation.

There seems to be some deterioration of the quality of the margin of restoration after 4 years. Almost half of the restorations were given a “Bravo” score, compared with less than one-quarter at 18 months. The amount of restoration with an “Alpha” score for marginal integrity also dropped from 80% (12-month) to 67% (18-month) to 59% (4 years).

The results of this investigation demonstrate at this stage the test product’s safety, efficacy and utility with regard to the intended indications.

Conclusions by the Sponsor at 48 months:

The 3 failures seen in the previous reports and the low number of restorations that could be evaluated at the 4-year report result in a relatively high cumulative failure rate.

Though it does not meet the performance criteria of the Revised (1989) ADA Guidelines for Composite Resin Materials for Posterior Restorations, Unrestricted Category, it is still within the limits of the Restricted Category for maximum allowed cumulative failures.

The rather disappointing results are in conflict with the results obtained from other investigations. They highlight the importance of the selection of cases and investigators. In

Hong Kong, the majority of cases involved the re-restoration of large old amalgam fillings in patients with low compliance. From the Hong Kong study, it can also be learned how important it is to include a control (a well established and researched reference material).

The results from another investigation of posterior restorations at the University of Munich allow to correct the picture. Based on the results from this study and on additional data from investigations on Dyract, Dyract AP, and Dyract eXtra, we strongly believe that Dyract eXtra is suitable for occlusal stress-bearing posterior restorations.

5.3 Post-marketing-surveillance-study on Dyract eXtra restorations

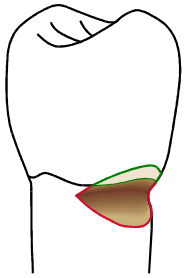
Objectives: Monitoring of product safety and efficacy regarding pulp and gingival compatibility, marginal quality (sealing properties), retention, surface quality, resistance to toothbrush abrasion, shade match, and colour stability under the conditions of daily practice.

Design (see **Figure 24** to **Figure 26**)	Design according to ADA Guidelines for Dentine and Enamel Adhesive Materials (2001), where applicable.

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

Tooth/Cavity Selection

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



Dyract eXTRA

Figure 24 Tooth and cavity selection criteria according to ADA

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

Dyract eXTRA

Figure 25 Patient selection criteria according to ADA

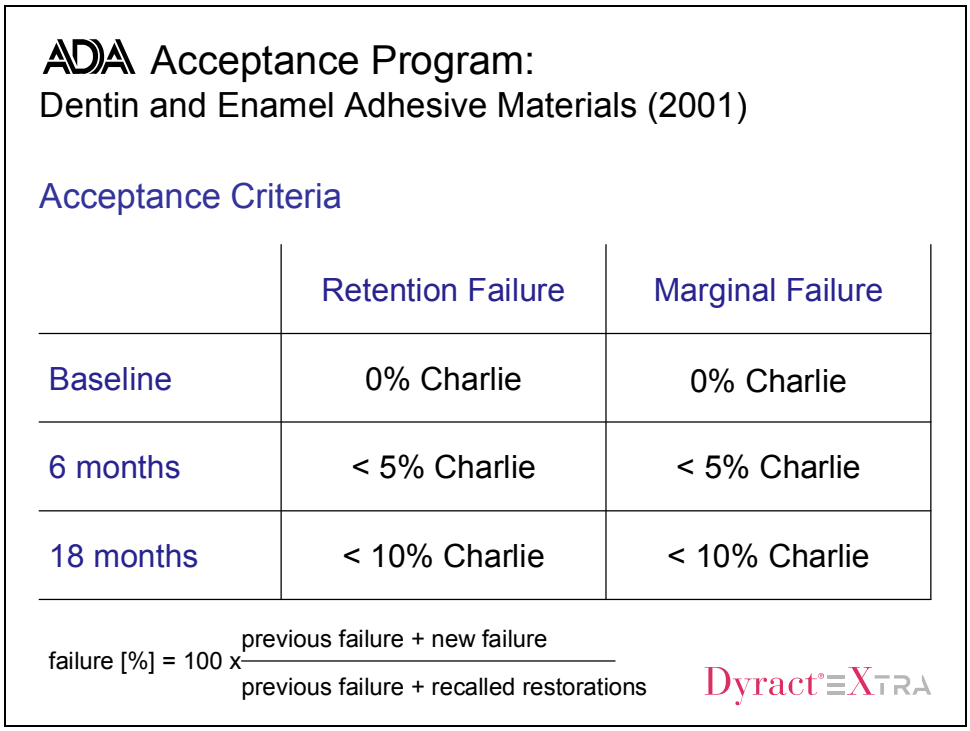


Figure 26 Accepted cumulative failure rates by ADA

Modifications with Regard to ADA Guideline	Higher number of patients and restorations. Finishing of margins. Bevelling of coronal part of margins, if appropriate (cosmetics).
Investigator/s	Dr. Markus Kopp (organisation), Prof. Dr. Elmar 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 are 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 According to ADA Acceptance Criteria

Final Results (see Table 15):

In the final report (2005-11-23) submitted for publication, Hellwig and Kopp presented the results based on 219 (all) restorations placed in 196 patients.

Out of 219 restorations which were observed in this project, 3 cases (1.4% of restorations) of retention loss were documented. Out of the set of 216 retained restorations, 215 (99.5%) restorations remained fully functional. Non-functionality was recorded for 1 restoration (0.5%) due to abrasion. Thus, the cumulative failure rate amounts to 1.8%, with an overall clinical success rate of 98.2%.

For detailed data based on the respective last re-evaluation visit (considering only the most recent information available on each restoration) see Table 15.

Apart from the above-mentioned case of non-functionality due to abrasion, the observed changes in parameters did not affect overall clinical functionality of the restorations.

Post-Marketing Surveillance Study Class V
Final Results, All (219) Restorations Recalled

Parameter	Scores (%)
• Restorations retained	98.6
• No marginal discolouration	90.3
• No marginal crevice	92.6
• No secondary caries	97.2
• No post op. hypersensitivity	99.5
• No endodontic treatment needed	100
• Absence of gingival inflammation	94.4
• Restorations furthermore functional	99.5

Cumulative failure rate: 1.8%

Mean observation time: 364.9 ± 137.8 days; min.: 77 days; max.: 609 days.

Dyract eXtra

Table 15 Final results post-marketing surveillance study

Conclusions by the investigators

The investigators conclude that Dyract eXtra, in combination with Xeno III, has proven its suitability for the restoration of Class V cavities under the conditions of daily practice. Thus, this post-marketing surveillance study may be considered an ideal addition to the clinical investigations on the product.

6 References

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Abbreviation	**Brand (Manufacturer)**
Clearfil SE Bond	Clearfil SE Bond (Kuraray Dental)
Prompt L-Pop	Prompt L-Pop (3M™ Espe™)
Silux Plus	Silux Plus (3M™ Espe™)
Syntac	Syntac® (Ivoclar Vivadent)
Tetric Ceram	Tetric Ceram® (Ivoclar Vivadent)
Z250	Filtek™ Z250 (3M™ Espe™)