

DENTSPLY
DeTrey

ceram • xTM
nano ceramic restorative



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SCIENTIFIC COMPENDIUM



Table of contents

1	Introduction	3
2	Composite Technology.....	3
2.1	Traditional Composites	4
2.2	Nano-Ceramic Technology.....	6
3	Material properties	8
3.1	Biocompatibility.....	9
3.1.1	Cytotoxicity	9
3.2	Mechanical strength	10
3.3	In-vitro simulations.....	14
3.3.1	Leinfelder Wear.....	14
3.3.2	Marginal integrity class V	15
3.3.3	Marginal integrity class II.....	16
3.3.4	CEBL – Simulating recutting and rebonding of composite	18
3.4	Handling Properties	18
3.4.1	Working Time.....	18
3.4.2	Stickiness	19
3.5	Polishability.....	20
3.6	Fluorescence.....	21
3.7	Radiopacity	22
3.8	Optical Properties.....	23
4	The Shade System	26
5	Clinical Investigations and Handling Evaluations.....	27
5.1	Clinical Investigation of Class I and II restorations at University of Freiburg, Germany	27
5.2	Clinical Investigation of Class V restorations at University of Bologna, Italy.	28
5.3	Field Monitoring Study, Germany.....	28
5.4	Handling Evaluation	29
6	Directions for Use	31
6.1	COMPOSITION	31
6.2	INDICATIONS FOR USE.....	32
6.3	CONTRAINDICATIONS.....	32
6.4	WARNINGS	32
6.5	PRECAUTIONS.....	32
6.6	ADVERSE REACTIONS.....	33
6.7	INTERACTIONS WITH OTHER DENTAL MATERIALS	33
6.8	STEP-BY-STEP INSTRUCTIONS	33
6.9	STORAGE	37
7	References.....	38
8	List of Figures and Tables.....	39

1 Introduction

DENTSPLY DeTrey develops advanced technologies for superior dental materials. A breakthrough was achieved by applying **Nano-Ceramic Technology** to develop our new Universal Nano-Ceramic Restorative **Ceram•X**.

Ceram•X is a light curable, radiopaque restorative material for anterior and posterior restorations of primary and permanent teeth. Based on proprietary Nano-Ceramic Technology, Ceram•X offers natural aesthetics achieved by an easy procedure, superior handling characteristics and excellent durability.

Ceram•X is available in two distinct shading systems:

Ceram•X mono, the Single Translucency System, comprises seven shades of intermediate translucency comparable to conventional composites (e.g. Spectrum[®] TPH), optimal for fast and easy restorations of posterior or anterior teeth.

Ceram•X duo, the Double Translucency System, offers four dentin shades with translucencies similar to natural dentin and three enamel shades which mimic natural enamel. Their design has been optimized for advanced aesthetic restorations achievable with a minimum number of shades. For the enamel shades, the Nano-Ceramic Technology creates an ideal balance between handling and optical characteristics.

2 Composite Technology

Modern light curable resin based restoratives may be classified according to the chemistry of the resins:

In this context dental composites are understood as materials comprising curable dimethacrylic resins based on hydrocarbon molecular structures (e.g. Bis-GMA, TGDMA, UDMA) and methacrylate functionalised but otherwise non-reactive fillers. Setting occurs due to radical polymerisation of the resins. Compomers as another important subgroup of dental restoratives comprise methacrylate functionalised reactive fillers and polyacid modified methacrylate resins which promote (after post-cure controlled water up-take) an additional ionomer setting reaction accompanied by fluoride release.

2.1 Traditional Composites

Traditionally, dental composites are classified according to their filler particle size distribution into subgroups of hybrid, micro-hybrid and microfilled composites:

- **Microfilled Composites** comprise only microfillers with an average agglomerate size (d_{50}) of $\leq 0.4 \mu\text{m}$. To increase filler load, microfilled composites contain also prepolymerised microfilled resin (Figure 1).
- To further increase filler load and mechanical strength, **Hybrid Composites** comprise besides the agglomerates known from microfillers solid glass fillers instead of the prepolymerized resin particles. These glass fillers are of an average particle size (d_{50}) of about $1 - 10 \mu\text{m}$ (Figure 2).
- Recent developments lead to smaller sizes of the glass filler fraction with an average particle size (d_{50}) of about $0.4 - 1 \mu\text{m}$ resulting in the so called **Micro-Hybrid Composites** (Figure 3).

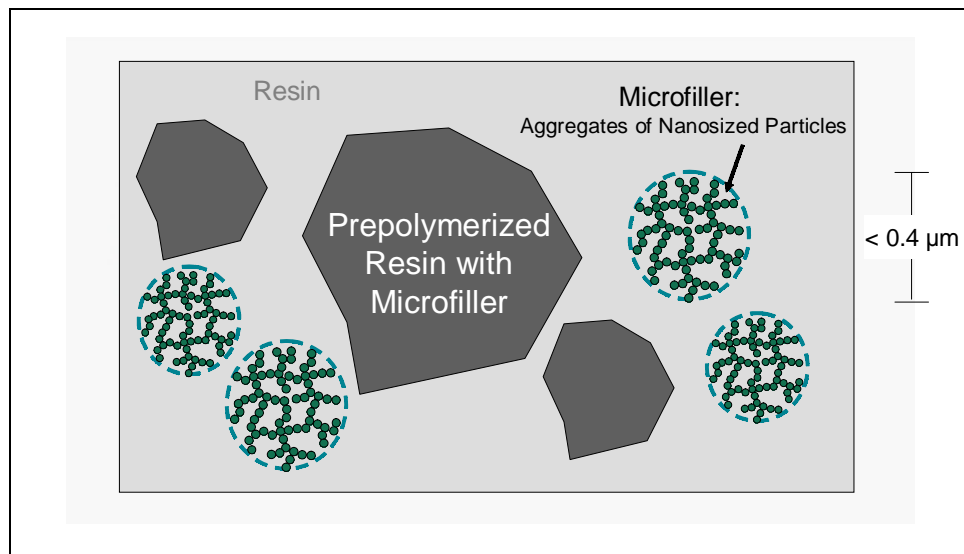


Figure 1 Schematic illustration of a microfilled composite.

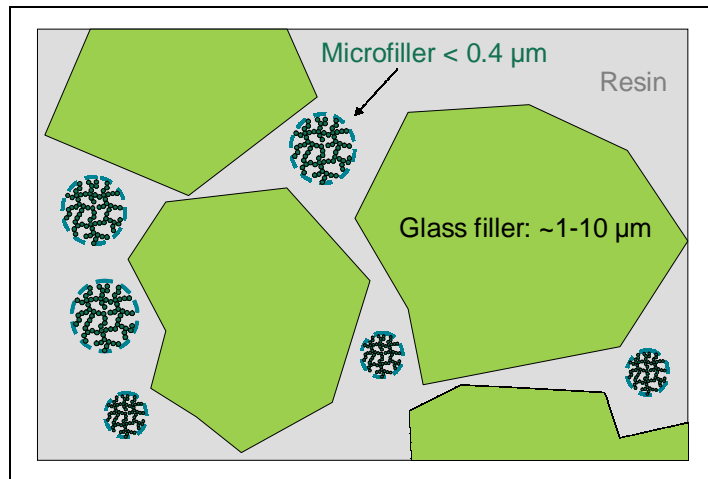


Figure 2 Schematic illustration of a hybrid composite.

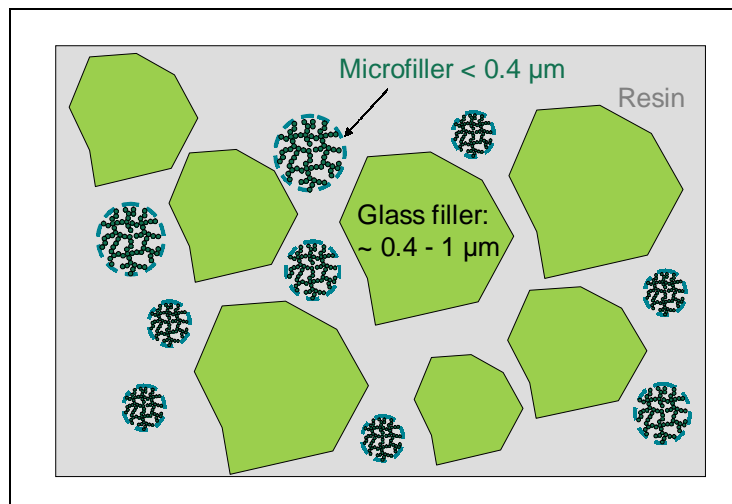


Figure 3 Schematic illustration of a micro-hybrid composite

In general, high filler loads support mechanical strength and reduce polymerisation shrinkage. Larger filler particles facilitate high filler loads due to their lower specific surface area and the corresponding lower energy to wet these particles with resin. On the other hand smaller particles are favourable to obtain superior aesthetics, polishability and wear resistance. However, smaller particles, i.e. sub-micron particles are more difficult to wet and are therefore often agglomerated and hence partially off-setting the desired effects.

Typically, primary particles in the size of ≤ 50 nm are not homogeneously dispersed but aggregate strongly to form large three-dimensional agglomerates of several 100 nm diameter up to ca. $0.4 \mu\text{m}$ (400 nm) (Figure 1).

The homogeneous dispersion and complete resin wetting of nano-sized filler particles is desired to improve the aesthetic and mechanical properties of composites and is the subject of Nano-Technology developments.

2.2 Nano-Ceramic Technology

In 1997 DENTSPLY applied Nano-Technology for the first time in dentistry introducing the innovative adhesive Prime&Bond[®]NT which is reinforced with highly dispersed and non-aggregated nanofillers.

Based on the long experience DENTSPLY gained in the field of nano-technology Ceram•X comprises **Organically Modified Ceramic** nano-particles and **Nanofillers** as used in Prime&Bond NT combined with **conventional glass fillers** of ~1 μm (Figure 4).

Ceram•X merges hybrid composite filler technology with advanced Nano-Technology. This results in **Nano-Ceramic Technology**.

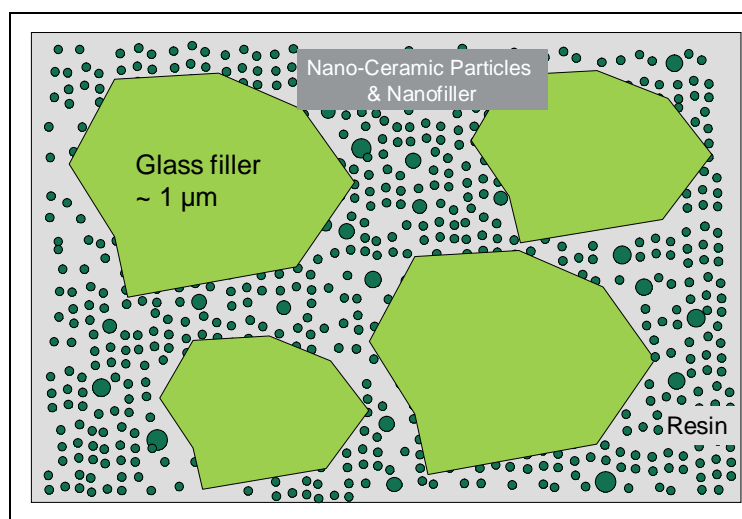


Figure 4 Schematic illustration of Ceram•X.

The Ceram•X nano-particles are highly dispersed due to an innovative manufacturing process: Starting from silane precursors the Organically Modified Ceramic nano-particles are achieved via controlled hydrolysis and condensation reactions (Figure 5).

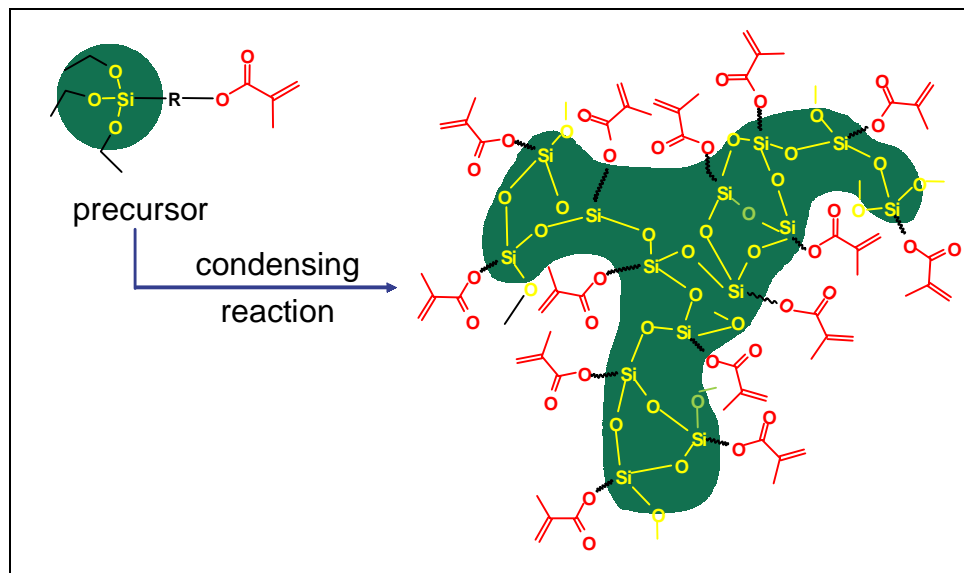


Figure 5 Processing of Organically Modified Ceramic nano-particles.

The Organically Modified Ceramic nano-particles comprise a polysiloxane backbone. The chemical nature of the siloxane backbone is similar to that of glass and ceramics. The degree of condensation was investigated by ^{29}Si -NMR-analysys. Figure 6 shows that the backbone is highly condensed.

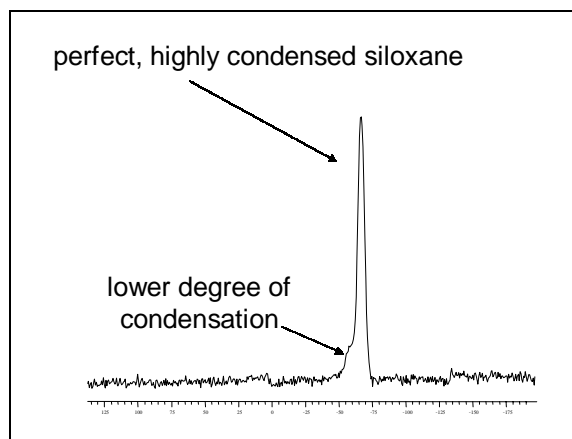


Figure 6 ^{29}Si -NMR-analysys (Mayer, 2003)

Methacrylic groups are attached to the backbone via silicon-carbon-bonds. These Nano-Ceramic particles can be best described as inorganic-organic hybrid particles where the inorganic siloxane part provides strength and the organic methacrylic part makes the particles compatible and polymerisable with the resin matrix.

The structure of the Nano-Ceramic particles is similar to the methacrylic modified Nanofillers as used in Prime&Bond NT (Figure 7).

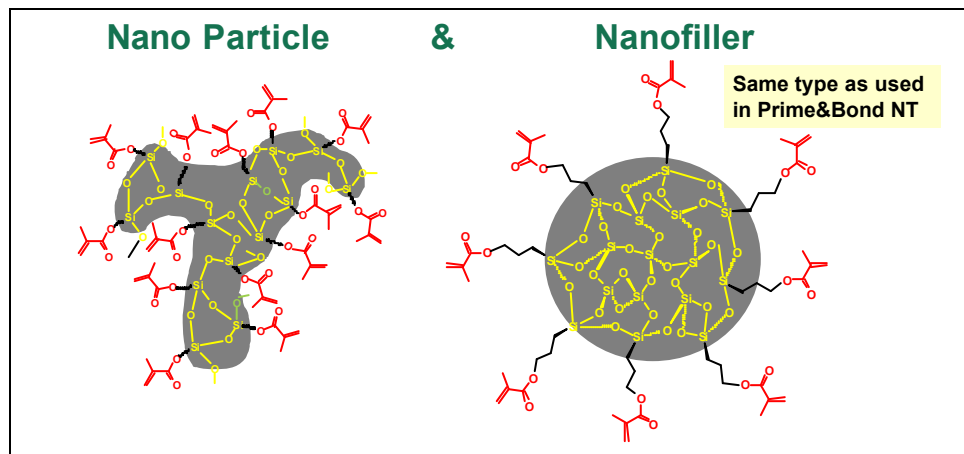


Figure 7 Schematic structures of Nano-Ceramic particles and nanofillers.

The size of the Nano-Ceramic particles was investigated by X-ray diffraction and was found to be ~2.3 nm (Figure 8).

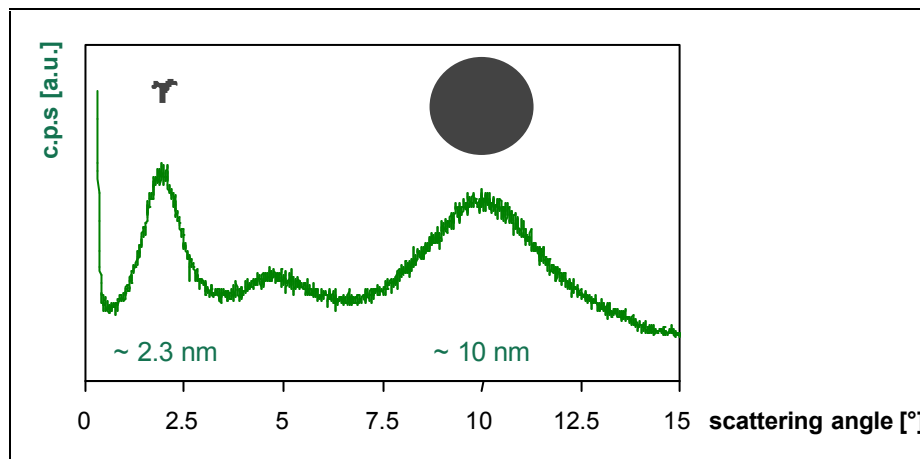


Figure 8 X-ray diffraction to determine the size of nano-particles (Lattermann, 2003)

Beside dentistry Organically Modified Ceramics are used in a variety of industrial or technical applications for instance in coatings with superior scratch resistance or corrosion protection.

3 Material properties

Nano-ceramic technology as applied in Ceram•X offers several advantages, such as high biocompatibility (chapter 3.1), high fracture toughness (chapter 3.2), and allows to use a new stabilizer resulting in excellent working time under ambient light (chapter 3.4.1).

The following chapters describe investigations performed to characterize Ceram•X in further details and in comparison to other currently used restoratives.

3.1 Biocompatibility

Due to the presence of the Nano-Ceramic particles the content of conventional resins in Ceram•X could be reduced significantly without compromising handling properties (see Chapter 5.4).

Besides standard investigations to confirm the safety of the used components in regard to toxicity, internal HPLC measurements confirmed that the reduced amount and kind of resins used in the formulation lead to a reduced post-curing monomer leakage.

Based on this reduced monomer leakage Ceram•X exhibits excellent biocompatibility as shown by cytotoxicity investigations.

3.1.1 Cytotoxicity

To test cytotoxicity samples of cured material are immersed in cell cultures (mouse fibroblasts L-929). After incubation the number of cells is counted and compared to the negative control (glass) which is assumed to have no adverse effect to the proliferation of the cells during incubation.

The relative cell number expresses the degree of cytotoxicity. Cells incubated together with freshly cured Ceram•X show significant higher proliferation than competitive materials and is therefore significant less cytotoxic (Figure 9).

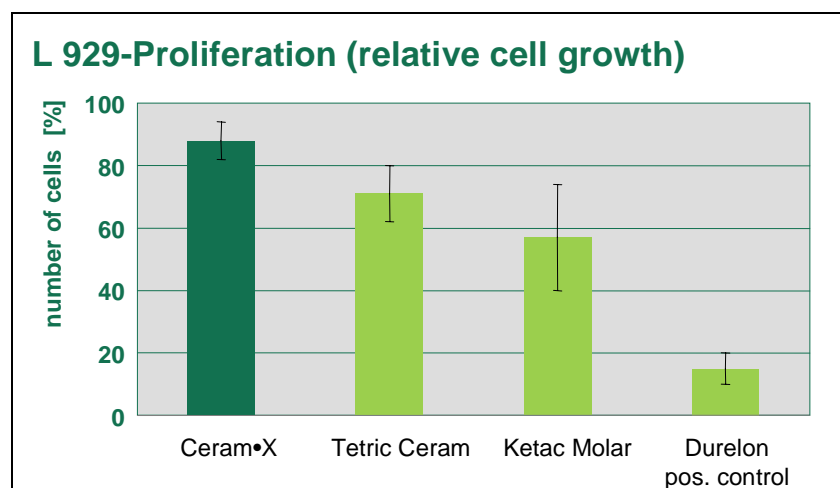


Figure 9 Initial Cytotoxicity by means of relative cell growth of various dental materials (Schedle, 2003)

In two additional experiments samples have been aged in the used incubation media beforehand for 7 days and 6 weeks, respectively. All materials under investigation showed lower cytotoxic effect. This suggests that cytotoxicity depends on the leakage pattern of relevant substances. Once, these are leaked out cytotoxicity drops.

In Ceram•X conventional resins are replaced by nano-ceramic particles to a great extent resulting in a better compatibility to cells. Further investigations on inflammatory properties are on-going.

3.2 Mechanical strength

Ceram•X was measured internally regarding compressive strength and flexural strength. From these measurements yield strength (reflecting the force needed to permanently deform the material) and E-modulus were determined as well.

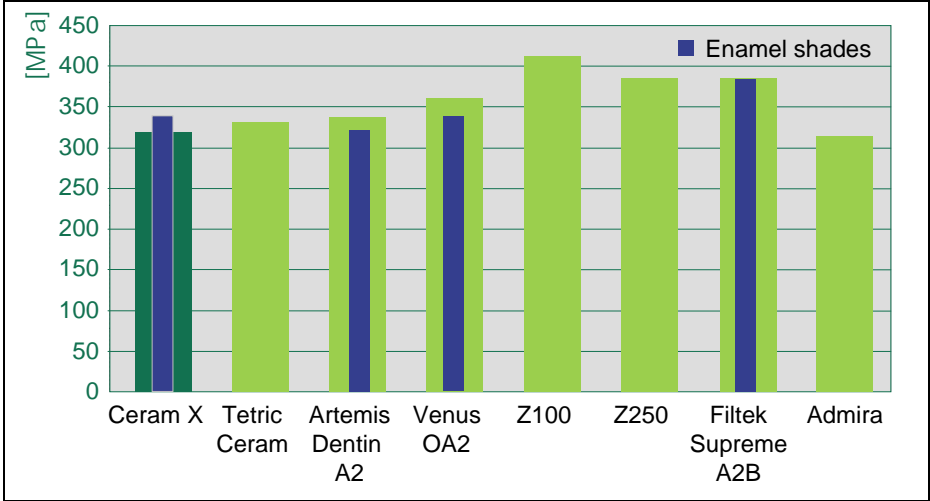


Figure 10 Compressive Strength

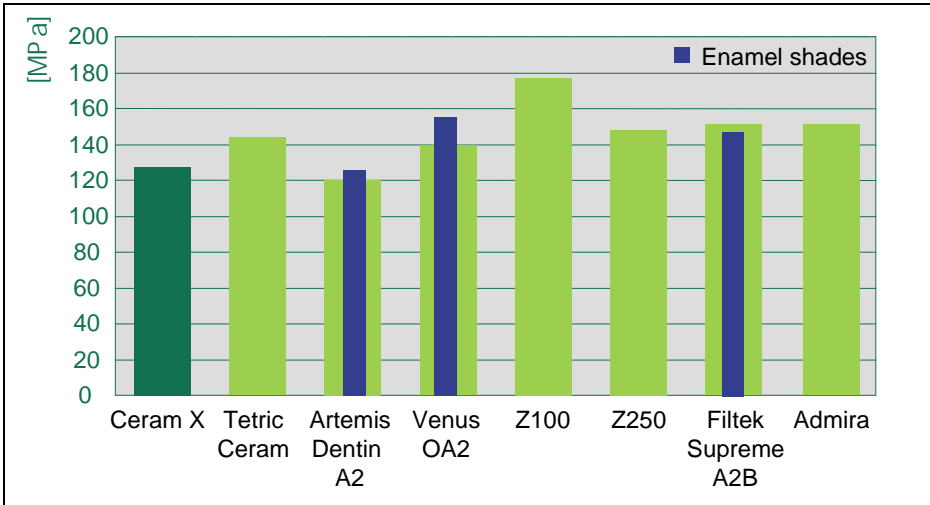


Figure 11 Yield Strength

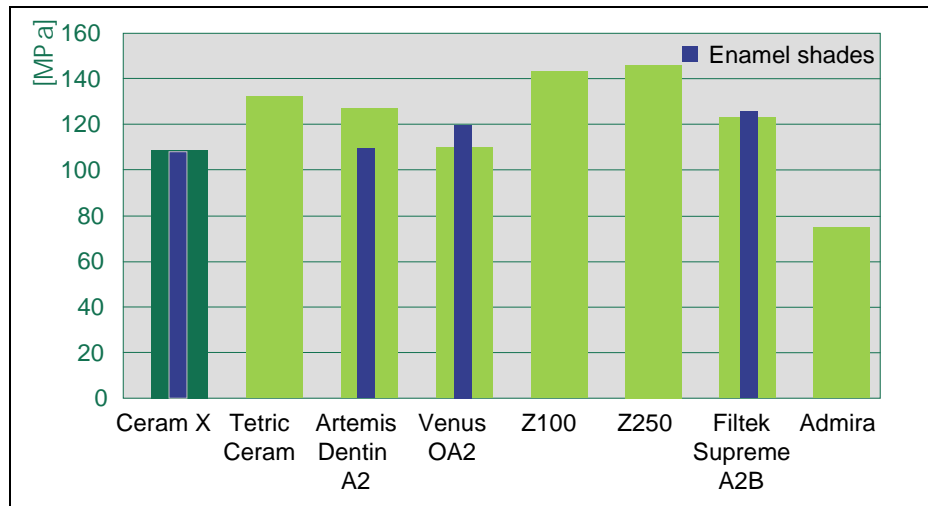


Figure 12 Flexural Strength

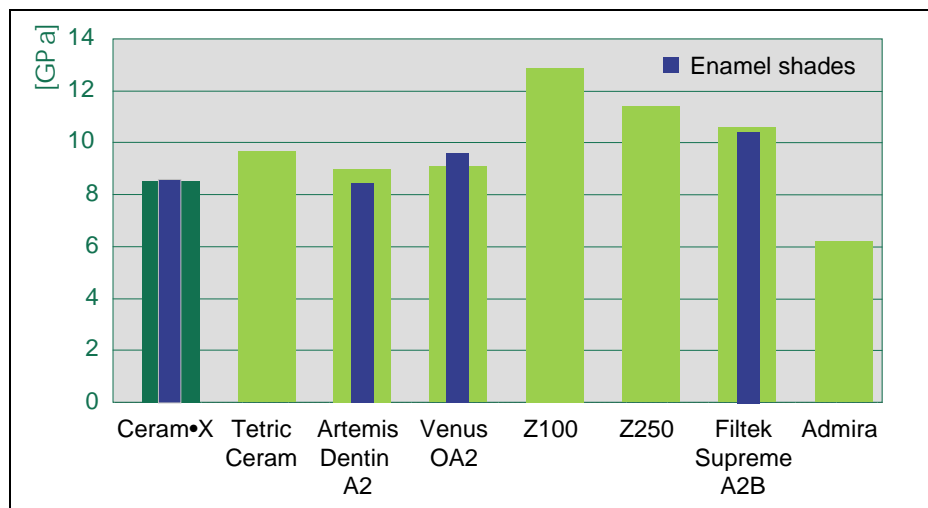


Figure 13 E-Modulus

Fracture toughness (K_{1c}) reflects the resistance of a material to crack propagation. The fracture toughness of Ceram•X is outstanding compared to competitive restoratives (Figure 14) and comparable to values found for dentin (Craig, 1997).

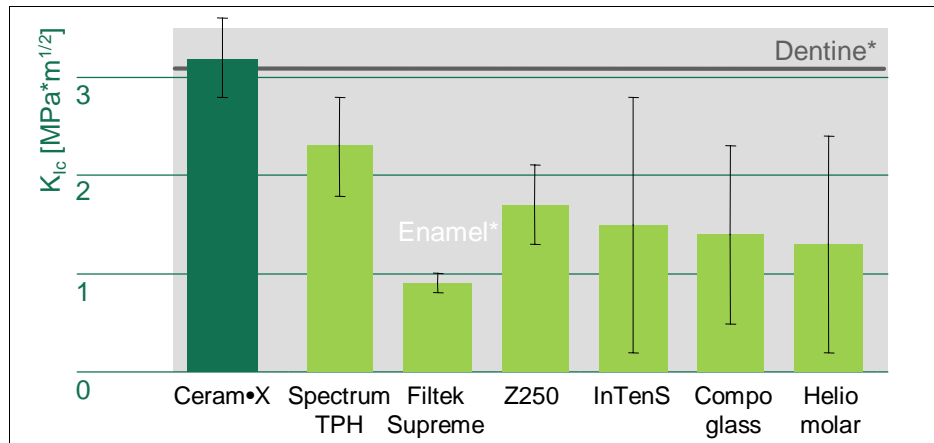


Figure 14 Fracture Toughness K_{1c}
(Schultz et al, 2003; except Ceram•X: unpublished data)

The good resistance to micro-crack propagation might be related to the strengthening effect of the nano-ceramic particles. Propagating cracks are either more often reflected or absorbed by the nano-ceramic particles (Figure 15).

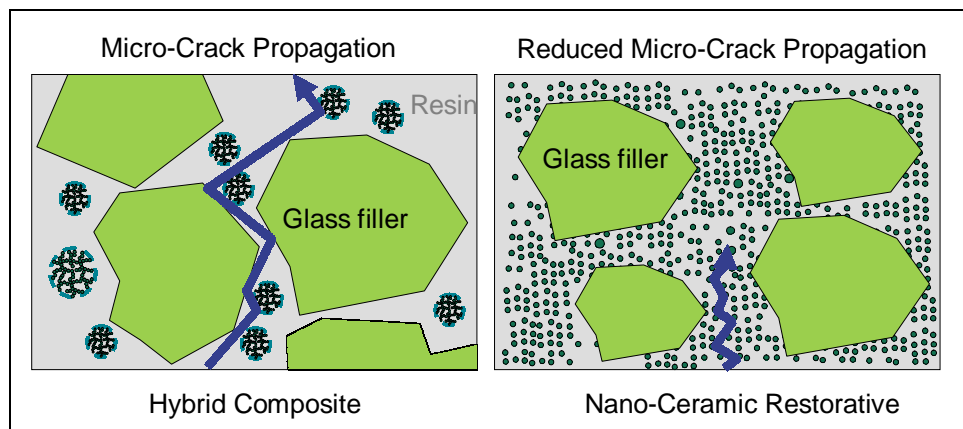


Figure 15 Schematic illustration of crack propagation in different materials

The physical properties of Ceram•X have been summarized in Table 1. The stipulated values represent typical findings.

Property	Unit	ISO 4049	Ceram•X		
			mono	duo D	duo E
Compressive strength	MPa		320		
Yield strength	MPa		130		
Flexural strength	MPa	> 80	110		
Flexural modulus	GPa		8.5		
Filler ¹ content (weight / volume)	%		76 / 57		
Glass filler size (mean)	µm		1.1 – 1.5		
Nano filler size (mean)	nm		10		
Nano particle size (mean)	nm		2.3		
Shrinkage (Archimedes)	% (v/v)		2.3		
Expansion in water	% (v/v)		0.5		
Water sorption	µg/mm ³	< 40	13.6		
Water solubility	µg/mm ³	< 7.5	-1.3 ²		
Curing time 2mm 500 mW/cm ² 800 mW/cm ²	s		20	40 30	10
Sensitivity to ambient light (10.000 lx)	s	> 60 (8.000 lx)	140	170	180
Measured radiopacity	mm Al		2		

Table 1 Technical data sheet Ceram•X

Conclusions:

- ⇒ The mechanical properties of Ceram•X are within the range of modern restorative materials with the exception of
- ⇒ Fracture toughness which is extraordinary high. It is expected that this will contribute to an improved durability.

¹ Conventional and Nano-Filler

² Negative value due to very low solubility and remaining absorbed water

⇒ The working time of at least 140 sec contributes to the ease of handling and gives the dentist sufficient time to manipulate the material under operating light conditions.

3.3 In-vitro simulations

In-vitro simulation of the final clinical usage provides further information on the expected clinical behavior of newly developed materials. Wear and marginal quality are among the most important investigations to predict a material's clinical performance in-vitro.

3.3.1 Leinfelder Wear

The Leinfelder Wear machine allows simulating different modes of wear. For this investigation masticatory stresses were transferred to a composite specimen by means of a stainless steel conical stylus in the presence of a slurry of polymethylmethacrylate beads (PMMA) simulating localized wear.

Surfaces of the samples are 3D profiled before and after wear to allow determination of volume loss and maximum depth in the wear facets (Figure 16).

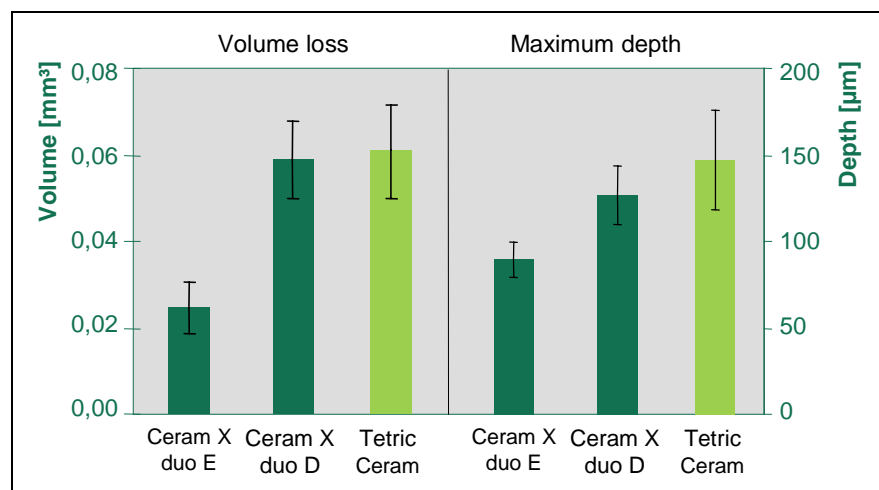


Figure 16 Leinfelder Wear: 400.000 cycles 1Hz, 80 N load, 30° rotation (Latta, 2003)

The results after a simulated wear period of ~3 years suggests that Ceram•X duo Dentin (which is besides shading identical to Ceram•X mono) compares well to the control material and that the tested Ceram•X duo Enamel shade wears significantly less compared to both.

Therefore it can be concluded that Ceram•X is suitable for all indications of a direct restorative in regard to wear.

3.3.2 Marginal integrity class V

Even though marginal integrity mainly depends on the used adhesive it is advisable to test newly developed restoratives on marginal integrity.

In this investigation restored teeth were immersed in a 0.5% water solution of basic fuchsin for 24 hours and rinsed for 5 minutes with distilled water. After this, the specimens were embedded in acrylic resin and bucco-lingual sections were obtained from each resin embedded specimen with a diamond saw. Microleakage was quantified separately for the occlusal and gingival walls of the class V cavities under an optical microscope. The extent of microleakage (Figure 18) along the restoration was expressed in grades as listed in Table 2 and shown in Figure 17.

Grade	Description
0:	Hermetic seal, no leakage
1:	Mild microleakage, dye infiltrating not more than half of the wall
2:	Moderate microleakage, dye infiltrating more than half of the wall, but does not reach axial wall.
3:	Massive microleakage, dye to the full extension of the wall and including the axial wall).

Table 2 Grading of dye penetration (Rosales, 2003)

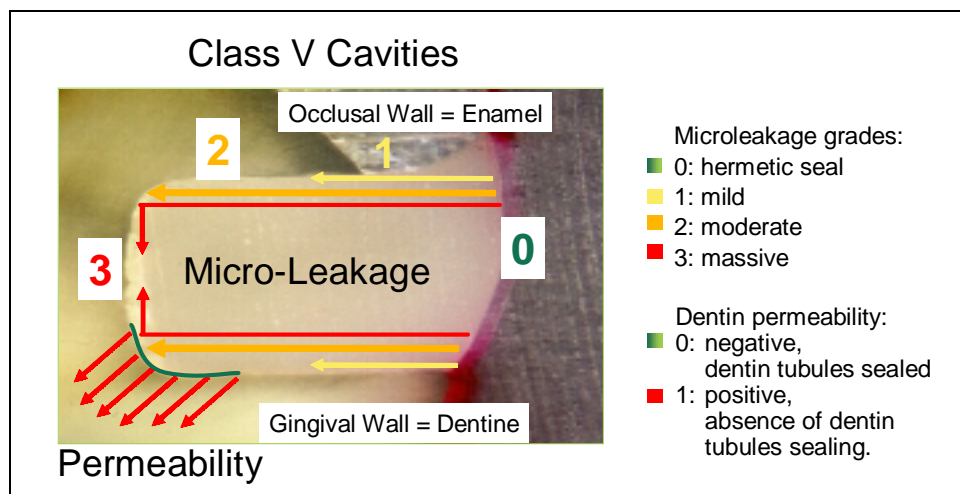


Figure 17 Legend for grades of microleakage and dentin permeability (Rosales, 2003)

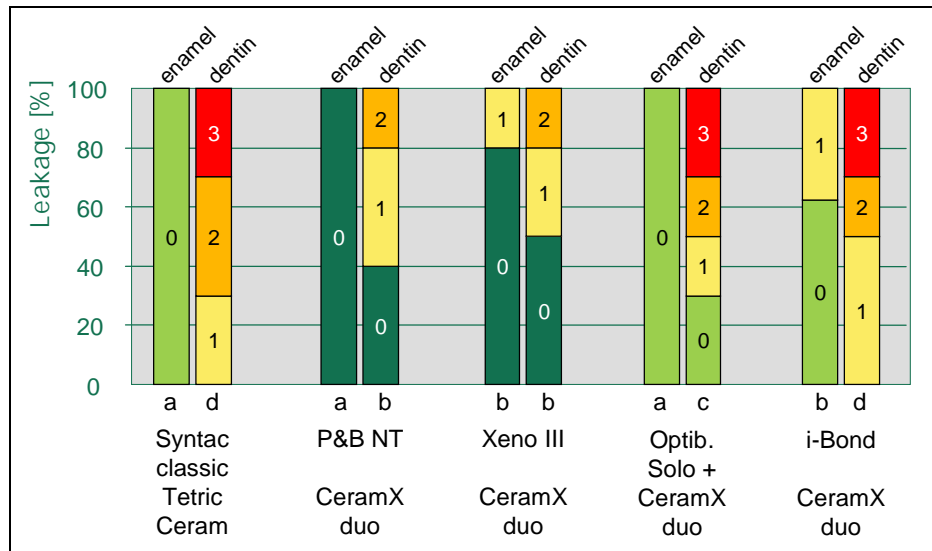


Figure 18 Grades of Microleakage (0 to 3) and statistical grouping (a to d) (Rosales, 2003)

Restorations with Ceram•X either in combination with Prime&Bond NT or Xeno® III showed overall less marginal leakage compared to the control groups.

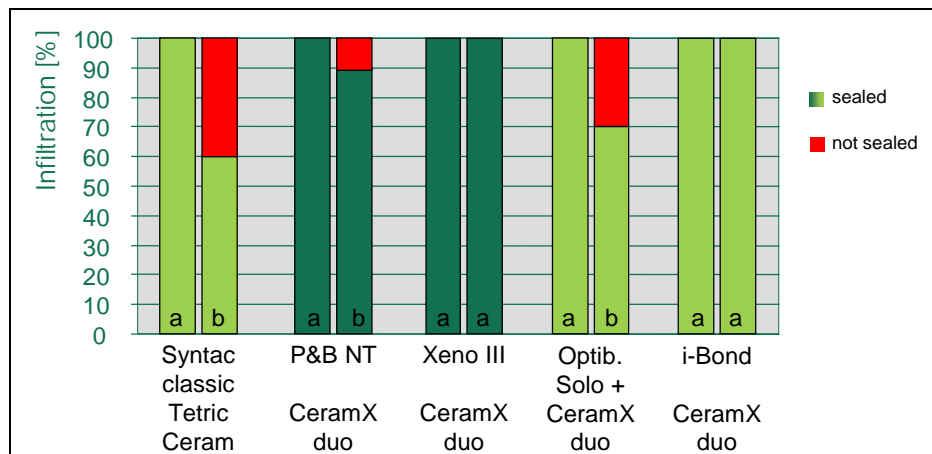


Figure 19 Dentin permeability (yes / no) and statistical grouping (a, b) (Rosales, 2003)

As Figure 19 shows dentine treated with self-etch adhesives did not show permeability despite the microleakage that was found (compare to Figure 18).

3.3.3 Marginal integrity class II

In this investigation a chewing simulator was used to age the samples. Freshly extracted human molars were used to prepare class II cavities with one approximal box limited to enamel and the other being extended into dentin. The incremental filling technique used is described in Figure 20.

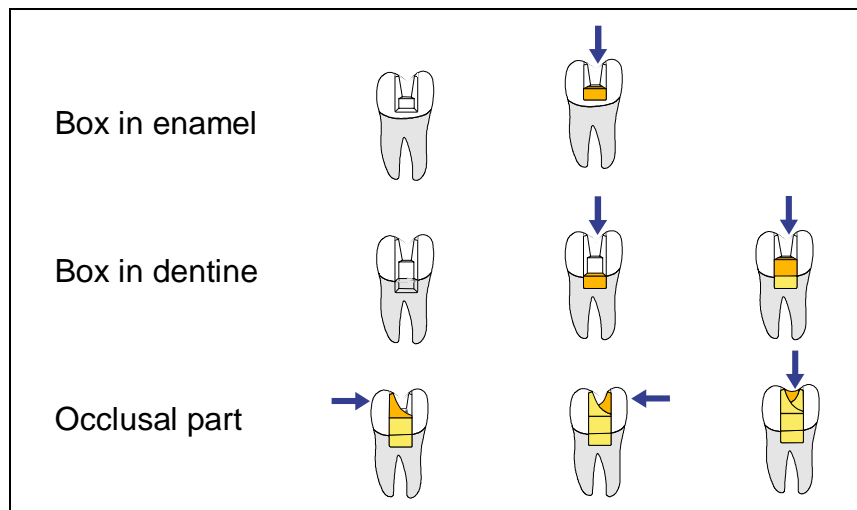


Figure 20 Incremental filling technique used for class II (Manhart, 1999)

After stressing the restorations by 2.000 thermo cycles between 5 and 55°C and 50.000 chewing actions with a load of 50N replicas were produced and approximal cavo surface margins were investigated under SEM by 200 magnifications. Percentage of perfect margins, gap (>1µm), swelling, and sites that can not be judged were recorded. Results of the present investigation and a former investigation under the same operator and the same experimental conditions are summarized in Figure 21.

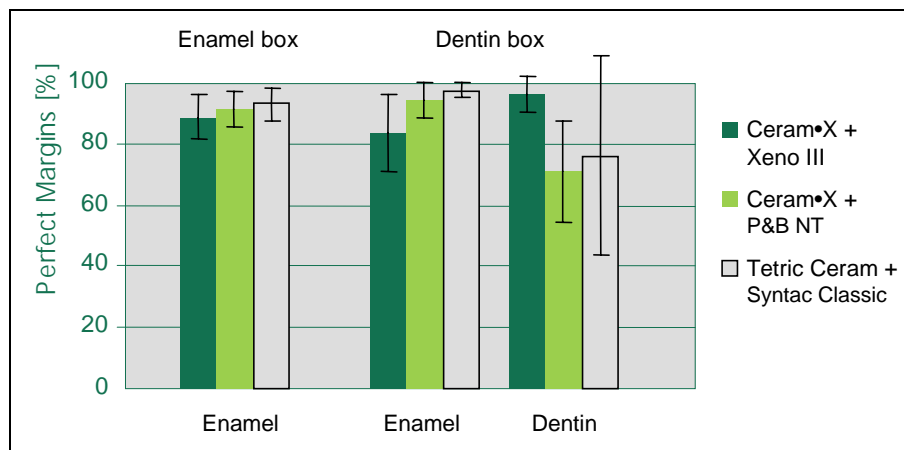


Figure 21 Distribution of perfect margins after aging in a chewing simulator (Ceram•X: Manhart, 2003; Tetric Ceram: Manhart, 2002)

Conclusions

⇒ Ceram•X in combination with either Prime&Bond NT or Xeno III offers marginal integrity similar or better to the control groups

3.3.4 CEBL – Simulating recutting and rebonding of composite

The final aspect of aesthetic restorations depends among others on the correct layering if different transparencies are used. Especially at the beginning of the learning curve when using a new material it may occur that the correct thickness of layers are not met. Instead of virtually building up the total restoration beforehand in order to know the correct thickness of each layer the CEBL-technique - **C**ut-**B**ack, **E**tch, **B**ond, **L**ayer – suggests to cut back cured composite either by purpose or in case layering was too thick, to etch and apply a bonding before finally placing the next layer (Blank, 2003).

First results are shown in Figure 22 where the positive control is layering composite without any treatment in between the layers and the test group comprises grinding with 320 grit, etching using phosphoric acid for 15 seconds, applying Prime&Bond NT as adhesive and finally placing the composite.

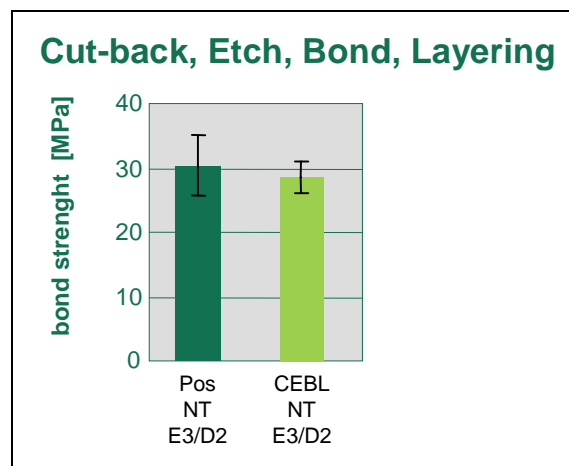


Figure 22 Bond Strength after CEBL technique (Latta, 2003)

Conclusions

⇒ The results suggests that immediate rebonding of Ceram•X during the placement of a restoration does not adversely affect the bond strength between each layer.

3.4 Handling Properties

3.4.1 Working Time

Ceram•X comprises an innovative non-leachable proprietary inhibitor system (Figure 23). The Working time is up to 180 sec (at 10.000 Lux) even in the case of highly translucent

enamel shades. This extended working time provides handling convenience. The non-leachable inhibitor molecule is polymerized into the network. Therefore it does not leach out and contributes to the excellent biocompatibility as described in chapter 3.1.

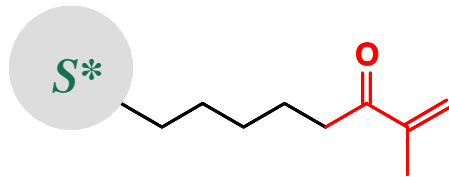


Figure 23 Schematic illustration of the new non-leachable inhibitor

The resulting working time for Ceram•X mono and Ceram•X duo Enamel and Dentine is compared to a variety of restoratives in Figure 24.

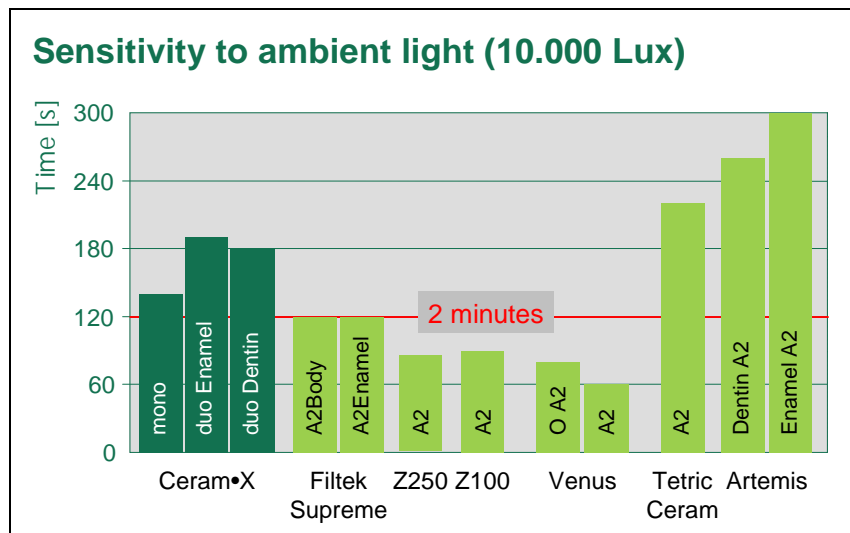


Figure 24 Working time of different restoratives and transparencies.

3.4.2 Stickiness

Paste handling is a very important factor not only for the convenience during restoration but for the long-term results as well. Placing sticky pastes into cavities and retracting the instrument may produce voids to the adhesive or previous composite layer even before curing. The assessment of paste handling could be done until now either by indirect measurements like determination of consistency or by trained evaluators.

In this study a recently published method (Al-Sharaa et al, 2003) was used to determine the stickiness for a variety of materials – including enamel shades where available. By placing a metal instrument onto the material and retracting it afterwards, material is torn upwards until the adhesion to the instrument is lower than the intrinsic cohesion of the material. The

pattern of resin (Figure 25) is than cured and measured for mean height (Figure 26) and surface area.

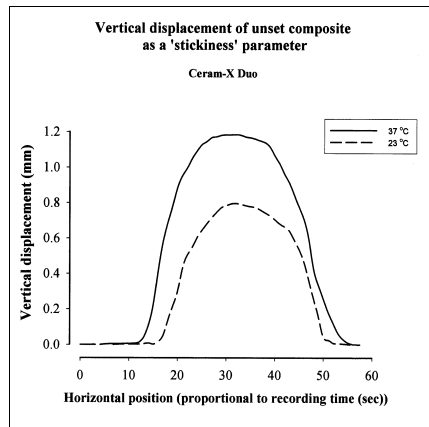


Figure 25 Plot to determine height of the resin pattern (Watts et al, 2003)

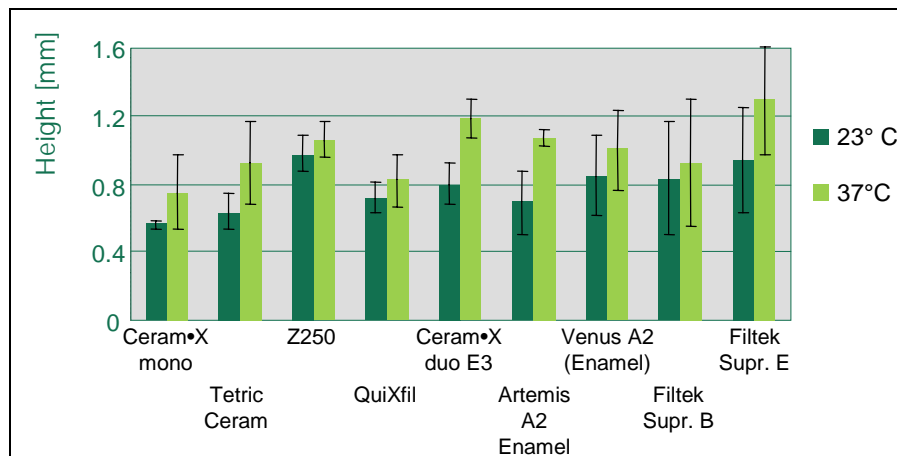


Figure 26 Stickiness to metal instruments (Watts et al, 2003)

Conclusions

⇒ This study supports the finding from an extended seeding trial in which course 1325 restorations were performed and dentists rated reduced stickiness to metal instruments as the most important advantage in handling for Ceram•X.

3.5 Polishability

Superior aesthetic restorations are one of the most demanding indications for dentists. Besides matching shade (see also chapter 4) and contour of the natural tooth, surface morphology of the final restoration is very important to achieve a highly aesthetic result.

In this investigation surface quality after polishing following different protocols (Table 3) was measured by means of the medium roughness R_a (Figure 27).

	SofLex	Enhance
Clinical situation	Approximal surfaces	Occlusal surfaces
Step 1	Coarse disc 5 strokes	Diamond bur : 30 μm 5 strokes
Step 2	Medium disc 5 strokes	Enhance disc until grooves removing
Step 3	Fine disc 10 strokes	Prisma gloss regular 20 s
Step 4	Super fine disc 10 strokes	Prisma gloss extrafine 20 s

Table 3 Protocols for polishing of different clinical situations (Salomon, 2003)

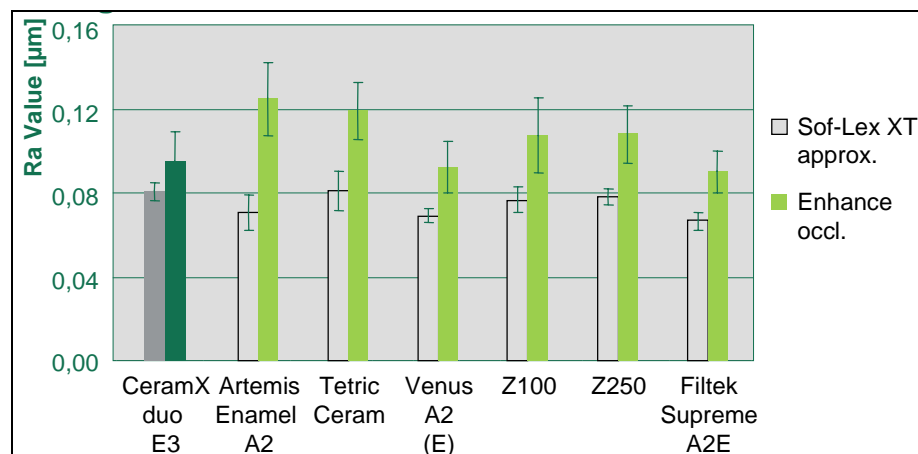


Figure 27 Surface Roughness after simulated polishing procedures for approximal and occlusal surfaces (Salomon, 2003)

Conclusions

⇒ Using the Enhance Polishing system for Ceram•X results in very low surface roughness and high gloss, respectively.

3.6 Fluorescence

Figure 28 shows that Ceram•X provides sufficient fluorescence whereas other restoratives show a lack of fluorescence. Non-fluorescent restorations exposed to so called black light will be prone to de-masking effects indicating missing tooth substance.



Figure 28 Fluorescence to light of 254 nm wavelength

3.7 Radiopacity

Besides measurement of radiopacity of Ceram•X (2 mm Al) a radiograph was taken to optically compare among various restoratives (Figure 29).

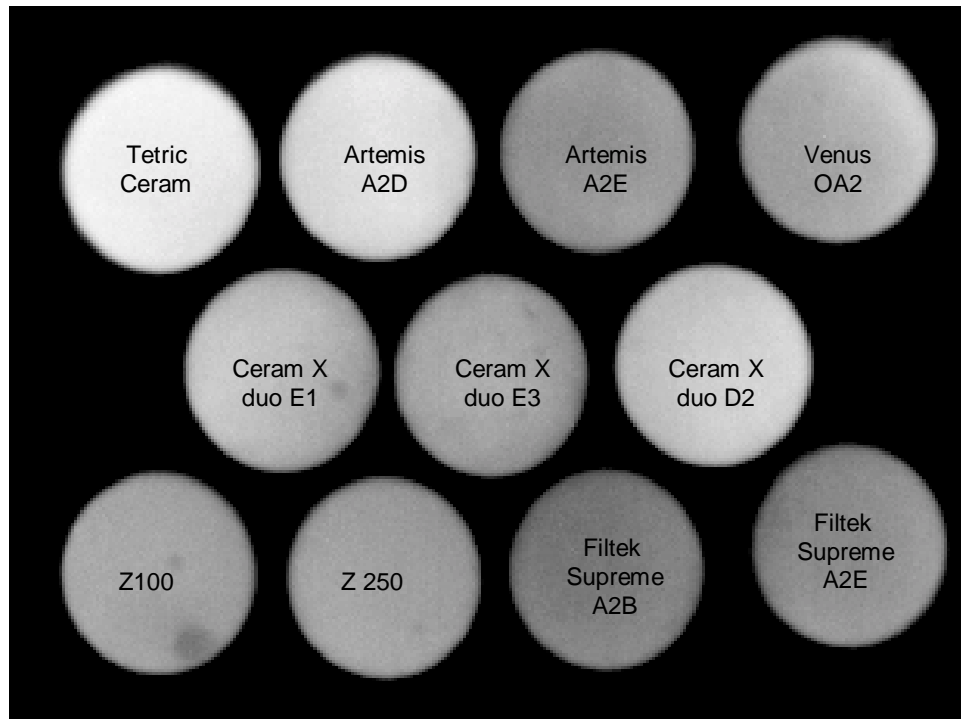


Figure 29 Radiograph of 2mm thick samples to compare radiopacity

Conclusions

⇒ Ceram•X offers a well balanced radiopacity and can easily be detected on radiographs.

3.8 Optical Properties

Ceram•X is offered in two distinguished systems: Ceram•X mono as universal single translucency system and Ceram•X duo as easy to use double translucency system to rebuild teeth naturally.

Only 3 enamel shades and 4 dentine shades of Ceram•X duo are sufficient to cover the whole VITA range. This is possible due to the precise tuning of chroma and opacity within these 7 shades. (An additional shade (DB) is available to restore bleached teeth.)

Measurements are based on the CIE – L*a*b* system and calculations are done according to DIN 5033, part 3 and DIN 6174.

In Figure 30 opacity³ of all Ceram•X duo enamel and dentine shades are shown. The opacity of various materials that are referred to as VITA A2 are shown in Figure 31. Ceram•X mono falls well into the opacity of other materials available in one translucency, only. On the other hand, it is noticeable that Ceram•X is from the products shown in Figure 31 the only double translucency system⁴ offering a difference in opacity between enamel and dentin shades that reflects the difference in opacity of human enamel to dentin.

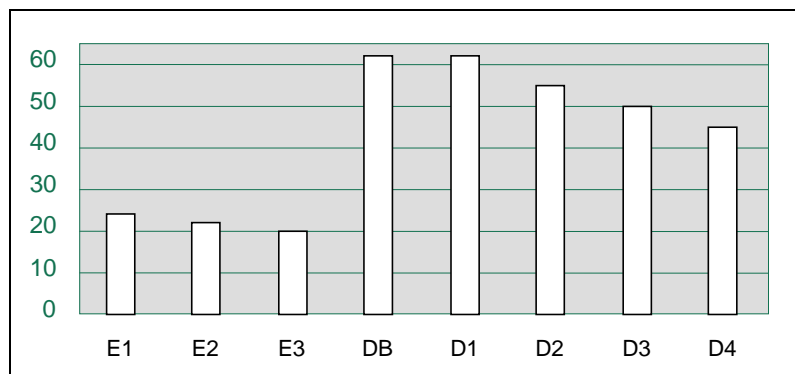


Figure 30 Opacity of Ceram•X duo shades

³ Y-value black background / Y-value white background in percentage

⁴ In other systems 3 or more translucencies are necessary to cover this spread in opacity.

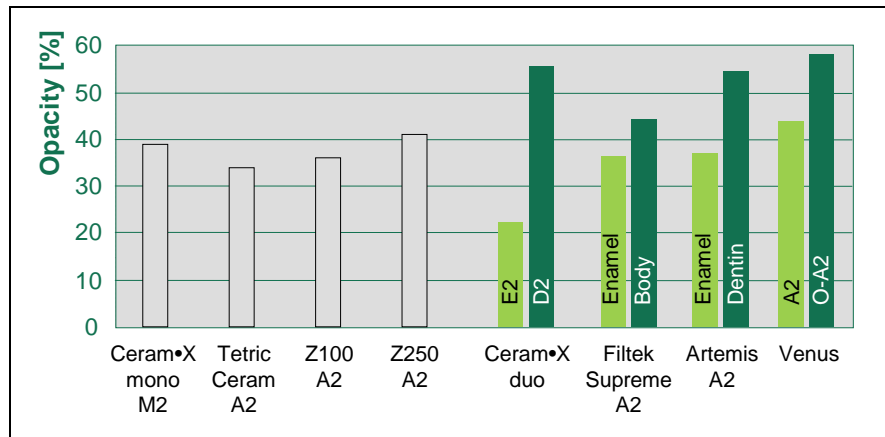


Figure 31 Opacity of single and double translucency restorative materials

The Chroma⁵ C* (which reflects the saturation of the colour) is shown in Figure 32. Note the even distribution among shades.

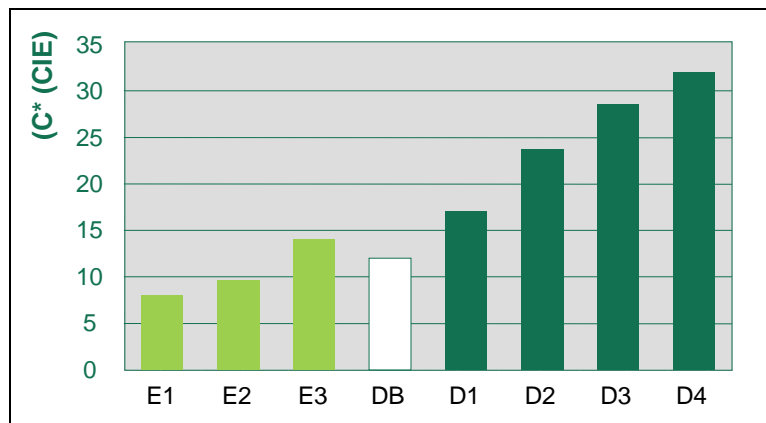


Figure 32 Chroma C* of Ceram•X

It can be seen that the Ceram•X duo system is systematically designed which is reflected in the overall difference (ΔE) between the shades as well (Figure 33) and makes it easier to learn and understand the shading concept during daily treatment in practice.

⁵ $C^* = \sqrt{a^{*2} + b^{*2}}$

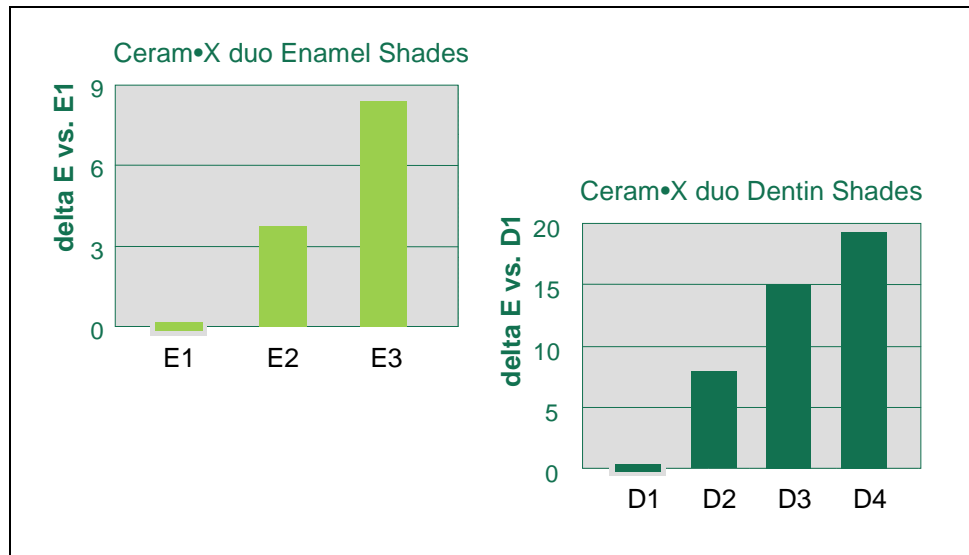


Figure 33 ΔE values for enamel and dentin shades

Younger teeth are more opaque, lighter and show less chroma compared to older teeth which show higher chroma in dentin and less opacity in enamel.

This is reflected in the Ceram•X duo system where shades with higher chroma have less value and opacity (Figure 34).

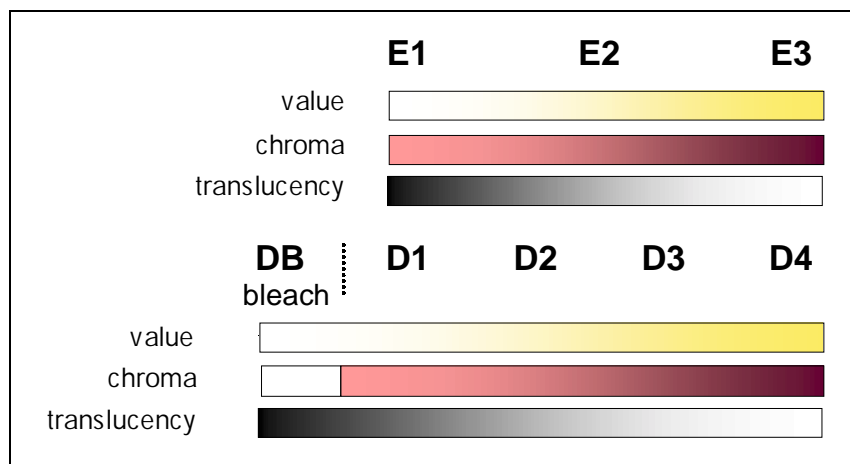


Figure 34 Schematic overview on properties influencing the final shade of a restoration

Conclusion

⇒ The shading concept of Ceram•X duo is systematically designed and reflects shade behavior of natural dentition. Therefore, it supports the dentist in achieving aesthetical restorations.

4 The Shade System

Ceram•X was designed to cover all aesthetic and practical demands in restoring natural tooth colours. The developmental goal was to provide an easy shading system for advanced aesthetic solutions as well as for fast restorations on a primary level. Thus, two separate shading concepts have been integrated in one product. Ceram•X is based on the colours of natural tooth substance, nevertheless both systems offer reference to the established Vita® system.

With the **Ceram•X mono** shades M1 to M7, Ceram•X comprises seven colours of intermediate translucency (similar to e.g. Spectrum® TPH or Dyract® eXtra) for the restoration of the complete defect. The Ceram•X mono concept is ideal for fast and easy anterior and posterior restorations. In order to ensure coverage of the entire Vitapan Classical shade range, each of the seven Ceram•X mono shades fits for several Vita shades similar in colour and lightness.

For aesthetically demanding cases, the **Ceram•X duo** system offers four dentin (duo D1 to duo D4) and three enamel colours (duo E1 to duo E3). Their colour values and translucencies are on a level similar to those of natural tooth substance. In their various combinations, the seven Ceram•X duo dentins and enamels enable the dental professional to benefit from a superior optical results. Additionally, one bleach dentin colour (duo DB) is available for restoration of bleached teeth.

Along with the packages comes a self-sticky recipe label (Figure 35), ideal for fixation on the rear side of the Vita Shade guide, providing a quick survey over the Vita dedicated Ceram•X shades in both mono and duo technique.



Figure 35 i-shade label for Vita reference of Ceram•X mono and duo

The Ceram•X mono and Ceram•X duo systems are available separately.

5 Clinical Investigations and Handling Evaluations

Despite of the significance of in-vitro investigations, conducted both internally and externally, clinical investigations provide final certainty concerning the efficacy of new restorative technologies. Therefore, several investigations on different cavity classes have been started and results have yet been obtained. In all studies, Ceram•X mono has been applied in combination with an experimental total etch adhesive (DENTSPLY code: K-0127).

5.1 Clinical Investigation of Class I and II restorations at University of Freiburg, Germany

Being one of the major indications of restoratives materials, the clinical behaviour of materials in class I and II cavities is of particular interest. Accordingly, a controlled longitudinal class I and II investigation is conducted at the Department of Operative Dentistry, Albert-Ludwigs-University of Freiburg, Germany (Head: Professor Dr. E. Hellwig). Under guidance of Main Investigator Priv.-Doz. Dr. P. Hahn, Associate Professor, 43 Ceram•X restorations and 43 controls (Tetric® Ceram/ Syntac® Classic) have been established in a corresponding number of patients. The 6-month results on 38 patients are provided in Table 4.

Restorative Parameter	Ceram•X [%]				Tetric [%]	
	alpha	bravo	charlie	delta	alpha	bravo
Retention	100	0	0	0	100	0
Marginal Integrity	94.7	5.3	0	0	92.1	7.9
Marginal Discolouration	94.7	5.3	0	0	94.7	5.3
Post-op Sensitivity	97.4	2.6	0	0	100	0
Secondary Caries	100	0	0	0	100	0
Colour Match	97.4	2.6	0	0	100	0
Anatomical Form	100	0	0	0	97.4	2.6
Surface texture	100	0	0	0	100	0

Table 4 6 month results in class I and II (Hahn, 2003)

The investigation is designed according to revised ADA (American Dental Association) guidelines for composite resin materials for posterior restorations. Ryge criteria are applied.

5.2 Clinical Investigation of Class V restorations at University of Bologna, Italy

As adhesion still remains one of the potential weaknesses of restorative therapy, data on clinical success of class V's is essential. Thus, Professor Dr. G. Dondi dall'Orologio, Head of Department of Operative Dentistry at University of Bologna, Italy, is conducting a longitudinal clinical investigation on restoration of caries free cervical lesions. 100 restorations have been established in 50 patients. The 6 month results in all 50 patients are provided in Table 5.

Restorative Parameter	Ceram•X [%]			
	alpha	bravo	charlie	delta
Retention	100	0	0	0
Marginal Integrity	100	0	0	0
Marginal Discolouration	100	0	0	0
Post-op Sensitivity	100	0	0	0
Secondary Caries	100	0	0	0
Colour Match	100	0	0	0
Anatomical Form	100	0	0	0

Table 5 6 month results class V (Dondi dall'Orologio, 2003)

The investigation is designed according to revised ADA (American Dental Association) guidelines for dentin and enamel adhesive materials. Ryge criteria are applied.

5.3 Field Monitoring Study, Germany

In this recently introduced study concept, Ceram•X Class V restorations established under conditions of private practice are investigated. 22 private practitioners placed up to 10 Ceram•X mono restorations each in patients of their practices. No special recall appointments are agreed, instead evaluation of restorations is conducted in connection with routine visits of patients.

Placement phase has been closed in February 2003, 188 restorations have been established. The clinical information available up to now concerns 88 restorations in total respectively 49 restorations monitored after at least 83 days (92 days - 10% = 3 month results). One retention failure has been reported. Information on change in parameters

“marginal discolouration”, “marginal crevice” and “secondary caries” is only available when necessitating the change of restoration. The results for 88 restorations are given in Table 6.

Change Parameter	Yes		no		total
	[%]	[n]	[%]	[n]	[n]
Retention	98.9	87	1.1	1	88
Marginal Crevice	0	0	100	87	87
Marginal Discolouration	0	0	100	87	87
Post-op Sensitivity	3.4	3	96.6	84	87
Secondary Caries	0	0	100	48	87
Replacement needed	0	0	100	48	87

Table 6 Results of the Field Study (Schaller, 2003)

This study is conducted under scientific guidance of Prof. Dr. H.-G. Schaller, Martin-Luther-University of Halle-Wittenberg, Germany.

Conclusion

⇒ Based on the results of the clinical studies, it can be concluded that for the considered interval neither safety nor efficacy problems were observed for Ceram•X.

5.4 Handling Evaluation

In context with the Field Study, handling properties of Ceram•X were rated by the participating practitioners. Stickiness, consistency, sculptability, polishability, marginal adaptability and processing time were rated in comparison to the restorative standard product currently used in the respective practice. For all those criteria, a clear majority of practitioners rated Ceram•X equal or better than the standard. The results are provided in Figure 36. The overall rating of handling properties is shown in Figure 37.

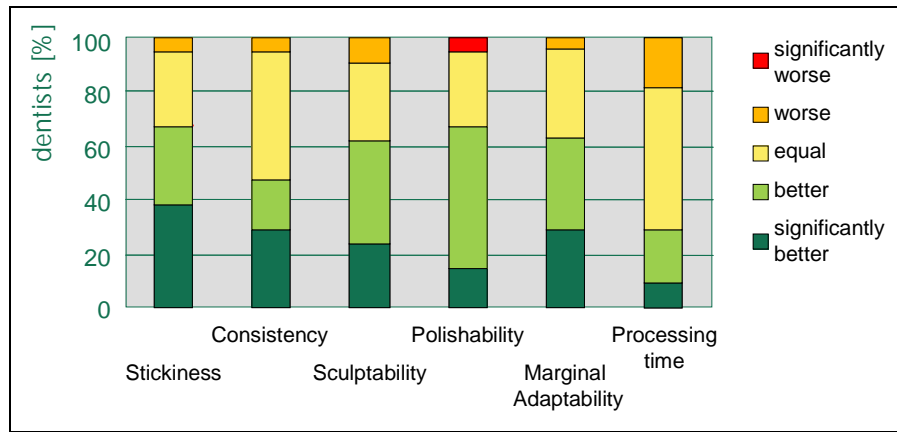


Figure 36 Rating of handling properties of Ceram•X compared to standard restorative product

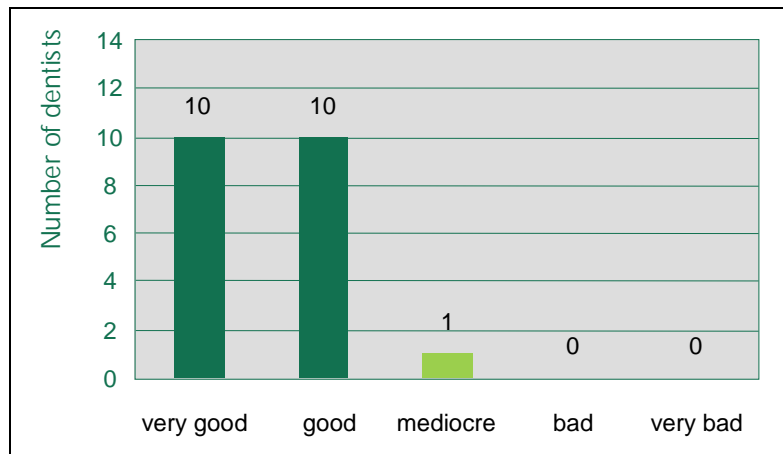


Figure 37 Overall rating of handling properties

In context with the Clinical Investigation of Class V restorations, a handling blind test was also conducted by the investigators of the University of Bologna concerning stickiness, slumping, layering and polishability of the material. For each investigator, a sum score was calculated. As a result, Ceram•X was rated equal or superior to the reference materials Z100 and Tetric Ceram.

Conclusion

⇒ From both handling evaluations, conducted in context with the field study and the clinical trial at University of Bologna, it can be concluded that the material shows very good handling properties. Ceram•X convinced the practitioners working with the material.

6 Directions for Use

Ceram•X™

UNIVERSAL NANO-CERAMIC™ RESTORATIVE

Ceram•X is a light cured, radiopaque restorative material for restoration of anterior and posterior teeth. **Ceram•X** combines **Nanotechnology**, proprietary to DENTSPLY and known from Prime&Bond® NT, with improved organically modified **Ceramic** particles, resulting in a **Nano-Ceramic Restorative** with unique features. Thus, Ceram•X offers natural aesthetics by simple procedure, extraordinary low monomer release and superior handling characteristics.

Ceram•X provides the convenient **Natural-Shade™** system: two shading systems in one product cover all clinical and aesthetic demands for anterior and posterior teeth.

Ceram•X o o, the Single Translucency System, comprises seven shades of intermediate translucency comparable to conventional composites (e.g. Spectrum® TPH), optimal for fast and easy restorations of posterior or anterior teeth.

Ceram•X duo, the Double Translucency System, offers four dentin shades with translucencies of natural dentin and three enamel shades which mimic natural enamel. Their design has been optimized for highly aesthetic restorations with a minimum number of shades. For the enamel shades, the unique Nano-Ceramic matrix in combination with the optimized filler particle size distribution create an ideal balance between handling and optical characteristics. Additionally, Ceram•X *d o* comprises one bleach dentine shade for the restoration of bleached teeth.

The **Ceram•X i-shade label** eases shade selection, covering the whole Vita®⁶ classical shade range for both the **Ceram•X o o** and the **Ceram•X d o** system.

Ceram•X is to be used with either total-etch nano-technology dental adhesive **Prime&Bond NT** or the single-step self-etching adhesive **Xeno® III**.

The **Ceram•X** restorative system is available in predosed Compules®-Tips and Easy-Twist™ syringes.

Caution: For dental use only.

6.1 COMPOSITION

methacrylate modified polysiloxane⁷

dimethacrylate resin

fluorescence pigment

UV stabilizer

⁶ Vita is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co. KG, Bad Säckingen, Germany.

⁷ organically modified ceramic

stabilizer

camphorquinone

ethyl-4(dimethylamino)benzoate

barium-aluminium-borosilicate glass

methacrylate functionalised silicon dioxide nano filler

iron oxide pigments and titanium oxide pigments and aluminium sulfo silicate pigments according to shade

6.2 INDICATIONS FOR USE

Direct restorations of all cavity classes in anterior and posterior teeth.

6.3 CONTRAINDICATIONS

Known allergy to methacrylate resins or any other of the components.

6.4 WARNINGS

- Ceram•X contains methacrylates which may be irritating to skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of soap and water. Do not take internally.
- Ceram•X contains polymerizable monomers which may cause skin sensitization (allergic contact dermatitis) in susceptible persons. Wash thoroughly with soap and water after contact. If skin sensitization occurs, or if a known allergy to methacrylate resin exists, discontinue use.

6.5 PRECAUTIONS

When using Ceram•X Compules tips, use a gentle, even motion when exerting pressure on the applicator gun. Use of excessive force or sudden movement could create a potential hazard with extrusion.

6.6 ADVERSE REACTIONS

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

6.7 INTERACTIONS WITH OTHER DENTAL MATERIALS

Eugenol and hydrogen peroxide containing dental materials should not be used in conjunction with these products because they may prevent setting and cause softening of the polymeric components of the material.

6.8 STEP-BY-STEP INSTRUCTIONS

Shade Selection

- The Ceram•X Nano-Ceramic Restorative comprises two separate shading systems:
- Ceram•X *mono*, the Single Translucency System with seven shades for clinical standard situations (Mono M1, M2, M3, M4, M5, M6 and M7)
- and
- Ceram•X *duo*, the Double Translucency System with four dentin shades (Duo D1, D2, D3 and D4) and three enamel shades (Duo E1, E2 and E3) for aesthetically demanding cases. Within Ceram•X *duo*, one bleach dentin shade (Duo DB) is available for the restoration of bleached teeth.

A) Shade selection using the Vitapan^{®8} classical shade guide

The Ceram•X shades can be attributed to the Vitapan classical shade guide. Thus, it is possible to select the tooth colour to be restored from a Vitapan classical shade guide for both the Ceram•X mono and the Ceram•X duo system:

Ceram•X *mono* (Single Translucency System)

Refer to the central regions of the natural tooth and the Vita shade fingers. Choose the Vita shade most closely matching the tooth colour.

Seven Ceram•X *mono* shades of intermediate translucency are available for restorations in Single Translucency Technique. Each Ceram•X *mono* shade is suitable for several similar Vita shades. Having determined the tooth colour by means of a Vitapan classical shade guide, select the corresponding Ceram•X *mono* shade from the below table:

⁸ Vitapan is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co. KG, Bad Säckingen, Germany.

		Vitapan Classical Shade															
		A1	A2	A3	A3.5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
Ceram•X	o o	M1	M2	M5	M6	M7	M1	M2	M6	M6	M3	M4	M4	M7	M3	M5	M4

Ceram•X duo (Double Translucency System)

Consider the colour of the natural tooth and the Vita shade fingers in their whole extent. Chose the Vita shade most closely matching the tooth colour.

Four Ceram•X duo dentin shades with translucencies of natural dentin and three enamel shades with translucencies of natural enamel are available. In combination, the available Ceram•X duo dentin and enamel shades cover the whole Vitapan classical shade range. Having determined the tooth colour by means of a Vitapan classical shade guide, select the corresponding combination of Ceram•X d o dentin and enamel shades from the below table:

		Vitapan Classical Shade															
		A1	A2	A3	A3.5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
Ceram•X	duo Enamel	E2	E2	E2	E3	E3	E1	E1	E3	E3	E2	E1	E2	E2	E2	E2	E1
Ceram•X	duo Dentin	D1	D2	D3	D3	D4	D1	D2	D3	D3	D2	D3	D3	D4	D2	D3	D3

Note: depending on the thicknesses of the respective layers, the optical result may vary from the considered Vita shade!

For a quick survey over the Vita corresponding Ceram•X o o and d o shades, the delivered Shade Identification Label (i-shade label) can be used. It is recommended to fix the label on the rear side of a Vita shade guide holder.

B) Shade selection with delivered Ceram•X shade fingers

Alternatively, the Ceram•X shade fingers delivered can be used for shade selection. For both the Ceram•X o o and the Ceram•X d o system, shade fingers made from original material are provided in two separate shade guide holders.

Ceram•X o o (Single Translucency System)

Refer to the central region of the natural tooth. Chose the Ceram•X o o shade most closely matching the tooth colour.

Ceram•X duo (Double Translucency System)

For selection of a suitable Ceram•X d o dentin shade, consider the cervical region of the natural tooth or the colour of the moist dentin as visible in the cavity. It is recommended to apply rather a darker than a lighter dentin shade, the succeeding enamel layer tending to lighten the resulting optical effect. For selection of the suitable Ceram•X d o enamel shade, consider the incisal, occlusal or proximal region of the natural tooth. Chose the dentin shade respectively the enamel shade most closely matching the tooth colours compared to.

Shades should be selected while the teeth are hydrated. Clean the tooth with an prophylaxis paste (e.g. Nupro®) to remove any extraneous plaque or surface stain. Be aware of room and ambient light effects on shade selection (ideal light is northern exposure with natural daylight). Observe tooth shades for short periods of time to neutralize the effect of extended shade viewing comparisons. Viewing a grey-blue background will have a relaxing effect on

the viewing operators photo/colour optic discrimination. Eyes should be rested. It might be useful to have ancillary corroboration on shade selection by dental personnel.

Cavity Preparation

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

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

Do not desiccate!

Moisture Control

Surface cleanliness is paramount for the development of adhesion. Isolate prepared tooth from contamination with saliva, sulcus fluid, or blood with adequate measures (e.g. cotton rolls or dental dam).

Pulp Protection and Base

In deep cavities cover the dentin close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (Dycal[®]) leaving the rest of the cavity surface free for bonding with Prime&Bond NT or Xeno III.

Placement of the Matrix

Use a matrix system (e.g. Automatrix[®] or Palodent[®]) with proper wedging for proximal contacts. Pre-wedging is advocated to achieve slight separation and facilitate optimal proximal contact. In class II cavities the use of a deadsoft, thin matrix band and subsequent burnishing of the matrix band will improve final interproximal contact and contour.

Conditioning and application of adhesive

Prior to the application of Ceram•X the cavity has to be conditioned and/ or treated with Prime&Bond NT or XENO III. In cases where the application of a HEMA containing adhesive is not desired, the application of Prime&Bond NT is recommended. For application please follow the directions for use of the respective adhesive.

Application of Ceram•X Universal Nano-Ceramic Restorative

Using Compules tips

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

Using Easy-Twist syringes

Dispense the necessary amount of Ceram•X restorative material from the Syringe onto a mixing pad by turning the handle slowly in a clockwise direction. To prevent oozing of the material when dispensing is completed, point the front tip of the syringe upwards and turn the handle anti-clockwise. Immediately re-close the syringe with the respective cap. Place Ceram•X in increments into the cavity and protect remaining material against light.

Rebuilding the tooth following either Single or Double Translucency Technique

Prior to the application of Ceram•X *o o* or *d o* shades, a flowable restorative material (e.g. X-flow[™]) can be used for e.g. cavity lining. For application please follow the directions for use of X-flow.

Ceram•X o o (Single Translucency System)

Fill the complete defect with the chosen Ceram•X o o shade (with reference to incremental polymerisation technique).

Ceram•X duo (Double Translucency System)

Rebuild the tooth with respect to the anatomical conditions. First rebuild a dentin core with the suitable Ceram•X d o dentin shade. In a second step, add an enamel layer with the suitable Ceram•X duo enamel shade. In the anterior area a silicon key (prefabricated under assistance of a mock-up) can facilitate the establishment of the anatomical form.

In any case incremental placement (in 2 mm layers or less) is recommended to minimize polymerization shrinkage. Light cure each increment according to the below table⁹:

	$\geq 500 \text{ mW/cm}^2$	$\geq 800 \text{ mW/cm}^2$
Ceram•X o o shades (M1 to M7)	20 sec	20 sec
Ceram•X duo dentin shades (D1 to D4 and DB)	40 sec	30 sec
Ceram•X duo enamel shades (E1 to E3)	10 sec	10 sec

When using a LED curing device, curing time according to manufacture's instructions should be applied.

Finishing and Polishing

Begin finishing immediately after final curing. For removal of excess and contouring finishing burs or diamonds may be used.

Additional finishing and polishing is obtained by using ENHANCE[®] Finishing Discs, Cups or Points. Alternatively, other standard aluminium oxide disc series may be used. Prior to proceeding to the use of polishing Discs, Cups or Points restoration surface should be finished to a final outline form and desired contour and anatomical features. Surface should be smooth and defect free.

For achieving a very high luster of the restoration use PoGo[®] Polishers or Prisma[®]-Gloss[™] regular paste followed by Prisma-Gloss Extrafine polishing paste with Enhance polishing foam cups.

Maintenance of the Compules Tip Applicator Gun

The applicator gun is sterilizable by autoclave (2,1-2,4 bar/135-138°C). Alternatively, suitable disinfecting solutions can be applied following the manufacturers' instructions. Do not continue use of damaged and/or soiled applicator gun. It is recommended that the applicator gun be disassembled for assured sterilization. Partially close the applicator gun and place thumb under the rear portion of the hinge. Push upward and lift hinge separating the applicator gun, exposing the plunger. Remove residual composite with a soft paper tissue and a suitable solvent (70 % alcohol). To reassemble, insert plunger into applicator gun barrel, press components together and snap hinge mechanism in place.

⁹ Check curing light for minimum curing output of at least 500 mW/cm².

6.9 STORAGE

Keep out of sunlight. This product is designed to be stored at room temperatures between 10 and 24°C. Inadequate storage conditions will shorten the shelf lives and may lead to malfunctions of the product. Humidity can adversely affect the handling properties of unsealed compules and syringes. Therefore, unsealed compules or syringes must be stored between 10 and 24 °C at max. humidity of up to 80 % and should be used up within 2 months.

All products should be used at room temperature.

BATCH NUMBER() AND EXPIRY DATE ()

Do not use after expiry date.

The batch number should be quoted in all correspondence which requires identification of the product.

If you have any questions, please contact:

DENTSPLY DeTrey GmbH (Manufacturer), De-Trey-Straße 1, 78467 Konstanz, Germany

Phone +49 (0) 7531- 583- 0

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

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8 List of Figures and Tables

Figures

Figure 1	Schematic illustration of a microfilled composite.	4
Figure 2	Schematic illustration of a hybrid composite.....	5
Figure 3	Schematic illustration of a micro-hybrid composite.....	5
Figure 4	Schematic illustration of Ceram•X.....	6
Figure 5	Processing of Organically Modified Ceramic nano-particles.....	7
Figure 6	²⁹ Si-NMR-analays (Mayer, 2003).....	7
Figure 7	Schematic structures of Nano-Ceramic particles and nanofillers.....	8
Figure 8	X-ray diffraction to determine the size of nano-particles (Lattermann, 2003)....	8
Figure 9	Initial Cytotoxicity by means of relative cell growth of various dental materials (Schedle, 2003).....	9
Figure 10	Compressive Strength.....	10
Figure 11	Yield Strength	10
Figure 12	Flexural Strength.....	11
Figure 13	E-Modulus.....	11
Figure 14	Fracture Toughness K _{1C} (Schultz et al, 2003; except Ceram•X: unpublished data).....	12
Figure 15	Schematic illustration of crack propagation in different materials	12
Figure 16	Leinfelder Wear: 400.000 cycles 1Hz, 80 N load, 30° rotation (Latta, 2003) ..	14
Figure 17	Legend for grades of microleakage and dentin permeability (Rosales, 2003)	15
Figure 18	Grades of Microleakage (0 to 3) and statistical grouping (a to d) (Rosales, 2003).....	16
Figure 19	Dentin permeability (yes / no) and statistical grouping (a, b) (Rosales, 2003)	16
Figure 20	Incremental filling technique used for class II (Manhart, 1999).....	17
Figure 21	Distribution of perfect margins after aging in a chewing simulator (Ceram•X: Manhart, 2003; Tetric Ceram: Manhart, 2002)	17
Figure 22	Bond Strength after CEHL technique (Latta, 2003)	18
Figure 23	Schematic illustration of the new non-leachable inhibitor	19
Figure 24	Working time of different restoratives and transparencies.....	19
Figure 25	Plot to determine height of the resin pattern (Watts et al, 2003)	20
Figure 26	Stickiness to metal instruments (Watts et al, 2003).....	20
Figure 27	Surface Roughness after simulated polishing procedures for approximal and occlusal surfaces (Salomon, 2003)	21
Figure 28	Fluorescence to light of 254 nm wavelength	22
Figure 29	Radiograph of 2mm thick samples to compare radiopacity	22
Figure 30	Opacity of Ceram•X duo shades	23
Figure 31	Opacity of single and double translucency restorative materials	24
Figure 32	Chroma C* of Ceram•X.....	24
Figure 33	ΔE values for enamel and dentin shades	25
Figure 34	Schematic overview on properties influencing the final shade of a restoration	25
Figure 35	i-shade label for Vita reference of Ceram•X mono and duo.....	26
Figure 36	Rating of handling properties of Ceram•X compared to standard restorative product.....	30

Figure 37	Overall rating of handling properties.....	30
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Tables

Table 1	Technical data sheet Ceram•X.....	13
Table 2	Grading of dye penetration (Rosales, 2003).....	15
Table 3	Protocols for polishing of different clinical situations (Salomon, 2003)	21
Table 4	6 month results in class I and II (Hahn, 2003)	27
Table 5	6 month results class V (Dondi dall'Orologio, 2003)	28
Table 6	Results of the Field Study (Schaller, 2003)	29

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